

**Integrated approaches to immunisation  
and other health services for  
maternal, newborn and child health in  
resource-constrained settings.**

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# ABSTRACT

## *Background*

Integrating immunization and other health services during infancy could dramatically expand access to health care. During the first year after childbirth, immunisation services reach over 115 million families globally, at a point in the life-course where disease prevention, nutrition, and other preventive services can have high impact. Immunisation coverage could also benefit from integration, when catch-up vaccination is incorporated into illness or other care. There is encouraging evidence for malaria, HIV, or family planning programs and many global strategies advocate integrated services, especially for resource-constrained settings. However there are significant unresolved implementation questions, such as how best to link services, avoid staff overload, and maintain quality. Some attempts at integration fail to achieve expected benefits due to difficulties in re-organisation of services, or unexplained gaps in demand for and uptake of new arrangements.

## *Methods*

This research focused on low- and middle-income countries, using methods from health policy and systems research. Firstly, a new systematic review of global evidence examined outcomes and processes in controlled studies attempting integration of other services with infant immunisation. Secondly, in rural Papua New Guinea (PNG), integration questions were nested in a prospective observational cohort study following 699 mother-infant pairs from first antenatal visit until 12 months after childbirth. Repeated assessments examined co-morbidity and preventive care needs, experiences of integrated services, and a unique open exploration of women's preferences for future integration. Thirdly, a cross-sectional health services assessment, in the same setting, examined integration practices and preferences of health managers and front-line staff.

### *Findings*

Review of global evidence documented new work integrating family planning, HIV, malaria and nutrition. Most linked services benefited, with mixed outcomes for immunisation. A new typology of integrated services emerged, with richer detail on what determines success. In PNG, need for integrated care is high but provision is low. PNG women's preferences surpassed current evidence, policy and practice; seeking addition of maternal illness care, comprehensive child illness care, better education on important disease threats, and sexual and reproductive health care. They had many insights for improved implementation of integrated services. Women privilege holistic quality care over savings in time and money, although the latter are valued. Acceptability is not universal, with sensitive topics needing careful management.

The existing immunisation program in PNG offers some integration opportunities, but meeting women's preferences will require additional investments in planning and staffing. Synergies when strengthening immunisation for integration may also expand routine coverage and capacity to support emergency responses. Priorities include addressing maternal health during immunisation clinics, integration of nutrition, family planning and immunisation in the first and second years of life, and reducing missed opportunities for vaccination during illness care.

### *Conclusion*

Integration of other services with immunisation in infancy should be pursued; first because it can offer holistic care for the multiple health needs in families, and then for potential efficiencies. Implementation details, especially addressing users' preferences, are critical to success. Better understanding of families' needs and preferences is essential to health planning, as more responsive services offer pathways to system resilience and universal coverage.

### *Word counts*

Abstract is 498 words. Thesis word count is 76,279, including Tables and Figures, but excluding Preface, Acknowledgments, References and Appendices.



# DECLARATION

Integrated approaches to immunisation and other health services for maternal, newborn and child health in resource-constrained settings.

This is to certify that:

1. This thesis contains original work towards my PhD research, except where indicated in the Preface;
2. Due acknowledgement has been made in the text of all other material used; and
3. The thesis is fewer than 100,000 words in length, exclusive of tables, maps, references and appendices.

Christopher John Morgan

31<sup>st</sup> January 2021 (revised, original submission 18<sup>th</sup> April 2020)

## PREFACE

This thesis presents original research from 2012 to early 2020, from three main sources. The first is a *systematic review* of global literature on integration of other services with immunisation in low- and middle-income countries, led in all phases by the author of this thesis, as presented in Chapter Five. The second and third are two *primary research studies in East New Britain Province of Papua New Guinea* within the Healthy Mothers Healthy Babies (HMHB) research program; led by the Burnet Institute in partnership with government authorities, the Papua New Guinea Institute of Medical Research and other research partners. The author of this thesis was a principal investigator on this program. He was fully responsible for developing the research tools, training data collectors, and conducting analyses for the integration questions presented in Chapters Six and Seven.

The author contributed significantly to other aspects of HMHB, working alongside the other principal investigators: Professor James Beeson (also the author's primary supervisor for doctoral studies), Dr Michelle Scoullar, Professor Peter Siba, and Professor William Pomat. Chapter Four describes all methods, the HMHB field site and in, Section 4.4, outlines the depth of the author's involvement in helping establish the site and the fieldwork. Each chapter, in methods sections, notes contributions of the research team, as do the Acknowledgements that follow immediately below. Full study protocols are appended to this thesis.

A publication arising from work presented in Chapter Seven appeared in BMC Public Health on 23<sup>rd</sup> January 2020 (full reference below); the author of this thesis was first author and conducted more than 50% of the work for the publication. Work in Chapters Five and Six are planned for submission for publication in 2021.

The author gratefully acknowledges scholarship support: Australia's National Health and Medical Research Council Postgraduate Scholarship grant number 1075065, 2014-17; a Melbourne Abroad Travel Scholarship (University of Melbourne) in 2014; and the higher education fee waiver provided under the Australian Government Research Training Scheme (now the Research Training Program <https://www.education.gov.au/research-training-program-faqs>).

## PUBLICATIONS

### *Publications directly arising from this thesis*

The author of this thesis led the following publication, arising from work presented in Chapter Seven. As first author, he conceived the study, developed data collection tools, oversaw data collection, conducted all analyses, and undertook the majority of the work for the paper.

**Morgan, C.J.**, Saweri, O.P.M., Larme, N. Peach, E., Melepia, P., Au, L., Scoullar, M.J.L., Reza M.S., Vallely, L.M., McPake, B.I., Beeson, J.G. (2020) Strengthening routine immunization in Papua New Guinea: a cross-sectional provincial assessment of front-line services. *BMC Public Health* **20**,100. doi:10.1186/s12889-020-8172-4

### *Publications arising from other research associated with this thesis*

The author contributed in study design, data collection tools, analysis and interpretation, to the following two publications, currently under submission. These drew from research complementary to this thesis; based on data collected within the same cohort of participants as presented in Chapter Six.

Scoullar, M., Boeuf, P., Peach, E., Fidelis, R., Tokmun, K., Melepia, P., Elijah, A., Bradshaw, C., Fehler, G., Siba, P., Erskine, S., Mokany, E., Kennedy, E., Luchters, S., Robison, L., Wong, N., Vallely, A., Badman, S., Vallely, L., Fowkes, F., **Morgan, C.**, Pomat, W., Crabb, B., Beeson, J. (2021) High burden of *Mycoplasma genitalium* and other reproductive tract infections among pregnant women in Papua New Guinea. *bioRxiv*. 2020 Jan 1.

Peach, E., **Morgan, C.**, Scoullar, M., Fowkes, F., Kennedy, E., Melepia, P., Homiehombo, P., Au, L., Luchters, S., Umbers, A., Vallely, A., Vallely, L., Kelly, A., Robinson, L., Crabb, B., Elijah, A., Siba, P., Pomat, W., Beeson, J., and the HMHB Study Team. (2021) Risk factors and knowledge associated with high unintended pregnancy rates and low family planning use among pregnant women in Papua New Guinea. *Scientific Reports*, 11(1), pp.1-13.

### *Publications (selected) during the period of candidature*

The author of this thesis contributed to the following publications during the period of candidature. These did not draw directly on research presented in this thesis but the author's contributions were informed by the doctoral studies.

Vallely AJ, Pomat WS, Homer C, Guy R, Luchters S, Mola G, Kariwiga G, Vallely L, Wiseman V, **Morgan C**, et al (2019) Point-of-care testing and treatment of sexually transmitted infections to improve birth outcomes in high-burden, low-income settings: Study protocol for a cluster randomized crossover trial (the WANTAIM Trial, Papua New Guinea) *Wellcome Open Res* 2019, 4:53  
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## ABBREVIATIONS AND GLOSSARY

|             |                                                                                                                                                       |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEFI        | Adverse events following immunisation                                                                                                                 |
| AIDS        | Acquired immunodeficiency syndrome                                                                                                                    |
| ANC         | Antenatal care                                                                                                                                        |
| BCG         | <i>Bacille Calmette Guerin</i> vaccine, against tuberculosis                                                                                          |
| BMC         | Bio-Med Central journals <a href="https://www.biomedcentral.com/">https://www.biomedcentral.com/</a>                                                  |
| CASP        | Critical Appraisal Skills Programme <a href="http://www.casp-uk.net">www.casp-uk.net</a>                                                              |
| CBA         | Controlled before-and-after study design                                                                                                              |
| CDC         | USA's Centers for Disease Control and Prevention                                                                                                      |
| CHS         | Church Health Services, health sector in PNG                                                                                                          |
| CHW         | Community Health Worker, most peripheral health cadre in PNG                                                                                          |
| CI          | Confidence Interval                                                                                                                                   |
| Countdown   | Network of academic, UN and development agencies for measuring progress in reproductive, maternal, child and adolescent health across countries       |
| CRCT        | Cluster randomised controlled trial                                                                                                                   |
| DTP1, DTP3  | Diphtheria-tetanus-pertussis containing vaccine, first and third doses.                                                                               |
| ECD         | Early Childhood Development                                                                                                                           |
| EID         | Early infant diagnosis, for HIV                                                                                                                       |
| ENB         | East New Britain province of PNG                                                                                                                      |
| EOC         | Emergency Operations Centres (for PNG's emergency polio response)                                                                                     |
| EPI         | Expanded Programme on Immunization                                                                                                                    |
| EPOC        | Effective Practice and Organisation of Care, a Cochrane evidence node                                                                                 |
| EPPI-Centre | Evidence for Policy and Practice Information and Co-ordinating Centre of the University of London                                                     |
| ERA         | Enhanced Routine Activity, form of immunisation outreach                                                                                              |
| FGD         | Focus Group Discussion                                                                                                                                |
| FIC         | Fully immunised child                                                                                                                                 |
| FP          | Family Planning                                                                                                                                       |
| GAPPD       | Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea                                                                          |
| Gavi        | Gavi, The Vaccine Alliance (formerly the Global Alliance for Vaccines and Immunization) <a href="http://www.gavi.org">www.gavi.org</a>                |
| Global Fund | Global Fund for AIDS, Tuberculosis and Malaria <a href="http://www.theglobalfund.org">www.theglobalfund.org</a>                                       |
| GRADE       | Grading of Recommendations Assessment, Development and Evaluation <a href="https://www.gradeworkinggroup.org/">https://www.gradeworkinggroup.org/</a> |
| GVAP        | Global Vaccine Action Plan                                                                                                                            |
| HEO         | Health Extension Officer, a paramedical workforce cadre in PNG                                                                                        |
| HDI         | Human Development Index                                                                                                                               |
| HIV         | Human Immunodeficiency Virus                                                                                                                          |
| HMHB        | Healthy Mothers Healthy Babies, a multi-partner research program in PNG                                                                               |

|             |                                                                                                                              |
|-------------|------------------------------------------------------------------------------------------------------------------------------|
| HPSR        | Health Policy and Systems Research                                                                                           |
| HPV         | Human Papilloma Virus                                                                                                        |
| iCCM        | Integrated community case management, of childhood illnesses                                                                 |
| IMCI        | Integrated Management of Childhood Illness, a WHO/UNICEF-led child-survival program implemented in many countries since 1992 |
| Infancy     | First twelve months of life, referring to infant and his/her caregivers                                                      |
| IPTi        | Intermittent preventive [malaria] treatment in infancy (first year of life)                                                  |
| IPTc        | Intermittent preventive [malaria] treatment in childhood (after infancy) or SMC                                              |
| IPV         | Inactivated poliovirus vaccine (injected form)                                                                               |
| IR          | Implementation Research                                                                                                      |
| IRB         | Institutional Review Board of the PNG Institute for Medical Research                                                         |
| ITN         | Insecticide-treated net/s                                                                                                    |
| IYCF, IYCFN | Infant and young child feeding, and nutrition                                                                                |
| JSI         | John Snow Incorporated, a public health consulting and research organization                                                 |
| Lao PDR     | Lao Peoples' Democratic Republic                                                                                             |
| LBW         | Low birth weight (<2.50kg)                                                                                                   |
| LLIN        | Long-lasting insecticidal nets, a subset of ITNs                                                                             |
| LMIC        | Low- and middle-income country (World Bank definition as at 2016)                                                            |
| MCH         | Maternal and Child Health                                                                                                    |
| MCHIP       | Maternal and Child Health Integrated Program, USA government aid                                                             |
| MCSP        | Maternal and Child Survival Program, USA government aid                                                                      |
| MCV         | Measles-containing vaccine, first (MCV1) and second (MCV2) doses                                                             |
| MDG         | Millennium Development Goal/s, with 2015 targets set against 1990 baseline                                                   |
| MMR         | Maternal mortality rate                                                                                                      |
| MNH         | Maternal and Newborn Health, and health care                                                                                 |
| MNCH        | Maternal, Newborn and Child Health, and health care                                                                          |
| MOV         | Missed Opportunity for Vaccination                                                                                           |
| MR          | Measles rubella combination vaccine, the usual presentation of MCV in PNG                                                    |
| NDOH        | National Department of Health, PNG                                                                                           |
| Neonatal    | Issues affecting the baby in the first 28 days after childbirth                                                              |
| NHMRC       | National Health and Medical Research Council, Australia                                                                      |
| NRCT        | Non-randomised controlled trial                                                                                              |
| OPV         | Oral polio vaccine                                                                                                           |
| PEC         | Provincial Executive Council, East New Britain Province, PNG                                                                 |
| Pentavalent | Combined vaccine against DTP, hepatitis B and Haemophilus influenzae B                                                       |
| PHC         | Primary health care, particularly comprehensive community-oriented essential health care promoted by WHO/UNICEF from 1978    |
| PHO         | Provincial Health Office, organising public health at province level in PNG                                                  |
| PNC         | Postnatal care of both mother and baby                                                                                       |

|            |                                                                                                                                                 |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| PNG        | Independent State of Papua New Guinea                                                                                                           |
| PNGIMR     | Papua New Guinea Institute for Medical Research                                                                                                 |
| POC        | Point-of-care – tests or testing                                                                                                                |
| Postnatal  | Period from childbirth to end of neonatal period, that is: first 28 days after childbirth - refers to both maternal and neonatal issues         |
| Postpartum | The period following childbirth, usually until 42 days                                                                                          |
| PPFP       | Postpartum family planning, usually extending 12 months after childbirth                                                                        |
| PPH        | Postpartum haemorrhage                                                                                                                          |
| RCT        | Randomised controlled trial                                                                                                                     |
| RDT        | Rapid Diagnostic Test (for malaria)                                                                                                             |
| RI         | Routine immunisation                                                                                                                            |
| RMNCAH     | Reproductive, Maternal, Newborn, Child and Adolescent Health, and care                                                                          |
| RTI        | Reproductive Tract Infection                                                                                                                    |
| SDG        | Sustainable Development Goal/s - globally agreed, with targets set for 2030                                                                     |
| SIA        | Supplementary Immunisation Activity, such as a measles or polio campaign                                                                        |
| SIREP      | Special Integrated Routine EPI Strengthening Program, policy in PNG                                                                             |
| SMC        | Seasonal Malaria Chemoprophylaxis, preventive anti-malarials, given over a broader age range than infancy                                       |
| SRH        | Sexual and Reproductive Health                                                                                                                  |
| STI        | Sexually Transmitted Infection                                                                                                                  |
| TB         | Tuberculosis                                                                                                                                    |
| UNICEF     | United Nations Children's Fund                                                                                                                  |
| UPNG       | University of Papua New Guinea                                                                                                                  |
| USA        | United States of America                                                                                                                        |
| USD        | United States dollar                                                                                                                            |
| USAID      | United States Agency for International Development                                                                                              |
| VHV        | Village Health Volunteer                                                                                                                        |
| WASH       | Water, sanitation and hygiene                                                                                                                   |
| WHO        | World Health Organization                                                                                                                       |
| World Bank | Refers to two of the World Bank Group agencies: International Bank for Reconstruction and Development and International Development Association |

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# 1 INTRODUCTION

More integrated health services are frequently proposed as a means to improve coverage and/or efficiency, especially in relation to immunisation and other services for families in resource-constrained settings. More generally, ‘integrated services’ are identified as a characteristic of good health care, as expressed in the World Health Organisation (WHO)’s desire to support countries in providing “*safe, high quality, effective, people-centred and integrated services*”.<sup>1</sup> The principle of integration is seen as essential to the advancement of ‘universal health coverage’<sup>1</sup> as an expression of the health aspirations within the United Nations’ Sustainable Development Goals (SDG).<sup>2</sup> While there is widespread policy support for the concept of integrated services, and it seems an obvious solution to the problems of weak and fragmented health systems, there are significant unresolved implementation questions<sup>3-5</sup> and attempts at integration often fail to achieve the hoped-for benefits.<sup>3,6-11</sup>

This thesis describes research that has generated evidence relevant to health managers responsible for putting integration into practice in resource-constrained settings characteristic of low- or middle-income countries (LMICs). The focus is on mothers and infants in the first months after childbirth; and the evidence needed by national and sub-national health managers who are asked to integrate childhood immunisation with other health services. This takes up the implementation research questions of when and where more integrated services will be beneficial, and how best to reform service delivery to maximise these benefits without damaging equitable access or quality of care.

## 1.1 The problem of fragmented health service delivery

This research examines the health system component often termed ‘service delivery’, referring to the way health care provision is organised in LMICs, especially at the front-line where health care is first received.<sup>12,13</sup> These concepts are expanded in Chapter Two.

Health service delivery in LMICs is often unhelpfully fragmented in planning.<sup>13-15</sup> Different health programs, such as those for maternal and child health, immunisation, or the control of Human Immunodeficiency Virus (HIV), malaria, or tuberculosis, may target the same population groups and support the same front-line staff, but have management and resources in separate structures that make for poor coordination.<sup>16</sup> For example: a maternal health program providing childbirth care that fails to align policy with an immunisation program providing vaccination against hepatitis B at birth can result in newborns being vaccinated too late or not at all.<sup>17</sup> Poor coordination can result in inefficient use of resources if staff, infrastructure or equipment are unnecessarily duplicated.<sup>7,16,18</sup> Fragmentation is exacerbated when particular programs receive disproportionately greater funding from external disease-specific partners.<sup>19,20</sup> Prior to 2010, in Lao Peoples’ Democratic Republic (Lao PDR) and Papua New Guinea (PNG) a surge of Global Fund support greatly expanded HIV and tuberculosis control investment. However this expansion was compromised by poor alignment between maternal and child health and communicable disease control programs,<sup>21</sup> as well as skewing of health workforce allocation and attention to the detriment of the broader health system.<sup>22</sup>

Fragmented systems can struggle to deliver clinically responsive treatment at the time it is needed or fail to extend essential preventive care to include all communities, especially those that are harder to reach. Such fragmentation can disastrously impair population health outcomes, often with disproportionate effect on pregnant women and children,<sup>15,23,24</sup> and on the poorest families.<sup>25</sup> The final report of the ‘Countdown to 2015’ group monitoring progress towards maternal and child health Millennium Development Goals (MDGs)<sup>26</sup> noted that gains in coverage were greatest for ‘vertical’ interventions

with dedicated delivery mechanisms, such as for vaccines, malaria or HIV, than for interventions that required contact with a more broadly functional health system, such as emergency care of complications during or soon after childbirth. Later reports<sup>27</sup> tracking progress on universal health coverage show similar discrepancies in intervention coverage.<sup>11</sup> A systematic review of health service delivery in LMICs<sup>28</sup> noted that inefficiencies and other system weaknesses created by fragmented services often lay beneath failures in health care coverage.

Access to important preventive health care such as family planning<sup>26</sup> and immunisation<sup>29</sup> is hindered when different health programs do not coordinate well. While immunisation is one of the stronger public health platforms, reaching over 115 million infants in 2019,<sup>30</sup> the core global measure of coverage (third dose of diphtheria-tetanus-pertussis containing vaccine (DTP3)) has remained relatively stagnant since 2010 at 82%,<sup>31</sup> and unchanged at 86% for the past four years. Many countries such as PNG fall well short of this global mean.<sup>30</sup> At 86% coverage in 2018 (the most recent formal global report<sup>31</sup>) this represented over 19 million children who were not fully vaccinated and 13.5 million who did not receive any doses of DTP vaccines. Missing the opportunity to vaccinate children who attend health services for other reasons (such as illness care) is an important contributor to this coverage deficit.<sup>29,32</sup> Similarly, omitting discussion of family planning, or other sexual health issues, when a mother brings a child for vaccination in the months after childbirth, is a failure of integration that reduces access to reproductive health care.<sup>33</sup>

From the perspective of families in LMICs, fragmentation can be a major barrier to appropriate use of health services. When vertically organised services are provided only on specified days or at differing sites, this can demand multiple visits for care. When providers are focused on just one program area, they may not consider all the needs of the client or family. This shifts the obligation for obtaining all relevant care onto the mother or other care-giver, adding the burden of being responsible for her own and her children's health needs.<sup>16</sup> The impact is harshest on economically poor families in LMICs who

have limited resources for travel or service fees, may have limited understanding of what might be needed, and limited time to divert from subsistence activities.

Consider, for example, a mother of two attending a routine child health clinic for vaccination of her baby one month after childbirth in a high morbidity setting such as rural PNG. Over and above the concerns of the new baby's care, she is likely to be aware of other illnesses affecting herself or her first child, and have other health concerns such as questions about family planning or sexual health. It costs time and money to make the difficult journey to an often distant health centre<sup>34</sup> that consists of a few rooms staffed by a nurse and an auxiliary staff member. Once at the clinic she is unsure whether any other health complaints will be dealt with, whether she will be screened for common co-incident conditions,<sup>35</sup> nor whether the other child she has brought along (for want of child-care at home) will be able to receive catch-up vaccinations or illness care at the same time. In a context where women may rate many other priorities higher than health,<sup>36</sup> the need to repeatedly sacrifice resources for multiple visits represents a major deterrent to care seeking.

## 1.2 Global interest in health service integration

### 1.2.1 *Integrated services are a marker of good primary health care*

A plethora of global documents mention some version of “*better integrated services*” as an important strategic element. Integrated service delivery is often included as a tactic in global strategies for immunisation,<sup>37</sup> as a means to better promote reproductive, maternal, newborn and child health (RMNCAH),<sup>15,38</sup> and as one tool for the control of a variety of infectious diseases including HIV,<sup>39,40</sup> malaria,<sup>41</sup> pneumonia and diarrhoea,<sup>42,43</sup> tuberculosis and others.<sup>44</sup>

Goal Three (“*Ensure healthy lives and promote well-being for all at all ages*”) of the Sustainable Development Goals implies the need for integrated services in several of its targets. Take for example, the mention in relation to target 3.7 to “*ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes*”.<sup>2</sup>

The concept of integrated health services is not new, including early<sup>45,46</sup> and renewed<sup>47</sup> concepts of comprehensive primary health care (PHC), especially for care during pregnancy and childhood. Integration is seen as an inherent and positive attribute of front-line services in the technical reports used in the 2018 meetings on PHC at Astana sponsored by WHO and the United Nations Children’s Fund (UNICEF), referring to “*Primary care and essential public health functions as the core of integrated health services*”.<sup>48</sup>

A WHO definition of integrated services as “*the organization and management of health services so that people get the care they need, when they need it...*” is often interpreted as meaning:

- the creation of packages of health interventions,
- provision at multi-purpose service delivery points, and
- continuity of care across time points and across different levels in the health system.<sup>49</sup>

In these global documents, more integrated health services are often seen as means of providing better quality care with more efficient resource use.<sup>1,50,51</sup>

This is important everywhere, but especially for settings characterised by high mortality rates in LMICs – the settings of core interest to this research.

### ***1.2.2 Immunisation services are a common integration ‘target’***

For immunisation services, as discussed further in Chapter Two, integration is a topic of recurring interest. When research priorities for strengthening routine immunisation were canvassed in 2009, high priority was given to programmatic research into how to integrate other services with immunisation.<sup>52</sup> Vigorous calls were made at the WHO’s influential Strategic Advisory Group of Experts meetings in 2012<sup>53</sup> and 2014<sup>54</sup> for stronger integration between immunisation and RMNCAH programs. The 2011-2020 Global Vaccine Action Plan<sup>37</sup> sets out a clear rationale for increased integration: to minimise missed opportunities for vaccination by ensuring immunisation is incorporated into other services, to make best use of resources to sustain and improve the reach of the immunisation platform, and to situate immunisation services within other disease control strategies. This emphasis continues in early drafts of the 2021-2030 global immunisation strategy under development in 2019,<sup>55</sup> also discussed further in Chapter Eight.

The childhood immunisation platform has demonstrated the greatest reach of any preventive health service<sup>56,57</sup> and is therefore of interest to other health programs. Because immunisation services reach so many families, integrated delivery through this platform is frequently proposed as a means to improve access for other health care. Some examples, among many, include the distribution of vitamin A, measures to prevent or control malaria,<sup>41,58</sup> management of HIV and related infections,<sup>59-61</sup> or family planning.<sup>62</sup>

### ***1.2.3 Questions for global strategies aiming for integrated services***

Many of the calls for more integrated services in disease-specific strategies seem largely driven by two aims: to make more efficient use of resources, and/or to maximise the uptake of specific high priority interventions. Many proposals take a supply-side perspective in seeing integration as a means to overcome logistic barriers and resource-constraints.<sup>32,39,63-66</sup> However if

strategic aspirations are limited to increased and more efficient coverage with particular priority interventions, they will overlook a further crucial rationale for integration.

A different, and arguably more important, stimulus to more integrated health services is the fact that many clients present to health services with more than one health care need; for example: a client with a sexually transmitted infection who is also seeking family planning advice. In addition, those at higher risk of death are those with the co-morbidity of several simultaneous disease processes; for example: pneumonia complicated by malnutrition. It is argued that this demand-side perspective, the simultaneous co-existence of multiple health needs within families and individuals, should be the prime driver of integrated service provision. Concepts of coordinated care or process integration are prominent in discussions in high-income countries,<sup>67,68</sup> especially in relation to primary care in such settings. These ideas are now seen in the technical series on PHC presented in 2018 at the Astana conference,<sup>69</sup> where integrated services are seen to represent better quality of care. However this client-need perspective as a rationale for integrated services has not been a focus in recent global strategies targeting specific health issues relevant to LMICs, such as those for immunisation,<sup>37</sup> HIV<sup>39,40</sup> or malaria.<sup>41</sup>

Some global strategies do recognise that integrated packages of care are essential to adequately meet the often multiple needs of health system users. Examples include those for the integrated management of childhood illness (IMCI),<sup>70,71</sup> linking HIV interventions with sexual and reproductive health care (SRH),<sup>72</sup> integrated primary care for adults,<sup>73</sup> or responses to tuberculosis or other infections.<sup>44</sup> A stronger emphasis on users has also recently re-emerged in health systems discussions as the need for ‘people-centred’ health services in LMICs,<sup>1,74</sup> in measures for universal health coverage,<sup>11</sup> and in 2018 descriptions of the future of PHC.<sup>48,69</sup> However many strategic documents that call for more integration of health services do not start with a characterisation of the clients’ need for integrated care; instead they start with the potential benefit of a

specific intervention and a target for increased coverage or uptake of that intervention.

Furthermore, and of core concern to the research described in this thesis, global strategies and national health plans rarely provide a clear description of what constitutes service integration, nor what steps are needed to introduce more integrated service delivery arrangements. They also rarely refer to what the current evidence base says regarding the trade-off of potential benefits against the risks of re-organising services to promote integration. As discussed in Chapter Two, optimal models for how to integrate health services are not well described,<sup>3,75</sup> and evidence on experiences with health service integration show both positive and negative effects.<sup>6</sup> For example, the additional burden placed on staff if they are expected to provide an expanded range of services. WHO and others have called for rigorous implementation research<sup>76,77</sup> to assess when and how more integrated care, and/or other improved service planning initiatives, are likely to be successful.



### 1.3 The role of this research

In the author's own experience of over 25 years of work in health programs in resource-constrained settings in Asia and the Pacific, integration of services has been a frequently raised topic. Discussions with health managers in LMICs, including local health managers from the Pacific,<sup>78</sup> and workshops with HIV program managers from Zimbabwe, Kenya, and South Africa,<sup>79</sup> suggest that making changes to increase service integration is not straightforward. Similar concerns from frontline staff in LMICs have been heard through the author's work with WHO's Immunization Practices Advisory Committee, including support of a workshop for the African Region in 2016<sup>80</sup> on *"Exchange of best practices on Reaching Every Community, equity and the integration of child survival interventions"*. In these and other interactions, managers reported being asked to 'integrate more' but were troubled by lack of guidance on likely resource requirement, lack of clear practical options on how to alter service delivery arrangements, and the paucity of evidence on likely benefits and risks.

There is scope to better apply the tools for researching health service delivery in LMICs,<sup>81</sup> drawing on the concepts of implementation research and delivery science,<sup>82</sup> to expand and strengthen the evidence base beyond the current state outlined below in Chapter Two.

The program of research described in this thesis seeks to elaborate the implementation questions relating to when, where and how to improve service integration, and how to guard against unintended negative consequences of such health service reforms in LMICs.

## 1.4 Thesis structure

This research examines integrated services from a global perspective, through a systematic review of immunisation service integration, and from a local perspective, through two field studies into integration in one LMIC: Papua New Guinea that is characteristic of many settings with fragmentation and health service challenges.<sup>83,84</sup> PNG instituted a number of approaches to increase service integration in 2013-15, which makes this an apt setting for this study.

This thesis comprises seven further chapters, structured as follows:

**Background** (Chapter Two): defines concepts of service delivery and integration used in this study, reviews the current evidence base, and describes PNG's health status, system and suitability as a study site.

**Research framework, scope and objectives** (Chapter Three): presents conceptual frameworks used, as well as the scope and objectives of this research.

**Methods** (Chapter Four): presents the methods that address these objectives, through a systematic review and two observational studies in PNG.

**Systematic literature review of immunisation integration** (Chapter Five): presents a new literature review of integration of immunisation and other services, discussing their implications for future health service innovation.

**Prospective observational cohort study in PNG** (Chapter Six): presents a demand-side study of women's and infant's need for integrated services, experience of integrated services, and preferences for future integrated services, from a nested study of a cohort of rural mothers in PNG.

**Cross-sectional health services study in PNG** (Chapter Seven): presents supply-side study of current service performance and future potential for integration in immunisation clinics in one province of PNG.

**Discussion and Conclusion** (Chapter Eight): synthesises the global and PNG findings, discusses the implications for health policy and practice in both arenas, and describes the dissemination and use of this research.

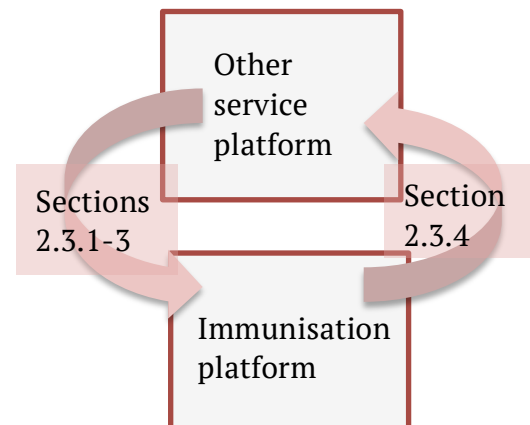
**Appendices**: provides full versions of approved research protocols, copies of ethical approvals, and supplementary data tables for Chapters Five, Six and Seven.

## 2 BACKGROUND

This chapter provides a review of the current evidence on integrated health services; covering definitions of integrated services (2.1), integrated service delivery in general (2.2), and integrated service delivery involving immunisation (2.3).

Section 2.3 covers two ‘directions’ of integration: when another service is added to the immunisation platform and when immunisation services are added to or strengthened within another service platform (see Figure 1).

**Figure 1: Directions of integration**



This review finds that while integrated services clearly have potential benefit in LMICs, there are outstanding research questions (2.3.5) and evidence gaps (2.3.6) that a new systematic review and studies in PNG can help fill.

In section 2.4, this chapter discusses PNG, demonstrating that in its challenged rural settings, the patterns of health care needs, system weaknesses, and contextual constraints often call for integrated services as a response; however these are commonly poorly implemented. Recent government plans that emphasise integrated services are then described to present PNG as a highly relevant setting for the study of integration.

### 2.1 Defining integrated health services

Before reviewing evidence or considering research approaches, it is necessary to define what is meant in this research by ‘integrated’ or ‘integration’ in relation to health service delivery. ‘Integration’ is a term that attracts many usages in global health and development discussions. At a higher level than service delivery, the word is often used to refer to development actors coordinating their information or resources, or where a particular health action needs to be incorporated within a broader strategy or policy. For example, Coker, McKee, Atun and Shigayeva, in 2010,<sup>7</sup> mapped varying concepts of integration in

researching the level of incorporation of disease-specific programs such as HIV or tuberculosis with health systems. This study, and other examples of overviews of integration concepts,<sup>85,86</sup> demonstrate the use of the term ‘integration’ as a synonym for coordination or joint use of resources, with its usage varying at different levels in the health system. The term ‘*integrated health services*’ is just one usage, but one that can be made helpfully specific.

For research that is focused on the service delivery level, as in this thesis, the definition most relevant is that proposed by WHO in a 2008 technical brief, that integrated health services are:

*“The management and delivery of health services so that clients receive a continuum of preventive and curative services, according to their needs over time and across different levels of the health system”.*<sup>49</sup>

This definition, in various guises, remains the most common reference point for the service delivery literature presented below. For example, being used in 2016 in a key WHO meeting on integrated services in Cape Town<sup>87</sup> and in an expanded form in the reframing of ‘people-centred’ health systems<sup>1</sup> as well as the 2018 reframing of PHC.<sup>48</sup> The people-centred perspective is seen in current United Nations reporting on universal health coverage, where “*integratedness*” is viewed as “*seamless, continuous and holistic care, tailored to the patient’s needs*”.<sup>11</sup> This conceptualisation relates well to the demand-side drivers of integration, although it omits the efficiency aspirations seen in earlier integration discussions. However, it is proving difficult to incorporate into strategy<sup>3,86</sup> and the 2018 United Nations report notes that there is not yet a reliable mechanism for measuring progress in this aspect of universal health coverage.<sup>11</sup>

The expanded definition in the 2008 WHO brief describes six main understandings of integrated health services, of which four are particularly relevant to the pregnancy, postnatal, and infancy periods:

1. Packages of care combining preventive and/or curative interventions;
2. Service-delivery points with multiple purposes and capacities;
3. Continuity of care over time; and

4. Vertical integration across health system levels, including home-based care, outreach services, and referral between facilities.<sup>49</sup>

These concepts were echoed in a technical review of integration experiences<sup>88</sup> in the end-of-project report of the large Maternal and Child Health Integrated Program (MCHIP\*)<sup>89</sup> funded by the United States of America (USA) government. MCHIP supported programs in maternal, newborn and child health, immunisation, family planning, nutrition, malaria and HIV/Acquired Immunodeficiency Syndrome (AIDS) in over 50 LMICs across Africa, Asia and Central and South America from 2008 to 2014. The technical review identified two models of integrated services: ‘full integration at point of service delivery’ where multiple services were available from a multipurpose provider; and ‘partial integration’ where providers shared some responsibilities and/or enabled linkages between services.<sup>88</sup>

Research into HIV service integration refined these distinctions: the *Integra Initiative* (see Section 2.2) categorised integration models as *fully integrated* (all services from one provider in one room), *partially integrated* (different services from different providers within one building), *partially stand-alone* (different units on the same campus), and *fully stand-alone* (separate single service clinics).<sup>8</sup> Others<sup>90</sup> distinguished between *single providers*, *multiple co-located providers*, and a *network* of services across different sites. Variations of these categorisations prove useful in reviewing global experiences of immunisation service integration, as discussed in Chapter Five.

Other concepts from the expanded version of the WHO 2008 definition, include better coordination of policy and planning and establishment of linkages across sectors. These concepts help when considering broader health system implications of introduction of integrated services.

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\* Available at <https://www.mchip.net/> (accessed 15<sup>th</sup> February 2018). MCHIP’s successor is the Maternal and Child Survival Program (MCSP) <https://www.mcsprogram.org/>.

† <http://www.integrainitiative.org/> (accessed 15<sup>th</sup> February 2020).

## 2.2 Review of integrated health services beyond immunisation

This section has been developed through a broad scoping search of published literature on integration, and by suggestions from professional contacts working in immunisation practice, particularly the WHO Immunization Practices Advisory Committee<sup>91</sup> and the Family Planning Immunization Integration Working Group.<sup>92,93</sup>

### 2.2.1 General reviews of integration and its effects

As noted in the introduction, integrated health services have been seen as an important characteristic of comprehensive *primary health care* programs<sup>94</sup> and integration concepts were viewed as essential to the success of early models of PHC in settings as diverse as India<sup>95</sup> or Bolivia.<sup>96</sup> Integration in this context described both the provision of multiple synchronous services at community level, and also close referral links between community-based care and a first-level hospital.<sup>95,97</sup> Henry Perry and colleagues, in 2006, when discussing the impact of “*local programmes which provide a comprehensive array of services*”<sup>98</sup> saw integrated services as critical to success but difficult to quantify, because the multiple interventions involved and resource-constraints in LMIC settings were not amenable to controlled trials.

A comprehensive 2008 review by Peters and colleagues<sup>99</sup> of World Bank interventions to improve front-line health service delivery noted the integration of services as one strategy, but found few controlled trials able to demonstrate the impact of integration.<sup>100</sup> Later PHC reviews in 2012, 2017, and 2018 clearly identified the degree to which services were integrated as a key determinant of whether community-based health care was successful or not.<sup>48,101,102</sup>

With the growth of *disease-specific initiatives* in the first decade of this century, particularly those supported by the Global Fund, there was recognition of the potential for their impact to be limited by weaknesses in the health system they were entering, and in the potential for ‘vertical’ programs to worsen fragmentation.<sup>103,104</sup> This recognition, along with renewal of interest in PHC

principles as contributors to health systems strengthening,<sup>105</sup> stimulated the collation of evidence in support of an integrated approach to health service delivery.

Two key systematic reviews, using the WHO concepts of integrated services applied in this research, are commonly referenced in integration discussions. A Cochrane review<sup>16</sup> attempted to systematically collate evidence (including that from PHC case studies noted above). This review was updated twice between 2001 and 2011 and used methods standardised by the Cochrane Effective Practice and Organisation of Care Group (thus excluding many observational or descriptive studies) to identify nine studies. It concluded that:

*“There is some evidence that ‘adding on’ services (or linkages) may improve the utilisation and outputs of health care delivery. However ... full integration probably decreases the knowledge and utilisation of specific services and may not result in any improvements in health status. More rigorous studies of different strategies to promote integration over a wider range of services and settings are needed.”<sup>16</sup>*

Atun and colleagues, publishing in 2011,<sup>6</sup> used similar Cochrane methods focused on “*priority population, health and nutrition interventions*” (including disease specific initiatives) and their integration into broader health systems, after first developing frameworks<sup>106</sup> for such analysis. From 8,274 citations, they included 12 studies, which examined just two sets of services: IMCI, using data from Tanzania and Bangladesh drawn from a multi-country evaluation of this program; and coordinated services for mental health and substance abuse in United States of America and the United Kingdom. This study also displayed a mix of positive and disappointing outcomes, but did conclude that these integrated models of service delivery had better quality of care and client acceptance. There were some efficiency gains, but these were not marked.<sup>6</sup> A broader 2010 review of health system perspectives on integration by the same group had similarly mixed findings.<sup>107</sup>

The overall conclusion from several iterations of these systematic reviews of broad implementations of health service integration was that the evidence base was too weak for firm recommendations.

### ***2.2.2 Reviews of integration in specific program areas beyond immunisation***

Over the years following the two systematic reviews discussed above, a range of theme-specific health programs re-examined service delivery strategies, particularly as 2015 MDG deadlines provoked progress assessments.

Concerning *child survival*, re-examination of the impact of IMCI, including new data not available to Atun's group in 2011, concluded that this integrated approach based on packages of care could improve health worker performance<sup>108</sup> as well as reduce deaths where intervention uptake was achieved, especially deaths beyond the newborn period.<sup>109</sup> Recognising that the fully integrated approach of IMCI was not achieving all it could in child survival,<sup>110</sup> WHO and partners launched in 2013 the Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD)<sup>111</sup> to draw attention to these persistent major causes of preventable child death. Despite the promotion of integrated services, annual reviews of GAPPD<sup>112</sup> showed patchy implementation, with coverage of exclusive breast-feeding and access to treatment care lagging behind coverage of the vaccines relevant to pneumonia or diarrhoea prevention. A large number of organisations receiving child survival grants linked to MCHIP used integration of activities in common delivery platforms and a strong community focus. One example is the community level form of IMCI known as integrated community case management (iCCM), whereby community health workers are trained in a simplified form of case management.<sup>88</sup> Although these were usually operating on a district (rather than national) scale, this approach consistently achieves impressive mortality reduction results, modelled to be likely to be double concurrent secular trends.<sup>113</sup> This mix of community-based care with integration of services is echoed in PHC evaluations as a powerful route to improved child survival.<sup>101,114</sup>



Global attention to the scale-up of *maternal, newborn or child health* (MNCH) as part of the MDGs led to a number of evidence reviews on how to improve outcomes in pregnancy and the newborn period. These highlighted two forms of integrated health services: multi-function delivery points; and integration across the life course, particularly resting on evidence from community-based care.<sup>115,116</sup> An examination of the potential to expand *antenatal care* by integrating other MNCH services into that platform reviewed 46 reports across HIV, tuberculosis, malaria, syphilis or nutrition services. This review found limited evidence of variable success, dependent on a range of provider, user and organizational factors.<sup>117</sup> The MCHIP integration review reported on four countries (Bangladesh, Honduras, Rwanda, and South Sudan) where community-based lay health workers successfully provided a platform for integrating many aspects of MNCH health information and care. These aspects included family planning (FP), prevention of postpartum haemorrhage (through distribution of misoprostol) and other aspects. Overall the MCHIP review concluded that:

*“... while the evidence base is thin, the experience to date seems to be that when integration of RMNCAH services is done well ... it has the potential to improve utilization (i.e., reduce missed opportunities) while maintaining quality of service provision.”<sup>88</sup>*

The immense power of early optimisation of *nutrition and development*, recognised by successive global evidence collections in 1999,<sup>118</sup> 2006/7<sup>119</sup> and 2016,<sup>120</sup> demands integrated approaches in two ways. First was the combination of interventions to promote nutrition with those that stimulate psychosocial development (‘nurturing care’).<sup>118,121,122</sup> Second was the use of any health care platform that could reach infants in the most biologically sensitive window between conception and the first two years after birth. This window is highly relevant to childhood immunisation services, as discussed later in this thesis. In addition, the importance of integrating counselling (for feeding and development) and nutritional supplementation into maternal health care is well recognized.<sup>120,123</sup> MCHIP experiences with integrated nutrition programs

highlighted improved coordination between medical and other cadres (Egypt), or linkage to other sectors such as sanitation (Cambodia) and agriculture (Nepal), in addition to the inclusion of nutrition in multifunction MNCH care.<sup>88</sup>

As treatment options for *HIV* expanded with a surge in global development interest,<sup>124</sup> particularly in perinatal settings, there was a parallel increase in assessing the evidence for integrating HIV interventions into general MNCH care.<sup>125,126</sup> This finding shows significant gains in coverage when HIV diagnostic and treatment services were combined with maternal, postpartum or infant care. High rates of unintended pregnancy and/or sexually transmitted infections (STI) often co-exist with HIV burdens, stimulating interest in integration of *sexual and reproductive health (SRH) services, including FP*, with HIV services. Review of this evidence base,<sup>72,127</sup> including empirical data from the *Integra Initiative*<sup>128-130†</sup> working across 16 countries in Asia and Africa, demonstrated the importance of the demand-side perspective in addition to seeking program efficiency. This review concluded that integration of SRH and HIV services is essential to properly address client needs.<sup>72</sup> Integration can demonstrably increase uptake of key interventions by those living with HIV, such as modern methods of contraception,<sup>131,132</sup> but there are challenges. Coverage gains can be patchy if there is poor managerial or system support.<sup>72</sup> Staff lapses can breach confidentiality making integrated services less acceptable than stand-alone care.<sup>72</sup> Quality may suffer if staff give less time or attention to complex counselling.<sup>130</sup> These studies were also important in demonstrating the value of mixed methods, facility level assessments, client interviews<sup>8</sup> and direct observation<sup>9</sup>; all methods influential on the research described in this thesis.

Beyond HIV, evidence for integrating *SRH* into general primary care services has been examined,<sup>133,134</sup> finding a range of problems in management, staff training and system support. A review of *FP* integrated with other services<sup>135</sup> found a variety of intensity in integration. Some just provided additional counselling by non-FP providers; others fully integrated contraceptive provision

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† <http://www.integrainitiative.org/> (accessed 15<sup>th</sup> February 2020).

alongside other services. Improvement in contraceptive coverage seemed dependent on the strength of implementation. Integration of *postpartum FP* with MNCH care is important when there is a desire to delay the next pregnancy. Counselling or referral during antenatal or the immediate postnatal period has been shown to improve contraceptive uptake, although this is highly dependent on the quality of service and availability of contraceptive services and commodities.<sup>33,135</sup> MCHIP experiences in India found it feasible to integrate FP into immediate postpartum care on a large scale through a mix of staff training, community education and systems support. A similar potential benefit was also demonstrated in Ethiopia, Kenya, Liberia, Malawi, Mozambique, Rwanda, Tanzania, Uganda, Zambia, and Zimbabwe.<sup>88</sup> Postpartum family planning integration after the neonatal period is largely dependent on integration with immunisation services, as discussed later in this thesis.

Preventive care for *malaria* during pregnancy provides a strong benefit to mother and infant in prevalent areas,<sup>136</sup> which is a strong driver to integrate these services with antenatal care. This follows a similar rationale for inclusion of malaria control for child health as part of IMCI. As with HIV, the childhood immunisation platform provided a clear pathway to scale for malaria services,<sup>137</sup> as discussed further in the section below. However, careful reviews of the mechanisms for some preventive services, such as insecticide-treated nets (ITN), demonstrated that while integration with MNCH care was useful for their distribution, it was not always the most effective. Often vouchers and other means of mass distribution (such as schools) proved superior.<sup>66,138</sup>

This section 2.2 has presented recent evidence reviews for integrated health services in program areas beyond immunisation. There are many examples of integrated services with positive outcomes, although the details of implementation remain critical to success. Staff motivations, skills and workload are especially important determinants; as are the attitudes of health service clients, with some examples where integrated services are not taken up as expected. The next section describes reviews of evidence to date for integrating other services with immunisation services.

## 2.3 Reviews of integrating immunisation and other services

The research in this thesis builds upon that by a number of groups working to strengthen immunisation in LMICs: the USA's Centers for Disease Control and Prevention (CDC), the MCHIP program, and John Snow Incorporated<sup>‡</sup> (JSI), working in collaboration with WHO at global, regional and national levels. Their work included several important systematic and scoping reviews published in a 2012 supplement to the *Journal of Infectious Diseases*.<sup>139</sup> This research, as well as other studies identified in the review below, identified a range of experiences of integration with immunisation programs, and a variety of measured outcomes of innovations attempting to integrate other services with immunisation.

### 2.3.1 Key reviews of integrating other services into immunisation, to 2012

Wallace, Ryman and Dietz (2012), of CDC, conducted a systematic review of experiences integrating other health interventions with immunisation service delivery, most often in the first year of life, up until 2011,<sup>58</sup> expanding on an earlier review.<sup>137</sup> They canvassed the main modes of immunisation service delivery: *routine services*, *enhanced routine activities* (ERAs, such as Child Health Days or periodic intensification of routine immunisation), and *immunisation campaigns* (usually annual or less common events with a particular disease control objective such as polio or measles eradication). Data were extracted from published and grey literature studies between 1993 and 2011 that assessed integration of another service with immunisation, and provided some measure of operational impact. Among 27 integration experiences (across 32 publications), a relatively limited range of services were reported as being provided alongside immunisation. The most common reports were for distribution of *vitamin A* or *anti-helminthic medicines*, or *malaria control and prevention* measures (intermittent

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<sup>‡</sup> <http://www.jsi.com/JSIInternet/IntlHealth/techexpertise.cfm> (accessed 15<sup>th</sup> February 2018).

preventive treatment for malaria in infancy (IPTi) or distribution of ITNs). Less frequently reported were the integration of services for *family planning*, *HIV*, *growth and nutrition*, and *hearing screening* (see table below).<sup>58</sup>

A companion scoping review by Partapuri, Steinglass and Sequeira (2012), of JSI/MCHIP, with broader inclusion criteria, examined integrated services at routine immunisation outreach. That is, settings for routine immunisation that are community-based and lack usual health facility resources such as refrigeration. Regular outreach visits are a common mode of immunisation service delivery in LMICs, to support overcome access difficulties.<sup>140</sup> The nine reports of integration with outreach services (see table below) encompassed a slightly different mix of added services: *antenatal care*, *vitamin A distribution*, *growth monitoring and nutrition advice*, as well as, to a lesser extent, *IMCI*, *family planning*, and *hygiene interventions*.

**Table 1: Number of reports of services integrated with immunisation by platform, in two key reviews 2012.** Adapted from Partapuri et al<sup>140</sup> for outreach, Wallace et al<sup>58</sup> for other platforms

| Service or intervention*                        | Immunisation service delivery platform<br>(parentheses indicate number of studies) |                         |                 |                 |
|-------------------------------------------------|------------------------------------------------------------------------------------|-------------------------|-----------------|-----------------|
|                                                 | Routine<br>(16)                                                                    | Enhanced<br>routine (5) | Campaign<br>(6) | Outreach<br>(9) |
| Malaria control (IPTi or ITN)                   | 8                                                                                  | 5                       | 5               | 1               |
| Anti-helminthic medicine                        | 1                                                                                  | 5                       | 4               | 1               |
| Vitamin A                                       | 2                                                                                  | 4                       | 4               | 4               |
| Growth monitoring and/or<br>nutrition promotion | 3                                                                                  | 5                       | 0               | 7               |
| HIV testing or referral                         | 3                                                                                  | 2                       | 0               | 0               |
| Family planning                                 | 2                                                                                  | 2                       | 0               | 3               |
| Hearing screening                               | 2                                                                                  | 0                       | 0               | 0               |
| Antenatal care                                  | -                                                                                  | -                       | -               | 6               |
| IMCI or illness care                            | -                                                                                  | -                       | -               | 3               |
| Hygiene                                         | -                                                                                  | -                       | -               | 1               |
| Newborn care                                    | -                                                                                  | -                       | -               | 1               |

Note: \*In many experiences more than one intervention was delivered with immunisation

It appears that different immunisation platforms vary in the degree to which they are suited to integrating different types of additional service, and this also varies by the type of service attempting integration. This is likely to reflect feasibility. For example, the constraints on time and resources in large national

campaigns may limit additional services to those that are quick and straightforward to provide. Or the need for staff to travel to (sometimes remote) community settings in outreach may limit the nature and volume of additional commodities taken along. In all cases, there is likely to be difficulties in integrating clinically responsive care (like IMCI) with an immunisation service that scheduled to a monthly or other routine.

The next section discusses the outcomes measured in these reviews.

### **2.3.2 Outcomes of integrating with immunisation, in reviews to 2012**

Of the 27 activities reported in the Wallace review,<sup>58</sup> 13 measured some aspect of coverage or uptake of the linked intervention. Benefits were seen for the added intervention in all cases, usually measured through increased population coverage, though often not to the coverage level attained by immunisation. In assessing the impact of integration on immunisation services, it was noted that only seven of the 27 experiences measured immunisation coverage, finding that there was usually (but not always) no decline. Immunisation coverage did not usually increase significantly with integration although there were exceptions. A randomised controlled trial (RCT) in Mali<sup>141</sup> found immunisation coverage increased along with integration of IPTi services. In addition, a grey literature report from India cited by Partapuri et al<sup>140</sup> suggested a similar boost when food supplements were distributed alongside immunisation.

Benefits to the linked service were seen in three of the service delivery platforms assessed: *routine*, *ERA*, and *campaign*. However, the review of *outreach* services was unable to consolidate outcome measures.<sup>58,140</sup> Contributions from community-based trained lay health workers were seen as key to the integration of other services with immunisation outreach visits.<sup>140</sup> Outcomes apart from coverage that were measured included acceptability to clients and providers. In most experiences integration was seen as positive and even able to reduce stigma in some cases (such as integration of leprosy care).<sup>142</sup>

Integrating *infant malaria control through IPTi* clearly benefited IPTi distribution without any harm to vaccine acceptability in African settings<sup>143</sup> or in

PNG,<sup>144</sup> although in the latter example overall knowledge was poor. By 2012, the immunisation platform was seen as the ideal route for delivery of IPTi, given the access it provided to children aged less than one year<sup>145,146</sup> with the WHO IPTi field manual (unusually) providing detailed instructions on the integration process<sup>147</sup>. Evidence was also strengthening for the integration of preventive malaria treatment in older age groups, through immunisation in the second year of life, and through other childhood platforms.<sup>41</sup>

Integration of *family planning* with immunisation was the subject of one of the earlier studies of integrated services, in Togo in 1994<sup>148</sup>. This can enable access to families at a time they are ready to control family size. The time when most countries schedule a primary series of vaccinations, between one and six months after childbirth, is also the period when post-pregnancy fertility is being re-established. This point in the life course is thus a golden opportunity to promote and distribute contraception to families who wish to delay another pregnancy.<sup>33</sup> Surprisingly, there were few publications on this available to the reviews to 2012, especially when compared to malaria or anti-helminthic medicines (see Table 1). Nevertheless, it was promoted as a promising practice<sup>62</sup>. Both *FP and HIV* need good counselling and commodities to be effective.<sup>59</sup> This raises a core implementation issue when integrating interventions that add time to the staff-client encounter, or require supplies that add logistical complexities.

### **2.3.3 Later reviews of integrating services into immunisation, 2012-19**

From 2012 to 2019 there were no published reviews across the breadth of immunisation and other service integration similar to those published by Wallace and colleagues.<sup>58,63</sup> Some health programs had reviewed experiences of integrating specific packages into immunisation services, discussed below.

Cohen and colleagues (2012) briefly reviewed the potential for adding non-vaccine *pneumonia* control interventions to immunisation sessions such as case-management or promotion of breast-feeding, hygiene or improved indoor air,<sup>149</sup> but noted the scarcity of evidence. This practice is tracked for pneumonia and *diarrhoea* by annual reviews of progress against the GAPPD strategy (introduced in section 2.2). The 2017 GAPPD progress update<sup>112</sup> continued to

record an absence of rigorous good practice examples, although does document some uncontrolled case studies combining nutrition advice with vaccination. The 2019 update did not add new implementation evidence to this.<sup>150</sup>

A systematic review of the integration of *HIV infant testing* into immunisation programs<sup>60</sup> noted the rapid increase in this practice over the twelve years prior to 2013, and found nine experiences (none of which were well controlled trials) among grey and peer reviewed literature. Measures of provider and client acceptability, and uptake of testing, suggested the practice was feasible and acceptable. The risk that HIV stigma may harm service acceptability was noted. Only one of the nine studies measured vaccination outcomes, finding no negative impact on the immunisation program. The review suggested the potential impact of integration required further research.

The 2015 review of *postpartum FP*<sup>33</sup> included six experiences of integrating FP with immunisation; four of these reported between 2012 and 2014. Five showed an increase in uptake of contraceptives and one showed no effect, possibly because of poor implementation. None measured the impact on immunisation coverage. The MCHIP technical summary on integration<sup>88</sup> also examined integration of FP with immunisation in Liberia. There was a call from both reviews for a stronger future focus on the details of implementation, deeming study of processes more pressing than studies of efficacy. They called for study of issues such as the burden on health staff, sustainable financing, policy and systems support, stronger monitoring and evaluation. Several of these were early reports of studies that were then eligible for inclusion in the systematic review reported in Chapter Five of this thesis.

An increase in *adolescent vaccination*, sparked by the scale-up of human papilloma virus (HPV) vaccination, led to a number of reviews of research into immunisation in this age group, particularly integration with school health programs. This includes experiences from the 19 LMICs in the Gardasil Access Program, last reviewed in 2016.<sup>151</sup> Success was enabled by knowing one's target population, community confidence and engagement, accessible financing, reliable supply chains, and active linkage to other services for the mothers of



targeted girls. Additional reviews examined the potential integration of non-vaccine interventions with HPV vaccination, refining a broader selection of 14 public health interventions<sup>152</sup> to nine priority additions<sup>153</sup> based on known efficacy data. All reviews identified the importance of local stakeholder involvement in integrated program design, with a Tanzanian study<sup>154</sup> highlighting potential pitfalls if lack of local experience with integrated adolescent health program is not taken into account. While this age group is outside the scope of the research in this thesis, lessons from integration in the first years of life are likely to be relevant to school vaccination programs and vice versa.

Beyond the reviews of particular program areas discussed here, a scoping search also found a considerable number of primary studies between 2012 and 2016 examining different aspects of integration of other services with immunisation. The volume of these, and the absence of any synthesis of this evidence since 2012, prompted the conduct of a systematic review of publications across those five years as one activity in this research, as discussed in Chapter Five.

### ***2.3.4 Integration of immunisation into broader MNCH services***

The evidence reviewed above describes the integration of additional interventions into the immunisation platform. This direction of change is more commonly studied and reported than the converse: the integration of immunisation services into other platforms. Although less common as a service delivery innovation, there is some evidence for strengthening immunisation in this way, of which the longest standing is that relating to IMCI.

#### *Integrated Management of Childhood Illness (IMCI) and immunisation*

Under the *IMCI* strategy, established in 1995, health workers in facilities are trained to administer a case management algorithm providing integrated assessment and management for the most important diseases of childhood, including malnutrition, as well as provide preventive care including checks on growth, feeding and immunisation status.<sup>70</sup> Thus, IMCI represents a form of

integration whereby catch-up vaccination is added into the clinical care of a child presenting with illness. Although IMCI implementation generates increased coverage with many child survival interventions, as discussed above, immunisation has not been reported to benefit as expected. The rigorous 2016 synthesis by Gera and colleagues<sup>109</sup> of IMCI studies in India, Bangladesh and Tanzania found little or no change in vaccine coverage in two RCTs and two controlled-before-after (CBA) studies of IMCI implementation. This was echoed by a CBA study in Benin that found improved mortality and illness treatment, but poorer immunisation coverage in the IMCI intervention sites.<sup>155</sup>

Reviews to build the evidence base for the *community-oriented form of IMCI (iCCM)*<sup>156,157</sup> have largely failed to assess how well immunisation was integrated, even though promotion of vaccination is a common aspect of the community health worker's role. A few program evaluation reports did claim gains for immunisation coverage through iCCM, for example in Malawi and Cameroon.<sup>158</sup> Many MCHIP initiatives included vaccination as a component of MNCH development projects.<sup>§</sup> MCHIP reports of improved immunisation coverage often came from community-based activities that included similar types of education and social mobilisation as that promoted in iCCM.<sup>88</sup>

Studies of *health worker practices* after IMCI training suggest it is difficult to integrate the checking of immunisation status and provision of catch-up vaccination into a clinical encounter for a sick child. In Ghana, immunisation status was checked in just 20% of sick children.<sup>159</sup> Studies of iCCM quality, such as in Ethiopia,<sup>160</sup> found that checking immunisation status was performed less well than treatment tasks for pneumonia, diarrhoea or malaria. A systematic review of IMCI training outcomes<sup>108</sup> found no overall difference in vaccination between IMCI-trained and control groups. However, in a subset of settings where health staff had lower baseline performance, IMCI training was associated with a greater likelihood (RR=3.45, 95% CI: 1.49–8.01) of catch-up vaccination.

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<sup>§</sup> MCHIP also directly supported immunisation in LMICs, through programs on global immunisation policy, routine immunisation, supply chains, and new vaccines.

*Missed opportunity for vaccination (MOV)*

'Missed opportunity for vaccination' refers to the failure to provide immunisation when a child interacts with the health system for another reason. The term has been used since the 1980s,<sup>161</sup> especially by the Pan American Health Organization's decades long program, which suggested MOV prevalence ranged from 34 to 77% of contacts.<sup>162</sup> A 2014 systematic review of 45 studies by Sridhar and colleagues<sup>32</sup> estimated prevalence at 32.2% (95% CI: 26.8–37.7). Causes for the failure to vaccinate include the attitudes of staff focused on acute clinical care, false contraindications, high workloads, logistic problems, or lack of community demand.<sup>32</sup> Remedial programs in the Americas in the 1990s were able to demonstrate decreased MOV in places such as Peru and elsewhere.<sup>163</sup> Using updated analytic tools, new work in Latin America and the Caribbean from 2014,<sup>164,162</sup> along with a global WHO program renewed in 2017,<sup>165</sup> are promoting a new program of work to identify corrective measures. Recent research, so far, has focused on problem analysis rather than testing interventions; as at 2019 there were no reports of recent controlled trials of MOV responses in LMICs.

*Integrating immunisation into maternal and newborn health programs*

Failures in integration of immunisation into *maternal health* services were identified in a 2011 systematic review<sup>166</sup> as an important contributor to under-vaccination. There are two particular points where immunisation must be integrated into MNH care. The first is *within antenatal care (ANC)*, where the incorporation of *tetanus toxoid vaccination* is essential to the elimination of maternal and neonatal tetanus. The 2015 global target for tetanus elimination was missed, with 18 countries (including PNG) still to achieve elimination; lack of integration is one contributor.<sup>167</sup> Given that such integration is now seen as simply one element of good quality ANC,<sup>168</sup> it is rarely the primary subject of a health services study. While ANC is stronger than other MNCH platforms, there is still work to do. A 2017 review of 20 countries in sub-Saharan Africa found close to one fifth of women missing out, with a median coverage for receipt of least one dose of tetanus toxoid vaccine of 82.1% (range: 56.7–97.3%).<sup>169</sup> Beyond the well-established role in tetanus elimination, maternal immunisation is also

of increasing importance<sup>170</sup> to the control of other diseases such as pertussis or influenza.<sup>171</sup>

The second MNH point of integration is for *vaccination at birth against hepatitis B*; recommended by WHO as necessary for all newborns within 24 hours of birth.<sup>172</sup> However, its inclusion as a standard aspect of quality newborn care is less advanced, often because national policies or local practices, do not support it, and/or because routine postnatal care (PNC) is at far lower coverage than is ANC.<sup>17</sup> A 2012 scoping review identified important service integration practices including local facility-level policy, standing orders, ensuring vaccine availability, clear delineation of responsibilities, and appropriate prioritization of vaccination in relation to other, sometimes more urgent, newborn care.<sup>17</sup> A community-based option for immunisation through postnatal home visits is documented in Indonesia<sup>173</sup> and in Burnet Institute's experience in rural PNG<sup>174</sup>. This latter study found it feasible to deploy community-based trained lay health workers as both vaccinators and providers of postnatal care.<sup>175</sup>

#### *Integrating immunisation into other programs*

Apart from those described above, there are few other research reports of integrating immunisation into other stand-alone health development programs. One exception from Zambia,<sup>176</sup> reviewed by Wallace et al,<sup>58</sup> included vaccination as part of a *growth monitoring* program, finding a boost to both immunisation coverage and timeliness.

### **2.3.5 Research and practice questions raised by reviews of integrated services**

The appraisal above highlights a number of research and practice questions important to efforts to promote more integrated services. The 2012 recommendation by Schuchat and de Cock<sup>139,177</sup> for strong evaluation and operations research into coverage, quality, acceptability, complexity and unintended consequences of integrated services, has been taken up by many. However significant questions remain unresolved.

A striking finding across most studies was that the details of implementation have a large effect on how beneficial any change is. The

implementation questions that are raised may be classified under categories of service delivery arrangements, acceptability, equity, and measurement challenges.

#### *Service delivery arrangements*

*When services are provided affects benefits.* For example, a review of the integration of malaria prevention in sub-Saharan Africa noted that “*low immunization coverage and incomplete overlap of the target populations for immunizations and linked interventions drew concern around efficiency*”.<sup>58</sup> This problem was particularly acute for seasonal malaria prevention, where the immunisation program may not be accessing the right age groups at the right time.<sup>178</sup> A similar challenge is seen in postpartum family planning<sup>179</sup> where it may not be straightforward to match the optimal timing for FP with immunisation schedules that are determined by immunological and programmatic factors.

*Which staff are expected to perform which services is critical* across almost all integration experiences, including many MCHIP projects,<sup>89</sup> with time burdens<sup>130,180</sup> or attitudinal factors<sup>18,181</sup> determining effectiveness. Many reviews note the potential for integrated services to over-load staff and managers, to the possible detriment of quality of care. The pregnancy and postnatal periods are also points where simply improving coverage is insufficient, and improved quality of care is especially necessary if health outcomes are to be improved.<sup>182-184</sup>

*Matching the linked intervention to the delivery setting* (for example avoiding combination of clinical with preventive) was mentioned by some reviewers<sup>17,140</sup>; especially important when logistics are under pressure such as during campaigns or on outreach visits.<sup>58,140</sup>

*Stress on support systems such as information or supply chains* may affect the success of integration. In many project evaluations, where integration was attempted in a less controlled setting, it was supply disruptions that often proved a serious constraint on impact.<sup>88</sup>

*Acceptability and uptake questions*

The acceptability of integrating services is examined from the provider viewpoint in most reports, less commonly from the client viewpoint. Many studies assessed some aspect of client satisfaction with the process of integration, usually finding a majority in favour. However the details of why a minority might not favour integration are infrequently elucidated. It has been identified that ‘socially sensitive’ services such as family planning may not always be seen as acceptable to clients,<sup>142</sup> and that there is a risk of stigmatization with HIV service integration<sup>60</sup> if implementation is not handled well. Warren and colleagues<sup>72</sup> noted, based largely on the Integra Initiative experience, that there is a “*complex relationship between stigma and service integration*” with some clients preferring but others disliking the experience of incorporating HIV services into general care. One aspect of community engagement has not been systematically incorporated into studies of integrated services. That is, the question of which model of integration clients would prefer, when services are being re-organized.

*Equity may not always be advanced by integration*

Equity may not automatically improve with integration. Equitable coverage across sub-populations such as the poor, ethnic minorities, rural and remote, or women and girls is rarely assessed in the studies discussed above. Victora, Barros and others, introducing the concept of ‘co-coverage’ (that is: coverage with a whole package rather than individual interventions),<sup>185,186</sup> demonstrated in a 2005 analysis<sup>187</sup> that integrated packaging of child survival interventions risked making coverage less equitable.<sup>\*\*</sup> A similar warning in 2002,<sup>188</sup> concerning SRH interventions, suggested increased marginalisation may follow integration. MCHIP emphasised the need for equitable coverage in their integrated MNCH development initiatives,<sup>89</sup> but integration was assumed to be

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<sup>\*\*</sup> The mechanism for inequity was that in a fragmented system the poorest children received at least some individual interventions. But after integrated packages were introduced those poorest still unreached by the program missed out on the whole package.

inherently equitable, based on the working hypothesis that “*in most circumstances, integrated services provide care more effectively and equitably than vertical services*”.<sup>88</sup> A search for equity assessments among other integration reviews above failed to find significant reporting of this issue. Although one study from Ethiopia<sup>189</sup> using co-coverage, found less inequity in integrated service access (although coverage was uniformly very low) when compared to household level inequities such as access to clean water.

#### *Measurement questions – outcomes and processes*

The importance of measuring coverage, acceptability and quality<sup>177</sup> is highlighted by many key reviews and the Countdown group,<sup>27,190</sup> often in response to a paucity of rigorous outcome measurement. The synthesis by Wallace and colleagues<sup>58,142</sup> highlights how infrequently immunisation coverage was monitored to check for detriment or benefit to immunisation after another service has been integrated. This alarming omission compromises the ability of service delivery innovations to check for unintended consequences. It also weakens the common practice of using immunisation coverage estimates to predict the potential gains that could be achieved for linked services with integration.<sup>191</sup> The need for stronger outcome measures is echoed by those promoting family planning and immunisation integration,<sup>62</sup> including the establishment of a dedicated sub-group to establish improved measures for monitoring and evaluating the greater integration of FP and immunisation. The Global Vaccine Action Plan<sup>37</sup> initially had no indicators in place to monitor its strategic objective of stronger health system integration. However from 2016 a Composite Coverage Index (conceptually linked to co-coverage discussed above)<sup>186</sup> used by the Countdown to 2030 monitoring group was introduced.

Improved process measures, including standardised models of service integration, are also essential to enable further research into the practice issues discussed above. A number of reviews examine the integration process, especially those for HIV services, where differing service models (see Section 2.1)<sup>8,90</sup> were identified as providing differing degrees of integration. The Integra Initiative identified the differing levels of integration for HIV service as

determinants of effectiveness<sup>72</sup>; noting that ‘structural integration’ of staff and facilities is insufficient without ‘functional integration’ in the practice of service delivery.<sup>129</sup> WHO field guides such as those for IPTi<sup>147</sup> and birth-dose vaccination against hepatitis B<sup>192,193</sup> also included some implementation advice on the process of integration. The international Countdown consortium,<sup>190</sup> looking forward to measures for 2030 have noted the need for better measures of quality, effective coverage, and multi-sectoral service provision.

The careful study of time taken in service delivery in integrated strategies<sup>180</sup> has been incorporated within other standard impact and cost modelling software to estimate cost saving of ‘bundling’.<sup>194</sup> However additional linkage to measures of quality of care have not yet been systematically undertaken.<sup>130</sup> Researchers and planners involved in integration evidence collation, in JSI,<sup>195</sup> CDC,<sup>177</sup> WHO<sup>76</sup> and other research leaders<sup>7,16,50,86,104,129</sup> have proposed various frameworks for analysis of these issues. However there is not yet a consensus definition of the different models of integrating services that would allow this aspect of implementation to be systematically studied.

### **2.3.6 The need for additional evidence**

The discussion above demonstrates that while integrating health services can bring gains in improved coverage, and immunisation services are a useful platform, there are documented risks of adverse outcomes, and the implementation evidence base is currently inadequate to define optimal models of integration.

Some authorities argued that the effectiveness of integrated services is beyond doubt. One opinion, addressing the Indian context, proposed that “... *the [immunisation] programme may be transformed to one of control of childhood communicable diseases, with the potential of ... integrating all other current vertical (single disease) control efforts with it*”.<sup>61</sup> A 2015 review of postpartum family planning concluded that “*The case for greater integration of family planning into MCH services in facilities and at the community level is strong, and it is doubtful whether further research, including expensive RCTs, is needed*”.<sup>33</sup> Some of these



more sweeping endorsements seem overly optimistic, given that integration does not always increase coverage, quality, or acceptability of care.

However there is consensus that the implementation details of integrating services require further study. Reynolds and Sutherland warned in 2013 that:

*“the rush to intervene [with integration strategies] without adequate monitoring and evaluation will continue to result in a weak evidence base for decision making and resource allocation”.*<sup>75</sup>

The 2014 meeting of WHO’s Immunization and Vaccines Implementation Advisory Committee meeting concluded that: *“the question is no longer whether to integrate but how, when and where to integrate”*<sup>76</sup> and the 2015 FP review quoted above goes on to state: *“a more important priority is the analysis of health systems and policies to identify the practical obstacles that impede such integration and ways of overcoming them”.*<sup>33</sup>

This call has been echoed by many public health leaders, at that time and subsequently, including WHO,<sup>77</sup> MCHIP,<sup>88</sup> the FP-EPI Integration Working Group,<sup>62</sup> and health system researchers,<sup>50,59,86,104</sup> representing a clear need for implementation research carried out within a health policy and systems frame, as discussed further in Chapter Three.

### **2.3.7 Evidence priorities for this research**

Two implementation research topics seem to be high priorities. The study of the disparate implementation issues noted above would be advanced by *better characterisation of models of integrated service delivery*, with different models elaborating key aspects such as where, when, by whom, and what services are being delivered. These dimensions could help establish, for different program areas and service delivery settings, which approaches to integration are most likely to work, and what resources they would require.

A richer description of demand-side factors is also important to refocus integration on its primary purpose of providing quality care for multiple co-existing health needs. This reorientation is also important to better understand acceptability, not just of individual interventions but also of offering them in

combination, and how the interaction between client and provider affects uptake. There is a need to better understand the consistent reports of a minority (sometimes sizeable) of health care clients who dislike integration. Lastly, more demand-side implementation research is needed to capture families' views on how they would prefer services to be organized, so this can be injected into local planning.

Three research activities were undertaken to help meet the need for additional evidence noted here.

*Firstly*, a *systematic review* of experiences integrating immunisation with other activities between 2012 and 2016 could update the synthesis last done in the CDC-led review of publications up until 2011.<sup>58</sup> This was also encouraged by the author's work with WHO, CDC, JSI and other colleagues on the collection of integration evidence to support an exchange of best practices for immunisation managers in the African region,<sup>87</sup> and to support WHO work to develop a global guidance document on integrating immunisation services.

*Secondly*, opportunity has been taken to incorporate integration questions into an unusual *prospective longitudinal cohort study*, tracking women in rural PNG through pregnancy and the first year after childbirth. This enables synchronised study of service delivery uptake and demand-side issues identified above. Service delivery aspects able to be studied include families' use of services and the degree to which they were integrated. Demand-side issues able to be studied include co-morbidity and/or co-existing health service needs that call for integrated services, as well as acceptability of, and preferences for, various potential future integration options.

*Thirdly*, integration questions have been included in a *cross-sectional assessment of preventive health services in the postnatal and infancy period (including immunisation services)* in PNG. This includes the perspective of health providers and the facilities in which they work, assessing the feasibility and quality of local attempts to integrate services.

Together these studies can generate evidence, in the PNG context, on what types of intervention and types of service delivery reform are high priorities

for immunisation and family health, what determines the success of efforts to increase integration, and how success might be monitored and evaluated.

Chapter Three maps out the research frameworks, scope and objectives that guide these three studies, making use of the issues identified in review of current evidence presented above. Prior to that, the final section in this chapter provides background on PNG, its health status, health system and services in MNCH, including current attempts at integration. All of these aspects make PNG an appropriate site for the study of integrated health services.

## 2.4 Papua New Guinea as a setting to study integration

Papua New Guinea has major barriers to health care access. These include the constraints in infrastructure that accompany a relative lack in economic resources, diverse cultures with differing attitudes to health care, a fragmented public sector, and a persisting high burden of morbidity and mortality. Health planners commonly seek integrated services as one response to these challenges. This section provides an overview of PNG, its health system, issues in service delivery, PNG's current aspirations for more integrated family health services. It also provides a rationale for East New Britain province (ENB) as a suitable sub-national site for study of integrated services.

### 2.4.1 PNG country overview

The Independent State of Papua New Guinea occupies the eastern half of the island of New Guinea (the second largest island in the world after Greenland) along with many nearby islands. It has a long land border with the Indonesian province of Papua and maritime proximity to the continent of Australia in the south and the Solomon Islands in the east. Its interior is characterised by rugged mountains, its coasts traversed by many large rivers, and offshore lie hundreds of islands that are either volcanic or low-lying.<sup>196</sup> Fertile highland and coastal regions of the main island and larger offshore islands such as New Britain have supported relatively concentrated populations for thousands of years.<sup>197</sup> PNG's recent history has been one of colonial administrations; German in the north and British in the south during the 19<sup>th</sup> century, then a United Nations protectorate under Australian administration from 1919, until independence as a Commonwealth nation from 1975.<sup>198</sup>

PNG's population, at the time this field research commenced, was estimated in World Bank datasets at just over eight million in 2016<sup>199</sup> although the government's 2011 Census,<sup>200</sup> which showed a 3.1% annual growth rate, would project a larger figure. The population remains over 80% rural,<sup>200</sup> many reliant on subsistence farming. PNG group identities are oriented to the local clan or village, with thousands of customary communities of extraordinary

diversity. This variety is illustrated by the existence of an estimated 853 distinct languages, of which 677 remain vigorous, developing or fully institutionalised.<sup>201</sup> The official languages are English, Tok Pisin (a fully developed creole), Hiri Motu (an older trade language) and PNG Sign Language.

Rugged geography and a low level of transport and other rural infrastructure pose great barriers to population movement and services. There are few major roads apart from a highway network that links major towns along the central highlands with one extension to the north coast; no trunk roads extend from the national capital Port Moresby. Travel by foot or by river is common, supplemented by an active but expensive internal aviation industry and a variety of coastal shipping.

Climate and natural environment can be extreme: tropical wet seasons can block road or river access, volcanic instability can make communities uninhabitable, the north coast has seen villages destroyed by tsunamis, and many provinces are exposed to earthquakes (ENB experiences more than 50 per year). Major highland earthquakes of February/March 2018, apart from immediate loss of life and property, brought long-term hardship; locally through destruction of food gardens needed for subsistence, and nationally through the disruption of mining and resource extraction initiatives that are critical to PNG's economy.

Infrastructure and development challenges mean that, despite significant natural resources that can be traded internationally, PNG's human development index (HDI) remains relatively low with a 2016 HDI of 0.516 placing it at 154 of 188 countries or territories, a ranking shared by Zimbabwe. While improving, PNG's HDI is increasing more slowly than comparators such as Cambodia or Myanmar.<sup>202</sup>

Complexity of administration constrains many of PNG's public sectors, including health. At the time of PNG's independence in 1975, pressure for autonomy from particular areas, including the then districts of Bougainville and East New Britain, meant that a quasi-federal structure emerged; with successive waves of increasing decentralisation of powers. Pressure to decentralise is seen in the "Organic Law on Provincial Governments" of 1977 and its expansion to

**Figure 2: Political map of PNG, showing provincial boundaries**



This mix of cultural, geographic and political fragmentation dominates public sector policy and implementation. It exacerbates the common challenges of geography and climate, and worsens the effect of constricted economic resources, through local perceptions of unequal access to funding flows.

## 2.4.2 Overall health outcomes in PNG

PNG's burden of disease, like many LMIC settings, has a mix of persisting infectious diseases at high prevalence, such as pneumonia, diarrhoea, malaria, tuberculosis and sexually transmitted infections,<sup>205,206</sup> complicated by rapid emergence of chronic diseases driven by social and lifestyle determinants.<sup>207</sup> Child mortality rates remain high; PNG is persistently one of the highest in Asia or the Pacific,<sup>208</sup> with under five mortality at 57 and newborn mortality at 24 deaths per 1,000 live births.<sup>209</sup> PNG children also suffer an extraordinarily high prevalence of under-nutrition, with surveys consistently showing between 40% and 50% of children under five as stunted.<sup>210,211</sup>

Table 2 sets out key health outcome measures for PNG at the commencement of the fieldwork for this research.

**Table 2: Health outcome measures in PNG over period of field studies**

| Indicator                     | Unit                           | 2015 | Source                                                  | 2016-18            | Source                                                                            |
|-------------------------------|--------------------------------|------|---------------------------------------------------------|--------------------|-----------------------------------------------------------------------------------|
| Life expectancy at birth      | years                          | 65.4 | World Bank <sup>199</sup>                               | -                  |                                                                                   |
| Under 5 mortality rate        | deaths per 1,000 live births   | 56.2 | WHO <sup>212</sup>                                      | 49                 | Demographic and Health Survey <sup>213</sup> (covers five years preceding survey) |
| Infant mortality rate         |                                | 43.8 |                                                         | 33                 |                                                                                   |
| Neonatal mortality rate       |                                | 24.0 |                                                         | 20                 |                                                                                   |
| Maternal mortality ratio      | deaths per 100,000 live births | 435  | 2015, Global Burden of Disease modelling <sup>214</sup> | 171 (range 95-247) |                                                                                   |
| Stunting (low height for age) | percent of children under 5    | 48.2 | 2011 Survey <sup>210</sup>                              | -                  |                                                                                   |

Note: Stunting was not reported from 2016 DHS due to data quality concerns.

Maternal mortality was estimated by the Global Burden of Disease modelling at a very high 435 deaths per 100,000 live births in 2015,<sup>214</sup> a ratio significantly higher than standard WHO estimates<sup>209</sup> and the most recent Demographic and Health Survey<sup>210</sup> but one that accords with local expert assessment.<sup>215</sup> Maternal deaths were highlighted as a national emergency in 2008, resulting in a ministerial task force and action plan,<sup>84</sup> however service provision (discussed below) has not changed significantly in the subsequent decade.<sup>211,213</sup>

### 2.4.3 PNG's health system

#### *Facilities and workforce*

Modern health systems were introduced under Australian administration in the early 20<sup>th</sup> century, alongside a patchwork of church-based health initiatives, reflecting the varied history of Christian missions in different provinces.<sup>216</sup> Prior to independence, government health services were highly centralised with a network of small hospitals, rural health centres and village-based 'Aid Posts', supplemented by regular outreach patrols. This era saw supplementation of the medical and nursing workforce with the introduction of auxiliary health cadres termed Health Extension Officers (HEOs) and a variety of community-based health workers including 'Aid Post Orderlies'.<sup>217,218</sup> These auxiliary cadres are critical in PNG. HEOs take on a variety of senior clinical and managerial roles, and community-based staff have been professionalised as Community Health Workers (CHWs), now a paid cadre within the formal health system with one to two years training based on national competency standards introduced in 2001.<sup>††219</sup>

Medical professionals are usually located only at hospital level, with HEOs, nurses and CHWs staffing peripheral facilities. An intensifying crisis in human resources for health is due to training shortfalls, with graduate numbers failing to keep pace with population growth.<sup>220,221</sup> Even modest proposals to redress the gap would require a tripling of trainee outputs by 2030,<sup>222</sup> however the government controls only a minority of training institutions. Doctors, specialist nurses, and allied health professionals are trained at the University of PNG's School of Medicine and Health Sciences (SMHS) in the national capital.<sup>223</sup> The Divine Word University, run by the Catholic Church in the provincial capital Madang, trains HEOs and other health professionals (including a fledgling second medical course). Nurses are trained at nine schools around the country

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<sup>††</sup> The term Community Health Worker (CHW) in PNG thus differs from common global usages that use 'CHW' to refer to trained or untrained lay health workers who are often volunteers.



(including one at the University of PNG) and CHWs at 11 schools. Seven nursing schools and all CHW schools are run by church health agencies.<sup>216</sup>

Trained lay health workers, usually volunteers, are active in many provinces, but without consistency across the country. In most sites these have been established by CHS or international non-government organisations such as World Vision, Save the Children and others. These workers are often enlisted in maternal and child health care (Section 2.4.5) with a variety of nomenclature such as ‘village birth attendants’<sup>224</sup> or ‘community based distributors’ (of contraceptives for example), or ‘marasin meri’ (medicine woman, often distributing antimalarials).<sup>217,225,226</sup> From 2003,<sup>227</sup> the National Department of Health codified this group as ‘Village Health Volunteers’ (VHV) with guidance on expected roles. Their oversight was assigned to government provincial health promotion units, however actual support and supervision remain the purview of non-state actors in most parts of PNG where they are active.<sup>217,225</sup>

#### *Non-state actors in health*

The relationship between government and other actors in health is complex. A large proportion of services are provided by non-state actors, especially various faith-based organisations that are the legacy of Christian missions, collectively known as ‘Church Health Services (CHS)’. These provide around 50% of all rural health services.<sup>221</sup> They are often the only provider of reliable care in many remote districts, for example providing the great majority of complex obstetric care outside of provincial capitals.<sup>216,228</sup> The government provides significant annual lump sum funding (possibly as much as 80% of operating costs) to registered CHS agencies; and in recent years attempted to codify the arrangement with central legislation and by requiring CHS facilities to adhere to new minimum standards. CHS vary greatly across the country in denomination, history and level of services provided. Several assessments have found that CHS provide services at higher quality with fewer staff, possibly because they have more control over human resources than government agencies.<sup>216,229,230</sup>

International non-government organizations have been active in PNG for 20 years. Many promote community-based care through support for lay health workers (noted above) and work in sub-sectors such HIV or tuberculosis control.<sup>221</sup> Some act as foreign aid contractors to deliver national, provincial and community level health services; more often as development initiatives and rarely as clinical care; two examples among many include World Vision<sup>‡‡</sup> or Clinton Health Access Initiative<sup>§§</sup>. The Burnet Institute<sup>\*\*\*</sup>, a sponsor of much of the research presented in this thesis, occupies an unusual place in this landscape in acting as grass-roots community partner, and implementer of externally funded development initiatives, as well as a research institute conducting studies with key partners such as the Papua New Guinea Institute of Medical Research.

More recently other private interests, such as resource extraction companies, also provide health care services. For example, the Oil Search Foundation plays a major role in health service delivery in several provinces.<sup>231</sup>

Development assistance from foreign governments (Australian, Chinese and others), development banks and other sources, currently funds many critical health functions at national and provincial levels; from infrastructure replenishment, through health professional education, to emergency responses for disasters or outbreaks. Approximately 25% of the USD108<sup>†††</sup> per capita spend on health in PNG comes from development assistance for health; a proportion well in excess of the 3% that is the aggregate across the World Bank grouping of lower-middle-income countries that includes PNG.<sup>232</sup> The majority of development assistance for health in PNG has come from the Australian government, with a high proportion provided in the form of technical advisors. This form of assistance is not always welcomed nor able to be effectively absorbed.<sup>233</sup>

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<sup>‡‡</sup> <https://www.wvi.org/papua-new-guinea>

<sup>§§</sup> <https://clintonhealthaccess.org/papua-new-guinea/>

<sup>\*\*\*</sup> [https://www.burnet.edu.au/countries/8\\_papua\\_new\\_guinea](https://www.burnet.edu.au/countries/8_papua_new_guinea)

<sup>†††</sup> 2015 purchasing power parity US dollars

*Decentralisation, health sector planning and research*

PNG's health system now follows a decentralized pyramidal model,<sup>221</sup> in which a National Department of Health (NDOH) provides policy, standards and monitoring oversight, as well as specific centrally administered services such as medical supplies and immunisation programs. PNG's 22 sub-national jurisdictions are responsible for health service provision through three levels of care: provincial and district hospitals (although not present in all districts), health centres and sub-centres (with limited inpatient and childbirth care), and community-based 'Aid Posts' or newer 'Community Health Posts'.<sup>83</sup>

The successive waves of public sector decentralisation discussed above have affected the health system. These often created difficulties in local health authorities losing control of human resources, and forcing sub-national health authorities to compete for funding with other local development priorities.<sup>230,234</sup> There has been fragmentation whereby provincial hospitals have separate management and accountabilities to rural health care and public health services. A 2007 reform to address this through the creation of Provincial Health Authorities, with powers for more unified management and increased autonomy over all health actors in the province, is providing some benefit to those provinces able to implement this effectively.

The current National Health Plan<sup>83</sup> 2011–2020 prioritises primary health care, the rural majority and the urban poor, and takes a systems approach to health services. There are a variety of other national initiatives to address critical issues in human resources and key health threats, such as drug-resistant tuberculosis. The plan, and an array of national health policies, are soundly evidence-based; the most common constraint is implementation.

Medical and public health research has a long history in the country. The PNG Institute of Medical Research is an independent statutory body, founded in 1968, with a proud history of discoveries informing global and national health policy, particularly in infectious diseases and child survival.<sup>235</sup> Other bodies, such as the National Research Institute, have provided important analyses of the financing and governance of public sectors including health. However there is

not yet a sustained body of effort that is researching the critical issues of health systems, policy and service delivery. This lack was recognised in the development of the country's first health research agenda in 2014,<sup>223</sup> which identified a range of research priorities, almost all of which relate to questions of implementation and service delivery.

#### ***2.4.4 General health service delivery issues in PNG***

Life-saving health services in PNG are often difficult to access, not optimally utilized, or do not properly meet families' health needs. Contributing factors described above include PNG's unique mix of diverse populations, rugged geography, and extraordinarily limited transport and infrastructure, especially in rural areas.<sup>83,236</sup> As well as these physical access difficulties, health care access is constrained by limits on human and other resources for health services, financial barriers, lack of understanding of the need for medical care, as well as other cultural factors (such as lack of partner support or preference for traditional arrangements).<sup>34</sup>

For many years, PNG's health system has responded through deploying HEOs, nurses and CHWs in smaller, more peripheral health facilities, and the provision of health services at community level through Aid Posts and mobile outreach clinics. However recent government and research analyses acknowledge that health service delivery to rural or urban poor communities has remained static or deteriorated,<sup>83,237</sup> including those for maternal and child health,<sup>84</sup> with fewer outreach visits, and permanent or temporary closure of peripheral facilities. Approximately half of the Aid Posts established in the late 20<sup>th</sup> Century have now been closed.<sup>83,238</sup> Government monitoring data show outpatient visits to hospitals, at 1.2 visits per person per year, have been static or declining since 2010 and remain well below expectations.<sup>239</sup>

There is a critical need, across the health services, to find new ways to make services more accessible and affordable for communities. Although free primary health care has been an aspiration since independence, the reality has been a jumble of varied, locally administered fees for health services; semi-formal in government facilities, and more formally in non-government

facilities.<sup>240</sup> This reality has meant significant out-of-pocket health expenses for PNG families, exacerbated by the fact that non-government agencies are the only service providers available to many rural populations.<sup>237</sup> The 2014 enactment of the Free Primary Health Care and Subsidised Specialist Services legislation aimed to eliminate fees for government and non-government primary care services. However the policy is proving difficult to implement.<sup>241,242</sup> Although PNG's proportion of 'out-of-pocket' health financing was estimated at 10% of 2014 figures<sup>232</sup> the more recent collapse of export revenue saw government health budgets cut by 20% in 2017, to a level 16% lower in real terms than 2012.<sup>243</sup> This has meant informal fees for services remain common, as facilities struggle to generate sufficient revenue to fund simple operational costs. Social health insurance, or other broad-based pre-payment arrangements are not yet feasible, and increased overall spending is unlikely to improve outcomes until inefficiencies in the system are redressed.<sup>244</sup>

A further critical need is to measure and improve quality of care. A major constraint on quality is the accelerating crisis in human resources faced by PNG's health sector. Staff shortages across the nation are felt in all locations, but especially in rural facilities. There are insufficient numbers in all cadres, especially acute in specialised nursing, and general medical categories.<sup>220,238</sup> The fragmentation of public sector responsibilities discussed above, has often resulted in provincial health agencies lacking authority to revise staffing structures and unable to replace underperforming or absent staff members. Those provinces that have converted to Provincial Health Authority legislative powers have gained some increased control over workforce, however the extent of this is limited. CHS capacity to directly manage their staff has been seen as a key contributor to improved quality of care.<sup>216</sup> A major over-riding constraint is the insufficient staff numbers discussed above. Overworked staff find it difficult to comply with national policy and standards, and this provides health planners a strong incentive to seek short-term efficiencies in service delivery.

Health planners in PNG are also grappling with questions relating to the organisation and management of services. These questions include how to

improve coordination across differing management of hospital, rural and public health services; how to ensure proper placement of staff; which services should be provided at the most peripheral levels (health posts or community outreach patrols); and how different services to families could best be planned, coordinated and resourced.<sup>83,237</sup> Health managers also recognize the ‘know-do’ gap in health care provision. That is: even with sound policy, evidence-based planning and sufficient training, local pressures make it commonplace for policy to not be put into practice, or health plans to not be implemented. These factors arise both internally within health teams and externally from their operating environment, however they are not well documented by health research in PNG.

#### ***2.4.5 Pregnancy, postnatal and infancy care in PNG***

PNG’s system weaknesses mean there are too few midwives or other skilled health workers, and too few equipped facilities, to provide sufficient pregnancy and childbirth care. The National Sexual and Reproductive Health Policy<sup>245</sup> enshrines free access to antenatal care and promotes skilled birth attendance for all women, however the service coverage has remained inadequate, and static, for more than a decade (see table below). The government estimates for 2018 suggest 47% of women attended at least one visit for antenatal care and 32% of births took place in facilities with a skilled attendant; proportions that have declined over the years since 2012.<sup>246</sup>

There is wide variation in these proportions between different geographical areas, with island provinces often showing higher coverage – as discussed below. High death rates and low uptake of care may reflect over-riding difficulties in access,<sup>247</sup> for example health facilities reached only by long walks on foot from highland villages<sup>34,248</sup> or paddled canoes in riverine communities.<sup>225</sup> Other barriers relate to families’ perception of facilities being poorly staffed, ill-equipped or unfriendly; noting the difficulties placed on birth attendants when they are asked to work as solo practitioners in remote locations in PNG<sup>249</sup> and similar settings.<sup>250</sup>

Quality of care for mothers, newborns and children has a direct effect on patient outcomes, where increased coverage without increased quality has been

shown to fail to improve survival of mothers or newborns both globally<sup>182,251</sup> and in PNG.<sup>84</sup> In addition, deficient quality of care can discourage health service utilization.<sup>252</sup> Studies in PNG, both published<sup>247,253</sup> and presentations made to internal medical forums,<sup>235</sup> highlight the importance of improving quality of care. International efforts to strengthen quality standards, for example for antenatal,<sup>168</sup> newborn<sup>254</sup> or postnatal<sup>255</sup> care, have had limited application in PNG,<sup>256-260</sup> and it is important to measure current practices and assess future potential for quality improvement.

**Table 3: Maternal and child health service coverage measures, PNG National**

| Indicator                                                               | 2006 | 2012 | 2016 | 2016-18* | 2018 | Source          |
|-------------------------------------------------------------------------|------|------|------|----------|------|-----------------|
| Antenatal care coverage with at least one visit                         | 70%  | 66%  | 54%  | 77.9%    | 47%  | 239,246,261 213 |
| Supervised childbirth in a health facility, coverage                    | 44%  | 44%  | 40%  | 54.7%    | 32%  | 213,239,246,261 |
| Outreach clinics, per 1,000 children under 5 (national target is 50)    | 29   | 34   | 29   |          | 31   | 239,246,261     |
| Pentavalent vaccine coverage, third dose, government estimate           | 77%  | 46%  | 44%  | 42%      | 41%  | 213,239,246,261 |
| Pentavalent vaccine coverage, third dose, WHO/UNICEF estimate           | -    | 74%  | 72%  |          | 61%  | 262,263         |
| Measles vaccine coverage, dose given between 9 and 11 months            | 58%  | 49%  | 36%  | 59%      | 33%  | 213,239,246,261 |
| Contraception, couple-year-protection per 1,000 women aged 15 -44 years | 91   | 70   | 102  |          | 126  | 239,246,261     |
| Contraceptive prevalence rate                                           | 32%  | -    | -    | 37%      | 29%* | 213,264,265     |

\*Demographic and Health Survey, reported November 2019

Noting that good quality health care early in the postnatal period is critical to preventing maternal and newborn deaths,<sup>266 267</sup> PNG's 2014 Newborn Health Policy<sup>268</sup> recommends three or more routine visits in the first week after childbirth. Reaching mothers and babies with preventive care, and emergency treatment if needed, at this point in time has proven difficult at global levels<sup>254,269</sup> and in PNG. Uptake of routine postnatal checks is currently not measured in PNG government monitoring, but is thought to be at extremely low levels for both home births and facility births,<sup>256,270</sup> the latter poorly implemented because many women leave a health facility very soon after childbirth.

Regular preventive care for infants after the neonatal period, including routine immunisation, is struggling under the many constraints discussed above. Contacts from six months of age onwards are often dependent on community outreach visits, however government monitoring demonstrates that outreach clinics for children under five years of age have been static or declining (see Table 3).<sup>239</sup> In PNG, routine immunisation commences at birth, with subsequent contact points at one, two, three, six, nine to twelve, and 18 months of age. Immunisation is usually provided through urban clinics, small rural health centres, scheduled outreach to community sites, and hospital children's outpatients. Vaccination coverage has remained static or declining over a ten year period, and is worst for vaccines delivered at later time points, such as measles. There are some differences between WHO/UNICEF coverage estimates and those of PNG's national immunisation program, which reflect difficulties in measuring population denominators.<sup>271</sup>

WHO/UNICEF coverage estimates for 2016<sup>262</sup> showed a relatively high drop-out between the first and third doses of pentavalent<sup>‡‡</sup> vaccine. Coverage of the first dose is estimated as at least 15% higher than that of the second dose, with government monitoring data measuring the gap as wider than this. A similar drop-out was seen in PNG's 2005 coverage survey.<sup>271</sup> The failure of families to return for follow-up visits, despite being able to access the service once, suggests problems in community engagement as well as difficulties in access. The drop-out measure had narrowed in 2018, but this was due to collapse in coverage of third dose of pentavalent (to 61%) rather than improvement in return visits.<sup>263</sup>

PNG's total fertility remains at a relatively high rate of approximately 4.0 with a high unmet need for family planning, and one of the lowest contraceptive prevalence rates in WHO's Western Pacific Region.<sup>200,245,265</sup> Distribution of

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<sup>‡‡</sup> 'Pentavalent' is an injected combination vaccine containing vaccines against diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae type B. It is also abbreviated as DTP (indicating diphtheria-tetanus-pertussis-containing vaccine).



modern methods of contraception (reported as couple-year-protection rates<sup>§§§</sup>) has shown modest increase in recent years (see Table 3), largely due to localised uptake of long-acting reversible contraceptives, but overall is still well below community demand.<sup>223,265</sup> A variety of reasons for low uptake of modern methods of contraception are reported, with lack of supply or access to services, as well as attitudes and beliefs of both health staff and clients, reported as similarly important.<sup>272,273</sup> Supply-side constraints are significant; including frequent stock-outs, poorly organised access points, and when particular CHS service providers are discouraged by internal policies from providing contraception directly, requiring them to refer clients to sometimes distant government-run facilities.<sup>228,273</sup>

Attempts to improve organization and management of services raise specific challenges for care during pregnancy, childbirth and the first years of life. These include: how to reach mothers and newborns following a home birth through facilities or home visits<sup>274</sup>; or how to provide postnatal care to women who have a facility-based childbirth but who return home very early after birth.

For many decades, lay health workers often termed ‘Village Birth Attendants’ have provided childbirth services in the community. Since codification as VHVs<sup>227</sup> (see above) government authorities have redirected their roles to antenatal education. Despite this shift, in many remote settings they continue to respond to long-standing community expectations by managing out-of-facility deliveries, but no longer receive policy support, or access to training or supplies.<sup>224,225</sup> A persisting challenge for family health planners is determining how best to partner with VHVs for pregnancy, childbirth and other care, and what mix of preventive and treatment services<sup>275</sup> can be provided at community level in remote settings where referral is difficult.

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<sup>§§§</sup> This indicator combines permanent (tubal ligation or vasectomy) and temporary (oral contraceptive pill, intra-uterine devices, long-acting reversible) methods, and is intended to measure the amount of contraception necessary to protect one couple per year.

#### **2.4.6 Current approaches to integrated services in PNG**

PNG is actively testing the potential of integration of different services to increase coverage, with a strong focus on the national immunisation program and RMNCAH services. Some of these echo the highly integrated models of care from the mid-twentieth century, however most are new responses to PNG's problems of fragmented service delivery. Immunisation is itself not as strong in PNG as in other similar countries, and does require strengthening to improve vaccination coverage, especially the newly introduced service at 18 months of age. Thus, any attempt at integration must provide benefits for immunisation as well as for the linked service. However, as an established aspect of PNG's routine preventive health services, the immunisation program does offer a platform that could be leveraged by other services that are currently at lower coverage.

PNG has some limited experience in integrating health services in the postnatal period (the first 28 days after birth), when the needs of both mother and newborn must be considered. Services may need to combine advice on feeding, nutrition, hygiene and danger signs, and discussions on family planning, with provision of the birth-dose of vaccinations against tuberculosis (TB) and hepatitis B. One experience in PNG,<sup>276</sup> led by the author, suggests that integration of birth-dose vaccination with postnatal care can increase coverage in both community and health facility settings. PNG is similar to other resource-constrained settings in low uptake of postnatal care. Better integration of services could help address the difficulties families face in travelling long distances to services and the likelihood of mother and baby having multiple co-existing health needs.

During infancy (the first year of life), service delivery questions include how to improve routine immunisation coverage and reverse recent declines,<sup>277</sup> and whether it is feasible to deliver other high priority interventions for nutrition, disease control, family planning or illness management at the same service points. PNG's sequence of measles vaccination campaigns (termed 'Supplementary Immunisation Activities (SIA)) were relatively successful in controlling measles between 2003 and 2012 and this period saw a steady increase

in the degree to which other interventions were integrated with these campaigns.<sup>278</sup> However this was not sustained in later SIAs after 2012.<sup>279</sup> Decreasing frequency and coverage of SIAs, along with sustained low coverage in the routine immunisation program meant measles returned to PNG in 2014 and polio in 2018,<sup>280,281</sup> the latter as an outbreak of type 1 vaccine-derived poliovirus disease. This is a form of polio that is directly related to persistent poor performance of routine immunisation services over many years.<sup>282</sup>

The National Department of Health had developed plans in 2014 for a new national strategy for preventive care in the first year of life, focused on improved immunisation services,

termed the ‘Special Integrated Routine EPI Strengthening Program’ (SIREP) and SIREP Plus.<sup>277</sup>

While the core driver was the introduction of new vaccines, this also incorporated other changes: improved planning of outreach services based on population density, and integration of other nutrition and disease control interventions with the immunisation platform. This strategy was introduced

across the country from 2015, including a high-level launch by WHO, Gavi and other immunisation partners in August of that year (Figure 3).<sup>283</sup> This timing provided an opportunity for SIREP to be one object of study in this research’s cross-sectional health services assessment (Chapter Seven). The relevance of SIREP to the 2018/19 polio outbreak response, and to the long-term renewal of routine immunisation is discussed in Chapters Seven and Eight.

**Figure 3: SIREP launch, photograph**



From Left to right- Dr Sergey Diorditsa, EPI Coordinator WPRO ; Dr Pieter Van Maaren,- WHO Representative to PNG; Ms Helen Evans, Special Representative of the Gavi CEO in the Asia Pacific Region (former Gavi Deputy CEO); Mr Michael Malabag, Minister for Health, PNG (giving speech) and Honourable Mr Peter Charles Paire O'Neill Prime Minister of Papua New Guinea. Credit: WHO Papua New Guinea.

Note: From WHO Global Immunization News, August 2015

PNG does not yet have a standardized policy on preventive services in the second year of life, however this time point is becoming increasingly important to provide booster doses of measles and new pneumococcal vaccines. This is also a critically important time for early intervention to improve child nutrition and psychosocial development, given the high burden of under-nutrition seen in a stunting prevalence of 48%, as well as low weight-for-age.<sup>239</sup> These imperatives, along with the need to support parents' access to sexual and reproductive health, make a case for routine visits between 12 and 24 months after childbirth.

A less formalised integration strategy involves the concept of front-line health facilities acting as a “one-stop shop” concept integrating family planning, antenatal care, postnatal care, childhood illness care and immunisation. \*\*\*\*

#### **2.4.7 East New Britain provincial health service**

PNG's 22 provincial-level governments have significant autonomy over the organisation and management of health services, with considerable variation in funding support for health and in implementation of health policy. One province, East New Britain, where the author was involved in establishing a new long-term research initiative, offers an ideal site for the study of health service innovations.

ENB has higher investment in the health sector, relative to elsewhere in PNG,<sup>284</sup> and relatively stronger rural infrastructure.<sup>237</sup> Despite this, ENB is similar to many resource-constrained settings with considerable unmet health needs, persisting preventable mortality and morbidity, and significant gaps in service coverage and uptake. Analysis of these can offer additional insight into how and where more integrated services could improve health outcomes. Additional detail on ENB, and the rationale for this as a site where examination of service delivery options can provide generalizable evidence, is provided in the Methods chapter below.

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\*\*\*\* Personal communications: Dr William Lagani, former Manager (until 2017), Family Health Services, NDOH; Dr Siddhartha Datta, Technical Officer, Expanded Programme on Immunisation, WHO, PNG Country Office

## 2.5 Conclusion to Chapter Two

This chapter has defined what is meant by integrated health services as applied to immunisation, reviewed the earlier evidence for integrating immunisation and other services, and discussed PNG as a setting where health system weaknesses demand better integrated services as one response (among many).

There is considerable consensus that more integrated services are needed to better meet the co-existing health needs of clients, and to maximise efficiency where resources are constrained. However, there are major gaps in the implementation evidence on how service delivery should be reformed to promote integration and how to maximise effective coverage. These gaps include key implementation questions such as better understanding of the model of integrated services employed, the demands made on staff, and the acceptability of reformed services to staff and clients. Such questions have rarely been examined in relation to what makes more integrated services succeed or fail. This makes integrated service delivery an important topic for implementation research; and the increasing calls for integration of immunisation and other services, makes this research especially timely.

The next chapter describes conceptual frameworks suited to the analysis of integrated services and presents the research scope and objectives.

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## 3 RESEARCH FRAMEWORK, SCOPE AND OBJECTIVES

This chapter outlines the academic discipline and conceptual frameworks that informed the choice of tools and structured the analysis for this research; and then provides a one-page outline of the research scope and objectives.

### 3.1 Frameworks for researching integrated health services

#### 3.1.1 *Health policy and systems research*

This research operates within the academic domain of health policy and systems research (HPSR),<sup>82,285</sup> which “*encompasses research on the policies, organizations, programmes and people that make up health systems, as well as how the interactions amongst these elements, and the broader influences over decision-making practices ... influence system performance*” with an emphasis on health system needs in resource-constrained settings.<sup>82</sup> HSPR studies extend conventional implementation research by examining how the whole health system functions for both clients (demand-side) and providers (supply-side) and by including the policy context and operating environment.<sup>82</sup>

These requirements influenced this research in three ways. Firstly, to ensure the study of service delivery is situated in a framework that provides conceptual links to the whole health system. Secondly, to ensure that both demand-side and supply-side perspectives are included. And thirdly, to actively engage with relevant global and national policy (and policy-makers) as the work was conducted.

#### 3.1.2 *Health systems frameworks*

In defining what constitutes a health system, this research follows the most commonly used definition, proposed by WHO in 2000 as:

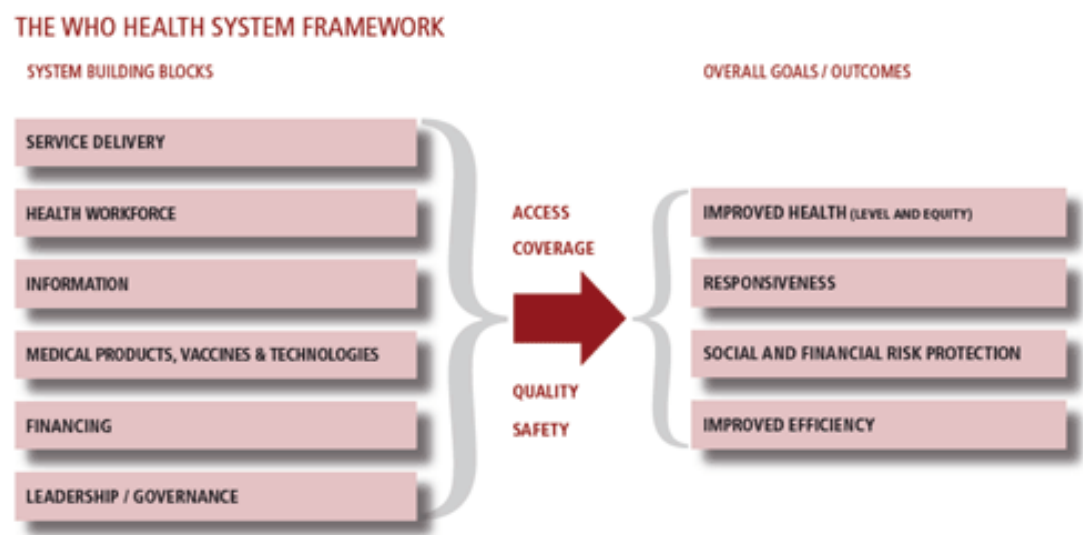
*“... comprising all the organizations, institutions and resources that are devoted to producing health actions. A health action is defined as any effort,*

*whether in personal health care, public health services or through intersectoral initiatives, whose primary purpose is to improve health”.*<sup>286</sup>

Other concepts introduced by WHO at that time were that health systems should not only promote and improve population health, but do so in a way that is fair to all sections of the population, responsive to their needs, and without incurring catastrophic expenditure.

Many frameworks have been proposed to analyse health systems over the 20 years the HPSR field has been evolving,<sup>287,288</sup> with varying applications to describe elements and functions,<sup>12</sup> compare across countries,<sup>287</sup> evaluate performance,<sup>289</sup> promote reforms<sup>290</sup> or inform efforts to strengthen the system.<sup>288</sup> The most widely popularised is the descriptive framework introduced by WHO in 2007, using the image of ‘building blocks’<sup>12</sup> (see Figure 4), which forms a useful starting point in conceptualising the research in this thesis.

**Figure 4: WHO Building Blocks Framework**



This categorisation of six health system building blocks was not designed as a research tool, however many groups have used it as an analytic framework to identify areas for improvement (for example in a global action plan to improve newborn health<sup>291</sup>). Two aspects make this framework helpful to research into integrated health services. Firstly, the characterisation of processes (access, coverage, quality and safety) that are highly relevant to preventive health care such as vaccination. Secondly, the inclusion of ‘improved efficiency’ as a health



system outcome; something that is a common goal of health planners promoting integration. In other health system frameworks<sup>290</sup> the outcomes of improved health (and equity), responsiveness and financial protection are commonly held, but efficiency is often seen as a process rather than system goal.

This ‘building blocks’ framework has been applied to research into the interaction between immunisation programs and health systems.<sup>292</sup> However Mounier-Jack and colleagues<sup>104</sup> reported that, while the framework was useful in providing a common language in discussing health system components, it lacked a dimension with which to capture the demand-side of community engagement. It also did not encourage analysis of the dynamics whereby various elements inevitably interact with each other. This oversight was typical of many other usages of this framework and, along with the incorporation of 30 years of experience with the concepts of PHC,<sup>293</sup> WHO’s conceptualisations of health systems now increasingly emphasise health care users (the demand-side), often expressed in terms such as ‘people-centred care’.<sup>294</sup> It was recommended that any future use of this framework incorporate some adaptation to make it fit for purpose; such adaptation is discussed further below.

### ***3.1.3 Concepts of service delivery, including immunisation services***

The study of innovations aiming to increase integration of health services is essentially the study of how health services are organized and delivered, that is: the component termed ‘service delivery’ in WHO’s framework. At its simplest, describing service delivery requires a description of *what* services are provided, *when* they are made available (for example: routinely scheduled, or responsive to clinical demand), *where* they can be accessed (for example: home, community, facility), and *who* provides the care.<sup>94,295</sup> These dimensions are all dependent on other health system functions, for which the other five ‘building blocks’ provide helpful categorisation.

Immunisation services are commonly delivered in one of three locations: at a permanent health facility as outpatient (rarely inpatient) care; as regular outreach visits to temporary locations in the community; or in the home (less commonly). Timing of service provision can vary: routinely scheduled (often

monthly), as a campaign (for example annual) or other intensified timing, or responsively during a clinical care visit or following childbirth. Providers can vary, including vaccinating, educating and supporting staff. Of most relevance to integration, the package of services provided (that is: those provided alongside immunisation) can also be varied.<sup>58</sup>

The uptake of services also depends upon demand-side factors, which may be encapsulated in the concept of ‘*community engagement*’. That is: families and other community actors who find the services acceptable, accessible and affordable; whose knowledge and beliefs are such that they use the services as planned; and who will expend energy and resources to help support service provision in their community. These demand-side dimensions apply differently to the delivery of clinical services where care-seeking is provoked by illness, as compared to preventive services such as vaccination, where community beliefs in efficacy and understanding of timing are crucial and cannot be taken for granted.<sup>166,296,297</sup>

For immunisation services, the nature of the provider-client interaction can vary, for example in content and nature of communication about vaccines, counselling on other health issues during a session, provision of pain relief, assessment of mother or infant, and in other ways.<sup>298</sup> Community access, affordability, understanding, beliefs and other aspects of engagement can also be modified to increase uptake.<sup>166,299,300</sup>

### ***3.1.4 Conceptual framework for service delivery used in this research***

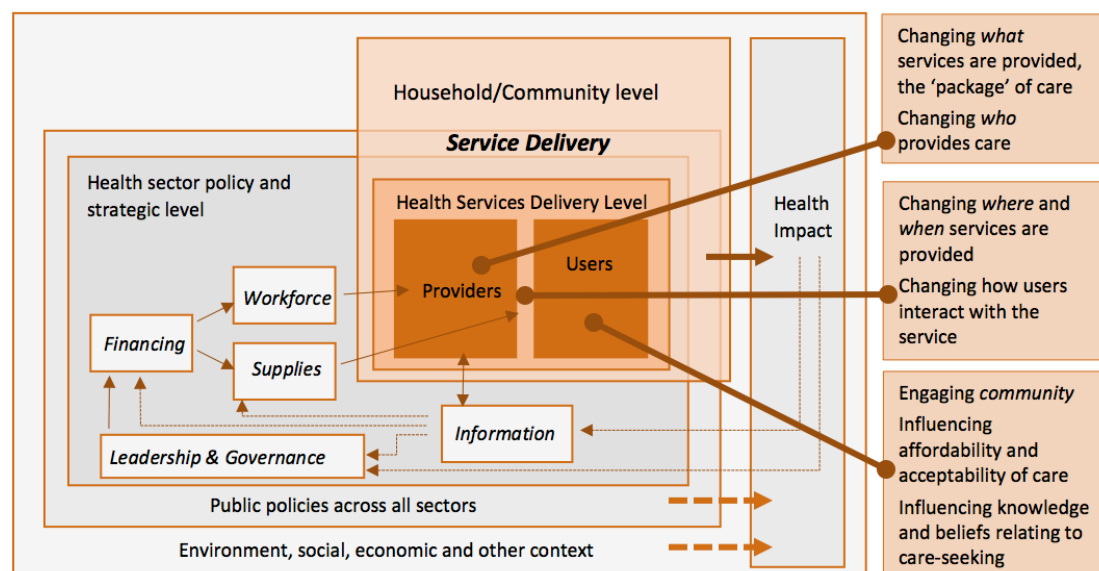
The two broad aspects referred to above, service delivery and community engagement, are reflected in the categorisation introduced by Hanson and colleagues early in this century to guide analysis of what constrains access to high priority health care.<sup>301</sup> They identified ‘community/household’ and ‘service delivery’ as the first two levels in their framework, which has been used by academia, WHO, the World Bank, the Global Fund and others. One use was by the Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre) of the University of London in 2013 to review the effectiveness of interventions to strengthen health service delivery in LMICs.<sup>28</sup> Both these

expansions of the WHO ‘building blocks’ framework have been helpful in constructing a conceptual framework for the research described in this thesis. The aim is for a framework suited to a study of innovations in front-line service delivery that adequately accounts for demand-side and supply-side influences.

The figure below presents an adapted framework that:

- unpacks the service delivery component so potential changes can be analysed;
- elaborates the interaction between service provision and client’s uptake of services;
- highlights other demand-side influences on service delivery;
- relates it to other key health system elements; and
- examines service outcomes in terms of improved health, equity, responsiveness, financial risk protection and efficiency.

**Figure 5: Conceptual framework for innovation in service delivery and its influences**



Adapted from Willey et al<sup>28</sup> and Hanson et al<sup>301</sup>

The conceptual framework for service delivery presented above can be used to describe modifiable options for immunisation service delivery that are relevant to the four aspects of integrated health services extracted from the 2008 WHO definition. An innovation to increase the level of integration of services can

involve modifying one or more of the elements of service delivery (what, when, where, who), with or without attention to community engagement. Assessing which of these elements have been changed, and how, is helpful to understand why some integration efforts have been more successful than others.

These service delivery factors are the focus of analysis in this research. Of course, as portrayed in the framework, other health system elements and the broader policy and social context must also be considered, because they also influence the success of integration initiatives. However this research is mainly concerned with those modifiable aspects of service delivery that are usually within the direct control of national or sub-national health program managers. Research approaches and tools to assess service delivery changes made within this framework are described in the next section.

### ***3.1.5 Research tools suited to integrated health services***

The approaches and tools in this research are drawn from the disciplines of HPSR, implementation science and program evaluation.

For the systematic review of integration experiences the key reference point was the Cochrane Effective Practice and Organisation of Care (EPOC) node,<sup>302</sup> which supports collation of implementation evidence, working closely with WHO research groups, oriented to LMICs and resource-constrained settings. One of these tools, from the Supporting Use of Research Evidence (SURE) collaboration,<sup>303</sup> is particularly suited to guide the extraction and organisation of findings from the studies included in the review. These categories mirror the different service delivery and community engagement elements in the framework above, as well as guiding the collection of evidence relating to the policy and social context. The aim of this framework is to organise information into forms useful to policy-makers in LMICs. The EPOC guidance is also helpful in describing what is needed for good quality research into health services.

Important concepts drawn from the field of implementation science included the importance of considering policy actors at various levels, the need for a structured explicit framework to categorise the details of implementation, and the value of incorporating both provider and supplier perspectives. These

are discussed briefly below, and elaborated in the application of the conceptual framework developed for this research (Figure 5).

Kruk and colleagues,<sup>304</sup> noted the importance of the combination of policy and implementation research as one means to work towards broader scale-up of promising approaches, by promoting both global learning and local accountability. They summarise the experience gained from involving prominent research and development assistance (aid) partnerships<sup>305</sup> in this endeavour as a need for policy and implementation research to:

- Understand the context, that is the implementation environment;
- Study the processes used in implementation;
- Test the potential and outcomes of innovative approaches; and
- Link new evidence to policy-making and program management.

For the PNG field studies, this research adopted these and other HPSR recommendations<sup>82</sup> to promote active interactions between researchers and other health actors, particularly national and provincial policy-makers and health managers, the officers-in-charge of health facilities, and front-line health care providers. This has resulted in a range of field methods including:

- Nesting integration questions within a prospective observational cohort study that allowed demand-side (women) assessment of the links between multiple co-existing health needs, preferences for services, and health service utilisation;
- Assessing policy-maker and manager (at various levels) attitudes to integrated services, and their contexts; and
- Assessing the opinions and actual practices of front-line staff relevant to integration.

In assessing service delivery, this research has focused on the analysis of two gaps: firstly the gap between policy expectations and actual practice that often relates to system deficiencies or the operating context, and secondly the 'know-do' gap<sup>306</sup> seen when health staff do not provide care as expected even when knowledge and resources would allow this. In designing data collection tools to explore these gaps, the concepts of realist inquiry or realist

evaluation<sup>307,308</sup> were examined. While full employment of realist methods was not feasible in this research, two key concepts informed tools development: the need to consider contextual influences, and the need to understand implementation mechanisms. This interplay of context and mechanism that features in realist approaches had also proven useful to Atun and colleagues in development of health system frameworks for analysing broader aspects of integration.<sup>7,309</sup>

In investigating contexts at the level of front-line services, concepts from a further monitoring and evaluation tool, the ‘most significant change’<sup>310</sup> technique was adapted for use in interviews. This has proven useful in several settings to understand changes in the operating context, and differentiate them from changes related to service delivery innovations. A further technique from both implementation research and evaluation domains,<sup>82</sup> was that of triangulation of data sources; employed to ensure that data on clients and providers were, wherever possible, measured by different means. For example, by employing observation and records review to cross-check interview findings.

The methods and tools derived from this methodological evidence base are described in Chapter Four, with additional detail in each of Chapters Five, Six and Seven, as relevant to the specific studies whose findings are reported in those chapters. The section below describes the scope and objectives for the research in this thesis.

## 3.2 Research scope and objectives

This research *aims* to study the potential benefits and risks of integration of other activities with immunisation services, and the barriers and enablers to changes in service delivery that could promote more integrated care.

The *key research question* is to test how integration of immunisation and other services in resource-constrained settings could meet a broader range of health needs during infancy, without adverse effects on equitable coverage, or on the quality or acceptability of care. The *scope* of this research is the consideration of:

- Immunisation services, and other health services during the postnatal period and in the first year after birth;
- Services for routine preventive care or first-line curative care;
- Delivery through first-line health facilities, and at outreach or community-based sites, or through special campaigns such as Supplementary Immunisation Activities;
- The perspectives of health care providers and of clients;
- Globally in resource-constrained settings of core interest to health systems in LMICs; and
- Locally in ENB province of PNG.

Within this scope, the *research objectives* are to:

1. Review the current experiences of integrating immunisation and other services, globally and in PNG;
2. Quantify and describe, in PNG, the current disease burden and health care needs that are relevant to integrated services;
3. Characterise opportunities for, and barriers to, new models of service delivery that promote greater integration, globally and in PNG; and
4. Estimate the potential impact (both positive and negative) of integrated services on intervention coverage and resources, client acceptance, equity of access, and quality of care.

The research *findings are discussed* in terms of their relevance to health policy and planning both in PNG (provincial and national levels) and globally. It is anticipated that these findings will provide insights into:

- How different models of service delivery change interact with other health policy initiatives;
- The conditions under which integrated services are more likely to improve health outcomes;
- Potential risks, for example to feasibility, acceptability or equity, that must be managed when service delivery changes are attempted; and
- A framework for monitoring implementation of service delivery changes aiming for greater service integration services.



## 4 METHODS

### 4.1 Overview of methods

The research methods comprise:

1. A *systematic review* of global experiences with integrated services in LMICs;
2. A *prospective observational study* of a cohort of pregnant women from first antenatal visit to six months after delivery, in ENB, PNG examining disease burden and health care needs warranting integrated services, as well as their preferences for, and experiences of, integrated services;
3. A *cross-sectional health services study* in ENB, PNG using interview, observation and document review to assess experiences with a recent attempt at integration of immunisation services, and identify enablers, barriers and risks with future attempts to integrate services.

These methods address some or all of each research objective as follows:

- **The systematic review** addresses:
  - *Objective 1* - review the current experiences of integrating immunisation and other services, globally;
  - *Objective 3* - characterise opportunities for, and barriers to, new models of service delivery that promote greater integration, globally;
  - *Objective 4* - estimate the potential impact (both positive and negative) of integrated services on intervention coverage and resources, client acceptance, equity of access, and quality of care.
- **The prospective observational study** in ENB addresses:
  - *Objective 1* - review the current experiences of integrating immunisation and other services, in PNG;
  - *Objective 2* – frequency and nature, in PNG, of disease burden and health care needs that are relevant to integrated services;

- *Objective 3* - characterise opportunities for, and barriers to, new models of service delivery that promote greater integration, in PNG;
- *Objective 4* - estimate the potential impact (both positive and negative) of integrated services on intervention coverage and resources, client acceptance, equity of access, and quality of care.
- **The cross-sectional health services study** addresses:
  - *Objective 1* - review the current experiences of integrating immunisation and other services, in PNG;
  - *Objective 3* - characterise opportunities for, and barriers to, new models of service delivery that promote greater integration, in PNG;
  - *Objective 4* - estimate the potential impact (both positive and negative) of integrated services on intervention coverage and resources, client acceptance, equity of access, and quality of care.

## 4.2 Systematic review rationale and methods

### 4.2.1 Systematic review rationale

Systematic reviews of published literature have, since the 1990s, become a critical tool in the formation of an evidence base for clinical practice.<sup>311</sup> From the mid-2000s, there has been increased emphasis on use of this research tool as an essential support to health policy and systems reforms,<sup>312</sup> as well as the development of global health guidelines.<sup>313</sup> As discussed in Section 4.4 below, this interest has been accompanied by a growth in tools for evidence collation that enable a more systematic application of review findings to questions affecting health services organisation and management.

An updated systematic review on integrated services offered opportunity for new analysis of the published literature to address several objectives of this research. The most recent comprehensive literature review collated research to February 2011<sup>58</sup> and the five years subsequent to that date saw a significant increase in publication of intervention and observational studies on the integration of immunisation and other services.

Scoping reviews undertaken in 2015 identified more than 30 new studies since 2011 that have either tested a new intervention integrating immunisation and another service, or researched aspects of existing service delivery to document level of, and barriers or enablers to, integrated services. Thus, an updated systematic review was felt to be able to update and expand the description of integration experiences. Application of an algorithm for assessing the utility of updating systematic reviews<sup>314</sup> confirms the potential value of an updated review.

In addition, deeper analysis and synthesis of findings is likely to be able to generate new evidence to support global and local policy choices. A number of studies have quantitative measures of service coverage – both of the vaccinations studied and of the interventions in the integrated service. It was hypothesised that there may be sufficient studies with adequate homogeneity to allow for meta-analysis of coverage changes. If so, it may be possible to estimate of the range of potential coverage changes generated by integration for immunisation or linked services.

Just as important is the evidence generated by systematic synthesis of qualitative findings across interventional and observational studies. This synthesis allows characterisation of implementation considerations relating to settings and service types, maintenance of quality of care, and the feasibility and acceptability of integrated services. These findings can add detail to inform when and where more integrated services will be beneficial, and how changes to service delivery can best be implemented.

The previous literature review work in 2011, published in a special issue of the *Journal of Infectious Diseases* in early 2012 was led by CDC researchers, JSI technical experts, and others involved in USAID-funded immunisation development work, with strong coordination with central WHO immunisation program staff.<sup>63</sup> Collaborators from these groups and other researchers had agreed to support the author in this new systematic review, ensuring its relevance to current policy discussions. The author of this thesis, however, conceived and led the conduct of the new review.

#### **4.2.2 Systematic review objectives**

This review hypothesised that variation in the effectiveness of attempts to integrate immunisation and other services in resource-constrained settings can be explained by intrinsic or extrinsic determinants. These include the characteristics of the intervention/s to be delivered with immunisation, the nature of the reform to service delivery, the level of acceptability of the change to staff or clients, and/or particular barriers or enablers in the service context.

The review objective was to especially examine services delivered in early childhood, especially services in the first year of life, when the majority of routine vaccinations are provided. However, the search criteria were constructed to also access evidence relating to older childhood, including school-age years, in order to allow for separate analysis of this important age group.

To investigate this a systematic literature review was undertaken that aimed to:

- Identify the range of interventions and service delivery arrangements used to promote more integrated services, both other services added to EPI, and EPI added to other services;
- Quantify the change in coverage in linked services and/or immunisation (if measured);
- Identify reported advantages and disadvantages, including changes in health care quality; and
- Identify the barriers to and enablers of service delivery changes.

#### **4.2.3 Systematic review methods**

A broad search of the literature was undertaken to maximise inclusion of relevant studies. Methods draw heavily on the work of the Cochrane Collaboration's Effective Practice and Organization of Care group – especially tools developed by the former Norwegian Knowledge Centre for the Health Services<sup>302</sup> (now incorporated into Norway's national Institute of Public Health). The review was limited to LMICs, as defined by the World Bank for 2016,<sup>315</sup> to capture experiences relevant to resource-constrained settings.

The protocol was checked against criteria required by Preferred Reporting Items for Systematic Reviews and Meta-Analyses<sup>316</sup> and registered with the International Prospective Registry of Systematic Reviews at <http://www.crd.york.ac.uk/PROSPERO/> as CRD4201604587.

The *search strategy* combined terms for service types (as done for the earlier review by Wallace et al)<sup>58</sup> with additional search terms using integration terminology. Publications from January 2011 to May 2016, in English language, were searched. The databases and search software used comprised:

- Medline via Ovid (including early and pre-publication)
- Embase (Excerpta Medica Database) via Ovid
- CABI Global Health, Web of Knowledge via EBSCOhost
- CINAHL via EBSCOhost
- Cochrane Central Register of Controlled Trials
- Cochrane Database of Systematic Reviews and Other Reviews

All study designs were admitted (and subjected to quality assessment), providing they contained quantitative or qualitative measures of the outcomes or processes involved in increasing integration of services.

*Inclusion criteria* were studies where:

- One or more linked services and one or more immunisation services were integrated during pregnancy, postnatally, in childhood (*including first two years of life*)<sup>†††</sup> as a function of health service innovation; and
- Outcomes were measured in terms of coverage, access to care, quality of care and/or equity of access or coverage, for at least one service.

A range of *review tools* were used to ensure rigorous application of inclusion criteria and assessment of quality. The Cochrane Collaboration's COVIDENCE (<https://www.covidence.org/>) software was used to streamline and ensure compliance with *a priori* rules for screening inclusion decisions by two

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<sup>†††</sup> Reports of integrated services for adolescents, including school years, were also collected, to be reserved for analysis outside the research in this thesis.

investigators: the author of this research and Ms Jessica Davis, Research Officer at the Burnet Institute in 2016. Quality assessment of individual studies, ensuring included studies met minimum quality standards were based on GRADE<sup>317</sup> for quantitative analyses, and the Clinical Appraisal Skills Program (CASP) tools<sup>318</sup> for qualitative papers, or for qualitative data included in mixed methods studies. The CASP criteria were adapted to focus attention on key aspects relevant to integration, as assessed in the research frameworks from chapter three.

*Categories to use in data extraction* were derived from two sources. Firstly, categories were developed from the adaptation of standard WHO health systems elements discussed in Chapter Three, and presented in the conceptual framework (Figure 5). These were supplemented by categories developed by the Supporting Use of Research Evidence Collaboration's guide to policy-relevant barriers and enablers,<sup>303</sup> a framework developed by the WHO Evidence Informed Policy Network (<http://www.who.int/evidence/>) that aims to enable research to generate findings useful to policy and practice for LMIC health services. This framework provided a good match for covering the range of service delivery and demand-side factors identified in the evidence review discussed in Chapter Two, and the conceptual framework presented in Chapter Three. These categories include client and provider characteristics, health system elements, community engagement, and contextual factors in society, ideology, politics, donors, corruption, or security. The data extraction categories appear in Appendix 10.2.1.

*Synthesis of findings* was guided by the Cochrane EPOC guidelines,<sup>302</sup> particularly in decisions on what weight to give to different study designs. Meta-analysis using a random effects model was considered for outcome measures (either linked service outcomes or immunisation outcomes) if sufficient homogeneity of study design would allow this. It was considered most likely, however, that narrative synthesis of quantitative and qualitative data in the included studies would best address the research objectives.

Narrative synthesis is suited to the synthesis of evidence for the needs of policy-makers and health managers.<sup>319</sup> Among its many expressions, the work of

researchers from the International Initiative for Impact Evaluation, the EPPI-Centre and the London School of Hygiene and Tropical Medicine,<sup>320</sup> provided helpful precedent in applying the technique to this type of review. It was expected that while included studies would have some relevant qualitative data, these would not be rich in detail. Given this shortfall, it was felt that more sophisticated interpretive qualitative approaches would not be feasible. Thus the narrative synthesis approach used was to combine elements of content analysis and thematic analysis, with some cautious vote counting to identify the most common determinants.<sup>319-321</sup> One guidance document used in reference is that prepared by the Economic and Social Research Council of the United Kingdom.<sup>322</sup>

A process developed by Cochrane EPOC researchers termed CERQual<sup>323</sup> was examined to support the assessment of qualitative data, which was clearly going to be important to illuminate determinants of success. While the CERQual process was not applied directly (because it is intended for assessment of reviews of qualitative research papers) the principles it makes explicit were found useful to help guide the narrative synthesis. In particular, to help ensure due consideration of methodological limitations, coherence, adequacy of data and relevance to the questions of integration in LMICs.<sup>324</sup>

The combination of narrative synthesis and Cochrane EPOC guidance aimed to maximise the inclusion of applicable evidence while being cautious about weighting in relation to research quality; a combination that seems appropriate to the generation of evidence useful for policy and practice in LMICs.<sup>325</sup>

The complete review protocol is appended (10.1.1), including search syntax, inclusion criteria, data extraction and analysis procedures. It is also formally registered at:

[http://www.crd.york.ac.uk/PROSPERO/display\\_record.asp?ID=CRD42016045876](http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016045876)

### 4.3 PNG field studies rationale and methods overview

The field studies in PNG are designed to provide both supply- and demand-side perspectives on integrated experiences, directly addressing this research's objectives, which emerged from study of gaps in existing evidence. As discussed in Section 3.1.5 above, they are also designed to make use of theory-based evaluation tools from the HPSR domain.

The two field studies are nested within two larger studies conducted by a new partnership research program, titled Healthy Mothers Healthy Babies (HMHB, described below), in East New Britain province of PNG. This section provides an introduction to the field setting in ENB, and an overview of the two field studies, with a rationale for the study designs. Chapters Six and Seven also note key aspects of methods to provide context to the results presented there. Full protocols as approved by ethics committees are appended (Appendix 10.1).

The PNG setting chosen for this research has poor health outcomes and service gaps characteristic of many resource-constrained settings. However provincial authorities have demonstrated commitment to invest in health services, and a willingness to support the study of new service arrangements, such that barriers and enablers discovered here are likely to be instructive for many other settings.

#### 4.3.1 Study setting: East New Britain province

ENB is located in PNG's Islands Region and has a population of over 393,000. The two HMHB studies are set in three of ENB province's four districts, Gazelle, Kokopo and Rabaul Districts, where the majority of the ENB population lives.<sup>326</sup>

The province is typical of PNG in much of its disease profile and geography. There is a high burden of malaria, tuberculosis and other respiratory infections, sexually transmitted infections, and malnutrition, although prevalence of human immunodeficiency virus infection is relatively low.<sup>239,326</sup> ENB occupies the eastern half of the island of New Britain, whose mountainous interior has some communities accessible only by walking tracks, and where



some coastal villages have access only by water. In contrast with most of PNG, there is relatively good road access for the most densely populated districts.<sup>327</sup>

ENB has two large hospitals (Nonga General Hospital and the Catholic-run St Mary's Vunapope), a rural hospital, two urban clinics, 11 health centres, 17 sub-centres and approximately 85 functioning aid posts (accurate data not available).<sup>326</sup> The provincial hospital, Nonga General Hospital, is managed by the PNG National Department of Health. The Provincial Health Office (PHO) and the district health administrations are responsible for all other health facilities in the province, including both government and church run services. Catholic and other church health services provide between one third and one half of the rural health services in this province.<sup>326</sup>

ENB is reported as being one of six provinces in PNG whose expenditure on health is at the higher end of the national range,<sup>284</sup> that is: closer to minimum requirements, and is also seen as having relatively better uptake of services for family health.<sup>237,326</sup> As this research was being planned in 2014, ENB had a higher coverage of facility-based delivery and antenatal care than other provinces: supervised delivery coverage was 70%, while ANC coverage was 81%. However ENB's reported coverage with infant vaccines in 2014 was no better than the national average. Provincial health information reported 53% coverage of the third dose of DTP3 (or "pentavalent"<sup>††††</sup>) and 50% for the first dose of measles-containing vaccine (MCV1) due between 9 and 11 months of age.<sup>239</sup> This coverage showed little change in subsequent years, with coverage of DTP3 at 60% and MCV1 at 48% in 2016<sup>239</sup> and at 58% and 46% in 2018.<sup>246</sup> Similarly, the provision of outreach clinics was reported, in 2016, as 22 per 1000 children under five years of age, contrasting with a national average of 29 and a national target of over 50.<sup>326</sup>

Higher usage of pregnancy care, compared with immunisation, suggests that factors other than physical access barriers restrict families' uptake of

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†††† "Pentavalent" signifies that this combination contains vaccines against *Haemophilus influenza B* and hepatitis B, as well as the older diphtheria, tetanus and whole-cell pertussis.

immunisation; implying that there may be scope for innovation in health service delivery to improve coverage. Some of the obvious barriers seen elsewhere in PNG, such as absence of roads or major under-funding of the health sector, are not as prevalent in ENB. This suggests that health service solutions discovered in ENB are likely to be more sophisticated, and possibly more informative to health policy, than those required for settings with a poorer operating environment. ENB solutions will need to go beyond the broad-brush remedies of improving transport and allocating more funds to health that are the necessary starting point for many other parts of PNG.

An added benefit of this site is the high level of interest in health systems research on the part of the ENB provincial health authorities. The Provincial Government's executive council reviewed and approved the HMHB program: the first time this government has considered a formal partnership with a medical research initiative. These factors make ENB an excellent setting for health services research.

#### ***4.3.2 Healthy Mothers Healthy Babies program overview***

The overall HMHB program was established in 2014, and is a partnership of the Burnet Institute, the PNG Institute of Medical Research, the University of PNG, the National Department of Health and the ENB Provincial Government. The HMHB program encompasses discovery and intervention. It aims to define the major causes of poor maternal, newborn, and child health, and to identify feasible, acceptable and effective interventions and service delivery strategies to improve RMNCAH outcomes in PNG. There are five overarching program objectives:

1. Quantify the burden of diseases (nutritional and infectious) that complicate normal pregnancy and postnatal periods in PNG, the interactions between them, and their relationship with pregnancy outcomes;
2. Identify key determinants of current maternal, newborn and child health care utilisation, patterns of utilisation through pregnancy

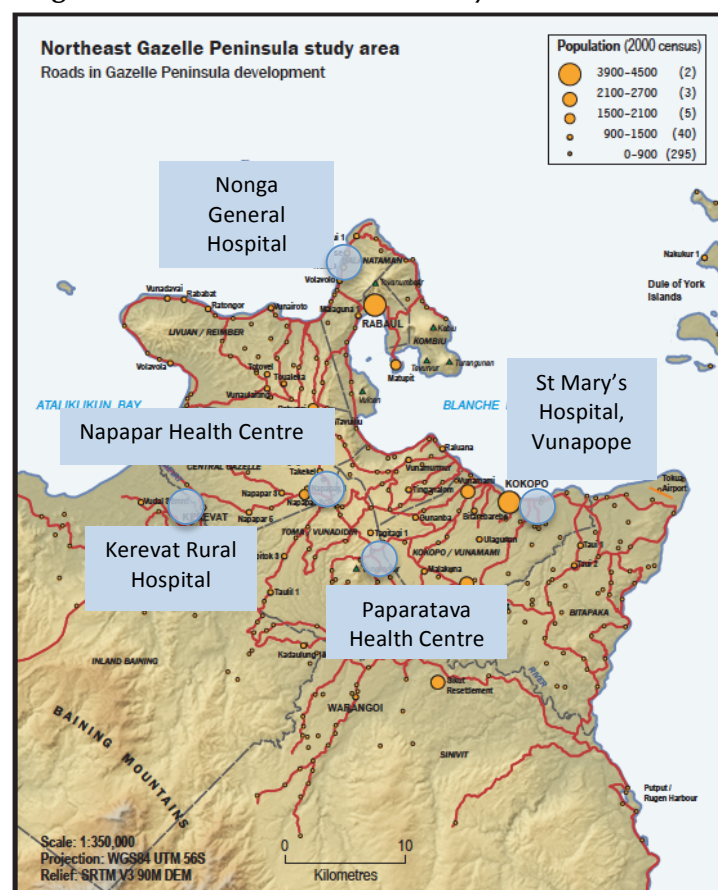
and the first year of life, and the predictors of optimal utilisation of health services for MNCH;

3. Evaluate RMNCAH services and identify strategies to improve services aimed at reducing morbidity and mortality;
4. Examine how adolescents and other young people can gain better access to health services, including sexual and reproductive health services; and
5. Identify strategies to improve RMNCAH care, and strengthen disease control, targeted to populations in PNG with varying levels of access to health services.

In close partnership with the ENB provincial health office and Catholic Health Services, the program works with staff and managers of the five busiest providers of maternal and child health care services in ENB. These facilities comprise Nonga General Hospital, St Mary's Hospital, Vunapope, Keravat Rural Hospital, Paparatava Health Centre, and Napapar Health Centre.

The HMHB program addresses eight of the top 20 priorities in PNG's National Health and HIV Research Agenda.<sup>223</sup> The wide range of collaborators enables engagement with important research and policy questions in PNG, and assists the development of national capacity in operational, implementation and health

**Figure 6: Location of HMHB study facilities in ENB**



Map source: Scales 2010. Facility labels by author.

systems research. As a partnership program, HMHB has a strong focus on capacity development including training for local research staff, mentoring of local researchers, and quality improvement in facilities and their managers.

The two field studies of integration described in this thesis are nested within the first two HMHB studies – described below. The author’s close involvement in the development of these two HMHB studies (see Section 4.4) enabled integration questions to be explicitly addressed within these study designs. The discovery phase of the HMHB program ran from 2015 to 2019, emphasising the generation of evidence for immediate use in ENB as well as informing future health policy in PNG and similar settings. The intervention phase commenced in 2018, overlapping the discovery phase, as discussed further in Chapter Eight.

### ***4.3.3 Prospective Observational Cohort Study of pregnant women in ENB***

#### *Rationale*

Important demand-side reasons for integrating services are: a) the co-existence of multiple health needs in mothers and their children; and b) family preferences for what services should, or should not be combined. A prospective observational cohort study can test two linked hypotheses: that women and infants in ENB have unmet multiple health needs requiring a broader range of integrated services; and that mothers’ have unexamined preferences for how care should be integrated care, preferences that can inform health service planning.

Observation of a cohort of pregnant women allows characterisation of their burden of significant morbidity, including conditions likely to persist into the period following childbirth. Given that 80% or more of pregnant women use ANC in ENB,<sup>326</sup> recruitment at a first ANC visit can be adequately representative for this setting. It is of core interest to integration research to ensure that observations are broad enough to describe the multiple morbidities that may complicate women’s and infant’s health during infancy. Understanding the range of co-existing health needs helps determine priorities for integrated services. Going beyond integration, it is also important to understand how coincident disease processes may interact to affect pregnancy outcomes,<sup>328</sup> interactions that have been infrequently investigated in PNG<sup>329</sup> or in other LMICs.<sup>330</sup>

A prospective cohort study can also examine women's experiences of health services, the degree to which the care they access is integrated, and the gaps between their health needs and the services they used. This design also allows assessment of women's preferences and plans, and their patterns of health care utilization, to generate evidence on which models of integration are likely to be acceptable and feasible. Client interviews were an essential contributor to the integration options explored by the influential Integra Initiative (see Chapter Two) in African settings<sup>8</sup> and other experiences<sup>331-333</sup> described in Chapter Five.

Although resource-intensive, the prospective longitudinal design is essential to investigate the associations between pregnancy multi-morbidities, birth-weight, other pregnancy outcomes, and child growth that are core questions for the broader study. It also enables the study of integrated health services: tracking families after birth through postnatal care and immunisation services over the key contact points in PNG's primary immunisation schedule. Tracking the same women can also enable measurement of how their health care plans translate into actual uptake, and how their preferences change with progression through this critical phase in the life course.

#### *Study design for the HMHB Prospective Observational Cohort Study*

Pregnant women were followed from first presentation for antenatal care (ANC) until one year after childbirth. Women were randomly selected from those presenting for first ANC visit at the five busiest (in terms of childbirth care) health facilities in three adjoining districts of ENB province. Both mother and baby were then followed up four more times: at delivery (within four days) and at one, six and twelve months after delivery.

The overall study sample size aimed for 700 women of all gestations, powered to detect clinically meaningful differences in birth weight (as the primary outcome measure) between women with and without malaria, STIs, TB, anaemia, iron deficiency, micronutrient deficiencies and detecting significant interactions between co-morbidities. In those sample size calculations, power had been conservatively set to 90% with 5% two-sided significance. For integration research this was expected to give satisfactory precision to

prevalence estimates, such as co-morbidity at ANC, as well as comparison of co-existing health needs at ANC with provision of services postpartum.

Data were collected from women through researcher-administered questionnaires, and inspection of patient-held and facility health records. The questionnaire (see extract at Appendix 10.3.1 and protocol) was study-specific, being adapted from various WHO standards, other surveys used in PNG, and referencing national RMNCAH policy. A mix of highly structured closed questions generating quantitative data were supplemented by limited semi-structured free-text options (such as “Any other comment”) providing qualitative information.

The questionnaire was designed to capture information on:

- Demographics;
- Reproductive history and illness history, prior to this pregnancy;
- Health-relevant behaviours including smoking and use of alcohol;
- Reported illnesses for mother and baby (including co-morbidity);
- Health care used during pregnancy, childbirth, postnatal periods (including the degree to which it was integrated);
- Plans for future care (including integrated care) and knowledge of danger signs and care options; and
- Satisfaction with services, and preferences or suggestions for the future (including questions relevant to integrated services).

Other data related to study objectives beyond integration: mother and baby had anthropometry measured and blood samples collected; and the mother also provided vaginal swabs and a urine sample. Biomedical samples were tested for infections (including malaria and STIs) and nutritional deficiencies by laboratory test and rapid test.

Rapid tests included in this study included:

- Haemoglobin (HemoCue, Ängelholm, Sweden)
- Malaria (CareStart)
- Syphilis (Determine, Alere)
- Gonorrhoea (Cepheid, Sunnyvale CA, USA)

- Chlamydia (Cepheid, Sunnyvale CA, USA)
- Trichomonas (Cepheid, Sunnyvale CA, USA)

Screening for the latter three reproductive tract infections is not yet standard in PNG and was introduced for this study, acknowledging the high prevalence of these infections and their importance for maternal health and pregnancy outcomes. The Cepheid GeneXpert platform provided a means to examine point-of-care screening in the PNG context. Rapid point-of-care test results are relevant to integration research in detailing the range of co-morbidity that could be visible to front-line staff with current or enhanced screening.

Data were collected by locally recruited PNG research officers expert in interview, the technical detail of the questionnaire items, and clinical sampling techniques; they also had deep insight into local customs and language. They were trained by this author and other HMHB principal investigators, as detailed in Section 6.2. All data were entered directly into electronic tablets, and uploaded daily to a protected database. Quality control was managed through close supervision of the HMHB team, guided by written standard procedures and led by three principal investigators. Detailed descriptions of the HMHB standard operating procedures are available in HMHB documentation and descriptions also available in the appended full protocol description (Appendix 10.1.3).

#### *Integration measures in the Prospective Observational Cohort Study*

The data collected by interview, anthropometry and point-of-care testing were analysed to address the integration research objectives described in Chapter Three.

The *integration measures* were:

- Mothers' and babies' use of services additional to standard pregnancy or immunisation care, describing the uptake and nature of integrated services (*research objective 1*);
- Proportion of mothers and babies with co-morbidity or co-existing health care needs from ANC onwards, that warrant more integrated services (*research objective 2*);

- Nature of co-existing health needs in the postnatal and infancy period in PNG (*research objective 2*);
- Preferences women express for integrated services that are and are not currently being met, expressed from ANC through infancy (*research objective 3*);
- Acceptability of more integrated services and reasons why more integration may or may not be valued (*research objectives 3 and 4*);
- Discrepancy between the proportion of women identified as needing additional care at ANC and those receiving care at later time points (*research objective 4*); and
- Relationship of women's proposals of more integrated services and current policy and practice in PNG (*research objectives 3 and 4*).

The longitudinal nature of this study means that both morbidity and health utilisation at later contact points may be influenced by participation in the study. As a result, measurements taken at first ANC visit will be taken as more representative of the general population of pregnant women in ENB, especially for prevalence estimates.

#### *Other HMHB outcomes measured in this study*

Other outcomes measured in the HMHB Prospective Observational Cohort Study beyond the measures of integration collected for this research included:

- *demographics* including age, education, occupation, partner;
- *clinical and laboratory markers* of nutrient deficiencies, malaria, RTIs and STIs, tuberculosis, genetic anaemias and iron stores;
- *birth weight*, and other measures of *infant growth*;
- *pregnancy outcomes* for mother and newborn;
- *general health service utilisation*;
- women's *knowledge and attitudes* regarding danger signs, health threats, family planning, and sexual risk behaviours;
- women's reported experiences of *quality of care*; and
- *household characteristics* such as water, sanitation and housing.



These outcomes are included in the full protocol for this study that is appended (Appendix 10.1.2). The author of this thesis also contributed to research in other areas, some of which are noted in the Preface, as publications arising during the period of candidature.

#### ***4.3.4 Health Services for Postnatal and Infancy Care in ENB***

##### *Rationale*

Supply-side perspectives on integrated services can be assessed through a cross-sectional assessment of health facilities, their staff and managers, with mixed methods preferred, as demonstrated in other integration research.<sup>8,334</sup> An assessment focused on postnatal and immunisation services in early infancy can help test the hypothesis that there are locally implementable options for more integrated services, especially integration of immunisation programs, to feasibly meet a broader range of health needs for women and their infants in ENB.

The assessment examined routine preventive health services at two time points: the postnatal period (first 28 days), and from one to twelve months after childbirth. Postnatal care is an opportunity to provide birth-dose vaccination and other high-impact interventions to promote health and survival for both mother and baby, however (as discussed in Chapter Two) is a point in the life course when service delivery is at lowest coverage.<sup>84</sup> After the postnatal period, PNG schedules five immunisation visits during infancy (up to age 12 months); at 1,2,3 then 6 and 9 months of age, with further vaccination at age 18 months.<sup>279</sup> The vaccinations during early infancy offer opportunity for integrated delivery of other interventions critical to the long-term health and development of both mother and baby. The first year of life is a critical time of infant vulnerability to nutritional and infectious threats, and the first six months postpartum are, for the mother, vitally important to re-establish nutrition, avert infections and manage her fertility. Although PNG policy prescribes other forms of routine preventive health care, such as growth monitoring and nutritional advice, provincial reports suggest that the immunisation service is the only regularly operational service provided at this point in the life course.

As detailed in Chapter Seven, the cross-sectional assessment was timed to assess implementation of a new national strategy for enhanced immunisation service planning that included aims for increased integration, which was introduced in 2015, known as the SIREP initiative (see also Section 2.4.6).<sup>277</sup> The study procedures were closely linked to current national and ENB provincial policy priorities, noting that the study team (see Sections 7.1 and 7.3.2), led by the author of this research, also includes a provincial health planner and national advisors. This enabled the study to assess how health facilities interpret and implement national and provincial health policy, and characterise options for more integrated care. The assessment also complemented demand-side data on integrated service uptake from the HMHB Prospective Observational Cohort Study.

A mixed methods approach was expected to allow assessment in depth of possible deficiencies in implementation, such as the ‘know-do’ gap<sup>306</sup> and illuminate options for increased integration. The research design (see below) drew on evaluation theories, including realist inquiry<sup>308</sup> and the ‘most significant change’ technique,<sup>310,335</sup> to construct consultation and interview tools useful to develop theories of how varying context, mechanisms or understanding of outcomes may explain difficulties in provision of good integrated care.<sup>307,336</sup> Interview findings were triangulated against direct observation using patient flow assessments similar to those in HIV integration research,<sup>9,90</sup> supplemented by an adaptation of the WHO Immunization Session Checklist<sup>298</sup> that provided a streamlined guide to good quality service provision.

#### *Study design for the cross-sectional health services assessment*

The consultations, tools development and data collection were in two phases. *Phase One* was to understand national policy and planners’ expectations to develop possible theories for implementation deficiencies that can focus and guide the data collection tools. This included collation and analysis of national policies and standards, including SIREP documentation and consultation interviews with national and provincial policy-makers or health managers to define what is expected of facilities and staff and gather possible explanations for deficiencies in service delivery.

The consultation interview guide was semi-structured with mostly open questions. Consultation findings were then reviewed and synthesised by the investigator team, named in Section 7.1, to adapt standard health service tools for audit, observation and interview so as to focus them on possible explanations for service delivery problems likely to be operating in ENB.

*Phase Two* comprised visits to selected clinics to carry out audit of infrastructure, equipment and supplies, observe patient flow and the provision of care, interview clinic staff, and carry out rapid focus group discussions with family health service clients.

Site selection for phase two was matched to the sites for the prospective observational cohort study, that is: the busier providers of preventive care services in the three districts of ENB where the HMHB program is established. A purposeful selection was made to include dedicated postnatal care clinics, hospital child health outpatients, and child health (immunisation) clinics provided both through static health facilities and by community. These clinics, often termed ‘child health’ or ‘Well Baby Clinics’ primarily provide immunisation, but may also include services for child growth and nutrition, and according to recent policy<sup>277</sup> may also offer family planning and reproductive health, or disease control services.

Staff to be interviewed included those who should have been covered by the nationally-sponsored training on SIREP<sup>277,283</sup> that was conducted in 2015. Interviewees included a total of approximately 20 health managers (detailed in the full protocol, and between 15 and 20 health care providers, comprising all those responsible for preventive care during infancy on the day of assessment. Interview guides drew on realist and ‘most significant change’ concepts to deepen questions. While these research tools were not formally employed, their essential concepts helped formulate question probes to: specify *context* for any general claims (especially made by policy-makers); push respondents to elaborate *mechanisms* by which any change they cite might come about; and to ask respondents to identify which changes are most *valued* by contrasting different changes and seeking their views on the most significant. In addition to

interview, the research team conducted an audit of infrastructure and review of facility records, observation of one to three patient flows, and structured observation of immunisation sessions. Study procedures were structured to assure confidentiality and study participants were not individually identifiable.

Data were collected by PNG research officers trained by this author and other principal investigators; as named in Section 7.3.2. Most data were entered directly into electronic tablets, supplemented by tailored paper forms, and uploaded daily to a protected database or stored in locked filing cabinets. Quality control was managed through close supervision by the investigators and guided by written standard procedures. Detailed descriptions of procedures are available in HMHB documentation and outlined in the protocol (Appendix 10.1.3).

#### *Integration measures in Health Services for Postnatal and Infancy Care study*

The measures listed below address three of the research objectives described in Section 3.2, namely: to review the current experiences of integrating immunisation and other services (Objective One); to characterise opportunities for, and barriers to, more integrated models of service delivery (Objective Three); and to estimate the potential impact (both positive and negative) of integrated services on intervention coverage and resources, client acceptance, equity of access, and quality of care (Objective Four).

Integration outcome measures included in the study instruments include:

- Current service integration (including SIREP objectives), including:
  - Non-immunisation services offered with routine immunisation;
  - Client flow and consultation times;
  - Quality of immunisation services; and
  - Coordination (vertical integration) across antenatal, delivery, postnatal and infancy preventive health services;
- Health care managers' and providers':
  - Knowledge of and attitudes to integrated preventive care;
  - Opinions on current service integration, gaps and strengths; and

- Opinions on the likely feasibility and acceptability of more integrated preventive services immediately after birth and in the first year of life.
- Care-givers opinions on barriers to and opportunities for integrated preventive care in postnatal and infancy periods

#### *Other HMHB outcomes measured in this study*

Other outcomes measured in the HMHB Health Services for Postnatal and Infancy Care study that go beyond the measures of integration collected for this research related to general policy and service characteristics, as well as opportunities for improvement in preventive postnatal or infancy care. These are included in the full protocol that is appended to this thesis at Appendix 10.1.5.

#### **4.3.5 Ethical approvals for field studies**

A detailed description of ethical issues is provided in the full protocols of both field studies. Important considerations in the Prospective Observational Cohort Study were to ensure privacy and confidentiality (for example: of clinical information), minimise participant distress during interviews on sensitive topics (for example: newborn death) or at difficult times (for example: straight after childbirth). For the Health Services study, consideration was given to ensure staff could contribute confidentially and free from blame. For both it was important to ensure fully informed consent and provide easy options for termination of interviews. In PNG, both studies were first submitted for review by the Institutional Review Board of the PNG Institute of Medical Research, then submitted by them for approval by the national Medical Research Advisory Committee. In addition, both studies were reviewed and approved by the Office of Ethics and Research Governance of The Alfred Hospital, Melbourne, which provides support and oversight to research conducted by the institutions of the Alfred Medical Research and Education Precinct; including the Burnet Institute. Copies of approval letters are provided at Appendix 10.1.4 and 10.1.6. The HMHB program was also reviewed in detail by the ENB Provincial Administration and approved by their Executive Council.

## 4.4 Author's involvement in the PNG field research

Given the many partners involved in HMHB, this section outlines the involvement of the author of this thesis in the field research. From 2013, the author was involved as one of a small group within the Burnet Institute who developed the concept of a privately-funded research collaboration. The group chose and negotiated PNG provincial partners to establish the Healthy Mothers Healthy Babies concept, and worked on fund-raising efforts; led in this by Burnet's Director, Professor Brendan Crabb, and Deputy Director, Professor James Beeson.

From 2014 to 2019, the author made over 20 visits to ENB for the HMHB program, some with extended stays. His work during this time included support to the research program managers (who were at various times, Dr Michelle Scoullar and Dr Elizabeth Peach) in establishing a new research office, recruiting and training local research and support staff, establishing local liaison and advisory groups, trouble-shooting logistics and administrative matters, and taking part in fund-raising and communications events in Australian and PNG.

The author is one of five Chief Investigators in the HMHB Prospective Observational Cohort study, having prime responsibility, along with Dr Scoullar and Professor Beeson, for the drafting of the interview and sample collection tools, including coding of software to allow data collection by electronic tablets, drafting of standard operating procedures for the study, and establishment of secure and compliant data management systems in the ENB office. In particular the author led the development of those interview questions that addressed the integration outcome measures noted above. The author also played an active part in training of research staff in correct administration of interviews, working with this team to ensure effective translation into Tok Pisin language. The author led the analysis of all sub-sections of health service utilisation results pertaining to integration, as reported in Chapter Six.

For the HMHB Health Services for Postnatal and Infancy Care study, the author was the lead chief investigator; other chief investigators were a researcher from PNG Institute of Medical Research, Ms Olga Saweri, and a senior

ENB policy maker, Mr Nicholas Larme. The author led the drafting of the consultation guides, interview and discussion guides, coding of software to allow data collection by electronic tablets, and establishment of study data management systems. The author also led the training of research staff for this study. The author was responsible for leading analysis and dissemination of results from this study, as noted in Chapter Seven.

The author has remained actively involved in health development and research initiatives in PNG during the writing of this thesis. This includes leading the development and implementation of a new intervention study on postnatal care, involvement as a chief investigator in two trials of enhanced antenatal care and related women's health issues, and leading a health systems group within a development initiative on disease surveillance; all of which drew on findings documented in this thesis (see Chapter Eight).

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## 5 GLOBAL EXPERIENCES, SYSTEMATIC REVIEW OF THE INTEGRATION OF IMMUNISATION WITH OTHER SERVICES IN LOW- AND MIDDLE-INCOME COUNTRIES, 2011-2016

### 5.1 Background

As discussed in Chapters One and Two, ineffective organisation and management of health services is seen as one important factor constraining the access to essential health care<sup>5,11,13</sup> needed to reach the third Sustainable Development Goal (Ensure healthy lives and promote well-being for all at all ages).<sup>2</sup> Lack of coordination between disease-specific programs, or between preventive health care and clinical services, has meant missed opportunities to improve access to life-saving interventions.<sup>18,103</sup> Recognition of these problems has led to repeated calls for greater integration for health services in general,<sup>1</sup> during pregnancy, childbirth and the first year of life,<sup>18,24</sup> and for more integrated delivery of immunisation services.<sup>54</sup>

Immunisation is seen as a platform that can benefit many services, for example distribution of vitamin A, control of malaria,<sup>58</sup> childhood illness management,<sup>41</sup> management of HIV and related infections,<sup>59,61</sup> or family planning,<sup>62</sup> among others. More integrated services are also needed to better reach all children with all the vaccines they need, as stated by a former director of WHO's Immunization, Vaccines and Biologicals, Dr Jean-Marie Okwo-Bele: *"If we are to raise the bar on global immunization ... every contact with the health system must be seen as an opportunity to immunize..."*<sup>337</sup>

Further study of integrated services is needed, as argued in Chapter Three, because changes to promote integration are not always successful<sup>15,16</sup> and there may be unintended adverse outcomes such as staff overload or exclusion of some clients. Attempts to increase service integration should therefore be based on careful study of coverage, quality, acceptability, complexity and unintended consequences,<sup>139</sup> especially in view of past weaknesses in the strength of

evidence.<sup>6,16,75</sup> Section 2.3 of Chapter Two describes a special supplement in the Journal of Infectious Diseases in 2012 that addressed many of these questions, including a systematic review by Dr Aaron Wallace and colleagues working in the United States Centers for Disease Control and Prevention that reviewed literature up until early 2011.<sup>58</sup> Discussions with colleagues within WHO and CDC confirmed that a new review that updated findings from 2011 onwards would be useful, especially if conducted in line with other guidance on updating of systematic reviews.<sup>314</sup>

## 5.2 Methods for systematic review

### 5.2.1 Overview of methods and protocol elements

Section 4.2 of Chapter Four describes the methods used for this systematic review and a full protocol description is appended, lodged as CRD4201604587 with the International Prospective Registry of Systematic Reviews at:

[http://www.crd.york.ac.uk/PROSPERO/display\\_record.asp?ID=CRD42016045876](http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016045876)

The search, data extraction and analysis aimed to:

- *Identify and describe the range of interventions and service delivery arrangements* used to promote more integrated services;
- *Quantify the change in coverage or uptake* in linked services and/or immunisation (if measured);
- *Identify advantages and disadvantages* of integrating services, including changes in health care quality or equity; and
- *Identify and classify the barriers to and enablers of innovations* in service delivery that are effective in increasing integration.

The search captured publications from January 2011 to May 2016 (timed to inform other research in this thesis as discussed below), in English language, from multiple databases. The review used open inclusion criteria to capture a broad range of study designs, provided they contained quantitative or qualitative measures of outcomes, and described an explicit attempt to change service delivery in order to promote greater integration of immunisation with other services in pregnancy or the first years after child-birth.

Data extraction used a template capturing intervention descriptions, setting and comparators, outcome measures, and a broad range of process determinants; drawing on the Cochrane Collaboration's EPOC group,<sup>302</sup> WHO guidance on what evidence is relevant to LMIC policy-makers<sup>303</sup> and health systems,<sup>104</sup> as well as health services concepts explored in Chapter Three of this thesis. This is appended (Appendix 10.2.1), as populated with study data. Narrative synthesis (see Section 4.2.3) of quantitative and qualitative data was the main method for consolidating and presenting findings. The section below

describes important modifications to the protocol that proved necessary, especially in the synthesis of findings.

### **5.2.2 *Modifications to protocol, synthesis of outcome measures***

The synthesis examined all included studies for quantitative and qualitative outcome measurements of changes in: *coverage* (of immunisation or the linked services), *service volume* (such as number of vaccines administered or commodities distributed), or *ancillary activities* such as uptake of referrals or changes in health-related behaviours.

Meta-analysis of quantitative outcome measures (either linked service outcomes or immunisation outcomes) was attempted, however the heterogeneity of study designs meant this was not a feasible means by which to synthesise outcome findings. Use of forest plots without meta-analysis did prove useful as a graphic comparison of study types – as presented in the results below.

To provide an alternative high-level overview of integration experience outcomes, a single qualitative summary assessment of outcome for both immunisation and the linked service was devised, following review of the breadth of data available. These summary assessments were based on review of individual study results using a predetermined hierarchy of outcome measures as described below.

Where coverage data were available, these assessments were examined for detail on the estimation of denominators, and where this was judged as of satisfactory quality, coverage data were used as the primary source for a qualitative judgement on outcome. If coverage data were not available then the paper was examined for service delivery quantities (such as numbers of vaccinations given), with special attention to the degree to which changes in service delivery were likely to provide valid comparisons (whether pre- compared to post-, or intervention compared to control), as judged by the author of this research.

This process allowed a single qualitative categorization of coverage or service delivery outcomes in relation to comparator or baseline as:

- “*negative*”: decline in coverage or service provision,
- “*mixed negative*”: some services declined but some remained static,
- “*static*”: no important change in coverage or service provision,
- “*mixed positive*”: some services improved but some remained static,
- “*positive*”: significant improvement in coverage or services.

A further option, where outcomes could be both positive and negative for immunisation or the linked service was not observed.

Other quantitative outcome measures specific to individual studies, such as changes in knowledge or attitude, were not used for this high-level qualitative synthesis of outcome. Instead these outcomes were included in results summary tables and used to validate or critique general conclusions on integration outcomes in the discussion of results. Qualitative outcome measures were used similarly in discussion, if quality assessment of reported methods were judged to produce locally valid results.

Ms Jessica Davis, when at Burnet Institute, acted as second reviewer for screening of inclusions. Dr Aaron Wallace, USA CDC, and Dr Emily Wootton at WHO EPI, advised on inclusions, grey literature and aspects of data extraction.

### **5.2.3 *Comment on review timing***

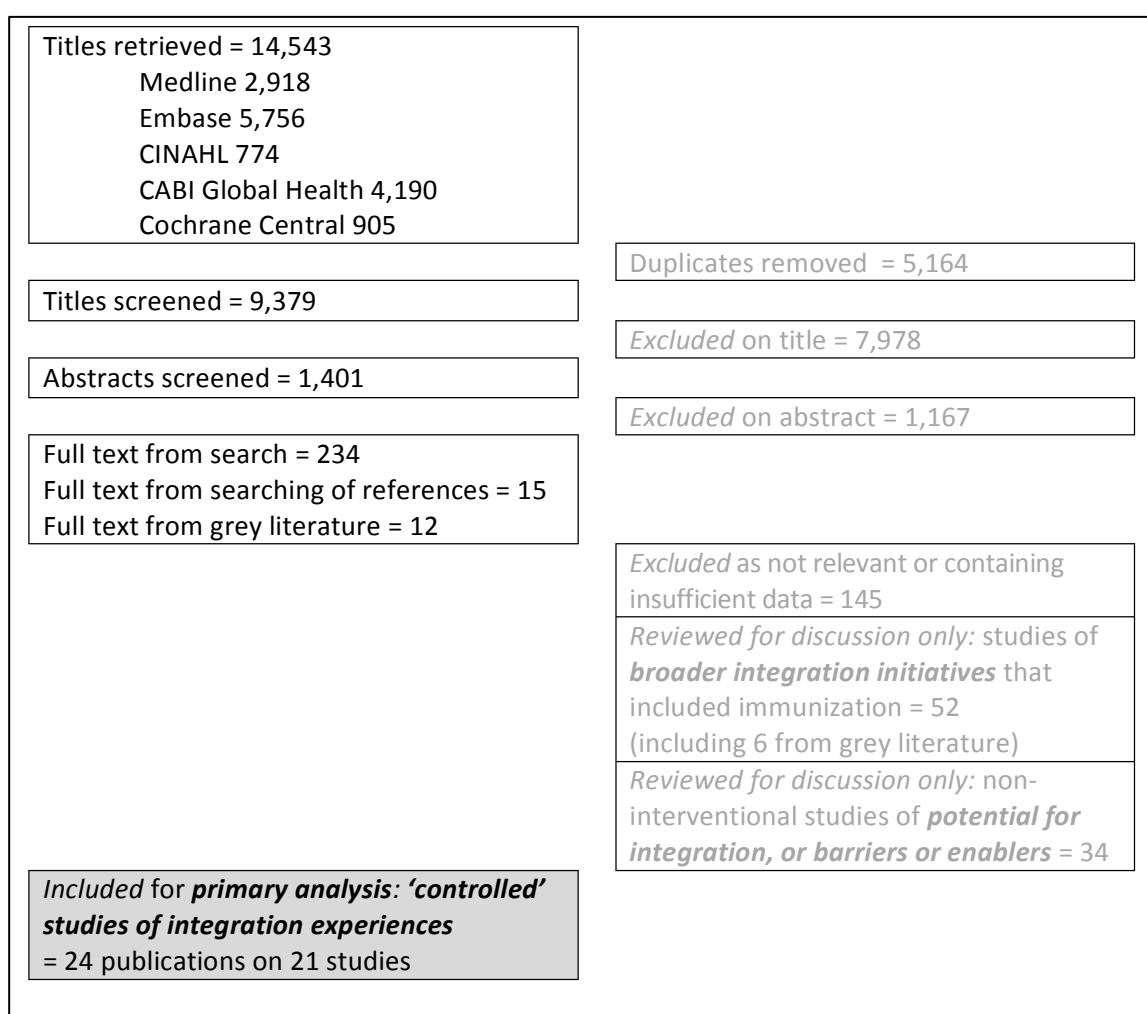
The results presented in this chapter captured studies published from 2011 to 2016, because the review was timed to inform other studies presented in this thesis and other discussions within WHO at that time. As described in Chapter Eight, interim aspects of the findings were presented at various WHO immunisation forums in 2017 and 2018 to ensure timely contribution to global discussions. Following completion of this thesis, a further update of the search is planned, that can then result in a peer-review journal publication involving CDC, WHO, and other partners as listed in the review protocol. As noted in Section 4.4 of Chapter Four, the author of this thesis led the detailed protocol development for this review, as well as its search, data extraction, analysis and synthesis of findings.

## 5.3 Results

### 5.3.1 Search results

Figure Seven shows the flow diagram of search results and final inclusions. The necessary use of broad search terminology resulted in a large number of titles retrieved over the period of January 2011 to May 2016 that were then screened in line with the inclusion criteria noted in Section 4.

**Figure 7: Flow diagram of systematic review search results**



Twenty four publications on 21 studies of services in early childhood were included for primary analysis. These were studies where: a) there was a specific intervention to change service delivery arrangements so as to promote more integrated services, b) the process of integrating services was a controlled part of the intervention preferably with a clear comparator, c) the process or outcomes

of the integration intervention was an explicit object of the research, and d) the study design met minimum quality criteria.

Two additional categories of publication were identified that could contribute to the discussion of the research objectives above through analysis of qualitative data, but were not eligible for inclusion in the primary analysis. These comprised:

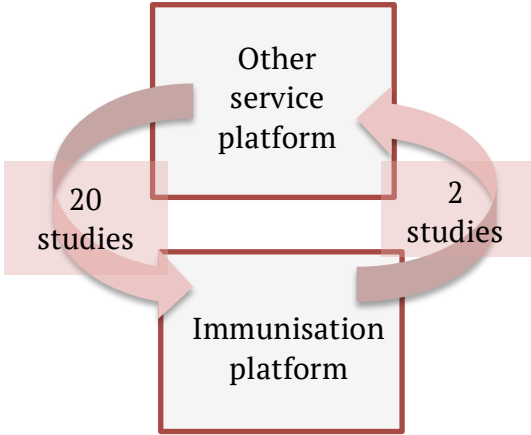
- 46 publications on initiatives supporting integrated services including immunisation, plus six from the grey literature document review; deemed not eligible because
  - either the process of integration was not an explicit object of research (often in studies with broader objectives), or
  - the process of integrating services was not clearly controlled as part of the intervention, or
  - insufficient measurement data were available; and
- 34 publications on the potential benefits of or opportunities for more integrated services, and/or the barriers to or enablers of integration; but which did not test an intervention.

Identification of 24 publications (on 21 programs) over slightly more than five years from 2011 represents an increase in publications on integration experiences, if one compares this with the 32 similar studies across 27 programs found by Wallace and colleagues<sup>58</sup> over the 18 years between 1993 and 2011. This suggests an acceleration of interest, both in making explicit attempts to integrate immunisation with other services and in researching health service outcomes, since global strategies such as the Global Vaccine Action Plan 2011-2020<sup>37</sup> development agencies such as USAID<sup>88,89</sup> increased attention on the potential of more integrated services.

5.3.2 Characteristics of included studies

Table 4 below summarises the study characteristics for the 24 publications over 21 programs in LMICs from January 2011 to May 2016. Most (18) were in sub-Saharan Africa and none were from PNG or other countries in the Western Pacific region. The variability in designs reflect the pragmatics of researching health service delivery in such settings, comprising: nine cluster randomised controlled trials, three non-randomised controlled trials (NRCT), five controlled before-after studies (CBA), and seven non-comparative or evaluation publications. While all designs were included in narrative synthesis, only data from controlled trials (RCT, NRCT or CBA) were used in a quantitative summary of outcomes.

Figure 8: Directions of integration in included studies



Note: one study examined both directions.

It was more common (see Figure 8) for researchers to study the incorporation of other services into the immunisation platform, than the reverse direction. Only one study, in Bangladesh,<sup>338</sup> integrated *vaccination into another service*; an intervention to reduce missed opportunities for vaccination when children presented with illness (one arm of a larger study into improved immunisation).

One study in Sierra Leone<sup>339</sup> integrated immunisation with interventions for different *combinations of family planning and nutrition*, with the aim of increasing uptake of all services, including measurement of infant growth, provision of advice on feeding and/or family planning, and/or provision of contraceptives, as well as provision of or counselling on vaccination.

All other studies examined the integration of additional interventions for a single disease priority into the immunisation platform.



Single disease priority studies included interventions for:

- *HIV*, for which seven publications across six studies examined the addition of either early infant diagnosis (EID) alone, or EID combined with treatment initiation;
- *malaria*, for which six publications across five studies examined the addition of ITN distribution, provision of IPTi (during infant vaccination), or provision of intermittent preventive treatment in childhood (IPTc, during older child vaccination);
- *family planning*, for which four studies examined addition of counselling for family planning, or counselling plus provision of contraceptives;
- *nutrition*, for which three studies examined the addition of nutrition counselling, or distribution of vitamin A and anti-helminthic treatment,
- *water, sanitation and hygiene (WASH)*, for which two publications across one study examined the addition of hygiene counselling and provision of domestic hygiene kits;
- *hearing screening*, for which one study examined the addition of a hearing screening test including audiology equipment; and
- *maternal depression*, for which one study examined the addition of maternal interview screening for symptoms of depression.

Some topics had been hypothesised as likely research objects (see also Section 2.1), but eligible studies could not be found despite active searching through search software, follow-up of citation lists, expert consultation, or key data repositories. These gaps included studies of: *missed opportunities for vaccination*, integration of *immunisation within general child illness care*, integration of immunisation with *nutrition* interventions, and the integration of *birth-dose vaccination within postnatal care*. A number of studies on these topics that did not meet inclusion criteria (Table 8) were reviewed for qualitative data that could contribute to discussion.

**Table 4: Characteristics of included studies**

| <i>Linked intervention</i> | <i>EPI platform</i> | <i>Study type</i> | <i>Country</i> | <i>Study year</i> | <i>Integration strategy</i>                                                                                                                        | <i>Immunisation outcome</i>                                                      | <i>Linked intervention outcome</i>                             | <i>Citation</i> |
|----------------------------|---------------------|-------------------|----------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------------------|-----------------|
| Sick child visit           | Routine             | CBA               | Bangladesh     | 2011              | Screening checklist added to sick child visits to promote catch-up vaccination. Compared to other strategies for increasing immunisation coverage. | Coverage increase                                                                | Not measured.                                                  | 338             |
| HIV, EID + treatment       | Routine             | CBA               | Tanzania       | 2013              | EPI staff identified HIV-exposed infants, offered testing, counselling and care. Compared to matched control sites.                                | Vaccinations given declined in rural sites, neutral or increased in other sites. | HIV service uptake increased in all sites.                     | 340             |
| HIV, EID + treatment       | Routine             | NC                | Tanzania       | 2014              | <i>This was a qualitative expansion of the research above<sup>340</sup></i>                                                                        | Not measured.                                                                    | Found stigma and some misconceptions associated with HIV.      | 332             |
| HIV, EID                   | Routine             | NC                | Malawi         | 2012              | EID offered in co-located service at six week EPI visit. Compared to baseline.                                                                     | Not measured.                                                                    | EID uptake increased.                                          | 341             |
| HIV, EID                   | Routine             | NC                | Cameroon       | 2011              | EID offered in co-located service at six week EPI visit, with follow-up at later EPI visits. Compared to baseline.                                 | Not measured.                                                                    | EID uptake increased but EPI timing may have limited follow-up | 342             |
| HIV, EID                   | Routine             | NRCT              | Malawi         | 2012              | EPI and co-located staff offered counselling and testing. Compared to child health clinic.                                                         | Not measured.                                                                    | EID uptake higher in EPI clinics.                              | 343             |
| HIV, EID + treatment       | Routine             | NRCT              | Kenya          | 2012              | EPI and co-located staff offered counselling testing, and care. Compared to HIV clinic.                                                            | Coverage higher in integrated clinics.                                           | EID uptake and follow-up higher in EPI clinics.                | 344             |
| HIV, EID                   | Routine             | RCT               | Zambia         | 2015              | EPI and co-located staff, with commodity support, offered counselling and testing. Compared to no intervention.                                    | Vaccinations given increased in integration and in control sites.                | EID uptake higher in integrated sites.                         | 345             |

Table continued on next page

**Table 4: Characteristics of included studies (continued)**

| <i>Linked intervention</i> | <i>EPI platform</i> | <i>Study type</i> | <i>Country</i>   | <i>Study year</i> | <i>Integration strategy</i>                                                                                                                                                                  | <i>Immunisation outcome</i>                                                                             | <i>Linked intervention outcome</i>                                                              | <i>Citation</i> |
|----------------------------|---------------------|-------------------|------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------|
| Malaria, ITN               | Campaign            | OBS               | Madagascar       | 2012              | ITNs distributed during measles vaccination campaign in selected sites.                                                                                                                      | Coverage and equity higher in integrated sites.                                                         | Earlier study <sup>346</sup> showed effective ITN coverage.                                     | 347             |
| Malaria, IPTi              | Routine             | RCT               | Tanzania         | 2011              | IPTi services and counselling by staff at EPI clinics. Compared to no intervention.                                                                                                          | Coverage unchanged in both arms.                                                                        | IPTi coverage attained in intervention. Survival gain equal in both arms.                       | 348             |
| Malaria, IPTi              | Routine             | RCT               | Tanzania         | 2011              | <i>Sub-study within the research above</i> <sup>348</sup>                                                                                                                                    | Coverage similar or better.                                                                             | IPTi coverage high. Non-significant trend to less morbidity.                                    | 349             |
| Malaria, IPTi ITN          | Routine             | RCT               | Mali             | 2011              | IPTi services and counselling by staff at EPI clinics. Compared to no intervention.                                                                                                          | Greater coverage increase in integrated.                                                                | High IPTi coverage and ITN uptake in integrated                                                 | 141             |
| Malaria, IPTc              | ERA                 | RCT               | Gambia           | 2011              | IPTc services during outreach by EPI and co-located staff. Compared to IPTc through community-based lay health workers.                                                                      | Coverage static, but better in community-based arm.                                                     | Coverage better in non-integrated community-based arm.                                          | 350             |
| Malaria IPTc               | Routine ERA         | RCT               | Ghana            | 2011              | IPTc services during outreach by EPI staff. Compared to IPTc in child outpatients or by community-based lay health workers.                                                                  | Not reported (was reported in earlier study before 2011 <sup>351</sup> )                                | Coverage and costs better in VHW service, increased in all                                      | 352             |
| Family Planning            | Routine             | CBA               | Liberia          | 2015              | FP counselling by EPI staff, with co-located service. Compared to no intervention.                                                                                                           | Mixed changes in vaccinations given.                                                                    | Increase in referrals and uptake of contraception                                               | 334             |
| Family Planning            | Routine             | RCT               | Rwanda           | 2016              | FP counselling by EPI staff, with co-located service. Compared to no intervention.                                                                                                           | Vaccinations given remained static.                                                                     | Increase in uptake of contraception.                                                            | 353             |
| Family Planning            | Routine             | RCT               | Ghana and Zambia | 2014              | FP counselling by EPI staff at nine month EPI visit. Compared to no intervention.                                                                                                            | Not measured.                                                                                           | No increase in knowledge or uptake.                                                             | 10              |
| Family Planning Nutrition  | Routine             | NRCT              | Sierra Leone     | 2015              | New visit at six months for Vitamin A, introduced to child health card. Extra co-located staff provided either IYCF counselling or IYCF and FP services. Catch-up vaccination also supplied. | Coverage static (and high) across all groups. More in integration groups received catch-up vaccination. | Increased uptake of contraception, vitamin A, and feeding advice; and increased weight-for-age. | 339             |

Table continued on next page

**Table 4: Characteristics of included studies (continued)**

| <i>Linked intervention</i> | <i>EPI platform</i> | <i>Study type</i> | <i>Country</i> | <i>Study year</i> | <i>Integration strategy</i>                                                                                                                         | <i>Immunisation outcome</i>                                                  | <i>Linked intervention outcome</i>                               | <i>Citation</i> |
|----------------------------|---------------------|-------------------|----------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------|-----------------|
| Nutrition                  | Routine             | CBA               | Mexico         | 2013              | Nutrition counselling on IYCF by EPI staff using scripted tool.                                                                                     | Not measured.                                                                | Change in reported feeding and beliefs.                          | 354             |
| Nutrition                  | Campaign            | NC                | Lao PDR        | 2011              | Provision of VA and AH by EPI staff during measles campaign. Compared to stand-alone VA and AH campaign.                                            | Not measured.                                                                | Effective coverage of VA and AH at lower cost.                   | 355             |
| WASH, hygiene kits, soap   | Routine             | RCT               | Kenya          | 2012              | Counselling and provision of hygiene kits by EPI staff. Compared with service by community-based lay health workers and with matched control sites. | Coverage increase with urban/rural differences.                              | Increase in reported knowledge and uptake of hygiene commodities | 356             |
| WASH, hygiene kits, soap   | Routine             | RCT               | Kenya          | 2012              | <i>Sub-study of the research above<sup>356</sup>.</i>                                                                                               | <i>Sub-study of above<sup>356</sup>.</i> Urban nurse-led coverage increased. | No difference in hygiene outcomes by distribution strategy.      | 331             |
| Hearing screening          | Routine             | NC                | South Africa   | 2012              | EPI staff administered a hearing screening test.                                                                                                    | Not measured.                                                                | Inadequate coverage in most sites.                               | 357             |
| Maternal depression        | Routine             | NC                | Nigeria        | 2014              | Depression screening service co-located with EPI clinic visits.                                                                                     | Not measured.                                                                | Detection of maternal depression feasible.                       | 358             |

Notes: EID = Early infant diagnosis, IPTi = Intermittent preventive treatment in infancy, IPTc = Intermittent preventive treatment in childhood, VA = vitamin A distribution, AH = Anti-helminthic distribution. EPI = Expanded Programme on Immunization. ERA = Enhanced Routine Activity. RCT= Randomised controlled trial (cluster randomised), NRCT=Non-randomised controlled trial, CBA=Controlled Before-After study, OBS = observational study, NC = non-controlled trial.

### 5.3.3 Outcomes of integration experiences

#### *Overall outcome findings*

Table 5 below summarises the outcomes of integration experiences, for 21 studies where outcome data allowed a narrative synthesis of reported outcomes. As described in Section 5.2.2 above, this used a single qualitative summary assessment derived from the narrative synthesis of changes in coverage or service provision. In six studies an immunisation outcome was not measured, in which case the row in Table 5 has been left blank. All studies had sufficient linked service outcome measures for a summary assessment to be obtained.

Overall, it was commonly reported that *the linked service benefited* in terms of service delivery volumes or coverage increase; most studies reported a positive outcome for the linked service. In contrast, *immunisation coverage or vaccinations given had mixed outcomes*. In most cases immunisation outcomes were either static or positive, with two examples where immunisation outcomes were worse than the non-integrated comparator.

Table 5 also displays the variety of immunisation platforms that were the subject of integration innovations: *most integrated into routine services* based in health facilities, two into immunisation campaigns, and one into an ‘enhanced routine activity’ (ERA) that intensified community outreach as extensions of the work of health facilities. Table 5 also summarises the *various integration strategies* that were employed, encompassing: immunisation staff providing extra services, or extra counselling, or both; and/or co-location of additional services with immunisation; and in one instance immunisation integrated into sick child services. These are discussed further in Section 5.3.4 below.

**Table 5: Overview of integration outcomes for vaccination and linked services, in 21 unique study sites**

| Linked intervention | EPI platform | Country       | Integration strategy | Vaccination outcome |       |        |       |     | Linked service outcome |       |        |       |     | Citation |
|---------------------|--------------|---------------|----------------------|---------------------|-------|--------|-------|-----|------------------------|-------|--------|-------|-----|----------|
|                     |              |               |                      | NEG                 | M-NEG | STATIC | M-POS | POS | NEG                    | M-NEG | STATIC | M-POS | POS |          |
| Sick child visit    | Routine      | Bangladesh    | D                    |                     |       |        |       | ●   |                        |       |        |       |     | 338      |
| HIV, EID/T          | Routine      | Tanzania      | A, B                 | ●                   |       |        |       |     |                        |       |        |       | ●   | 340      |
| HIV, EID            | Routine      | Malawi        | C                    |                     |       |        |       |     |                        | ○     |        |       |     | 341      |
| HIV, EID            | Routine      | Cameroon      | C                    |                     |       |        |       |     |                        |       |        | ○     |     | 342      |
| HIV, EID            | Routine      | Malawi        | B, C                 |                     |       |        |       |     |                        |       |        |       | ●   | 343      |
| HIV, EID/T          | Routine      | Kenya         | C                    |                     |       |        |       | ●   |                        |       |        |       | ●   | 344      |
| HIV, EID            | Routine      | Zambia        | A, B, C              |                     |       | ●      |       |     |                        |       |        |       | ●   | 345      |
| Malaria, ITN        | Campaign     | Madagascar    | A, C                 |                     |       |        |       | ○   |                        |       |        |       | ○   | 347      |
| Malaria, IPTi*      | Routine      | Tanzania      | A                    |                     |       | ●      |       |     |                        |       |        | ●     |     | 348      |
| Malaria, IPTi*      | Routine      | Tanzania      | A                    |                     |       |        | ●     |     |                        |       |        |       | ●   | 349      |
| Malaria, IPTc       | Routine, ERA | Gambia        | A, B, C              |                     | ●     |        |       |     |                        | ●     |        |       |     | 350      |
| Malaria, IPTi ITN   | Routine      | Mali          | A                    |                     |       |        |       | ●   |                        |       |        |       | ●   | 141      |
| Malaria, IPTc       | Routine      | Ghana         | A                    |                     |       |        |       |     |                        |       |        |       | ●   | 352      |
| Family Planning     | Routine      | Liberia       | B, C                 |                     |       |        | ●     |     |                        |       |        |       | ●   | 334      |
| Family Planning     | Routine      | Rwanda        | B, C                 |                     |       | ●      |       |     |                        |       |        |       | ●   | 353      |
| Family Planning     | Routine      | Ghana, Zambia | B                    |                     |       |        |       |     |                        |       |        | ●     |     | 10       |
| FP, VA, IYCF        | Routine      | Sierra Leone  | C, D, E              |                     |       |        |       | ●   |                        |       |        |       | ●   | 339      |
| Nutrition, IYCF     | Routine      | Mexico        | B                    |                     |       |        |       |     |                        |       |        |       | ○   | 354      |
| Nutrition, VA, AH   | Campaign     | Lao PDR       | A                    |                     |       | ○      |       |     |                        |       |        |       | ○   | 355      |
| WASH                | Routine      | Kenya         | A, B or C            |                     |       |        | ●     |     |                        |       |        |       | ●   | 356      |
| Hearing screening   | Routine      | South Africa  | A                    |                     |       |        |       |     |                        | ○     |        |       |     | 357      |
| Maternal depression | Routine      | Nigeria       | C                    |                     |       |        |       |     |                        |       |        |       | ○   | 358      |

**Notes:**

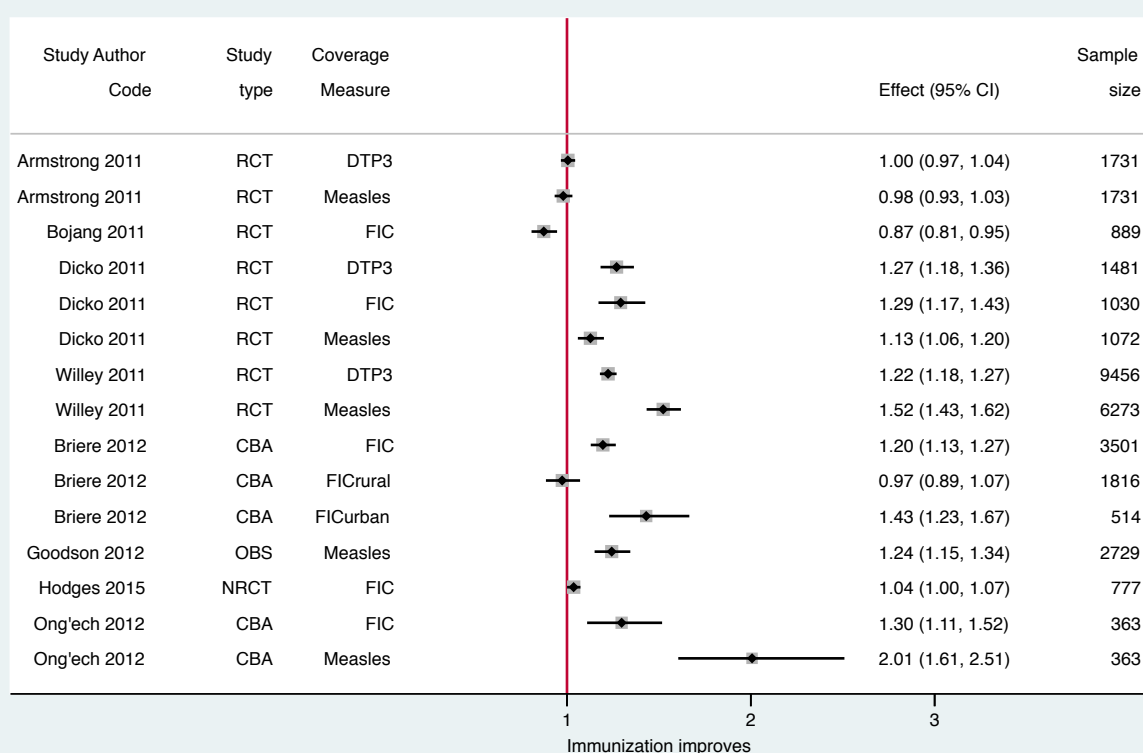
- EID = Early infant diagnosis, EID/T = Early infant diagnosis with treatment, ITN = Insecticide treated net distribution, IPTi / IPTc = Intermittent preventive treatment in infancy or childhood, VA = vitamin A distribution, AH = Anti-helminthic distribution, FP = Family Planning, IYCF = Infant and Young Child Feeding counselling, WASH = Water, Sanitation and Hygiene. EPI = Expanded Programme on Immunization. ERA = Enhanced Routine Activity. \*One IPTi study in Tanzania has two different outcome measurement publications<sup>348,349</sup>
- Integration strategy codes: A = Extra services by EPI staff; B = Extra counselling by EPI staff; C = Co-located linked service; D = Vaccination advice +/- service by non-EPI staff; E = Counselling on immunisation by non-immunisation staff.
- Overview assessment of coverage in relation to comparator: NEG = Coverage decrease, M-NEG = Mixed coverage outcome, with decrease and static, M-POS = Mixed coverage, with static and increase, POS = Coverage increase. ● = cluster RCT, ● = CBA, ○ = other study type. Some studies had no outcome data.

*Quantitative meta-analysis* was explored for studies reporting potentially suitable outcome measures. For *linked services*, the outcome measures were too heterogeneous to allow construction of meaningful comparison tables. For *immunisation* outcome measures, eight studies (four RCTs and four other designs) provided sufficient detail to extract coverage measures for exploration using the *metan* command, with random effects model, in Stata. However meta-analysis was considered to be invalid due to the observed heterogeneity and inconsistency in study designs and the variety of coverage indicators. This conclusion was confirmed by very high  $I^2$  quantity measures<sup>359</sup> (in excess of 90%) across all study groupings, even when only RCTs were consolidated. Further discussion on outcomes, and an illustrative forest plot, are provided below.

#### *Outcomes for the immunisation service*

As seen in Table 5, with two exceptions relating to HIV services and malaria IPT in childhood (discussed below), immunisation outcomes were at least unharmed, or slightly improved in relation to the comparator during integration experiences.

A forest plot is presented below, using extracted immunisation outcome data, but without meta-analysis, to provide a graphical illustration of this finding. This includes all vaccines reported in studies with sufficient data to allow extraction of immunisation coverage measures in both integration and comparison groups (a table of the extracted data used to develop this is appended at Appendix 10.2.2).

**Figure 9: Forest plot of immunisation outcomes (illustrative purposes only)**

Notes: RCT = Randomised controlled trial; DTP3 = third dose of diphtheria/tetanus/pertussis-containing vaccine; FIC = fully immunized child (at one year); CBA = Controlled before- and after-study; OBS = Observational study; NRCT = non-randomised controlled trial. Effect is the relative change in immunisation coverage. Plot produced from extracted outcome measures, using StataSE (2017) running IDPmetan package. Citations: Armstrong 2011,<sup>348</sup> Bojang 2011,<sup>350</sup> Dicko 2011,<sup>141</sup> Willey 2011,<sup>349</sup> Briere 2012,<sup>356</sup> Goodson 2012,<sup>347</sup> Hodges 2015,<sup>339</sup> Ong'ech 2012.<sup>344</sup> All studies were conducted in sub-Saharan Africa.

As noted above, meta-analysis by subgroup was not possible, limiting the ability to comment on quantitative comparisons for different study types, or different vaccines. Inspection of the forest plot and Table 5 does demonstrate that, *among the larger RCTs, either neutral or beneficial outcomes for immunisation are seen*; and seen across a variety of vaccination timings, encompassing those given in the first half of infancy (DTP3) and those in late infancy (measles). The one RCT with a 'negative' immunisation service outcome was in a study of IPTc integration providing services in the second year of life and later,<sup>350</sup> for which immunisation coverage was less in the integrated arm as compared with community-based immunisation service delivery. For most RCTs, the coverage benefit, where it existed, ranged from 10 to 30% increases over the comparator.



It is notable that it was the smallest study<sup>344</sup> (which may have been at a higher risk of bias) that demonstrated the highest improvement in vaccine coverage.

Some studies not included in the figure above measured different immunisation indicators, such as trends in number of vaccine doses given. These studies also informed the qualitative summary reported in Table 5, as well as the narrative below that describes the variety of immunisation outcomes, by the disease focus of the linked intervention.

*When HIV services were added there was a mix of beneficial, negative, and neutral effects on immunisation.* Immunisation measures were available for three of the six reports. A CBA in Kenya<sup>344</sup> measured higher coverage with measles vaccine and full completion of vaccination by 12 months of age (FIC, or ‘fully immunized child’) when HIV testing and treatment was provided alongside immunisation in MCH clinics. One study in Tanzania<sup>340</sup> found a reduction in vaccine doses in rural (but not urban) clinics when HIV diagnosis and treatment was integrated with immunisation, with qualitative follow-up<sup>332</sup> suggesting this was due to an unfounded fear that testing may be mandatory. A RCT in Zambia<sup>345</sup> found that vaccine doses increased over time, with no difference between integration and comparison sites.

*When malaria services were added during infancy there were either beneficial or neutral effects on immunisation.* Two studies reported clearly beneficial immunisation outcomes when malaria preventive interventions were integrated. In a campaign setting in Madagascar<sup>347</sup> vaccination coverage was higher (and more equitable) in districts where distribution of insecticide-treated nets had been added. In a RCT of IPTi in Mali,<sup>141</sup> immunisation coverage improved in both controls and intervention zones, with the greater increase seen in integrated clinics, and in those vaccines associated with IPTi. In two analyses of a large RCT in Tanzania testing provision of IPTi, coverage of the third dose of DTP3 measured by trial data<sup>348</sup> or by routine health information<sup>349</sup> showed immunisation coverage as static or slightly higher in integrated services (an earlier report from this study was also reviewed by Wallace et al<sup>58</sup>).

*Malaria services later than infancy differed in outcomes.* One study in Gambia<sup>350</sup> compared two strategies for providing intermittent preventive malaria treatment for older children (IPTc, over one year in age) to rural communities: comparing integration with vaccination as part of the work of outreach teams, against provision by community-based lay health workers. The integrated outreach approach was associated with slightly lower immunisation coverage.

*When nutrition interventions were added, it was difficult to assess the effect on immunisation* because only the non-randomised trial in Sierra Leone<sup>339</sup> measured immunisation outcomes. This study included both nutrition and family planning interventions, finding more catch-up vaccinations took place in clinics providing an integrated package of care.

*When postpartum family planning was added, overall the effect on immunisation was mixed, but mostly neutral.* A RCT in Rwanda<sup>353</sup> measured measles coverage, finding “no downward trend in numbers immunized for measles in intervention over study period” and a CBA in Liberia<sup>334</sup> measured vaccine doses before and after integration, showing a mix of increases and decreases that overall suggested no significant detriment to immunisation service provision. One RCT on family planning and immunisation integration<sup>10</sup> did not report immunisation outcomes.

*One WASH integration experience in Kenya<sup>142,356</sup> found increased immunisation coverage in urban clinics* integrating WASH counselling and hygiene commodity distribution, but this was not replicated in rural sites.

*One intervention to reduce missed opportunities for vaccination reported an increase in immunisation coverage.* This CBA in Bangladesh attributed the benefit to the deployment of an immunisation-specific reminder checklist when children were brought to rural clinics for illness care. Other studies, such as those attempting to integrate screening for hearing deficit or maternal depression, did not report measures of immunisation outcomes.

#### *Outcomes for the linked service/s*

Tables 4 and 5 also summarise the outcomes for linked services, as measured through a variety of indicators of coverage, services provided, or other

service uptake measures. *Most reports demonstrated benefit to the linked service, in terms of increased coverage or service quantities*, especially seen in services for HIV and malaria; disease priorities for which there was the greatest number of eligible studies.

*All HIV services saw large and important benefits* to the provision of early infant HIV services, through integration with immunisation clinics or other maternal and child health services when compared with standalone HIV services. The increased uptake was especially seen in uptake of infant testing and diagnosis.<sup>340-345</sup> Improved initiation of early infant treatment was also commonly seen, but in at least two reports<sup>341,342</sup> implementation lapses, such as prolonged test turnaround times or failures in individual client follow-up, meant that treatment gains did not match increases in EID uptake.

*For malaria control services, integration showed mixed benefits.* Distribution of ITNs through a measles campaign found relatively high (77%) coverage of households in integration districts.<sup>347</sup> Intermittent preventive treatment services showed significant benefit, but only for the infant age group. Two RCTs of IPT during infancy<sup>141,348</sup> achieved higher coverage when integrating the distribution of preventive medicines into vaccination clinics, although the increase was less than expected in Tanzania.<sup>334</sup> For children older than one year receiving IPTc, community-based lay health workers achieved equivalent<sup>352</sup> or higher<sup>350</sup> coverage, and at lower cost, than integrating distribution with static or outreach immunisation clinics.

*Family planning service studies reported mixed outcomes* from integration. A randomized controlled effectiveness trial in Rwanda<sup>353</sup> and a CBA feasibility study in Liberia<sup>334</sup> both reported increased uptake of modern contraceptive methods when services were integrated with immunisation clinics. However a multi-country RCT in Ghana and Zambia<sup>10</sup> that added family planning counselling onto immunisation services found only a small increase that was not statistically significant. It was speculated this was due in part to incomplete implementation of the intervention as designed. This is a factor that may reflect

the model of integration chosen for the intervention, a determinant reported on in Section 5.3.4 below.

*Both family planning and nutrition services showed benefit in one more complex study*, a non-randomized but well-controlled trial in Sierra Leone<sup>339</sup> that included family planning services alongside nutrition counselling and distribution of vitamin A with immunisation clinics. This study found benefits to family planning service uptake and infant growth outcomes in the most comprehensive integrated services (although outcomes were confounded by differing rates of exclusive breast feeding at baseline).

*Two nutrition service studies showed benefit in nutrition outcomes*. One CBA feasibility study in Mexico<sup>354</sup> reported improved feeding practices and beliefs following delivery of counselling scripts by vaccinators during immunisation clinics. A non-controlled implementation study of distribution of vitamin A and anti-helminthics during an immunisation campaign in Lao Peoples Democratic Republic reported improved coverage and capacity for observing treatment uptake.<sup>355</sup> Both studies were assessed as having higher risk of bias in outcome measurement.

*One WASH intervention*, a RCT in Kenya,<sup>356</sup> reported improved self-reported hygiene behaviours and knowledge, when information and kits were distributed at immunisation clinics. Although a sub-analysis<sup>351</sup> found no improvement in hygiene outcomes such as improved water quality, this was attributed to a variety of measurement and behavioural factors rather than the model of integration. *Other interventions reporting improved outcomes*, including hearing screening<sup>357</sup> or maternal depression<sup>358</sup> screening, noting both were study designs assessed as having a higher risk of bias in outcome measurement.

*Equity of outcome* was formally assessed in two studies. In the Madagascar campaign-based model<sup>347</sup> integrating ITN distribution with vaccination, coverage for both services was higher among poorer households. In the Gambia study of childhood IPT,<sup>350</sup> coverage of IPT was slightly higher in the poorest quintile in both integrated and non-integrated (community-based) arms. Several other studies<sup>332,352</sup> noted the relative disadvantage suffered by rural households, and the

potential shown by integrated service delivery to overcome this. Qualitative data from the WASH study in Kenya<sup>331</sup> suggested that clients perceived the process of linking hygiene products to immunisation as potentially inequitable, disadvantaging other children or families not attending for immunisation.

#### **5.3.4 Models of service integration**

An important inclusion criterion for the review was that studies make an explicit change to service delivery so as to promote more integrated services. All included studies were reviewed to understand the nature of the change to service delivery to identify the variety of models of integrated services being tested. Categories of integration efforts that emerged from this review were compared to those reported in other studies<sup>8,58,106,137</sup> and informed by the conceptual framework developed for this research (Section 3.1.4, Figure 5). This enabled categorization of integration models into five general types of service delivery change that were introduced to promote more integrated services. These comprised:

- A. Extra services (commodities) provided by immunisation staff; and/or
- B. Extra counselling on a linked health priority by immunisation staff;
- C. Co-location of extra services (including extra staff) at the same time and linked to immunisation service provision;
- D. Extra immunisation counselling and vaccination provided by non-immunisation staff; and/or
- E. Extra counselling on immunisation by non-immunisation staff.

#### *Frequency of different models of integration seen in included studies*

Table 6 lists the frequency of these integration models seen in the 21 included studies, noting that nine studies used a combination of more than one model of service delivery change.

**Table 6: Types of service change introduced to promote integration in 21 studies**

|                          | <b>A: Extra <i>services</i> provided by EPI staff</b>                                                                                                                                                                                                                                                      | <b>B: Extra <i>counselling</i> provided by EPI staff</b>                                                                                                                      | <b>C: <i>Co-location</i> with extra services linked to immunisation place/time</b>                                                                                                                                                                                                                                                                                          | <b>D or E: <i>Vaccination (D) or immunisation counselling (E)</i> by non-EPI staff</b>                                                                                                                                     |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Number of studies</i> | 10                                                                                                                                                                                                                                                                                                         | 8                                                                                                                                                                             | 11                                                                                                                                                                                                                                                                                                                                                                          | 2                                                                                                                                                                                                                          |
| <i>Examples</i>          | <ul style="list-style-type: none"> <li>• HIV testing and counselling</li> <li>• Intermittent preventive treatment for malaria</li> <li>• Distribution of ITNs</li> <li>• Distribution of vitamin A and/or anti-helminthic</li> <li>• Hygiene kit distribution</li> <li>• Hearing screening test</li> </ul> | <ul style="list-style-type: none"> <li>• Family planning and postpartum fertility counselling</li> <li>• Infant feeding counselling</li> <li>• Hygiene counselling</li> </ul> | <ul style="list-style-type: none"> <li>• Early infant HIV diagnosis +/- treatment initiation</li> <li>• Distribution of ITNs (+/- counselling)</li> <li>• Family planning counselling +/- contraceptive services</li> <li>• Feeding counselling and support</li> <li>• Hygiene counselling and hygiene kit distribution</li> <li>• Maternal depression screening</li> </ul> | <ul style="list-style-type: none"> <li>• Vaccination during visit for other purpose</li> <li>• Volunteers counselling on EPI</li> <li>• Catch-up vaccination in routine visit for nutrition +/- family planning</li> </ul> |
| <i>Seen in:</i>          | 340, 345, 347, 348, 141, 350, 352, 355, 356, 357                                                                                                                                                                                                                                                           | 340, 345, 352, 334, 353, 10, 354, 356                                                                                                                                         | 341, 342, 343, 344, 345, 347, 334, 353, 339, 356, 358                                                                                                                                                                                                                                                                                                                       | 338, 339                                                                                                                                                                                                                   |

*Co-location of a linked service (model C) was the more common change, by a small margin, to promote integrated services; aiming to make the linked service accessible in time and place to families receiving immunisation services. This involved making extra staff and commodities available at or near the immunisation site to, for example, provide counselling and testing for HIV, distribute health commodities, or provide family planning advice or services. The additional staff varied from trained lay health workers (such as for ITN, antimalarial medicine, or hygiene kit distribution) to additional professional staff, such as for HIV counselling, testing and treatment initiation. Some co-located services adjusted clinic infrastructure to ensure privacy for HIV<sup>343</sup> or family planning<sup>334,339</sup> counselling.*

The next most common change observed in these studies was the provision of training support and extra commodities to enable *vaccination staff to provide extra services (model A)*. These extra services varied from relatively straightforward tasks, such as distribution of vitamin A or ITNs, to more demanding roles such as provision of antimalarial medicines (with some clinical

advice), performing HIV testing and treatment initiation, or screening for hearing loss. In some settings *vaccinating staff provided additional counselling (model B)*, based on training and sometimes additional communication tools. The counselling covered topics such as fertility and child spacing (for FP services), infant and young child nutrition (IYCF), and family hygiene. For FP the counselling usually included referral to a linked service.

*Adding vaccination (model D) or counselling on immunisation (model E) to other services* was tested in just two studies. In Bangladesh<sup>338</sup> one study arm used a screening checklist to integrate catch-up vaccinations into sick child visits, comparing this to other strategies (not involving integration) to improve immunisation coverage. The Sierra Leone initiative<sup>339</sup> integrating nutrition services, with or without family planning, into the immunisation schedule, provided a new opportunity at six months of age at which catch-up vaccination could be offered. This was also the only study that included counselling on immunisation by non-immunisation staff. Other reports of non-immunisation staff providing vaccination or immunisation counselling (including as part of IMCI) did not have the process of integration as a primary object of research; as such they were excluded from the primary analysis for this review, although they were screened for their potential to add qualitative data on barriers and enablers to the discussion below. A table including analysis of these studies is at Appendix 10.2.3.

#### *Models of integration and measured outcomes*

The codes (A, B, C, D, E) listed above were included in Table 5 to allow visual comparison of the model of integration used with the outcomes for immunisation and linked services. While quantitative sub-group analysis was not possible, for the reasons described in Section 5.2 above, inspection shows that each of models A, B and C were associated with a mix of both positive and negative outcomes, both for immunisation and/or the linked service. Both campaign experiences using model A were associated with positive outcomes for the linked services and either positive or neutral outcomes for vaccination.

Two studies tested model D, adding immunisation to other services. In Bangladesh<sup>338</sup> integrating catch-up vaccinations into sick child visits was reported to increase immunisation coverage. In Sierra Leone (also testing model E, immunisation counselling), adding immunisation to nutrition assessments showed some benefit in catch-up vaccination.<sup>339</sup>

Two studies were designed to directly compare different integration strategies. A study of co-located HIV testing and immunisation services in Zambia<sup>345</sup> compared one arm with additional training and commodities against another arm with these inputs plus extra support to service planning. Hodges and colleagues' study in Sierra Leone<sup>339</sup> compared three arms: firstly, minimal integration was undertaken through the addition of a new six month visit for vitamin A administration to the printed schedule in the immunisation home-based record (along with other new family health information). This was compared to two models of co-located services, one comprising IYCF services, and another comprising both IYCF and family planning services. The arms with more intensive inputs showed better outcomes for both immunisation and the linked services.

#### *Community-based care as part of integration models*

Community-based trained lay health workers were deployed in supporting the process of integrating services in a number of studies, with examples in all four models of service integration. In a Kenya study,<sup>331,356</sup> additional hygiene counselling and commodity distribution was provided either by the vaccinating nurse or, in comparison sites, by a co-located trained lay health worker based in the family's community. In several HIV service studies<sup>343-345</sup> trained lay health workers (volunteers in these cases) helped counsel or make connections for clients between immunisation and co-located HIV services.

Two RCTs<sup>350,352</sup> aiming to reach children older than one year with malaria prevention used community-based lay health staff as alternative providers of IPTc, comparing these with integrated professional staff teams (either outreach or facility-based). In both cases coverage was higher in the community-based ('non-integrated') arms.



*Type of immunisation platform associated with integration models*

The majority of studies researched integration of linked services within the *routine infant immunisation platform*, generally in fixed facilities. The most common model C (co-located services) leveraged attendance by families at immunisation clinics to provide additional services on site or nearby. Other models A and B also asked staff in routine vaccination clinics to provide additional services or counselling.

Two studies assessed the use of immunisation *campaigns* to integrate distribution of ITNs<sup>347</sup> or vitamin A and antihelminthics.<sup>355</sup> Both were classified as model A, in that the campaign vaccinating staff provided additional non-vaccine services.

One *enhanced routine activity*<sup>350</sup> involving vaccination outreach teams integrating IPTc found that, while overall vaccination coverage was maintained, the ‘non-integrated’ community-based delivery arm performed better than the ERA for both linked service and for vaccination, and was less costly. A number of publications were retrieved that dealt with the integration into other forms of ERA or special immunisation activities, such as campaigns or ‘child health days’. These, however, did not meet inclusion criteria and thus were screened for additional qualitative information to inform the discussion (see Section 5.3.6 below), but not included in the primary analysis.

**5.3.5 Integration processes, enablers and barriers**

Important processes, enablers of and barriers to service integration were captured in qualitative data in all 24 studies. To extract these, the WHO framework for policy-relevant evidence<sup>303</sup> provided a comprehensive frame, as seen in the data extraction table (Appendix 10.2.1), even though a number of categories retrieved few data. Grouping of these results drew on this framework, an early 2018 publication by Topp and colleagues<sup>86</sup> on general health service integration, and the conceptual framework developed for the research in this thesis (Figure 5, Section 3.1.4). Adapting these three frameworks allowed organization of qualitative process data under six categories: front-line service characteristics, health care worker issues, community and client issues,

management and logistics, health records and technical tools, and policy and governance issues, summarised in Table 7 and described in the narrative below.

**Table 7: Processes affecting integration in 24 publications on 21 studies**

| Category                           | Process, enabler, or barrier                                                                               | Studies reporting                       |
|------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Front-line service characteristics | Existing immunisation services satisfactory                                                                | 333,334,339,341-343,345,348,352,355,357 |
|                                    | Existing immunisation services need improvement                                                            | 10,140,141,338,340,344,347,334,350,356  |
|                                    | Type of linked intervention: preventive or clinical; counselling, commodity or treatment; age group match. | 340,344,345,350                         |
|                                    | Campaigns with limits on time and logistics                                                                | 347,355                                 |
| Health care worker issues          | Staff acceptance of tasks, motivation to extend reach                                                      | 141,338,332,344,334,331                 |
|                                    | Staff skills development, refresher training if needed                                                     | 10,141,334,340,343,344,345,334,331,333  |
|                                    | Staff time sufficient for extra tasks                                                                      | 10,141,338,343,331                      |
|                                    | Allocation of extra staff                                                                                  | 344,350                                 |
|                                    | Shortened counselling times comprising efficacy                                                            | 10,332,352,354,358                      |
| Community and client issues        | Time and money saved through fewer clinic visits                                                           | 332,340,344                             |
|                                    | Longer wait times at clinics                                                                               | 334,340,355                             |
|                                    | Access to valued health care                                                                               | 141,324,326,332,347,348,352,356,342     |
|                                    | Sensitive topics (HIV or FP) addressed by trusted staff                                                    | 10,334,344,333                          |
|                                    | Reluctance by a minority to take up linked service                                                         | 334,332,340,342                         |
|                                    | Role of male partners inhibits uptake                                                                      | 334,332,341                             |
|                                    | Community-based lay health workers extend access                                                           | 343-345,350,352,331,356                 |
| Management and logistics           | Active supervision and cross-program communication                                                         | 141,334,357                             |
|                                    | Medical supplies reliability                                                                               | 141,334,344,345,350,356                 |
|                                    | Infrastructure supports privacy, communication, flow                                                       | 334,332,341                             |
|                                    | Cost savings, or feasible costs                                                                            | 350,352,355,331,333                     |
| Health records and technical tools | Revision of health records, including home-based                                                           | 141,339,341,334,                        |
|                                    | Job aids for counselling and education, technical checklists for quality improvement                       | 10,320,338,339,354,333                  |
| Policy and governance issues       | National and local policy commitments to integration                                                       | 10,343,345,347,333                      |
|                                    | Standing orders for linked service delivery                                                                | 338                                     |
|                                    | Development and research partner priorities                                                                | <i>Implicit in most (see narrative)</i> |

#### *Front-line service characteristics*

*The background functionality of existing immunisation services*, where this was satisfactory (for example, coverage approximately 80% or more of target population) was an important enabler for most experiences adding new services onto the immunisation platform (see table above). In contrast a number of studies of HIV,<sup>340,344</sup> malaria,<sup>141,347,349,350</sup> and hygiene<sup>356</sup> added to immunisation services that had only moderate levels of coverage. Of these experiences, immunisation outcomes were harmed in one,<sup>325</sup> benefited in one,<sup>141</sup> and either stable or un-measured in the remainder. Of the three FP integration studies, the two with positive FP outcomes<sup>333,334</sup> integrated into relatively strong immunisation platforms, and the one with no increased uptake of FP<sup>10</sup> used

immunisation services that variable in functionality. In the study that integrated vaccinations into other services<sup>338</sup> this was a response to a weakly functioning immunisation service.

*The nature of the linked intervention* was commonly reported as either enabler or barrier. HIV counselling and EID were often noted as feasibly integrated into routine care,<sup>340,344,345</sup> but their complexity and clinical nature proved a barrier to integration into clinical outpatient care, causing unhelpful variation in patient flow.<sup>343</sup> Mismatch in target ages between routine immunisation (largely under one year) and childhood IPT (over one year) was seen as a barrier to IPTc integration in Gambia,<sup>350</sup> a problem also noted by Wallace and colleague's 2012 review.<sup>58</sup> The two studies researching integration into immunisation *campaigns*, in which client interaction time may be limited, both noted the relatively straightforward nature of the linked services, comprising distribution of ITNs<sup>347</sup> or provision of vitamin A and antihelminthic medication.<sup>355</sup>

#### *Health care worker issues*

*Staff acceptance* of a new linked service was documented in studies in Bangladesh,<sup>338</sup> Tanzania,<sup>332,344</sup> and Mali<sup>141</sup>; reporting the motivation of seeing more children protected and families reached with new services as a key enabler. However in a large IPT in infancy trial<sup>348</sup> in Tanzania, staff were reluctant on occasion to provide antimalarials alongside vaccination, and there were some reports of falsifying health records, such as marking IPT as provided when it had not been. Additional incentives to compensate for outreach time were provided to staff in Gambia.<sup>350</sup> These were not directly linked to the integration tasks, although they were effective in encouraging outreach. No other studies documented provider incentives to provide a linked service. In Kenya<sup>331</sup> staff acceptance was coloured by the perceived inequity of offering hygiene commodities only to families presenting for vaccination.

*Staff skills development* was an essential enabler, with most studies finding it feasible to train vaccinating nurses in relatively complex extra skills such as HIV EID and management in Tanzania,<sup>340</sup> Kenya,<sup>344</sup> Malawi,<sup>343</sup> and Zambia,<sup>345</sup>

hygiene education<sup>331</sup> in Kenya, and nutrition counseling in Mexico,<sup>354</sup> as well as less complex care such as provision of preventive medicines such as vitamin A and anti-helminthics.<sup>355</sup> Training to provide IPTi<sup>141,348</sup> was generally seen as feasible, although staff performance still lapsed in some settings.<sup>334</sup> In Liberia,<sup>334</sup> developing vaccinator staff skills for family planning education was generally feasible, but some family planning staff missed providing messages about catch-up vaccination. In Rwanda,<sup>333</sup> as well as Ghana and Zambia,<sup>10</sup> repeated rounds of staff training were needed, and the latter study reported deficiencies in the delivery of counselling or education. All three FP integration experiences emphasised the importance of consistent and good training across cadres.

*Staff time* was a key consideration, with attempts to minimise the time taken by any additional task/s. Use of short one to two minute checklists by non-immunisation staff proved feasible and effective in boosting immunisation uptake in Bangladesh.<sup>338</sup> Extra hygiene and WASH education tasks in Kenya<sup>331</sup> were reported as consuming only 6% of staff time, which was considered feasible. Most HIV integration studies found extra tasks as feasible within staff timing. In Malawi<sup>343</sup> it was reported to be easier for immunisation providers than for clinical care providers to add HIV counselling for EID. In Mali<sup>141</sup> immunisation staff were reported to have spare time that enabled integration of IPTi spending a mean of 12.4 minutes (range 1.6 – 28.9) per client. *Allocation of extra staff* was an important enabler of HIV services in Kenya<sup>344</sup> and for childhood IPT by outreach in Gambia (although the outreach teams were still out-performed by the community-based comparator).<sup>350</sup> *Concerns regarding time taken for integrated services* included: providers' worry that shortened counselling would compromise efficacy in HIV,<sup>332</sup> FP<sup>10</sup> and nutrition<sup>354</sup> studies; an estimation in Ghana<sup>352</sup> that an unsustainable 20% of vaccinating nurse's time was consumed by IPT duties; and attribution of low coverage of a hearing screening intervention in South Africa to the use of "*already over-burdened staff*".<sup>358</sup> In Ghana and Zambia,<sup>10</sup> even though family planning referral messages were designed to take less than one minute, and thus feasible within the vaccination encounter, some staff still delivered

messages by group rather than individual education. The authors speculated that group education may have been less effective for behaviour change.

### *Community and client issues*

*Time was an important element for clients* of integrated services. Most studies reporting acceptability of integrated arrangements cited savings in time and travel costs through fewer clinic visits<sup>332,340</sup>; one reported parents as saying that asking for less time off work helps with job security.<sup>344</sup> Longer clinic wait times, whether actual or perceived, were a barrier to uptake; for example as reported by 20% of staff in Lao PDR<sup>355</sup> when adding vitamin A and anti-helminthics to campaign vaccination. Long clinic wait times proved a disincentive to take up co-located FP services in Liberia<sup>334</sup> and integrated HIV services in Tanzania,<sup>340</sup> though it was unclear whether integration was the cause.

*Access to valued health care* contributed to the acceptability of newly integrated services. In Tanzania, integration was perceived as offering a chance to learn about important health topics such as HIV.<sup>332</sup> Also in Tanzania the highly visible threat of endemic malaria was seen to drive acceptability,<sup>348</sup> and in Mali<sup>141</sup> this was seen to contribute to increased vaccination uptake when malaria interventions were added. The prospect of receiving hygiene and WASH commodities was said to spur vaccination visits in Kenya<sup>356</sup> but not enough, in rural areas, to overcome the barrier of transport costs.<sup>331</sup> In a HIV pilot in Cameroon,<sup>342</sup> a new vaccine against haemophilus influenzae B (now standard) was offered at integrated clinics to encourage uptake of both HIV and vaccination services. The benefits of reaching remote populations with a broader range of care was seen as a clear benefit of integrated services by clients and staff in several studies,<sup>332,338,340</sup> with integrated outreach<sup>352</sup> and campaigns<sup>347</sup> seen as means to reach marginalised groups.

*Attitudes to potentially sensitive topics such as FP or HIV* were important both as enablers and barriers. In Liberia<sup>334</sup> and Rwanda<sup>333</sup> integration pilots measured some positive change in knowledge and attitudes towards FP. However an increase in knowledge was not seen in Ghana or Zambia,<sup>10</sup> possibly because the education by vaccinators was not carried out as planned. One particular

entrenched attitude, that FP was not relevant before postpartum menses returned, was a key barrier to FP uptake in all three studies, one not overcome by integrated counselling.

*Attitudes and beliefs contributed to reluctance by a minority to take up the linked service.* For example in Rwanda,<sup>333</sup> while 98% of mothers attending vaccination were happy to receive FP information, fewer (73%) preferred to take up services on the same day. Those who delayed often stated they were waiting for menses to return or needed to check with a spouse, the latter reason also reported in Liberia.<sup>334</sup> Approximately 10% of mothers' studied in Rwanda expressed concern that their husband would be unhappy with her receiving family planning information during immunisation visits.<sup>333</sup> In Cameroon<sup>342</sup> the fear of an HIV test result was cited as a reason for non-attendance at integrated clinics, and in Tanzania HIV stigma and an unfounded fear of mandatory testing led to a decrease in uptake of vaccinations when integrated with HIV services in rural (but not urban) clinics.<sup>332,340</sup> Planners there had expected that the high level of community trust in vaccines would transfer to HIV services by association, but in-depth research found that this did not hold true.<sup>332</sup> In Kenya,<sup>344</sup> in contrast, it was found that there was possibly less stigma by having the same service provider for both vaccination and HIV care.

*The role of male partners contributed to lower uptake in HIV and FP integration,* with lack of support,<sup>332</sup> or the need to seek permission for HIV testing<sup>341</sup> or FP initiation<sup>334</sup> reported as contributing factors.

*Community-based trained lay health workers* contributed by providing some linked services in studies adding HIV in various sites,<sup>343-345</sup> malaria IPT<sup>352</sup> in Ghana, or hygiene services<sup>331,356</sup> in Kenya. In Kenya the lay health worker was sometimes seen as a better educator due to having more time and more accessible communication style. They were reported to support additional education and relieve professional staff time in HIV services in Zambia<sup>345</sup> and enabled co-located counselling and other care for nutrition and FP in Sierra Leone,<sup>339</sup> in which setting they also provided education on immunisation. As noted above, in the Gambia study of childhood IPT,<sup>350</sup> the lay health workers in

the comparator (non-integrated) arm contributed to better uptake of IPT, and through advocacy and education, higher immunisation coverage.

### *Management and logistics*

A range of management and infrastructure processes were deemed critical to effective implementation of the integration effort.

*Active supervision and cross-program communication* were seen as essential across many experiences.<sup>141,334,357</sup> In a Zambia HIV integration study<sup>345</sup> on-site support to implementation in one arm, including optimisation of patient flow and staffing, enabled better uptake of linked services. Where co-location of FP services was the integration strategy, frequent communication between EPI and FP staff to maximise service availability was important in Liberia.<sup>334</sup> Deficiencies in this area may have been a factor in the lack of uptake of FP seen in Ghana and Zambia.<sup>10</sup>

*Medical supplies reliability* was a pre-requisite to successful implementation, with specific program supports to maintain supply logistics included in Mali,<sup>141</sup> Zambia,<sup>345</sup> Gambia,<sup>350</sup> and Ghana.<sup>352</sup> Vaccine and other commodity stockouts were reported as a barrier in malaria,<sup>344,348</sup> FP,<sup>334</sup> and hygiene interventions.<sup>356</sup>

*Clinic infrastructure promoting privacy, communication and patient flow* was an important enabler. Private space for counselling was a key factor in HIV and FP experiences, constraining uptake of counselling on HIV in Malawi<sup>341</sup> and Tanzania<sup>332</sup> and FP in Liberia,<sup>334</sup> the latter experience reporting that addition of privacy screens in out-patient areas supported focused discussion and referral. Signage for clear way-finding and posters, as well as proximity of the linked service were also important to co-location success in that study.

*Cost savings or feasible costings* were documented in relatively small number of studies, but where apparent, were a clear enabler of acceptance by program managers. This was seen for example in vitamin A and antihelminthic distribution in Lao PDR,<sup>355</sup> for FP in Rwanda,<sup>333</sup> hygiene and WASH interventions in Kenya,<sup>331</sup> and malaria IPT in Ghana.<sup>352</sup> In the childhood IPT studies in Gambia<sup>350</sup> and Ghana<sup>352</sup> costs were higher when EPI nurses provided IPT

compared with community-based lay health workers. In Ghana, where childhood IPT was integrated into clinics, this cost was deemed feasible, but not in Gambia, where vaccinator outreach teams generated significantly higher costs.

#### *Health records and technical tools*

*Revision of or integrating new fields into health records*, including home-based vaccination records, were an important integration process. In Mali<sup>141</sup> and Tanzania<sup>334,360</sup> recording IPTi doses was successfully added to immunisation records. In Sierra Leone<sup>339</sup> the revision of the child health card was a key part of the intervention; adding fields for vitamin A and de-worming as well as information on feeding, growth, FP and other family health topics. Conversely, in one HIV study,<sup>341</sup> failure to record HIV status on the EPI record (to protect confidentiality) was reported as key factor constraining integrated services. An increased commitment to record keeping was reported for FP integration in Liberia.<sup>334</sup>

*Job aids for counselling and checklists* formed part of the integration intervention in a number of studies. Examples included: a simple vaccination checklist in Bangladesh<sup>338</sup> that successfully reminded clinical child health staff about catch-up vaccination; a nutrition education script for vaccinators<sup>354</sup>; and a range of job aids<sup>10,333,334</sup> for counselling on postpartum fertility and family planning options that targeted known gaps in knowledge such as lactational amenorrhoea or return of menses.

#### *Policy and governance issues*

*National and local policy commitments* in support of integrated services were noted as enablers in studies in Malawi,<sup>343</sup> Madagascar<sup>347</sup> and seen as especially important to the FP pilot in Rwanda.<sup>333</sup> Interruptions to policy support may have contributed to reduced uptake of FP in Ghana and Zambia.<sup>10</sup> National 'opt-out' policies for HIV testing were reported enablers of HIV integration efforts in Malawi<sup>343</sup> and Zambia.<sup>345</sup> At a clinic level, *standing orders* for catch-up vaccination were reported to play a role in integrating immunisation into clinical child care in Bangladesh.<sup>338</sup>



*Development and research partner priorities* clearly played a role in directing efforts over the period captured by this review, first to HIV and malaria integration trials, and then to FP-immunization; with attention to integrated services raised by USAID's MCHIP program<sup>88,89</sup> and its successor,<sup>361</sup> as well as specific initiatives such as the FP-Immunization Integration Working Group.<sup>92,93</sup>

### **5.3.6 Overview of potentially relevant but excluded studies**

A number of potentially relevant integration initiatives were identified in the search, however they did not meet inclusion criteria for various reasons (see Section 5.3.1). From this group of studies, 49 (including six from grey literature) with their key characteristics are listed in the table below (Table 8) to display the breadth of health themes and reported outcomes. While not included in the full data extraction, and thus not subjected to narrative synthesis or formal quality assessment, these two groups of relevant but excluded studies were screened for information that could contribute to this chapter's discussion section below.

Many of these publications reported on broad health improvement activities, such as PHC or IMCI, which included integrated services, but integration itself was not a primary focus of study. This group included 16 studies where immunisation was integrated into PHC services, child health services using IMCI, or (as birth-dose vaccination) early postnatal care. Had these been eligible for inclusion, they would have added to the single study in Bangladesh<sup>338</sup> that was included in the primary analysis.

Others in this list examined the uptake of interventions similar to those included in the primary analysis, such as HIV, ITNs, FP, vitamin A or WASH in integrated services, but were excluded because they did not include controls or sufficient measures to be able to draw conclusions regarding the integration process.

Also of note among this group of publications were three studies (not included in the table) where immunization was integrated into non-health service platforms, including play-centres,<sup>362</sup> farmers days,<sup>363</sup> or animal vaccination campaigns.<sup>364</sup> A more detailed table that also shows the researcher's assessment of the publications is provided at Appendix 10.2.3.

**Table 8: Relevant intervention studies that did not meet inclusion criteria**

| <i>Service being added</i> | <i>Receiving Platform</i> | <i>Service type</i> | <i>Setting</i> | <i>Year</i> | <i>EPI benefit</i> | <i>Non-EPI benefit</i> | <i>Citation</i> |
|----------------------------|---------------------------|---------------------|----------------|-------------|--------------------|------------------------|-----------------|
| Immunisation               | PHC service               | Mixed               | India          | 2015        | POS                | M-POS                  | <sup>365</sup>  |
| Immunisation               | PHC service               | Outreach            | Somalia        | 2012        | POS                | NR                     | <sup>366</sup>  |
| Immunisation + others      | PHC service               | Mixed               | Mongolia       | 2012        | POS                | POS                    | <sup>367</sup>  |
| Immunisation + others      | PHC service               | Fixed clinic        | Kenya          | 2012        | POS                | POS                    | <sup>368</sup>  |
| Immunisation + others      | PHC service               | Fixed clinic        | Argentina      | 2011        | M-POS              | POS                    | <sup>369</sup>  |
| Immunisation + others      | PHC Service               | Outreach            | Guatemala      | 2015        | POS                | POS                    | <sup>370</sup>  |
| Immunisation + others      | PHC Service               | Outreach            | Guatemala      | 2011        | POS                | POS                    | <sup>371</sup>  |
| Immunisation + others      | PHC Service               | Outreach            | India          | 2016        | M-POS              | M-POS                  | <sup>372</sup>  |
| Immunisation               | IMCI                      | Fixed clinic        | Yemen          | 2011        | NR                 | M-POS                  | <sup>373</sup>  |
| Immunisation               | IMCI                      | Fixed clinic        | India          | 2013        | NEG                | M-NEG                  | <sup>374</sup>  |
| Immunisation               | cIMCI                     | Mixed               | Ethiopia       | 2016        | STATIC             | POS                    | <sup>375</sup>  |
| Immunisation               | cIMCI                     | Mixed               | Ethiopia       | 2014        | POS                | M-POS                  | <sup>376</sup>  |
| Immunisation - birth       | Postnatal                 | Inpatient           | PNG            | 2016        | M-POS              | NR                     | <sup>377</sup>  |
| Immunisation - birth       | Postnatal                 | Inpatient           | India          | 2015        | POS                | NR                     | <sup>378</sup>  |
| Immunisation - birth       | Postnatal                 | Mixed               | China          | 2013        | POS                | NR                     | <sup>379</sup>  |
| Immunisation - birth*      | Postnatal                 | Outreach            | PNG            | 2011        | POS                | M-POS                  | <sup>380</sup>  |
| HIV - EID                  | EPI                       | Fixed clinic        | Rwanda         | 2013        | NR                 | POS                    | <sup>381</sup>  |
| HIV - EID + treatment      | EPI                       | Fixed clinic        | Sth Africa     | 2013        | NR                 | POS                    | <sup>382</sup>  |
| HIV - EID + treatment      | EPI                       | Fixed clinic        | Malawi         | 2014        | NR                 | POS                    | <sup>383</sup>  |
| HIV - EID + treatment      | EPI                       | Fixed clinic        | Sth Africa     | 2015        | NR                 | M-POS                  | <sup>384</sup>  |
| HIV - EID + treatment      | EPI, MCH                  | Fixed clinic        | Zimbabwe       | 2014        | NR                 | POS                    | <sup>385</sup>  |
| HIV - EID + treatment      | EPI, MCH                  | Fixed clinic        | Uganda         | 2011        | M-POS              | POS                    | <sup>386</sup>  |
| Malaria - ITN              | EPI                       | Campaign            | Sth Sudan      | 2012        | NR                 | POS                    | <sup>387</sup>  |
| Malaria - ITN              | EPI                       | Campaign            | Africa region  | 2013        | NR                 | M-POS                  | <sup>388</sup>  |
| Malaria - ITN              | EPI                       | Campaign            | Africa region  | 2016        | NR                 | POS                    | <sup>389</sup>  |
| Malaria - ITN              | EPI                       | Fixed clinic        | Kenya          | 2011        | NR                 | STATIC                 | <sup>390</sup>  |
| Malaria - ITN              | EPI                       | Fixed clinic        | Africa region  | 2016        | NR                 | M-POS                  | <sup>391</sup>  |
| Family Planning*           | EPI                       | Mixed               | India          | 2012        | NR                 | M-NEG                  | <sup>392</sup>  |
| Family Planning*           | EPI                       | Fixed clinic        | Mali           | 2012        | NR                 | POS                    | <sup>393</sup>  |
| Family Planning*           | EPI                       | Fixed clinic        | Liberia        | 2013        | STATIC             | POS                    | <sup>394</sup>  |
| Family Planning*           | EPI                       | Fixed clinic        | Senegal        | 2015        | STATIC             | M-POS                  | <sup>395</sup>  |
| Family Planning*           | EPI                       | Fixed clinic        | Philippines    | 2015        | POS                | POS                    | <sup>396</sup>  |

*Table continued on next page*

**Notes:**

- Excluded studies, not subjected to narrative synthesis or formal quality assessment.
- EPI = Expanded Programme on Immunization, IMCI = community Integrated Management of Childhood Illness, cIMCI =community IMCI, CHD = Child Health Day.
- NEG = Outcome worsened, M-NEG = Mixed outcome, with some worsened and some no change, M-POS = Mixed outcome with no change and some improvement, POS = Outcome improved, STATIC = no change, NR= not reported.
- Three additional studies in this group, not listed, examined integration into non-health platforms such as play-centres,<sup>362</sup> farmers days,<sup>363</sup> or animal vaccination campaigns.<sup>364</sup>

**Table 8: Relevant intervention studies that did not meet inclusion criteria (continued)**

| <i>Service being added</i> | <i>Receiving Platform</i> | <i>Service type</i> | <i>Setting</i> | <i>Year</i> | <i>EPI benefit</i> | <i>Non-EPI benefit</i> | <i>Citation</i> |
|----------------------------|---------------------------|---------------------|----------------|-------------|--------------------|------------------------|-----------------|
| Vitamin A                  | EPI                       | Campaign            | Sierra Leone   | 2014        | POS                | POS                    | <sup>397</sup>  |
| Vitamin A                  | EPI                       | Fixed clinic        | India          | 2014        | NR                 | POS                    | <sup>398</sup>  |
| Vit A, antihelminthic      | EPI                       | Campaign            | Zambia         | 2013        | POS                | POS                    | <sup>399</sup>  |
| Vit A, antihelminthic      | EPI                       | Campaign            | PNG            | 2014        | POS                | POS                    | <sup>278</sup>  |
| Vit A, antihelminthic      | EPI                       | Campaign            | Sth Africa     | 2013        | POS                | POS                    | <sup>400</sup>  |
| Vit A, antihlm, WASH       | EPI                       | Campaign            | Somalia        | 2012        | POS                | POS                    | <sup>401</sup>  |
| Vit A, antihlm, WASH       | EPI - CHD                 | Campaign            | Africa region  | 2013        | NR                 | POS                    | <sup>402</sup>  |
| Vit A, antihlm, WASH       | EPI - CHD                 | Campaign            | Africa region  | 2015        | POS                | POS                    | <sup>403</sup>  |
| Vit A, multiple others     | EPI                       | Campaign            | Honduras       | 2012        | NR                 | POS                    | <sup>404</sup>  |
| WASH                       | EPI                       | Campaign            | India          | 2013        | M-POS              | NR                     | <sup>405</sup>  |
| WASH                       | OCV                       | Fixed clinic        | Bangladesh     | 2015        | STATIC             | M-POS                  | <sup>406</sup>  |
| WASH                       | OCV                       | Campaign            | Bangladesh     | 2013        | POS                | NR                     | <sup>407</sup>  |
| Nutrition                  | EPI - PHC                 | Outreach            | Lao PDR        | 2014        | POS                | POS                    | <sup>408</sup>  |
| Child development          | EPI                       | Fixed clinic        | Bangladesh     | 2014        | NR                 | M-POS                  | <sup>409</sup>  |
| Meningococcal vacc.        | EPI - PHC                 | Campaign            | Mali           | 2014        | M-NEG              | M-NEG                  | <sup>410</sup>  |
| Healthy behaviours         | EPI                       | Fixed clinic        | Mali           | 2012        | NR                 | STATIC                 | <sup>411</sup>  |
| Hearing screening          | EPI                       | Fixed clinic        | Sth Africa     | 2013        | NR                 | M-NEG                  | <sup>412</sup>  |

**Notes:**

- Excluded studies, not subjected to narrative synthesis or formal quality assessment.
- EPI = Expanded Programme on Immunization, IMCI = community Integrated Management of Childhood Illness, cIMCI =community IMCI, CHD = Child Health Day.
- OCV = Oral Cholera Vaccine.
- NEG = Outcome worsened, M-NEG = Mixed outcome, with some worsened and some no change, M-POS = Mixed outcome with no change and some improvement, POS = Outcome improved, STATIC = no change, NR= not reported.
- The report on meningococcal vaccination in Mali documented high coverage with the campaign vaccination, but mixed negative effects on other routine EPI or primary health care services.
- Three additional studies in this group, not listed, examined integration into non-health platforms such as play-centres,<sup>362</sup> farmers days,<sup>363</sup> or animal vaccination campaigns.<sup>364</sup>

A further category of 34 potentially relevant but excluded studies comprise those that researched the potential for integration of immunisation and other services, but did not examine implementation or an intervention to promote more integrated services. These assessments were usually cross-sectional and with mixed methods, of potential pathways for or benefits of more integrated health services, including potential barriers or enablers.

## 5.4 Discussion

The discussion in this chapter follows the review objectives, to:

- describe *the range of interventions and service delivery arrangements*;
- quantify the *change in coverage or uptake*;
- identify *advantages and disadvantages* of integrating services; and
- describe the *barriers* to and *enablers* of integration success.

To this is added a section on research gaps and future directions.

### 5.4.1 Range of interventions and service delivery arrangements

There has been a marked increase in published experiences integrating interventions for HIV and FP into immunisation services since Wallace and colleagues'<sup>58</sup> collection of studies until 2011 and similar reviews by USAID.<sup>413</sup> The word cloud graphic (Figure 10) compares the counts of themes found in reviews to 2011<sup>58</sup> against those found in this review.

The predominance of studies in sub-Saharan Africa, and the trend in the themes being studied, are likely to reflect development partner priorities, coupled with a desire for measurable outcomes. Two examples are the need to increase uptake of early infant diagnosis and management of HIV made possible by antiretroviral therapy,<sup>39</sup> and the focused support by USAID's MCHIP applying integration to postpartum family planning.<sup>89</sup> Apart from these changes, the range of interventions found in this research closely mirrors that seen previously, comprising a relatively limited set of interventions to address HIV and FP (as noted), malaria (IPT and ITN

**Figure 10: Word clouds of integration study themes**

Studies to 2011:



Studies 2012 – 2016:



Note: word clouds generated from tallies of number of studies by program category, at [www.wordart.com/create](http://www.wordart.com/create)

distribution), distribution of vitamin A and anti-helminthics, nutrition counselling, and WASH.

There were two significant gaps in the evidence able to be admitted. The first is that only one where immunisation was the target of improvement<sup>338</sup> proved eligible. This is surprising given the emphasis on integrated services as a means to reduce missed opportunities for vaccination in the GVAP.<sup>37</sup> The second is the paucity of reported experiences integrating nutrition counselling, growth monitoring, or early childhood development (ECD) interventions. Given these are routinely schedulable, optimally timed in the first two years of life, and align well with the increasing need to administer vaccines in the second year of life,<sup>414</sup> this is a concerning omission. Later sections discuss the need for further implementation research these gaps highlight (Section 5.4.5).

Compared to previous reviews, this research found fewer integration experiences involving outreach services: just one ERA, in which the integrated performed less well than the comparator. There were also fewer campaigns, just two: looking at distribution of ITNs, vitamin A or anti-helminthics alongside vaccination. In the relevant but not excluded studies (Table 8), there were some outreach experiences, almost all for broader PHC, and a further 12 campaign experiences. It may also be that this era of controlled studies was oriented more to linked interventions such as HIV or FP that are relatively more demanding in needs for commodities, skill and time; making outreach settings less suited to the controlled study designs that were made criteria for inclusion. This bias away from outreach studies may partially explain the limited benefits to immunisation benefit, discussed below.

This research also generated a new characterisation of integration models (Figure 11 below), which were used in Table 6, Section 5.3.4. These emerged naturally from a functional analysis of the included studies. These typologies aim to be helpful descriptively, especially to highlight the process of inserting new tasks into an existing platform. The use of this typology in the review so far has helped understand which process of integration may link to specific determinants of success (see Section 5.4.3). The emphasis of new functions

rather than structures (such as clinic or staff placement) also builds on measurement insights made by others, including Fields in 2007<sup>195</sup> and the Integra Initiative<sup>129</sup> in 2016. In the latter, Mayhew and colleagues emphasised the need to assess both *structural* and *functional* integration in initiatives in sub-Saharan Africa, in settings relevant to similar resource-constrained settings (including PNG). These categories also fit well with the dimensions of service delivery change highlighted in the conceptual framework for this research (Figure 5, Section 3.1.4).

**Figure 11: Integration models**

|                                                                                      |
|--------------------------------------------------------------------------------------|
| A: Extra <b>services</b> provided by vaccinating staff                               |
| B: Extra <b>counselling</b> provided by vaccinating staff                            |
| C: <b>Co-location</b> with extra services linked to immunisation place and time      |
| D: <b>Vaccination</b> by staff who are not usual immunisation providers              |
| E: <b>Immunisation counselling</b> by staff who are not usual immunisation providers |

**5.4.2 Outcomes – changes in service coverage or uptake**

This review found more studies with outcome measures than previously seen, with 16 of 24 publications with some aspect of coverage or uptake measured against a credible comparator. The qualitative synthesis (see Table 5) suggests an imbalance in outcomes between the linked service, which benefited in most studies, and immunisation where outcomes were either static or improved by only a modest degree. This pattern, with immunisation showing inconsistent benefit compared to the linked service, was seen in the previous review to 2011,<sup>58</sup> and a USAID systematic review<sup>413,415</sup> covering a similar period.

*Immunisation may benefit, is generally static, and only occasionally harmed*

Among the 21 study sites analysed here, where immunisation outcomes were lower in an integrated service this reflected either specific circumstances, such as HIV stigma as seen in Tanzania<sup>332,340</sup> (and also noted in a descriptive study in Uganda<sup>416</sup>), or higher performance by the comparator service option, such as community-based delivery, as seen in Gambia.<sup>350</sup> There is weak evidence (Figure 9 Section 5.3.3) that the more tightly controlled study designs, especially RCTs, tended to display a lower benefit to immunization coverage, suggesting

some reports of immunisation benefiting from integrated services may be subject to bias or difficult to generalise.

Community values contributed to beneficial immunisation outcomes. This is seen when commodities of perceived worth, such as ITNs<sup>347</sup> or hygiene kits<sup>331,356</sup> were distributed, or where a well-recognised health threat such as malaria was addressed through IPT<sup>141</sup>; the latter conclusion also supported by broader reviews of ITN deployment.<sup>389</sup> Beyond the included studies (see Table 8), the eight experiences of integrating immunisation into broader PHC all report immunisation as improved, albeit in research designs judged at significant risk of bias. Less encouraging are outcomes for immunisation within IMCI. Even though IMCI is explicitly designed to integrate catch-up vaccination into general child health, Gera and colleagues' careful review<sup>109</sup> found no clear evidence of IMCI's benefit to immunisation (Section 2.3.4). This is echoed in the four IMCI experiences listed in Table 8 that had mixed results. Of two community case management studies immunisation coverage improved in just one,<sup>376</sup> and was found low or declining in both facility-based studies.<sup>373,374</sup> It appears that if 'every opportunity' vaccination is to improve in clinical childhood illness management settings, new targeted tools such as those introduced in Bangladesh,<sup>338</sup> and a new emphasis on studying MOV<sup>165</sup> are needed.

One potential explanation for the difference in outcome between immunisation and linked services in the collection analysed here is that it is inherently more difficult to achieve gains in immunisation coverage. Vaccination depends on reliable commodities, and it may be that integration attempts paid more attention to the linked service's commodities than to those for vaccines. Immunisation improvement also often relies on more, or better-planned, outreach services, especially in resource-constrained settings such as the African ones that dominated this collection (an issue that also applies to PNG).

*Most linked services benefit, but there are differences across programs*

For HIV interventions there are clear benefits seen in this review, and others,<sup>60</sup> with examples of up to seven-fold increases in coverage.<sup>343</sup> Where the

expected improvements have not been obtained,<sup>341,342</sup> it was lapses in systems or staff performance that were only indirectly linked to the integration process.

Positive outcomes for *postpartum family planning* from Liberia<sup>334</sup> and Rwanda<sup>333</sup> in this review are supported by grey literature reports (Table 8) from Mali,<sup>393</sup> Liberia<sup>394</sup> and the Philippines.<sup>396</sup> These renew encouragement, echoed by others,<sup>33,92</sup> for this promising practice. Increased uptake is not assured, as seen in the Ghana-Zambia multi-country study<sup>10</sup> and other grey literature reports from Senegal<sup>395</sup> and India,<sup>392</sup> with close attention to feasibility and acceptance needed to ensure success. FP, like HIV, is highly dependent on effective counselling,<sup>417</sup> as well as the need to counter socio-cultural barriers to uptake as discussed further below. However, based on the evidence reviewed here, the core concept of integrating postpartum FP with immunisation does appear capable of achieving effective outcomes, especially during the critical months after childbirth when delaying the next pregnancy is so important.

For *malaria* interventions the demonstrated benefit is for IPT distribution in infancy, but not yet proven for IPT after the first year of life (now deemed seasonal malaria control). It is likely that this requires stronger national commitments to immunisation in the second year of life<sup>414</sup> and possibly to other child growth and development interventions at that time (some discussed in relation to nutrition below). Distribution of ITNs through immunisation clinics or campaigns has promising outcomes, although other evidence makes it clear that other distribution models are potentially more important. Free household distribution rather than immunisation integration seems key to an ITN campaign's success,<sup>389</sup> and the EPI platform is often out-performed by ANC clinics,<sup>391</sup> schools and/or vouchers.<sup>418</sup> Integration of ITNs with immunisation services may better serve as a complement to maintain coverage once established by other channels.

For *nutrition* interventions, a promising synergy with infant immunisation is seen in the unusual and hard-won gains in anthropometry in Hodges and colleagues' informative Sierra Leone study,<sup>339</sup> reinforced by a broader community-level intervention in Lao PDR<sup>408</sup> (which also showed immunisation



benefits), and the counselling intervention in Mexico.<sup>354</sup> Both Hodges<sup>339</sup> and a non-immunisation study from Kenya<sup>419</sup> combined counselling on feeding and FP to generate improved uptake of services. In addition, immunisation remains well established, from the data in this review, as a feasible platform for specific supplements (vitamin A) or preventive medicines (anti-helminthics), delivered through fixed clinics, campaigns or enhanced outreach such as ‘Child Health Days’.<sup>278,355,397-399,402,420</sup>

While this review found no eligible studies on the integration of birth-dose vaccination into *postnatal care*, three studies from China,<sup>379</sup> India<sup>378</sup> and PNG<sup>377</sup> that did not have integration as their main object did demonstrate improved immunisation when offered through childbirth or postnatal care in facilities. The China study,<sup>379</sup> as well as a grey literature report from PNG,<sup>380</sup> documented integrated community outreach efforts. In PNG this included integration of other aspects of postnatal care delivered by community-based trained lay health workers, including preventive checks on the welfare of the mother or infant, as well as advice on danger signs, nutrition and family planning. This experience local to PNG informed work described in Chapter Seven.

#### *How the immunisation platform or integration model relates to outcomes*

A range of outcomes was found across immunisation platforms, with positive and mixed outcomes seen in fixed clinics, scheduled outreach and campaigns. From very limited data (one included study and scanning of those in Table 8), it appears that outreach by professional vaccination staff is a more difficult setting, compared with fixed clinics, from which to benefit either the linked service or immunisation. Campaigns in contrast, also based on limited data, seem more uniformly positive when integrating low-intensity tasks such as distribution of vitamin A and anti-helminthics.

Regarding the integration model, there was no single approach to integrating services that was consistently associated with successful outcomes either for immunisation or the linked service, as seen in Table 5. This inference echoes the conclusion also drawn by Wallace and colleagues<sup>58</sup> for evidence

published up to 2011. In each case included in the current review success depended on, firstly, an appropriate matching of the services to be integrated with the integration model (for example: ensuring sufficient capacity for counselling for services dependent on client behaviours) and, secondly, the details of the implementation process.

The outcomes achieved were all highly dependent on implementation processes and their interaction with various barriers and enablers, discussed further in Section 5.4.4. Prior to that the section below discusses outcomes other than coverage and uptake.

### ***5.4.3 Other advantages and disadvantages of integrated services***

The most common program objective across the 21 experiences included in this review was to increase coverage of the linked intervention. However some<sup>332,338,340,347,352</sup> also aimed to improve equity of access, with the purpose of integration being to specifically reach marginalised or remote populations through outreach and other activities. Integration does not guarantee improved equity, and integrating services at fixed facilities may limit uptake to those who already have access. This potential adverse outcome was raised by staff in an included study in Kenya,<sup>331,356</sup> and also seen in postpartum family planning experiences in Kenya and India<sup>90</sup> where more distant clients were less likely to access integrated care. Both resonate with the broader concerns raised by Victora and others<sup>185-187</sup> (see also Section 2.3.5).

The clearest evidence for increased equity in coverage rests with campaign experiences, including the Madagascar ITN experience<sup>347</sup> in this review. Campaigns or SIAs, despite their limitations,<sup>410</sup> can achieve equity gains that other service delivery forms cannot.<sup>346,401</sup> Johri<sup>421</sup> and others argue that the case for integrating extra services into immunisation campaigns is strongest where inequity of coverage is worst. One step down from campaigns, scheduled immunisation outreach, or other forms of ERA such as child health days,<sup>402,422</sup> have been a key to extending immunisation to the hard to reach,<sup>423</sup> but their performance when integrating additional services remains mixed, based on this review,<sup>350,372</sup> and earlier evidence.<sup>140</sup> The discussion of IPTc in Ghana<sup>352</sup> suggested

freeing IPT from its immunisation linkage may in fact improve equity where immunisation coverage is low. Extending equity of coverage perhaps depends more on the effective deployment of community-based services, as originally conceived in comprehensive primary health care.<sup>97</sup> The application of integrated services to community-based care is discussed further below.

A commonly mooted benefit of integrated services is efficiency, including reducing the cost of service provision. However, only five of the 21 studies documented cost information. Integrated service delivery was assessed as more cost-effective in campaign mode when adding vitamin A and anti-helminthic,<sup>355</sup> a finding also supported by broader studies of SIAs<sup>424</sup> and child health days.<sup>401</sup> However, for outreach, integrated services were less cost-effective than community-based delivery in the two trials assessing IPT in children including ages beyond the first year of life.<sup>350,352</sup> Integration of FP with EPI in Rwanda<sup>333</sup> and hygiene kits in Kenya<sup>331</sup> measured locally acceptable costs per client reached, but without comparators.

Another potential advantage of integrated services is increased acceptability to families. Generally families appreciated integrated services, as reported in Section 5.3.5, either for saving time and money, and/or for the chance to access or hear about valued services. These findings were borne out in a qualitative study in Kenya, Mali, Ethiopia and Cameroon.<sup>142</sup> In addition, some studies hoped to see increased acceptability of the linked service, hypothesising that provision of, for example, malaria<sup>425</sup> or HIV<sup>344</sup> services by a trusted vaccination provider, would encourage demand and lessen stigma. Such aims were not always realised, especially for HIV or FP, as discussed in the section below. Other common bars to acceptability were not part of the integration process directly, in that they related to implementation issues such as long turnaround times waiting for test results,<sup>385</sup> supply interruption or long wait times (see Section 5.3.5), rather than the fact of integration in itself.

One hypothesised advantage was that integration may better meet the co-existing health needs, or co-morbidity in the families accessing immunisation services. This intention is implicit in many of the eight PHC services displayed in

Table 8. However explicit consideration of all of a client's multiple needs was not a feature of any studies of controlled integration initiatives found in this search.

#### **5.4.4 *Determinants of success***

Overall, it is the details of implementation, including the degree to which the integration model matches the services to be linked that determines success in these 21 studies. In a minority, issues of acceptability relating to stigma or socio-cultural sensitivities affect success. Table 9 below summarises discussion of the key determinants of success, drawn from the presentation of integration processes, barriers and enablers in Section 5.3.5. The determinants tabulated are largely based on analysis of the 24 studies that underwent formal data extraction as reported above. Some narrative expansion on determinants follows. This also includes, where relevant, discussion of findings from potentially relevant studies noted in Section 5.3.6.

A clear, well-defined and executed integration model that maximises synergies of feasibility and acceptance across the linked services seems to be the most important key to success. It is essential that the populations using the immunisation service are well matched to the target population for the linked intervention, especially noting the difficulties in integrating IPT and EPI in the second year of life<sup>350-352</sup> when both are at low coverage.

**Table 9: Determinants of successful integration found in 24 publications**

|                                                                                                                                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Intervention and service delivery elements                                                                                                                           |
| Ensuring existing immunisation services have sufficient uptake (if the 'receiving' platform)                                                                         |
| Matching age groups and other family characteristics targeted by each program                                                                                        |
| Matching the type of service with model of integration, considering co-location where more complex services such as counseling or treatment initiation are required. |
| Matching the type of service to the immunisation platform, ensuring complexity of intervention does not overburden campaigns or ERAs                                 |
| Ensuring staff capacity and motivation                                                                                                                               |
| Staff awareness of integration benefits to promote motivation                                                                                                        |
| Staff skills development, refresher training if needed                                                                                                               |
| Ensuring time sufficient for extra tasks, especially clinical or counseling added, consider allocating extra staff                                                   |
| Job aids for counselling and education, technical checklists for quality improvement targeting newly integrated service provision                                    |
| Management, supervision, infrastructure, and medical supplies                                                                                                        |
| Active supervision and cross-program communication, especially with co-location                                                                                      |
| Medical supplies reliability                                                                                                                                         |
| Infrastructure that supports privacy, client education, client flow between services                                                                                 |
| Accurately assessing and monitoring cost savings or additional costs needed                                                                                          |
| Addressing the demand and engaging community support                                                                                                                 |
| Raising community awareness of benefits of linked services and potential client savings                                                                              |
| Formative research on client perspectives, especially for sensitive topics like HIV or FP                                                                            |
| Monitoring and assessing reasons if a minority fail to take up linked services                                                                                       |
| Communications and education for whole family, including male caregivers and partners                                                                                |
| Optimising roles for community-based trained, lay health workers                                                                                                     |
| Health information and records                                                                                                                                       |
| Revision of facility and home-based health records to communicate and track new interventions                                                                        |
| Revision of information systems to track progress in linked services                                                                                                 |
| Policy and governance                                                                                                                                                |
| National and local policy commitments to integration                                                                                                                 |
| Standing orders and other procedures promoting linked service delivery                                                                                               |
| Development and research partner harmonise and align in support of integrated services                                                                               |

Careful *formative data collection can identify key points of feasibility*, as seen in all three FP studies.<sup>10,333,334</sup> These studies emphasised cross-program planning, attention to the infrastructure and communication details (such as patient way-finding) needed for good co-location. Reliance on referral messages alone, rather than co-location may have been a factor in the lower uptake seen in Ghana and Zambia.<sup>10</sup>

Most studies illustrated the *need to respect the additional time, attention and skill demanded* when vaccinating staff members are asked to undertake extra tasks. In all cases this involved training, the quality of which was critical to success, and in some cases was enabled through extra staff, support to local service planning, and the technical tools noted above. It is also critical to *understand staff motivations* and ensure they understand the rationale and likely benefits of integration. Low coverage with additional FP was seen in grey literature reports from Senegal<sup>395</sup> and India<sup>392</sup> where staff issues of feasibility or motivation presented barriers. Other fields of service improvement have used health worker incentives, and it was surprising to find no studies here that used incentives to directly support the integration process.

*Counselling interventions make special demands* on staff and infrastructure. Even for well-recognised health needs such as malaria, the extra effort of IPT counselling limited staff performance in Tanzania.<sup>348</sup> For HIV and FP, adding counselling is more taxing where attitude and behaviour change is required. Additional staff time and skill are needed,<sup>130</sup> and the demands of privacy heightened for both infrastructure and records. Ineffective client engagement, or substituting group education for individual counselling, is the likely explanation for a number of implementation lapses in FP experiences.<sup>10,392,395</sup> *Measuring service delivery time* is a key means to assess feasibility and track progress, as proposed by Wallace and colleagues,<sup>180</sup> and a means to track quality of care through time spent in client communication, as employed by the Integra Initiative.<sup>130</sup> Monitoring effectiveness of staff-client communication offers a new quality of care challenge to immunisation programs, but is one that could be of significant benefit to vaccine uptake as well.<sup>426</sup>

On the demand-side, there is a *potential synergy of acceptability* when associating immunisation with well-recognised health threats such as malaria,<sup>141</sup> or valued commodities such as hygiene kits.<sup>331,356</sup> Conversely, several included studies<sup>332,333,340</sup> demonstrate difficulties in implementation where the linked interventions attract *stigma or other socio-cultural barriers*; especially affecting HIV and FP.<sup>142</sup> For FP the sensitivities can have dangerous consequence, given the frequency with which anti-vaccination rumours have played on community fears regarding covert sterilization of women, seen across Africa and Asia.<sup>427,428</sup> For example, in a low uptake setting in Pakistan,<sup>429</sup> close to a third of those expressing negative views about vaccines cited fear of infertility as their key concern. This applies most acutely to campaigns and SIAs, perhaps due to their need for rapid coverage across large population groups, and led global partners promoting FP-EPI integration to recommend it be applied only to routine immunisation settings.<sup>430</sup>

*Good formative data on client attitudes and behaviours* can inform the communication approaches used in integrated services. In the three included FP studies<sup>10,333,334</sup> this approach resulted in new educative and decision-support tools suited to the front-line. However for a service such as FP there may remain limits on what even the best staff, tools and integration model can achieve. Demand-side factors beyond the excellence of the integrated service can be seen in the included studies in Liberia<sup>334</sup> and Rwanda<sup>333</sup> and other work from Senegal,<sup>417</sup> and Nigeria.<sup>431</sup> Some women required more time to digest new information, especially if challenging a widely taught belief around return of menses, and others felt the need to consult male partners or other family members. This was exemplified in the Nigerian study in which while 41% of women received a FP referral in the integrated service only 15% said they would go that same day; a pattern that significantly affects the degree to which co-location can be successful. These factors suggest there will commonly be a minority of clients with concerns that require special consideration.

*Community-based lay health workers* feature in several experiences, such as supporting nutrition, immunisation and FP in Sierra Leone,<sup>339</sup> hygiene in

Kenya,<sup>331</sup> and IPTc in Gambia<sup>350</sup> and Ghana.<sup>352</sup> In all settings they were valued community health informants, often valued as educators more than a professional (vaccinating) nurse. However they were generally either providing competition to the integrated outreach (for IPTc) or used only to support the linked intervention rather than vaccination. Only in Hodge and colleagues' study<sup>339</sup> did they counsel on immunisation. This suggests that this cadre could be more deliberately employed both in support of the vaccination element of integrated services and perhaps, noting the communication challenges discussed above, more widely in FP experiences.

*Community-based service platforms* in general, such as Village Health and Nutrition Days in India<sup>432,433</sup> or the work of Health Extension Workers in Ethiopia<sup>434</sup> are intended to be strongly integrated platforms, however they often underplay immunisation as a priority<sup>375,433</sup> (see also Section 2.3.4). Considering that community-based worker attitudes to vaccination and its integration with other services are strongly positive in several reviews<sup>435</sup> more intensive work at to enlist this cadre in supporting vaccination could bring success. Prioritising preventive over curative<sup>434,435</sup> care functions at this level also seems to make best use of their potential.

*Clinical curative care settings pose special challenges* to integration. The included HIV study in Malawi,<sup>343</sup> and a grey literature observational study from Senegal<sup>395</sup> confirm that additional counselling by clinical staff is rarely provided during sick child care; especially compared with those doing routine preventive care whether vaccination (Malawi) or postnatal checks (Senegal). It is likely that the barrier is more than simply insufficient staff time and may reflect staff attitudes regarding the primacy of curative over preventive care.

This is also true when integrating immunisation into child illness care. Three of the IMCI studies,<sup>373-375</sup> the IMCI effectiveness review,<sup>109</sup> and a child health care study from Ghana,<sup>159</sup> all demonstrate the difficulty of incorporating routine preventive care such as vaccination (or nutrition and growth interventions) into a clinical encounter. Vaccination may be especially difficult, perhaps because of the need to access supplies: one experience in Nigeria<sup>436</sup>



found twice as many providers integrated nutrition assessments into IMCI as vaccination. One implementation lesson the included Bangladesh<sup>338</sup> and Sierra Leone<sup>339</sup> experiences offer to, for example, IMCI or MOV implementation, is the introduction of a *support tool to help busy staff identify needed vaccinations*. Other studies listed in Table 8 from India,<sup>365</sup> Somalia,<sup>366</sup> and Mongolia,<sup>367</sup>, while not meeting inclusion criteria, do provide support that every opportunity vaccination can be strengthened.

#### **5.4.5 Limitations and areas not studied**

##### *Limitations to the review*

This review has a number of limitations. Firstly, there is an inherent difficulty in researching integration as applied to LMICs due to the complexity of studying health services and the limits on resources in such settings. The review did include a broad range of study designs in recognition of this (and in keeping with standard health policy and systems research practices) and tried to account for any limitations. The larger issue is that a focus on controlled studies may have limited the field to settings where external development partners are willing to fund such studies; this in part may explain why most included studies are from sub-Saharan Africa, with notable absence of eligible research from Asia, the Pacific, and the Americas. There is a risk in applying lessons obtained largely in sub-Saharan Africa to other resource-constrained settings, although it is noted that PNG, for example, shares many similar constraints on service delivery and patterns of disease threat such as malaria, STIs, and high fertility.

Some eligible publications may have been missed because the search was restricted to certain databases, for resource reasons, and to English language publications. The six databases employed were tested against known key publications from the search period, and evidence repositories from the Americas and Asia were scanned, but foreign language (especially Chinese, Spanish, Portuguese, and French) publications could not be included in the full search. This may mean that some potential eligible studies were missed, including those from parts of the world mentioned above. The list of inclusions

was circulated to experts from CDC, Johns Hopkins University and the FP-EPI Integration Working Group for possible additions and all leads provided were followed up. Many were eventually included in the relevant but excluded studies in Section 5.3.6.

Given the majority of papers found increased uptake or coverage for the linked (non-immunisation) services, there may be some publication bias towards positive integration outcomes. This was not able to be formally assessed using standard Cochrane or other systematic review methods.

The frameworks used for data extraction and consolidation, while attempting to draw on relevant and rigorous resources, do have the limitations common to any such framework, in that they reflect a particular view of health services and systems, and may miss identification of unanticipated or surprising data. However the frameworks, as displayed at Appendix 10.2.1, were felt to provide a comprehensive survey of relevant data.

While the review of publications retrieved and decisions on inclusion were done by two researchers, the data extraction, analysis, presentation and discussion was performed by one; the author of this thesis. This has the usual potential for bias that applies to any single author analysis.

#### *Areas not studied*

To keep the review at a manageable level, some research domains that could potentially illuminate integration processes were excluded from this work. Promising topics of study that were considered for inclusion, and for which publications of potential relevance were observed include the following:

- Assessments of innovations in adapted health service planning tools used for immunisation to other programs, such as HIV<sup>437</sup>;
- Studies of the integration of health information systems across programs, including home-based health records<sup>438,439</sup>;
- The use of immunisation contact points for surveillance and program monitoring beyond immunisation<sup>383,440</sup>;
- Innovations in vaccine delivery such as compact-prefilled auto-disable devices,<sup>175</sup> needle-free devices,<sup>441</sup> or deployment beyond

the cold chain<sup>442</sup> that can enable integrated services especially at community level;

- Studies of school health services including vaccination that represent a form of integration targeting a different age group, usually for human papilloma virus vaccine,<sup>152,154</sup> but also for ITN distribution and other relevant interventions; and
- Immunisation during ANC was included in initial protocol drafts, but studies retrieved were too disparate for inclusion here.

#### **5.4.6 Research gaps, measurement and typology issues**

While the volume of research on integrated services has increased, there remain critical gaps in the evidence base. Apart from the geographic bias noted above (including for example the absence of studies from PNG and elsewhere in the Western Pacific region) there is a continued need for evolution in research into key themes as discussed below.

##### *Missed opportunities for vaccination*

Most importantly, it is likely that many of the implementation lessons and determinants of success discussed above would hold true for attempts to incorporate catch-up or opportunistic vaccination into other services. However our search could include only one such study, albeit one with promising results. There is considerable work completed to consolidate evidence on the prevalence and causes of MOV,<sup>32</sup> as discussed in Section 2.3.4, but limited study of well-designed and measured interventions. To further global aspirations to improve immunisation coverage in LMICs, study of MOV in clinical and other non-immunisation settings is urgently needed, and should adopt new tools that represent the consensus of global partners.<sup>165</sup> Also needed is careful identification of study setting to distinguish catch-up vaccination at *routine preventive clinics* (including immunisation clinics) from vaccination integrated into *outpatient or inpatient clinical care* settings. This will help make measures of intervention efficacy more precise as it is likely to differ in each setting. This distinction is not universally seen in publications assessed for this review.

*Integration in the second year after childbirth, combining interventions for nutrition, child development, women's health and immunisation*

Just as there is strong life course synergy in linking postpartum family planning with immunisation during infancy, there is a need to integrate preventive interventions for the child and other family members in the second year after birth. This is driven by the increasing vaccinations scheduled for this age,<sup>414</sup> and the fact that the first two years represent the most powerful time points at which one can intervene to turn around under-nutrition and sub-optimal child development.<sup>120,123</sup> The Sierra Leone experience reviewed here<sup>339</sup> offers encouragement that integrating services can play a part in responding to the global scandal of stunting and under-nutrition.<sup>443</sup> However the two IPTc studies reviewed, and other experiences for seasonal malaria control,<sup>444</sup> demonstrate the difficulties in reaching this age group with preventive care. In addition, other family health priorities such as women's sexual and reproductive health are important at this point in the life course and there is some evidence, for example from Kenya,<sup>419</sup> that family planning and nutrition for mother and child can be usefully integrated. This is an area that desperately needs more implementation evidence, and global partners have recognised in the 2019 merger of working groups for FP-EPI integration and that for integration of FP and maternal, infant and young child nutrition.

*Service delivery studies, costs and cost-effectiveness*

This review illustrated the relative paucity of service delivery studies with rigorous, tightly controlled study designs; this does not assume all should be RCTs, but all would be stronger with clearly defined and credible comparators. This review also highlights the fact that few studies contain good measures of program or client costs, and fewer have comparators to allow costs of integrated and non-integrated services to be contrasted, or incremental cost-effectiveness measured. Several studies in this review have demonstrated that the integrated option is sometimes the more costly, especially where outreach is involved. Given that efficiency is a commonly cited reason for pursuing more integrated services, testing this in future integration research is essential.

Another omission is study of the use of supply- or demand-side incentives to support delivery and uptake of more integrated services. These have proven effect on changing provider and client behaviours in other RMNCAH domains and could be applied the integration process.

The analysis for this review has also developed a useful typology for integrated service description (see Figure 11), which has the potential to relate integration models to outcomes. Further development of this approach will be useful in future studies to better draw conclusions on how integration can work. This can add to the emerging toolbox of integrated service measures that include:

- Health intervention delivery times<sup>180</sup>;
- Measures of client flow<sup>9,90</sup>; and
- Indexes of the quality and intensity of integration.<sup>129</sup>

*A demand-side gap: client preferences and needs for integrated service delivery*

Although many studies examine family and clients' views on the acceptability of new interventions, what is rarely explored are their preferences for how services should be organised and delivered. The importance of clients' opinions on what happens in clinics or other health care is predicted by the conceptual framework developed for this research (Figure 5, Section 3.1.4). A detailed search within included studies for demand-side factors such as acceptability found relatively few<sup>142,333</sup> helpful quantitative or qualitative data on families' preferences for how health service integration should be introduced. Families are likely to have views on whether service delivery changes should include more outreach or fixed facility services, more weekend or after-hours, the mix of providers, and the combination of integrated services. There is work to be done to add a common set of questions and observations to service delivery research tools that will capture what families, especially women, prefer in the arrangements made for health service delivery.

A second demand-side gap in current research<sup>328</sup> is the careful examination of the range and prevalence of co-morbidity or co-existing health care needs, in caregivers or children attending for vaccination. As with the

original rationales for comprehensive health care and IMCI (see Chapter Two of this thesis), these patterns of needs in caregivers and children should be the starting point for design of integrated service packages. However none of the research assessed for this review, nor any of the publications that did not meet inclusion criteria (Section 5.3.6), included broad-based assessments of demand-side needs for integrated care.

*A future review of qualitative and process data in integration initiatives*

The review reported here took a particular view of the type of evidence useful to health services and systems innovation, as acknowledged in the Limitations section. This was done, in part, to enable continuity with the earlier reviews by Wallace and others.<sup>58,140</sup> There is also likely to be considerable information in descriptive or non-interventional studies that were not included, including observations on the potential for greater integration. Realist synthesis<sup>445-447</sup> or qualitative synthesis<sup>323</sup> methods may be useful in the future to consolidate the qualitative and process data available from a different mix of studies of integration efforts; especially in view of the potential value of realist approaches to the study of integrated services as briefly discussed in Chapter Three. Future reviews with a broader scope of inclusion could usefully contribute to understanding how integration could be implemented. To some extent, this challenge is taken up in the approach used for analysis of findings in Chapter Six, however a formal review process would make a strong stand-alone contribution to integration research.

*The need to update this review*

As noted in Section 5.2.3, this review captured publications only until 2016 to enable relevance to other work in this thesis. Limits on researcher time, especially in relation to the field studies reported in Chapters Six and Seven, meant the review could not be updated prior to submission of this thesis. However, as noted in Chapter Eight, the researcher, and Burnet Institute have committed resources in 2020, to update this review for publication.

## 5.5 Conclusion

This review adds 21 experiences of integrated services and a significant number of new comparators and outcome data to the earlier review of integration of other services with immunisation.<sup>58</sup> Gains in coverage or uptake are possible through integration of other services with immunisation, especially for the linked service, with clear benefits seen for HIV, malaria, family planning and nutrition interventions. Immunisation is generally unharmed, or moderately benefited, from the integration process. As with Wallace and colleagues,<sup>58</sup> this review finds the importance ensuring compatibility between the linked service, and the underlying strength of the immunisation platform. The analysis reported here adds to the earlier findings a new typology of integration, and a further range of implementation issues to be considered; reflecting the greater emphasis in recent years of integrating HIV or FP services that are especially demanding of capacity for counselling, commodities and clinical skills.

Where the expected outcomes were not obtained for the linked service, this is due to either: implementation lapses such as ineffective counselling for behaviour change or referral; or to a mismatch between the linked services targets and the immunisation platform's capacity, such as attempting to link malaria services for children older than one year.

Where immunisation coverage is potentially harmed, this is due to stigma or other socio-cultural sensitivities relating to the linked service. Such a risk can be managed with appropriate formative research, strong communications, and community engagement. Demand-side factors of acceptability and community dynamics, as well as the clients' attitude to the health services in general seem to mean there is a minority that refuse or dislike the integrated service delivery. It is imperative to understand their reasoning so these barriers can be either accepted or mitigated.

The use of a comprehensive, validated, policy-relevant framework for data extraction allowed characterisation of the integration processes that determine success or failure. These determinants included: carefully matching of intervention with integration model and immunisation platform; ensuring staff

capacity and motivation, including tailored technical tools for decision support and communications; supportive management, supervision, infrastructure and supplies; addressing the demand and engaging community support; adapted health information and records; and supportive policy and governance. This analysis also generated a typology of integration models that proved useful in relating process to outcome, comprising four categories of: a) extra services provided by vaccinating staff; b) extra counselling provided by vaccinating staff; c) co-location with extra services linked to immunisation place and time; d) vaccination by staff who are not usual immunisation providers; and e) immunisation counselling by staff who are not usual immunisation providers.

Important priorities for further implementation research have emerged. These include more studies that aim to integrate immunisation into other services, including research to reduce missed opportunities for vaccination. Integration of nutrition, child development, women's health and immunisation in the second year after childbirth is also of prime importance to child and maternal health outcomes alike, and at present this evidence base is worryingly thin. Future studies should include better analysis of cost-effectiveness, with good quality comparators of integrated and non-integrated services, in addition to well-developed characterisations of service delivery models that could draw on typologies that emerged in this research.

There are also major gaps in the current evidence regarding families' preferences for how integrated services should be organised, and in our knowledge of the range and prevalence of co-morbidity or co-existing health care needs in caregivers or children attending for vaccination. This last item is crucial if future integrated services are to truly focus on the most pressing health needs of vulnerable children and their families in resource-constrained settings. It is taken up in Chapter Six of this research.



## 6 WOMEN'S PERSPECTIVES ON INTEGRATED SERVICES IN RURAL PAPUA NEW GUINEA

### 6.1 Rationale for an observational cohort study

As discussed in Chapter Five, there is a pressing need for more research into the demand-side influences on the integration of other services with immunisation.

Women's attitudes towards integrated services need better elucidation. Several studies reviewed in Chapter Five noted the importance of positive community attitudes<sup>142,331</sup> to successful integration experiences, and researchers into HIV integration efforts highlight the role played by positive or negative client-provider interactions.<sup>8</sup> While most clients welcome more integrated services (as reviewed in Sections 5.3.5 and 5.4.3), many acceptability assessments identify a minority of users who have concerns about integration changes. These concerns range from discomfort with sensitive topics such as HIV<sup>332</sup> or FP,<sup>333</sup> to worries about disrupted or prolonged clinic procedures.<sup>142</sup> However such assessments are scarce and given the documented potential to reduce uptake of new services, a better understanding of the acceptability of certain forms of integration is warranted. In addition, with a few exceptions<sup>142,333,334</sup> it is rare to see research into caregivers' preferences for how future integrated services should be organised or delivered.

Co-morbidity in rural PNG and similar resource-constrained settings appears common (although poorly studied) and may have serious consequences for mother and baby.<sup>328</sup> There is an important gap in knowledge of the patterns of co-morbidity or co-existing health care needs among caregivers or children attending for vaccination; and the implications for which services should be integrated in places like ENB. This demand-side rationale was, as argued in Chapter Two, a feature of approaches such as comprehensive PHC that see integration as primarily a way to address the array of health needs in families. However this holistic approach to family care is not evident in many experiences

collated in Chapter Five and, as seen in Chapter Seven, is not always evident in current immunisation services in ENB or elsewhere in PNG, despite national policy aspirations.<sup>277,448</sup>

The longitudinal design of this study provided a valuable opportunity to examine elements relevant to integration through the postnatal period and across the main immunisation program touch points during the first year after childbirth. PNG's unusual (in global terms) immunisation schedule requires vaccination at: birth (hepatitis B vaccine, *bacille calmette guerin* (BCG) against tuberculosis); one, two and three months (pentavalent, inactivated polio vaccine (IPV), oral polio vaccine (OPV), pneumococcal vaccine); six months (measles vaccine) and nine to twelve months (measles vaccine second dose). As discussed in Chapter Two, these are generally provided through 'Well Baby Clinics' at either static facilities or through outreach; noting that research described in Chapter Seven below, suggests that such clinics emphasise vaccination over other services.

The repeated interviews with the same cohort of women from pregnancy through the extended postpartum period, required for tracking patterns in biomarkers of disease, also provided an opportunity to track changes in women's preferences as they moved through this intense period of the life-course.

In light of this rationale and opportunity, the aims of the integration research nested within the cohort study (see also Chapter Four) were to understand:

- Pregnant, and later postpartum, women's and babies' disease burden and health care needs relevant to services that could be integrated with vaccination;
- Women's experience of current services, including their degree of integration;
- Women's preferences for and attitudes (both positive and negative) to more integrated services in the first year after childbirth; and
- The potential for more integrated services in this context.

## 6.2 Cohort study methods, selected features

The full protocol for this cohort study is appended (Appendix 10.1.2) to this thesis, and Chapter Four describes the methods in relation to other research in this thesis. As noted, this integration research was nested within a prospective observational study of a cohort of pregnant women in ENB, followed from first ANC visit to either six or 12 months after childbirth (or other pregnancy outcome). The integration research draws principally on tailored items in the study-specific questionnaire administered to participating women. It also draws on data from an expanded suite of point-of-care (POC) rapid tests, listed in Section 4.3.3), and review of patient-held and clinic health records that also form part of the cohort study.

The questionnaire and other data collection were conducted at five time points: *first ANC* visit, *delivery* (usually childbirth), and then *one, six and twelve* months after childbirth. This timeline allowed assessment of the disease burden experienced by pregnant women as they first contacted preventive care for themselves and their babies, and then their experience and opinions of services across the most important vaccination time points in PNG.

Women were enrolled from the five health facilities that were the busiest providers of childbirth care in ENB. Women were offered participation based on random selection from all eligible women attending ANC on a given day. Random selection was achieved through two dice rolls: firstly to determine a starting point in the clinic list (to avoid bias related to arrival sequence), and secondly to choose which women to offer participation. This aimed to provide a credible representation of women in the province noting that approximately 80% of pregnant women in ENB make at least one ANC visit.<sup>239</sup> No attempt was made to weight by clinic catchment population, although smaller clinics did mean less women available for enrolment.

After informed written consent, a trained research officer administered a detailed study-specific questionnaire. The questionnaire covered socio-demographic and clinical information and asked about women's experiences of integrated care, preferences for future care including types of integration, and

acceptability of integrating other services with immunisation clinic visits in the first year after childbirth. Appendix 10.3.1 provides an outline of the questionnaire structure and full versions in English and Tok Pisin of representative questions directly relevant to integration.

The questionnaire was administered as a structured interview using standardised questions in either English or Tok Pisin in accordance with the woman's preference. In some cases there was supplemental explanation in local language. The interview also included semi-structured items allowing for short open responses, to capture women's suggestions not anticipated in the questionnaire structure. Interviews were done in a private space at ANC clinics, postnatal wards (delivery assessment) or a community setting (some delivery and other later assessments), usually the participant's home. Some questionnaire items called for review of clinic records and patient-held home-based records. These latter comprise a mother's health book ('Helti Mama Buk'), and an infant's (the 'Helti Beibi Buk'); both are more consistent and reliable than the un-indexed paper-based files used in most facilities. If a mother did not have either health book with her, data were derived from interview, or recorded as 'missing'.

Participant responses were entered directly by research officers during interviews into an electronic tablet running Mobile Data Studio 7.3 (Creativity Corp, Perth, Australia). Data were uploaded to a secure study database each day, checked for completeness, and exported through Microsoft Office Excel for further analysis in Stata 15.1 SE (Statacorp LLC, College Station, Texas USA).

A range of *POC tests* were available as part of the broader study (see also Chapter 4), including those normally administered in PNG's ANC screening: haemoglobin measured by HemoCue™, fingerprick blood for malaria of any species (CareStart), or syphilis (Determine, Alere). To these were added new POC tests for certain reproductive tract infections (RTIs) whose high prevalence is increasingly recognised in PNG<sup>206</sup> and similar settings,<sup>449</sup> and for which rapid POC testing is currently under trial in PNG.<sup>450</sup> These included tests for chlamydia, gonorrhoea or trichomonas on vaginal swab and urine, using an automated DNA testing platform in common use in PNG for other purposes (GeneXpert, Cepheid,

Sunnyvale CA, USA). Procedures for the administration and analysis of POC tests are described in the full study protocol at Appendix 10.1.2.

The key *integration measurements* were obtained from review of interview responses, POC test results, and clinical records review. These measurements aimed to assess mothers' and babies' disease burden and health needs warranting integrated services, their experience of integrated services, and their preferences for and attitudes towards more integrated services in the future (see listing in Section 4.3.4).

As research nested within a larger study, there were many contributors to the research process. Professor James Beeson, as lead principal investigator, and Dr Michelle Scoullar, as co-principal investigator along with Dr Morgan (the author of this research), established the HMHB program and finalised study methods and data collection tools; noting Dr Morgan led those tools relevant to integration, and that all investigators (see full protocol at Appendix 10.1.2) contributed to specific aspects of study methods. Professor Beeson, Drs Scoullar and Morgan, and later Dr Liz Peach, finalised standard operating procedures to guide research officers in data collection, data management, POC testing and laboratory operations. Two principal investigators from PNG IMR, Professor Peter Siba (until his retirement in 2017) and Professor William Pomat, oversaw all research operations and coordination with other research initiatives in PNG.

Drs Scoullar and Peach at different times managed the ENB HMHB team of research officers undertaking data collection over four years, including: Pele Melepia, Thalia Wat, Lucy Au, Priscah Hezeri, Zoe Saulep, Kerryanne Tokmun, Elizabeth Walep, Irene Daniels, Primrose Homiehombo, Rose Suruka, Allan Tirang, Eremas Amos, Gabriella Tade, Dorish Palagat, Chris Sohenaloe, Wilson Kondo, Noelyne Taraba, Noreen Tamtilik, Ellen Kavang and Wendy Keakopas. Wilson Philip, in the ENB Burnet office, managed databases and data security. Hadlee Supsup, Dukduk Kabi, Michael Palauva, Ioni Pidian, and Teddy Wanahau provided logistics and driving support, especially important at later time points that needed home visits. Ruth Fidelis, Burnet Institute, and Benishar Kombut, PNG IMR, managed laboratory operations and POC testing.

The author of this research devised and conducted all analyses for the integration studies reported here. Dr Michelle Scoullar, Dr Liz Peach, Ms Clarissa Moreira, and Mr Long Nguyen of Burnet Institute contributed to aspects of Stata coding. Mr Paul Agius, also of Burnet Institute, advised on statistical analyses.

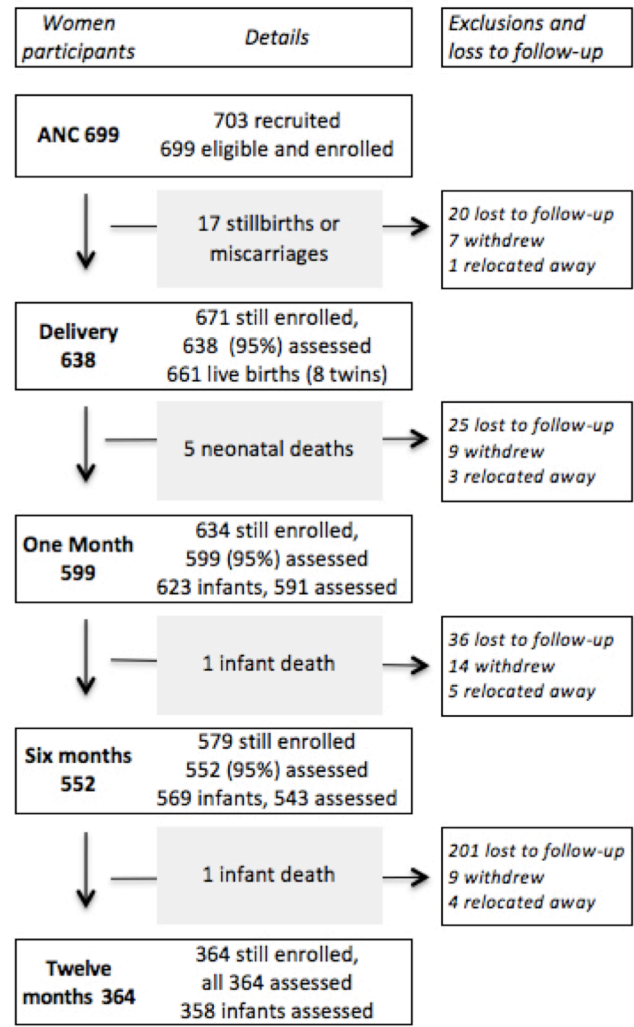
6.3 Cohort study results

6.3.1 Cohort characteristics

Of 703 women recruited to the study, 699 were enrolled, with four exclusions needed when ineligibility (usually due to home address) was discovered after recruitment. Figure 12 shows the numbers assessed at each contact point, and the losses to follow-up, withdrawals, relocations and deaths. Of the 699 women, 638 (91%) were assessed at Delivery, 599 (86%) at One Month, 552 (79%) at Six Months, and 364 (52%) at Twelve Months after childbirth or other pregnancy outcome.

Enrolment of women commenced in March 2015 and continued until June 2017. The final twelve-month follow-up assessment was conducted in December 2018. Given the operating environment, and relative mobility of families in the postpartum period in rural ENB, the follow-up to six months was viewed as good, and secondary analysis did not show particular bias in those lost to follow-up prior to six months. The larger drop off in those able to be followed up until twelve months reflects the logistic difficulties of long-term participant tracking; such as monsoonal weather disruptions and major constraints on the availability of transport facilities and research staffing. At twelve months there was a slight bias to less remote families remaining enrolled. Voluntary withdrawals,

Figure 12: Flow chart of study participants



comprising 39 of the 699 women, were most commonly due to women or other family members wishing to avoid the inconvenience of study procedures.

Table 10 below shows the demographic, reproductive history, and other characteristics of the cohort of women enrolled in the study. Reported uptake of at least one ANC visit in ENB was 85%<sup>246</sup> when enrolment commenced, so this was felt to be representative of a majority of the pregnant women in the province.

**Table 10: Characteristics of women and babies enrolled in cohort study**

| <i>Details</i>                                                        | <i>Number</i> | <i>%</i> |
|-----------------------------------------------------------------------|---------------|----------|
| <i>Enrolment health facility (administering agency), n=699</i>        |               |          |
| Vunapope, St Marys Hospital (Catholic Church Health Services)         | 184           | 26.3     |
| Nonga General Hospital (government)                                   | 83            | 11.9     |
| Keravat Rural Hospital (government)                                   | 125           | 17.9     |
| Napapar Health Centre (Catholic Church Health Services)               | 158           | 22.6     |
| Paparatava Health Centre (Catholic Church Health Services)            | 149           | 21.3     |
| <i>Enrolment facility location, n=699</i>                             |               |          |
| Rural (remainder were urban)                                          | 357           | 51.1     |
| <i>Age (years), n=692</i>                                             |               |          |
| 16-24                                                                 | 275           | 39.7     |
| 25-34                                                                 | 334           | 48.2     |
| 35+                                                                   | 83            | 12.0     |
| <i>Religious denomination, n =698</i>                                 |               |          |
| Catholic (remainder were other Christian denominations)               | 345           | 49.4     |
| <i>Mothers education, n=697</i>                                       |               |          |
| Primary school or less                                                | 325           | 46.5     |
| Completed secondary school                                            | 177           | 25.3     |
| Completed tertiary or vocational training                             | 196           | 28.1     |
| <i>Household monthly expenditure* n=663</i>                           |               |          |
| Less than or equal to 150 PNG kina                                    | 354           | 53.4     |
| <i>Water and sanitation (measured at Twelve Months) n=360</i>         |               |          |
| Access to improved sanitation** in the household                      | 204           | 56.7     |
| Access to protected water (piped to house or tap, covered well)       | 69            | 19.1     |
| <i>Previous pregnancies, n=699</i>                                    |               |          |
| None                                                                  | 177           | 25.3     |
| 1-4                                                                   | 384           | 54.9     |
| ≥5                                                                    | 138           | 19.7     |
| <i>Birth outcome, n varies – see cell reference</i>                   |               |          |
| Stillbirth or miscarriage (where reported)                            | 17/670        | 2.6      |
| Female (remainder male) live births, 8 sets of twins                  | 329/661       | 50.2     |
| <i>Uptake of health care services, n varies – see cell reference</i>  |               |          |
| Ever used a modern method*** of family planning before this pregnancy | 124/698       | 17.8     |
| Attended four or more ANC visits (remainder attended 1 – 3 visits)    | 476/631       | 75.4     |
| Childbirth care in a health facility (remainder in community or home) | 607/670       | 90.6     |
| Infant received one dose of pentavalent vaccine                       | 459/500       | 93.8     |
| Infant received three doses of pentavalent vaccine                    | 276/444       | 62.2     |

Notes: \*One PNG Kina was USD0.36 to 0.31 over the course of enrolment, PGK150 was the median reported monthly household expenditure. \*\*Improved sanitation meant flush toilet (32/204) or pit latrine with slab (169) or slab and ventilation (3). \*\*\*Modern methods of family planning included



contraceptive injections or implants, condoms, tubal ligation, or vasectomy. Vaccination measures were based on health record assessments at six months, supplemented by women's recall.

The cohort had a median age of 26 years (inter-quartile: 22-30), 25% were in their first pregnancy, half identified as Catholic, and slightly more than half had been educated beyond primary school. Enrolments were equally balanced across urban and rural sites, and 70% were attending church-run facilities for first ANC (reflecting the pattern of maternal and newborn health service providers in ENB). In developing each of the analyses below, differences were sought both by individual health facility, and by urban compared to rural sites; hypothesising that these could illuminate socio-cultural or service quality difference. However no significant variation by health facility was found using simple proportions or regression models; this was interpreted as indicating that the population sampled was relatively homogenous and representative of women in rural ENB.

Families in this cohort were relatively high users of health care services. As seen in Table 10 above, 75% attended four or more ANC visits (nationally estimated at 49%, 2016-18<sup>213</sup>). The fact that 91% of our cohort received childbirth care in a health facility signifies a higher level of uptake than provincial estimates across ENB; which measured 78% by survey<sup>213</sup> and 77 down to 61% by administrative data over 2015 to 2018.<sup>246</sup> Coverage for some vaccinations was high: 93% received at least one dose of pentavalent vaccine (national estimates range from 83% declining to 67%, over 2015 to 2018<sup>263</sup>), although fewer, 57%, received three doses by six months. The third dose of pentavalent vaccine, a core measure of sustained uptake of immunisation by families, is usually assessed at age 12 months or over, rather than the Six Month time point reported here. For comparison, national estimates for third dose of pentavalent vaccine range from 73 to 61%<sup>263</sup>) by twelve months of age.

### 6.3.2 *Multi-morbidity and co-existing health care needs*

The tables below present assessments of co-existing illness (co-morbidity) and health care needs (such as family planning advice and provision) that were measured in this cohort. These focus on: a) women at first ANC (Table 11), representing the additional burden of morbidity or health care needs that accompany their pregnancy care needs and are carried into the postpartum period; and b) women and infants at various time points after childbirth (Table 12), representing the health care needs that could potentially be met by extra service provision during immunisation visits in the first year after birth.

A range of measures were found useful to represent these needs, extracted from clinical report, records review and the expanded suite of POC diagnostic tests, comprising:

- *Reported symptoms of potentially important illness* including report of fever, serious cough (defined as with fever, weight loss or of more than two weeks duration), genital discharge;
- *Low middle-upper-arm circumference* (MUAC), less than 23cm in pregnant women, consistent with under-nutrition<sup>451</sup>;
- *Haemoglobin less than 100g/L*, moderate or severe anaemia<sup>452</sup>;
- *Positive rapid tests* by fingerprick for any malaria, or syphilis;
- *Positive POC for selected RTIs*: chlamydia, gonorrhoea or trichomonas on vaginal swab;
- *Family planning intentions*, or desire to delay next pregnancy; and
- *Clinical history of illness since last time point* in woman or infant.

It should be noted that these are not formal prevalence estimates; not all anaemia is likely to be iron-deficiency,<sup>35</sup> current syphilis rapid diagnostic tests RDTs include past exposure and may cross-react with yaws,<sup>453</sup> and malaria RDT positivity is a significant under-estimate.<sup>454</sup> True malaria positivity during pregnancy in this cohort from quantitative polymerase chain reaction testing by other HMHB researchers was estimated as 12.5% of 615 women tested.<sup>455</sup> Rather, the measures below are viewed as signals that could be visible to preventive care services, require follow-up, and reinforce priorities for integrated services.

Table 11 below demonstrates a high proportion of women carrying non-pregnancy health concerns, and likely co-morbidity, into the pregnancy and postpartum period. Clinical signs of illness or under-nutrition are seen in 47% of women, 58% have moderate or severe anaemia that would require iron treatment, and 43% have a positive screening test for either malaria or a reproductive tract infection; the latter dominated by women testing positive to syphilis, chlamydia or trichomonas. *Overall, 89% of women had a clinical or screening test signal of possible morbidity complicating pregnancy, all of which are long-term and likely to extend postpartum.*

**Table 11: Co-existing health needs of women at first ANC visit**

| Details                                                                        | Number Reported | Proportion (%) | Total assessed |
|--------------------------------------------------------------------------------|-----------------|----------------|----------------|
| <i>Clinical signals of potentially important illness</i>                       |                 |                |                |
| Fever during pregnancy or at time of clinic                                    | 170             | 24.4           | 697            |
| Cough, serious (with fever, weight-loss, or > 2 weeks)                         | 61              | 8.7            | 698            |
| Vaginal discharge, abnormal, any time in pregnancy                             | 134             | 19.3           | 696            |
| Low MUAC <23cm consistent with under-nutrition                                 | 65              | 9.4            | 693            |
| <b>One or more* clinical signals of potential illness</b>                      | 322             | <b>46.7</b>    | 690            |
| <i>Low haemoglobin – moderate or severe anaemia</i>                            |                 |                |                |
| <b>Moderate or severe anaemia</b> (HemoCue < 100g/L)                           | 341             | <b>58.1</b>    | 587            |
| <i>Positive result on infectious disease POC screening tests</i>               |                 |                |                |
| Malaria RDT**                                                                  | 25              | 3.63           | 689            |
| Syphilis RDT                                                                   | 79              | 18.1           | 437            |
| Gonorrhoea by new POC test                                                     | 35              | 5.5            | 640            |
| Chlamydia by new POC test                                                      | 122             | 19.1           | 640            |
| Trichomonas by new POC test                                                    | 117             | 20.1           | 581            |
| Any* one of four RTIs by RDT or POC test                                       | 135             | 41.7           | 324            |
| <b>Any* screening test positive</b>                                            | 138             | <b>43.2</b>    | 322            |
| <i>Proportion of women with any clinical signal, anaemia or screening test</i> |                 |                |                |
| Any* clinical signal or positive POC screening test                            | 225             | 70.5           | 319            |
| <b>Any* significant anaemia, clinical or positive POC test</b>                 | 220             | <b>89.1</b>    | 247            |
| <i>Family planning intentions</i>                                              |                 |                |                |
| Planning to use FP after childbirth, of whom:                                  | 590             | 84.7           | 697            |
| <b>Intending, or open to consider, a modern method</b>                         | 572             | <b>82.1</b>    | 697            |

Note: \*For combined estimates, denominators were restricted to women who had a measure for all relevant parameters. \*\*Malaria RDT is under-estimate, true prevalence estimated at 12.5%.<sup>455</sup>

As can be seen in Table 12 below, the proportions of women experiencing similar patterns of co-morbidity remain high in the months after childbirth. In addition, a significant proportion of infants in this cohort have signals of under-nutrition (low weight-for-age, anaemia) and morbidity from mostly infectious

diseases. These patterns can thus help set theoretical priorities for integrated maternal health care before and after childbirth.

Women's intentions regarding family planning were also assessed, as a high priority proxy for a range of preventive health care and counselling that women are likely to need in the postpartum period. Table 11 above demonstrates 82% of women with family planning intentions that would require health service support, and Table 12 below demonstrates this demand persisting, often unsatisfied, throughout the period after childbirth.

**Table 12: Co-existing health needs of women and infants after childbirth**

| <i>Details</i>                                                                       | <i>Number</i> | <i>Proportion (%)</i> | <i>Total</i> |
|--------------------------------------------------------------------------------------|---------------|-----------------------|--------------|
| <i>Morbidity reports, postpartum women</i>                                           |               |                       |              |
| Selected intra or postpartum complication*                                           | 256           | 39.0                  | 656          |
| Other non-pregnancy related illness reported by One Month                            | 124           | 20.1                  | 599          |
| Other non-pregnancy related illness reported by Six Months                           | 227           | 41.1                  | 552          |
| Women with moderate or severe anaemia at One Month                                   | 140           | 24.4                  | 574          |
| Women with positive malaria RDT** at One Month                                       | 10            | 1.7                   | 570          |
| Women with positive POCT for gonorrhoea, chlamydia, and/or trichomonas at Six Months | 65            | 21.9                  | 297          |
| <i>Morbidity reports, infants</i>                                                    |               |                       |              |
| Infants with any illness reported by One Month                                       | 198           | 33.5                  | 592          |
| Infants with any illness reported between One and Six Months                         | 411           | 75.7                  | 543          |
| Infants with any illness reported between birth and Six Months                       | 420           | 82.3                  | 510          |
| Infants with low weight-for-age at Six Months                                        | 64            | 12.0                  | 532          |
| Infants with moderate or severe anaemia at Six Months                                | 66            | 12.0                  | 551          |
| Infants with moderate or severe anaemia at Six Months                                | 56            | 25.8                  | 217          |
| <i>Family planning intentions, Six Months</i>                                        |               |                       |              |
| Women wanting to avoid or delay*** future pregnancy, at Six Months                   | 394           | 72.0                  | 547          |

Note: \*Complications assessed for intrapartum or postpartum period were bleeding (by self report or clinical record), retained placenta, hypertension, or puerperal sepsis. \*\* Malaria RDT is a likely under-estimate, true prevalence pending. \*\*\*Women were classified as wanting to avoid or delay future pregnancy if they said they either did not want more babies, or wanted to delay the next pregnancy by 12 months or more.

Table 12 above demonstrates that *over 80% of families have health care needs in both mother and/or baby, during the first six months of infancy*. An important proportion of recently pregnant women have either obstetric and/or non-obstetric morbidity present from the immediate postnatal period onwards. These encompass the need for follow-up of sustained infections (such as malaria,

serious respiratory symptoms, or RTIs), prevention and management of under-nutrition, and/or responses to families' desire for preventive health care such as family planning. Most infants experienced one or more illnesses before six months, with respiratory, then fever, then diarrhoeal symptoms predominating. Even if the almost universal experience of acute infant illness is excluded as not always suited to follow-up at routine schedulable services, at least one in four infants had signs of chronic illness or under-nutrition that could benefit from attention at immunisation visits.

### **6.3.3 *Women's experience of integrated services***

The table below shows how frequently women reported additional services representing integrated care, as having been received when making immunisation visits to 'Well Baby Clinics'. Women were especially asked to reflect on services received at any of the four visits that should take place at one, two, three and six months after childbirth.

Few women (11%) reported receiving postnatal checks after a family was discharged from a childbirth facility; noting that PNG's Newborn Health Policy<sup>268</sup> recommends three checks in the first week. Women's report of postnatal check services (not tabulated), wherever received, mainly referred to checks for the newborn such as weight (30% of mothers reporting), vaccinations (27%) or neonatal illness (19%). Women infrequently reported receiving checks of their own illness (10%), advice on their own nutrition (5%) or advice on family planning (4%) at any postnatal care encounter. There was high uptake of birth dose vaccination against hepatitis B, most of which (over 83%) was provided in facilities immediately after childbirth.

As seen in in Table 13 below, although over 90% of women reported making at least one immunisation visit from one month of age onwards (represented by the uptake of one dose of pentavalent vaccine), fewer (62%) had by six months accessed the three or more visits prescribed by PNG's national vaccination schedule. Fewer (33%) had accessed the first (six months) measles vaccine dose on time, although most caught up in subsequent months.

Possible associations between *parity* (comparing women with their first baby with those with more), *education* or *rural* address and reports of services received were explored using standard statistical tests of association in Stata 15.1, however no trends or significant associations were observed.

**Table 13: Women's report of services received, postnatal and immunisation visits**

| <i>Uptake of routine preventive care after childbirth</i>                                      | <i>Number</i>              | <i>Proportion (%)</i> | <i>Total assessed</i>       |          |
|------------------------------------------------------------------------------------------------|----------------------------|-----------------------|-----------------------------|----------|
| Postnatal check after discharge from facility                                                  | 59                         | 11.4                  | 519                         |          |
| Use of modern FP methods at Six Months                                                         | 156                        | 28.9                  | 539                         |          |
| Use of modern FP methods at Twelve Months                                                      | 97                         | 26.9                  | 360                         |          |
| Birth-dose of hepatitis B vaccine                                                              | 370                        | 87.9                  | 421                         |          |
| First dose of pentavalent vaccine (due at 1 month)                                             | 469                        | 93.8                  | 500                         |          |
| Third dose of pentavalent vaccine (due at 3 months)                                            | 276                        | 62.2                  | 444                         |          |
| First dose of measles vaccine as at Six Months                                                 | 123                        | 33.0                  | 373                         |          |
| One or more measles vaccines as at Twelve Months                                               | 279                        | 87.5                  | 319                         |          |
| <i>Additional non-immunisation services reported by women as received at Well Baby Clinics</i> | <i>Reports at 6 Months</i> |                       | <i>Reports at 12 Months</i> |          |
|                                                                                                | <i>Number (n=410)</i>      | <i>%</i>              | <i>Number (n=243)</i>       | <i>%</i> |
| Baby weight and/or growth check                                                                | 224                        | 54.6                  | 166                         | 68.3     |
| Baby illness check and management                                                              | 154                        | 37.6                  | 111                         | 45.7     |
| Baby advice on hygiene and general care                                                        | 65                         | 15.9                  | 40                          | 16.5     |
| Baby advice on feeding                                                                         | 40                         | 9.8                   | 27                          | 11.1     |
| Baby nutritional supplement, vitamin A or other                                                | 9                          | 2.2                   | 6                           | 2.5      |
| Mother advice on her nutrition                                                                 | 30                         | 7.3                   | 21                          | 8.6      |
| Mother advice on family planning                                                               | 20                         | 4.9                   | 10                          | 4.1      |
| Mother illness check and management                                                            | 13                         | 3.2                   | 4                           | 1.7      |
| Mother advice on sexual health                                                                 | 8                          | 2.0                   | 4                           | 1.7      |
| Provision of bed-nets (ITNs)                                                                   | 7                          | 1.7                   | 3                           | 1.2      |
| Advice on danger signs for mother or baby                                                      | 15                         | 3.7                   | 11                          | 4.5      |

Notes: Modern methods of family planning included contraceptive injections or implants, condoms, tubal ligation, or vasectomy. Vaccine doses were based on inspection of the infant's home-based record supplemented by mother's recall. Pentavalent vaccine is scheduled age 1, 2 and 3 months, and first dose of measles vaccine at 6 months with a second at 9 to 12 months.

Women's reports of additional services at immunisation clinics ('Well Baby Clinics') show a similar *predominance of infant over maternal care* as that seen in the postnatal period. Checks of weight and/or growth of babies were reported by a majority of mothers, with checks on a baby's illness the next most frequent. Counselling on infant hygiene or feeding was reported less frequently.

Receipt of vitamin A or other supplements (including anti-helminthic medicines) was reported by a low proportion of women at all time points. This may underestimate true uptake as examination of home-based records noted some infants recorded as receiving vitamin A supplements when not reported by women; however this proportion was still estimated as less than 10% (data not shown).

*Additional services targeting the postpartum mother's needs were rare,* reported by well under 10% of women. Advice on maternal nutrition, then family planning, were the two most commonly extra maternal health services reported. Checks on a woman's illness were infrequently reported (by 3% of women at six months); a finding that may be contrasted with the high burden of sustained maternal morbidity recorded in Section 6.3.2. These proportions can also be compared with findings obtained from observation of clinics as presented in Chapter Seven (also discussed in Section 6.4 below).

#### **6.3.4 Women's suggestions for future integrated services**

Women were asked, with open questions then clarified and categorised by research officers, for suggestions as to which services would be valued if added to immunisation visits ('Well Baby Clinics'); noting these are the only routine preventive health services that are regularly available to families.

A high proportion of women responded to the question: over 92% at Delivery interviews and over 98% at One, Six and Twelve Month interviews. Although approximately 20% at each time point stated that they were unsure what to suggest or preferred to add no additional services.

*Types of additional services suggested, and proportions of women suggesting*

Figure 12 below charts the proportion of women making suggestions for services to integrate, noting women could offer more than one suggestion. These are presented in five categories of preference to contrast the proportion of women who were *unsure* or preferred no additional service; with proportions suggesting extra services for the *infant*, the *woman*, other *family* members (siblings or woman's partner), or other changes to *service delivery* arrangements.

Among additional services targeting the *infant*, the largest proportion of women suggested services for *illness care*, checks on *growth* (from One Month onwards), and education with *vaccination information*. Infant illness care requests emphasised thorough checks, with many responses including wording such as:

*“Do proper check up of baby, thoroughly check baby’s vitals for any sickness, and give treatment” (at One Month), or*  
*“Thorough check on growth, and advice on baby care” (at Six Months).*

Among additional services for *women*, higher proportions of women suggested *maternal illness care*, *family planning* counselling and services, and advice on *maternal nutrition*. The gaps in receipt of postnatal care in general and in follow-up of maternal infections or nutritional deficits reported in Section 6.3.3 were well recognised by many women, examples including requests for:

*“... advice on other diseases affecting mother ...” (at Delivery) or*  
*“... advice to mother on how to take care of herself after all the complications she went through (at Delivery), or*  
*“Check mother to make sure she’s good” (at One Month), or*  
*“Extend postnatal care for mum. After delivery mums must have a special check-up again” (at Twelve Months).*

Among *family care* preferences, the highest proportion suggested advice on disease prevention, for example: *“any health talk that will help us mothers help our family” (at Six Months)*, sometimes with specific mention of sexually transmitted infections, tuberculosis or HIV. Lesser proportions sought vaccination or illness care of siblings, or sexual health or family planning counselling for partners.

The quantitative categorised data on suggestions for integrated care were examined for associations with women’s number of pregnancies, educational level or rural location (see Table 10). It was hypothesised, for example, that first time mothers or less educated women may make fewer suggestions, or that rural women may request specific services or more services overall. After exploring with standard tests of association in Stata 15.1, including univariable and



multivariable logistic regression, there were very few significant associations with any of these factors. The only association of note was that women in their first pregnancy were slightly more likely to suggest an “Unsure” response at Delivery, but this trend did not persist at later time points. Because the data are descriptive, further statistical comparison between groups was not performed.

#### *Variation in frequency of suggestions across the life course*

Figure 13 also demonstrates that the frequency of some, but not all, suggestions for integration varies with the point in the life course that women were interviewed.

At Delivery, 24% of women proposed checks on *maternal illness* to be integrated with immunisation visits, the second highest proportion at this time point (after vaccine education). This proportion was lower at later time points, less than the three common infant service suggestions and similar to requests for advice on disease prevention for the whole family. In contrast, the proportion of women requesting *family planning* services to be added remained relatively constant; approximately 10% of women suggesting this at each time point.

For additional infant care preferences, the proportion suggesting *illness care*, and checks on *growth*, increased from Delivery to Twelve Months. Overall, the proportion of women suggesting additional services for the baby was greater than those suggesting services for the woman or other family members.

The statistical significance of trends in the four preference categories noted above were tested using a generalised linear latent and mixed model.<sup>456§§§§</sup> There was a significant decrease in the proportion of women offering ‘*Mother – illness care*’ suggestions from Delivery to One Month (Wald  $\chi^2(1)=7.95$ ,  $p=0.005$ ) but not from One to Twelve Months (Wald  $\chi^2(1)=3.21$ ,  $p=0.073$ ).

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§§§§ This used the gllamm package in Stata 15.1 ([www.gllamm.org](http://www.gllamm.org)), to account for the follow-up design, fitting a logistic regression model and Wald test comparing risk differences between discrete time points (Delivery, One and Twelve Months), with Poisson distribution and robust standard errors, generating a Wald  $\chi$  statistic for differences between time points.

There were significant increases from Delivery to Twelve Months for all of '*Baby – illness care*', '*Baby – check growth, feeding, care*' and '*Advice – disease prevention*' (Wald  $\chi^2(1)=171.35, 117.51, 11.49$ ;  $p=0.000, 0.000, 0.001$  respectively). There were also increases over the One to Twelve Month points for '*Baby – illness care*' (Wald  $\chi^2(1)=9.84, p=0.0017$ ), and for '*Advice – disease prevention*' (Wald  $\chi^2(1)=60.24, p=0.0477$ ) but not for '*Baby – check growth, feeding, care*'.

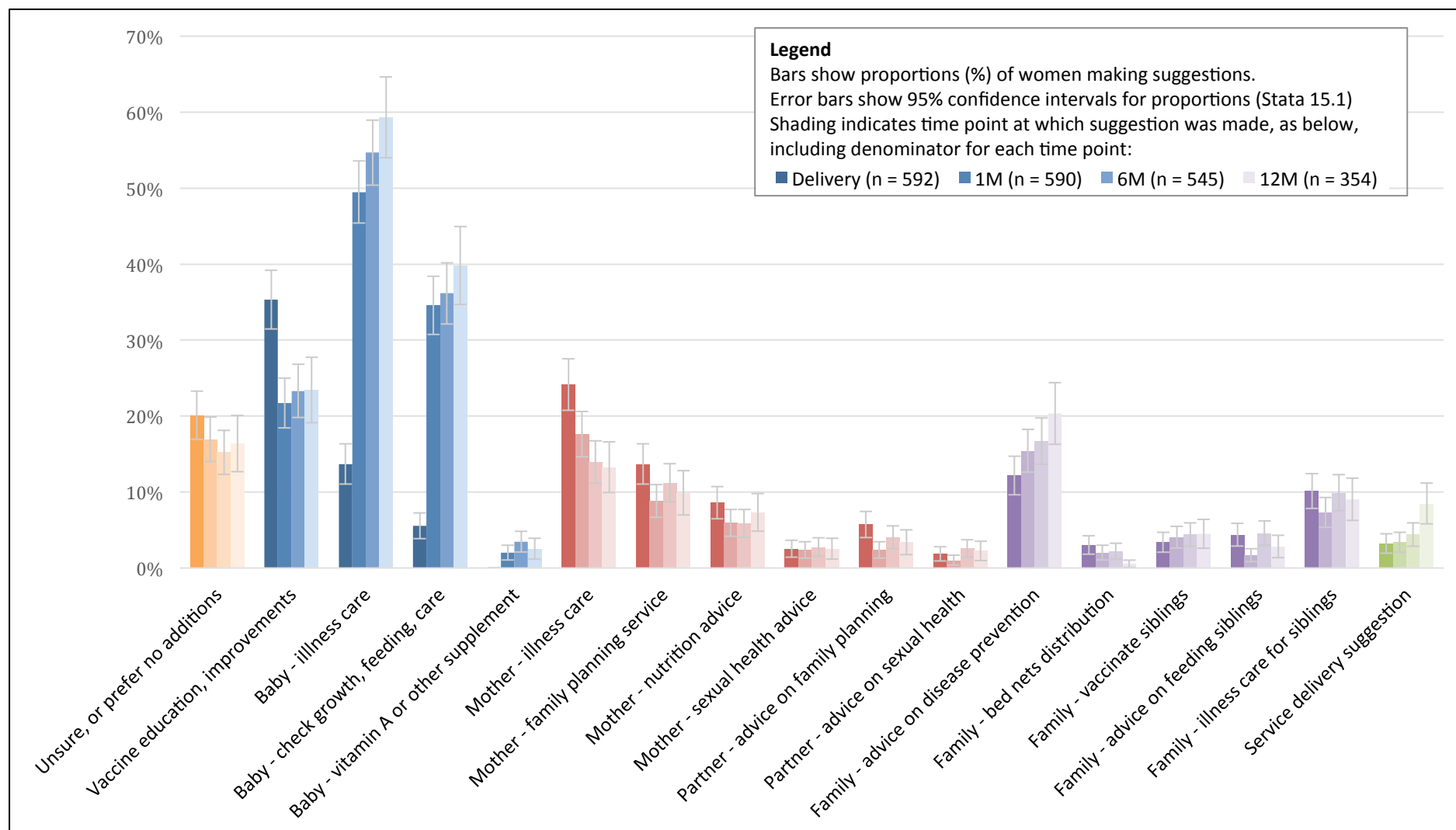
**Figure 13: Preferences for services to integrate with immunisation clinics, suggested by women at four time points**

**Table 14: Preferences for services to integrate with immunisation clinics, suggested by women at four time points**

| Category of suggestion                                      | Delivery<br>n=592 |         |       | One Month<br>n=590 |         |       | Six Months<br>n=545 |         |       | Twelve Months<br>n=354 |         |       |
|-------------------------------------------------------------|-------------------|---------|-------|--------------------|---------|-------|---------------------|---------|-------|------------------------|---------|-------|
|                                                             | %                 | 95% CIs |       | %                  | 95% CIs |       | %                   | 95% CIs |       | %                      | 95% CIs |       |
| <b>Preferred not to suggest or <i>unsure</i></b>            |                   |         |       |                    |         |       |                     |         |       |                        |         |       |
| Unsure or prefer no additions                               | 20.10             | 16.94   | 23.56 | 16.95              | 14.01   | 20.22 | 15.23               | 12.32   | 18.53 | 16.38                  | 12.68   | 20.66 |
| <b>Extra services for the <i>infant</i></b>                 |                   |         |       |                    |         |       |                     |         |       |                        |         |       |
| Vaccine education, improvements                             | 35.30             | 31.45   | 39.30 | 21.69              | 18.43   | 25.24 | 23.30               | 19.81   | 27.08 | 23.45                  | 19.13   | 28.21 |
| Baby - illness care                                         | 13.68             | 11.02   | 16.72 | 49.49              | 45.38   | 53.60 | 54.68               | 50.39   | 58.91 | 59.32                  | 54.00   | 64.48 |
| Baby - check growth, feeding, care                          | 5.57              | 3.87    | 7.74  | 34.58              | 30.74   | 38.57 | 36.15               | 32.11   | 40.34 | 39.83                  | 34.69   | 45.14 |
| Baby - vitamin A or other supplement                        | Not measured      |         |       | 2.03               | 1.06    | 3.53  | 3.49                | 2.11    | 5.39  | 2.54                   | 1.17    | 4.77  |
| <b>Extra services for the <i>mother</i> or partner</b>      |                   |         |       |                    |         |       |                     |         |       |                        |         |       |
| Mother - illness care                                       | 24.16             | 20.76   | 27.81 | 17.63              | 14.64   | 20.95 | 13.94               | 11.15   | 17.14 | 13.28                  | 9.92    | 17.26 |
| Mother - family planning service                            | 13.68             | 11.02   | 16.72 | 8.81               | 6.65    | 11.40 | 11.19               | 8.67    | 14.14 | 9.89                   | 6.98    | 13.48 |
| Mother - nutrition advice                                   | 8.61              | 6.48    | 11.17 | 5.93               | 4.17    | 8.15  | 5.87                | 4.05    | 8.19  | 7.34                   | 4.85    | 10.58 |
| Mother - sexual health advice                               | 2.53              | 1.42    | 4.14  | 2.37               | 1.30    | 3.95  | 2.75                | 1.55    | 4.50  | 2.54                   | 1.17    | 4.77  |
| Partner - advice on family planning                         | 5.74              | 4.01    | 7.93  | 2.37               | 1.30    | 3.95  | 4.04                | 2.55    | 6.05  | 3.39                   | 1.76    | 5.85  |
| Partner - advice on sexual health                           | 1.86              | 0.93    | 3.30  | 1.02               | 0.37    | 2.20  | 2.57                | 1.41    | 4.27  | 2.26                   | 0.98    | 4.40  |
| <b>Extra services for the <i>family</i></b>                 |                   |         |       |                    |         |       |                     |         |       |                        |         |       |
| Family - advice on disease prevention                       | 12.16             | 9.64    | 15.07 | 15.42              | 12.60   | 18.59 | 16.70               | 13.66   | 20.10 | 20.34                  | 16.27   | 24.91 |
| Family - bed nets distribution                              | 3.04              | 1.81    | 4.76  | 2.03               | 1.06    | 3.53  | 2.20                | 1.14    | 3.81  | 0.56                   | 0.07    | 2.03  |
| Family - vaccinate siblings                                 | 3.38              | 2.08    | 5.17  | 4.07               | 2.62    | 5.99  | 4.40                | 2.84    | 6.48  | 4.52                   | 2.61    | 7.24  |
| Family - advice on feeding siblings                         | 4.39              | 2.89    | 6.37  | 1.69               | 0.82    | 3.09  | 4.59                | 2.99    | 6.70  | 2.82                   | 1.36    | 5.13  |
| Family - illness care for siblings                          | 10.14             | 7.82    | 12.85 | 7.29               | 5.32    | 9.69  | 9.91                | 7.53    | 12.73 | 9.04                   | 6.27    | 12.52 |
| <b>Other suggestion, especially <i>service delivery</i></b> |                   |         |       |                    |         |       |                     |         |       |                        |         |       |
| Service delivery suggestion                                 | 3.21              | 1.94    | 4.97  | 3.39               | 2.08    | 5.19  | 4.40                | 2.84    | 6.48  | 8.47                   | 5.79    | 11.88 |

Many women did not give consistent responses across time points. Table 15 below shows that, for more frequently suggested service categories, between 22% and 57% of individual women changed their response from making a suggestion to not making a suggestion in a particular category, or *vice versa*, between time points. Statistical tests of this agreement across time points were not performed because of the descriptive nature of the data. For this reason, the proportions in the main chart (Figure 13 above) should be read as indicating measures across the whole cohort at different stages in their life course, rather than changes in preference for individual women.

**Table 15: Consistency of individual women's responses across time points for three categories of suggestions**

| Differences between:                   |                              | Delivery and One Month | Delivery and Six Months | Delivery and Twelve Months | One Month and Six Months | One Month and 12 Months | Six Months and 12 Months |
|----------------------------------------|------------------------------|------------------------|-------------------------|----------------------------|--------------------------|-------------------------|--------------------------|
| Number responding at both time points: |                              | 540                    | 488                     | 327                        | 510                      | 333                     | 323                      |
| Suggestion category and consistency:   |                              | Proportions (%)        |                         |                            |                          |                         |                          |
| Unsure, or prefer no addition          | Not suggested at either time | 68.7                   | 67.6                    | 66.4                       | 73.1                     | 72.7                    | 71.5                     |
|                                        | Suggested at both times      | 6.1                    | 3.3                     | 4.6                        | 4.7                      | 5.4                     | 3.4                      |
|                                        | Changed response             | 25.2                   | 29.1                    | 29.1                       | 22.2                     | 21.9                    | 25.1                     |
| Baby illness care                      | Not suggested at either time | 45.4                   | 39.8                    | 35.2                       | 24.1                     | 22.2                    | 18.9                     |
|                                        | Suggested at both times      | 10.0                   | 8.4                     | 7.7                        | 29.4                     | 34.2                    | 34.7                     |
|                                        | Changed response             | 44.6                   | 51.8                    | 57.2                       | 46.5                     | 43.6                    | 46.4                     |
| Mother illness care                    | Not suggested at either time | 63.3                   | 65.2                    | 66.7                       | 71.6                     | 73.0                    | 77.1                     |
|                                        | Suggested at both times      | 5.4                    | 2.7                     | 3.4                        | 3.3                      | 3.3                     | 2.2                      |
|                                        | Changed response             | 31.3                   | 32.2                    | 30.0                       | 25.1                     | 23.7                    | 20.8                     |

Note: Cells show proportions of women, for three categories, who provided responses at two time points. Proportions are those who either a) consistently did not provide a response or b) consistently provided the same response, or c) responded differently at the two time points.

*Additional suggestions captured in qualitative open text fields*

There were more than 100 additional suggestions from women that went beyond the classifications anticipated in the data collection tool. Beyond that, other proposals from women included:

- Advice on child-care (including umbilical cord care) and child rearing in general (including stimulation of development);
- Cancer screening services (usually breast or cervical);
- Healthy cooking advice for families;
- Advice and commodities for improved water and sanitation;
- Suggestions on how to involve a male partner, noting he often helps with transport to a Well Baby Clinic;
- More screening tests for common diseases; and
- Concerns for maternal mental health and well-being, and special supports for younger mothers.

A proportion, increasing at Six and Twelve Months, made specific suggestions for improved service delivery, including:

- More reliable clinic timing and sites, with one quotation illustrative of many *“I went to [X] clinic for immunisation but was sent back by a nurse and told to go back this week” (at Six Months)*;
- More reliable medical supplies, with women reporting missed vaccination or treatments due to stock outs;
- Abolition of any fees for preventive services, for example requests to *“Give free medications for children so parents don’t have to pay for them”* or *“medicine should be given free at baby clinic, children don’t work for money” (both at Twelve Months)*;
- More community-based outreach, including outreach visits to community sites and vaccination on market days; and
- The institution of ‘Well-Woman’ or ‘Well-Man’ clinics to supplement the ‘Well Baby Clinic’, for example *“Men’s health advice needs to be in place” (at Twelve Months)*.

Improved communication and education, including but going beyond health prevention topics, was a consistent theme. Some illustrative suggestions included: “Any health talk that will help us mothers help our family” (at Six Months), “Awareness on new emerging diseases” (at Twelve Months), “Explain what vaccination was given and what it does” (at Six Months); and “Give advance notice of future clinic times and dates” (at One Month).

A number of women, at all time points, requested more *time* from staff, a shift in *attitude*, and *infrastructure that allowed more privacy*; all to enable good quality counselling on sensitive topics such as family planning or sexual health. This theme also appeared, with greater strength, in responses to questions on the acceptability of adding extra services to immunisation, reported below.

Requests for a *greater number of screening tests*, usually blood tests, but also other biological samples such as urine or vaginal swabs, was an unexpected category of suggestion. This was repeatedly suggested by 2% to 5% of women at different time points (reported within the ‘Service delivery suggestion’ category in the figure and table above). Women usually referenced the additional POC tests done as part of the HMHB research program, and often mentioned specific illnesses of concern including *malaria, tuberculosis, anaemia, and sexually transmitted infections*.

### **6.3.5 Acceptability of integrated services**

#### *Overall acceptability of proposed integration of services*

Women were specifically asked to raise any good or bad aspects about integrating other services with immunisation clinics. They were presented with the example of adding family planning counselling and services to immunisation when this question was asked. As seen in Table 16 below more women offered positive opinions than negative and a consistent proportion (58% at One Month, 51% at Six and Twelve Months) offered no negative opinions about integration even when prompted.

Overall the acceptability of integrated services was reported as high, with 75 to 83% of women seeing this as a good change, with positive opinions

sustained through the three time points this was tested. Many women welcomed the potential inclusion of maternal health concerns, for example: *“would be good for mum’s health, having babies is hard work”*, *“good because many mothers come to the baby clinic”*, *“convenient to check mother and baby”* (all at One Month), or *“convenient for mums, spacing is important, allows baby to grow well”* (at Six Months). Certain women were seen as more vulnerable, with potentially more to gain: *“good to help teenage mums so they planned and avoid unplanned pregnancies”* (at Twelve Months). Additional detail on why integrated services were valued is provided in a later section.

**Table 16: Positive and negative opinions provided by women, on integrating FP and EPI services at different time points**

| Category of opinion and time point | Number of women | Proportion (%) | Total |
|------------------------------------|-----------------|----------------|-------|
| <i>Positive opinion given at</i>   |                 |                |       |
| 1 month after childbirth           | 492             | 83.4           | 590   |
| 6 month after childbirth           | 430             | 78.9           | 545   |
| 12 month after childbirth          | 264             | 74.6           | 353   |
| <i>Negative opinion given at</i>   |                 |                |       |
| 1 month after childbirth           | 147             | 24.9           | 590   |
| 6 month after childbirth           | 143             | 26.2           | 545   |
| 12 month after childbirth          | 117             | 33.1           | 353   |

An important proportion of women (25-33%), as seen in the table above, did raise concerns regarding integrating other services, particularly family planning services, when asked to consider this. Some women stated this unequivocally, for example *“answer is ‘no’, these two clinics must be on different days”* (at Six Months).

A possible trend was observed whereby at later time points, more women suggest negative aspects of integrated services, and fewer provide positive opinions. When testing this trend (using the generalised linear latent and mixed model noted above) to compare One Month with Twelve Months the proportion of women offering positive opinions did decline significantly across the three time points, and the proportion offering negative opinions increased (positive opinion change Wald  $\chi^2(1)=9.67$ ,  $p=0.002$ ; negative opinion change Wald  $\chi^2(1) = 7.67$ ,  $p=0.006$ ).

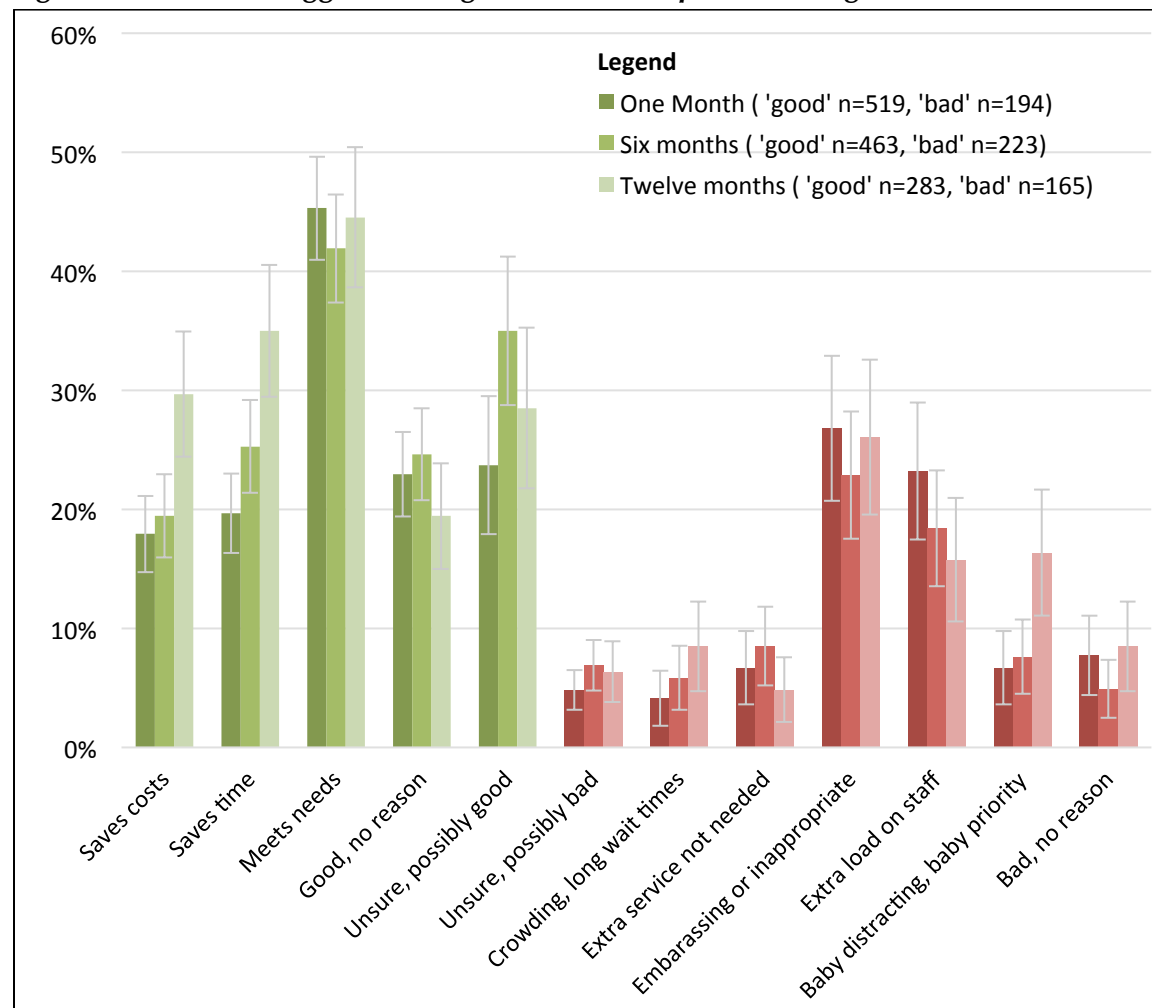


The characteristics of *women who consistently offered negative opinions* at Six and Twelve Months were explored with logistic regression, using univariable and multivariable models. There was no association with age, religion, parity, rural site, level of health service uptake, household expenditure, or enrolment site. There was an association with such women *having education higher than middle high school* (adjusted odds ratio 3.31, 95% confidence intervals 1.30-8.39,  $p=0.012$ ), and *if their male partner attended the ANC visit with them* (adjusted odds ratio 2.74, 95% confidence intervals 1.06-7.07,  $p=0.038$ ), estimated using a multivariable model that controlled for educational level, household expenditure (a proxy for wealth), age and enrolment site (a proxy for unmeasured socio-cultural determinants). It should be noted that many of these women also consistently offered positive opinions at these time points (noting that women had the opportunity to offer both negative and positive opinions).

*Reasons why women felt integrated services may or may not be valuable*

Women were also invited to suggest reasons why they felt integrating services like family planning with immunisation might be a good or a bad change. These were categorised during the interview with results presented in Figure 14 below. The many additional comments women provided were also captured, reviewed, and categorised by the researcher.

Overall, more positive rationales (519 at One Month, 463 at Six, 283 at Twelve) for integrated services were offered than negative rationales (194, 223, and 165 respectively).

**Figure 14: Reasons suggested for good and bad aspects of integrated services**

**Notes:** Chart shows proportions of opinions offered at each time point, with differing denominators for positive and negative opinions as indicated in Legend. Shading indicates time point. Error bars show 95% confidence intervals for proportions, calculated in Stata 15.1

The most common category of reasons for why women had a positive view was that integrated services would better meet their and their family's *needs* (42 – 45% of women at different time points). Typical examples of women's comments include: *"it's good so many mothers must know about family planning and other sickness"*, *"proper education regarding different types of family planning methods"*, *"good to emphasise on family planning because of land shortage"* or *"while mother is still breast feeding she will decide on what family planning method to use"* (all at One Month). A number of women at each time point noted that male partners often helped with transport to Well Baby Clinics and so

integration would offer an opportunity for partners to be involved in family planning education and services. For example, *“Most husbands are there so they can also hear about FP” (at Twelve Months)*.

Efficiency gains, such as savings in *time* (19 – 36% of respondents at different time points), or in *travel and related costs* (18 – 30%) featured next most commonly. Both these were relatively more frequently suggested at the Twelve Month assessment than at the One Month time points (McNemar  $\chi^2(1) = 195.98$  for time, 229.34 for costs,  $p=0.000$  for both). Illustrative comments include: *“convenient, saves the bus fare”, “very convenient for working mum”, or “yes as sometimes that’s the only time health workers see all mothers together” (all at Six Months)*. A consistent proportion (19 – 22%) felt the change would be good, but could not offer a reason why. A minority of women, less than 10%, responded to this question by saying they were not sure there was anything good in more integrated services.

When asked if there might be anything bad about proposed integration, the most commonly offered concerns related to *embarrassment* or the *inappropriateness* of discussing fertility at an immunisation clinic (23 to 27% of women suggesting this). Women offered comments suggesting inherent concerns or sensitivities about contraception: *“mums all joke around during family planning education” (at Six Months); “mums feel afraid because of adverse effects of family planning”; or “some health education messages makes mums confusion” (all at Twelve Months)*. Others in this category saw family planning as a personal and potentially sensitive topic, wanting *“family planning to be conducted at another day so I can go on my own” (at Twelve Months)*, or seeing it as *“bad when doing one by one family planning in front of other mums” (at Six Months)*. Some women raised the absence of *privacy*, which was not currently provided for in most clinics, as a major consideration in why this form of integration may not always be a good thing.

Other common categories of concern were *overload on staff* (16 – 23%), *longer wait times* or *over-crowding* (4 – 9%). Illustrative comments include *“do them on separate days because of long hours of waiting” or “these clinics usually*

*take long hours and if they are mixed would be even worse*". A particular concern raised by a minority related to the *need to prioritise baby care* at the time of immunisation, to manage crying or adverse effects such as fever: *"when the baby is vaccinated they will be irritable so I have to concentrate on baby only"* (at Six Months), *"because, I must take my baby home early after immunisation"*, or *"time for immunisation must be alone because we have to concentrate on our babies"* (both at One Month). A related concern was the potential that babies would distract from family planning discussions *"when baby cries, will disturb mum and she will not be attentive to family planning advice"* (at Twelve Months). This category of rationale was suggested more at Twelve Months (16%) than at One or Six Months (7 and 8%).

In contrast to the women who saw male partners' presence at Well Baby Clinics as a positive feature, others noted that, for example: *"it's not good because sometimes our husband goes with us so it will be embarrassing"*, or that the service should be on a *"different day so both couple can go together for family planning so baby won't disturb"*. Some noted objections from the male partner to family planning as potentially creating negative attitudes towards integrated clinics. This last item was carefully sought in the qualitative data, but was specifically expressed by less than 0.5% of women at any time point.

## 6.4 Discussion, women's experiences and preferences for integrating other services with immunisation

### 6.4.1 High unmet need for integrated services

#### *Co-morbidity and co-existing health needs demand more integrated care*

Our findings show a high proportion of women and infants carrying sustained health needs from pregnancy through the postpartum period. Over 89% of women had clinical or screening tests suggestive of co-morbidity at first ANC visit, 42% testing positive for a treatable sexually transmitted infection (mostly RTIs). By six months after childbirth, maternal illness was reported by 41% and infant illness by 82%. This burden complicates the health of mothers and babies presenting for routine preventive care in the first year after childbirth. The level is often under-recognised, as many of this study's measures are either inconsistently offered or not yet standard practice. The importance of malaria in pregnancy (likely 12% of this cohort<sup>455</sup>) is well established,<sup>454</sup> as is that of RTIs,<sup>457</sup> or under-nutrition.<sup>458</sup> Combinations of illnesses are also significant<sup>330</sup> and the critical role of multi-morbidity is gaining increasing recognition.<sup>328,459</sup>

Beyond co-morbidity, a number of routine family care needs besides vaccination were found. Education and commodities for family planning are needed by at least 72% of families, and many need advice on family sexual health, given how many women carry sexually transmitted RTIs (42% at ANC, over 22% at six months postpartum). These measures are consistent with STI prevalence estimates across PNG,<sup>206</sup> and reinforce the potential value of expanded POC screening, given the poor performance of symptom based management in PNG.<sup>460</sup>

The number of women and their infants with significant anaemia and other signs of under-nutrition show the need for counselling and care on nutrition, growth and development for both mother and baby. This health risk is seen in the high proportions of significant anaemia in both mothers (58% at ANC, 24% at one month postpartum) and their infants (26% by age six months), and in markers of acute malnutrition; with 9% of mothers with low MUAC at ANC) and 12% of infants with low weight-for-age by six months.

*Integration at immunisation is not meeting needs, or policy expectations*

Women and families are not receiving the range of integrated services that these needs demand, or that PNG health policy proposes; noting that the 2015 immunisation strategy termed SIREP<sup>277</sup> advocated a range of additional services to be added to immunisation (see Section 2.4.6, and Chapter Seven). These findings show that most services beyond vaccination at ‘Well Baby Clinics’ address only infant needs, and these incompletely. Only half of all infants were reported to receive weight or growth checks, and illness checks in just over one third; with even fewer reporting active advice on feeding (10%). Reported provision of vitamin A or anti-helminthics was similarly low, which is discouraging given this is PNG’s main policy target for integrated service provision.<sup>277</sup> Other care during immunisation clinics was rare; only 5% to 10% of women reported receipt of maternal nutrition advice, and less than 5% for any of family planning, maternal illness care, or sexual health counselling.

These low levels of integrated service by women’s report, for infant or mother, are remarkably consistent with those seen in structured observations of ‘Well Baby Clinics’ in ENB,<sup>461</sup> as reported in Chapter Seven, and less than reported from a similar community perspective study in Kenya, Mali, Ethiopia and Cameroon.<sup>142</sup> There is a stark contrast between the paucity of routine checks on the postpartum mother’s health, and the high burden of infections and nutritional deficits she is carrying. This deficit is not unique to PNG, with routine postnatal care struggling at the lowest coverage of all services across pregnancy and the first year postpartum in LMICs.<sup>462,463</sup> Missed opportunities for reproductive and sexual health care at the time of infant vaccination are also widely recognised in similar settings such as Senegal,<sup>417</sup> Ethiopia, Malawi or Nigeria.<sup>464</sup>

*The immunisation platform has potential, but must consider the demand-side*

The question arises, then, of what should and could be done at ENB’s immunisation visits, based on these findings. Consultations for the health services study in Chapter Seven confirms that there are no regular alternative platforms for routine preventive care offered to women in the critical

postpartum period. The families in this cohort did access infant vaccinations in high proportions, with over 90% making one or more visits to a static clinic or outreach immunisation session. This reinforces the potential of immunisation clinics as possible platforms to better address the unmet needs noted above. Measures of immunisation coverage have been promoted as ways to assess the size of potential gains: for multiple services,<sup>191</sup> for malaria prevention,<sup>465</sup> or for postpartum family planning.<sup>466</sup>

Taking family planning as an example, and noting that uptake of modern contraception by twelve months postpartum was limited to just over one quarter of women, this suggests that an additional 65% of women could be presented with family planning options if these were offered at immunisation clinics. Such expectations are clearly over-simplistic, and most of the 22 international experiences testing integration, presented in Chapter Five (see Table 5), have focused first on the supply-side issues of feasibility that would constrain potential gains. This supply-side orientation has been noted by other integration researchers.<sup>142</sup> The approach of this cohort study, however, started with the demand-side, theorising that women's preferences and concerns will be just as important in determining whether and how integration can meet the service delivery gaps seen here.

#### **6.4.2 Women's preferences for and concerns on integration**

This study, uniquely in integration literature, started with a blank slate when seeking women's suggestions for integrated care at immunisation clinics. Women's responses show that many understand the extent and nature of their unmet need, as one suggested in an open text comment that they: "*... need care for mum's health, having babies is hard work*" (at One Month).

*Women's preferences for integration go beyond current policy and practice*

Many of women's suggestions are only partially matched by current practice (as shown above), or by current policy; noting that the SIREP Plus<sup>277</sup> (see Section 7.3.1) priorities for integration were vitamin A, an anti-helminthic (albendazole), growth monitoring and limited illness care for the baby. Women

already echo national policy aspirations for good checks on infant illness, growth and feeding, as displayed in Table 17 below, which ranks the categories of suggested extra services for different time points (based on Figure 13, Section 6.3.4).

The major contrast between policy and women’s preferences relates to services addressing women’s own needs, including maternal illness care, support with family planning, and advice on maternal nutrition and other reproductive health. This contrast is strongest at the Delivery time point, as displayed in Table 17 below. The suggestions on maternal health priorities also closely echo comments from focus group discussions with care-givers visiting immunisation clinics in the health services study reported in Chapter Seven (Section 7.4.1)

**Table 17: Rankings of women’s preferences across time points**

| Delivery                      | One Month                     | Six and Twelve Months         |
|-------------------------------|-------------------------------|-------------------------------|
| Education, vaccines           | Illness care, baby            | Illness care, baby            |
| Illness care, mother          | Growth and feeding, baby      | Growth and feeding, baby      |
| Family planning               | Education, vaccines           | Education, vaccines           |
| Illness care, baby            | Illness care, mother          | Education, disease prevention |
| Education, disease prevention | Education, disease prevention | Illness care, mother          |
| Illness care, siblings        | Family planning               | Family planning               |
| Growth and feeding, baby      | Illness care, siblings        | Illness care, siblings        |

Note: Boxes show categories for the top seven additional services, ranked by proportion of women suggesting at each time point. Colours distinguish whether oriented to baby, mother, or family (see Figure 13). Arrows show change in ranking for selected categories.

Table 17 also demonstrates the shift in women’s attention, when asked the same question at different points in the life course, from maternal to infant and family health. Nevertheless, the cohort study’s longitudinal data show maternal morbidity, and need for preventive health care such as family planning, do persist through the first year after childbirth. Internationally, reviews,<sup>33</sup> individual studies<sup>333,334,417,467</sup> and development initiatives<sup>468-470</sup> have demonstrated



women's interest in receiving counselling on postpartum contraception and reproductive health, however few reports have shown the importance to women of maternal illness care that is demonstrated in these findings. Ryman and colleagues<sup>142</sup> did record an Ethiopian community health worker valuing the integration of services mostly because it allowed them to meet the mothers' needs simultaneously with those of the infant. In the same study, when suggestions on adding services were offered in Cameroon, women suggested family planning and men suggested incentives for improved nutrition.

*Women prize good communication and health education*

Women in the ENB cohort place a high priority on health education in general, with vaccine education a first priority consistently across time points. One woman's comment on this need is typical of many: *"we want more awareness on the names of the vaccines and what they are used for"*. Observations of immunisation sessions reported in Chapter Seven suggest that absence of good communication between staff and clients is a common gap in service quality.

The next highest health education priority was disease prevention for the whole family, with specific mentions of malaria, HIV, tuberculosis, and other infections, suggestions repeated in women's requests for an expanded suite of screening tests. After this came issues of nutrition, then reproductive and sexual health for women and male partners. Noting these suggestions were in response to open non-leading questions, this demonstrates the level of awareness that women have regarding the health threats in their physical and social environment, as well as their role in managing the whole family's health. This desire for information as much as service provision is seen in sub-Saharan African and south Asian settings similar to PNG, across general MCH topics,<sup>142</sup> nutrition,<sup>339,419,471</sup> malaria control,<sup>141,348,425</sup> HIV,<sup>332,416,472</sup> and WASH.<sup>356,473</sup>

*Acceptability of integration is good overall, but specific concerns are important*

Overall acceptability of integration as a concept is high; *women's opinions on the prospect were more often positive than negative* at all time points. The trend for more negative views on integration to be voiced at later time points is

interpreted as women feeling freer to offer suggestions as time passes after childbirth, given that the women who offered critique commonly specified positive aspects of integration as well, and that the only distinguishing characteristic of women offering negative opinions was a slight trend to being better educated.

More women value integration for its potential to meet family health care needs than for savings in time and money, although the latter are seen as important. This emphasis on meeting multiple health needs reflects the earliest rationales for integrated services, as seen in PHC<sup>101</sup> or IMCI,<sup>109</sup> and was reinforced by the free text comments of many women in this study, as presented in Section 6.3.5 above. Some others have similar findings: with community informants valuing “*more holistic treatment*” in Cameroon,<sup>142</sup> benefits to the whole infant in Lao PDR,<sup>474</sup> and to the whole family in Malawi<sup>470</sup> (when combining family planning with immunisation). Such reports are less common, however, than the savings in time and money offered by receiving multiple services at one clinic visit. This emphasis was noted in all of the reports above, as well as in other community viewpoints<sup>140,142,322,339,419,471,356,473,475</sup> and the findings in Chapter Five (Section 5.3.5); all of which attribute the acceptability of integration to clients’ appreciation of such savings.

Others have also noted the potential of positive community attitudes towards vaccination in boosting acceptability of linked services that are undervalued, such as preventive malaria treatment,<sup>476</sup> or stigmatised, such as HIV or family planning.<sup>142</sup> This theme, however, was not apparent in the ENB cohort of women reported here.

The concerns of women in this cohort have important implications for any attempt at integration. *The primary concerns relate to services that are potentially sensitive*, particularly family planning in the ENB context, and the perceived difficulty in achieving private, personal counselling and services during immunisation clinics. Many women added detail to their concern categorised as ‘embarrassment’ with observations on the attention needed by infants in Well Baby Clinics, and the potential disturbance of crying. Such

concerns have also been seen by others,<sup>334</sup> including a detailed study by Pfitzer and colleagues (still under review<sup>477</sup>) in Kenya and India of client views on successful integration experiences. They found privacy and infrastructure to support counselling to be a key discriminator between well and poorly integrated facilities in India, along with staff with sufficient training to provide contraceptive services. Similar requirements in facility layout pertain to HIV integration experiences such as in Malawi<sup>341</sup> and South Africa.<sup>472</sup>

*These concerns seem to relate much more to the need to achieve a satisfactory standard of care,* rather than an inherent lack of acceptability of an addition like family planning, either as an intervention in its own right or as an accompaniment to immunisation. Some women in ENB offered opinions distrustful of contraception, quoting rumours regarding adverse effects or religious prohibitions, but these were a small minority. Pfitzer and colleagues in Kenya and India, as with reports from Liberia,<sup>334,475</sup> also reported a minority who felt discomfort with contraception as a practice, but this did not preclude a successful integration experience.<sup>33</sup>

It was notable that the prospect of *long wait times, or the staff overload that could lead to this,* ranked slightly lower as a potential drawback to integrated services for ENB women, although it was important to many. This is more often the prime concern in other settings, especially for services where counselling was important such as HIV<sup>332,416</sup> or postpartum family planning.<sup>469,475,477</sup> It may be that not all immunisation clinics in ENB were so crowded that this was a concern; a topic assessed in the health services study (Chapter Seven).

*Male partners' attitudes* to potentially sensitive services were important in the reports just cited, and in our study population. Women in ENB took contradictory positions on this. For some the presence of men in immunisation clinics would inhibit uptake of family planning; for others the fact that men accompanied women to clinic, and could thus potentially share in a family planning or other family-oriented service, was a clear benefit. There are few studies in LMICs on male involvement in immunisation. One in Nepal<sup>478</sup> found men present at 39% of ANC clinics, but only 10% of immunisation; similar low

involvement was seen in Uganda<sup>479</sup> and the health services observations in ENB reported in Chapter Seven. It was notable (see Section 6.3.5) that women in this cohort who were prepared to provide repeated critical opinions on integration (and positive opinions as well) were both more likely to have had a male partner present at their ANC enrolment visit, and to be better educated.

Women in ENB had a range of *suggestions on how service delivery could be improved* (Section 6.3.4), however most of these, such as removing fees or ensuring reliability of clinic timing or medical supplies, related to broader issues in the health service, rather than the integration process itself. Such perspectives are aired in many sites when women are given the chance to comment on service delivery, including India, Kenya, Mali, Ethiopia and Cameroon.<sup>142,477</sup>

### **6.4.3 Implications of women's views for integration policy and practice**

It seems that some of ENB women's highest priorities for integration with immunisation would be the toughest to implement, that is: *high quality client communication and health education* ranging across vaccines, disease prevention, nutrition, family planning and sexual health; and *effective illness screening and management* for mothers, infants and their siblings.

Some of these are already called for in immunisation guidance in PNG,<sup>277</sup> more are advocated by national health leaders,<sup>278</sup> and others go beyond current policy calls, notably the demands of *maternal illness* screening and management. This also calls for a need to offer a range of service delivery options to respond to client preferences. The discussion below on implications for change is organised by the categories in the conceptual framework for this research (Section 3.1.4, Figure 5).

#### *Implications for what care is provided (the package) alongside immunisation*

Starting with less complex interventions that are already included in current immunisation policy, there is *room to improve vitamin A and anti-helminthic administration* alongside vaccination. These specific interventions were infrequently recognised by women, and inspection of home-based records ('baby books') confirm low coverage. Women value nutrition interventions, so

their addition would be welcomed if better understood, and some community education on both commodities may boost uptake. For malaria control, distribution of ITNs was noted by a low proportion of women and while valued, other international evidence<sup>389,391</sup> suggests alternative distribution channels may be more effective. For these linked interventions, broader supply-side changes are more relevant as discussed below.

Many women are seeking *stronger support for child nutrition, growth and development*. A high priority would be consistent checking of weight to improve from half to all infants. However this will be ineffective without a major increase in regular counselling on feeding that, according to WHO<sup>109</sup> and PNG<sup>480</sup> guidelines, should be offered to care-givers of all infants under two years. Given that a number of women sought advice on general (non-health) care of the baby, this raises the potential of adding advice on stimulation of early childhood development using the interventions of proven power<sup>121,123</sup> that WHO has streamlined<sup>481</sup> for child health clinic settings.

Other *frequently requested education topics included vaccination and disease prevention*, noting women mentioned common concerns such as *malaria, HIV and tuberculosis, as well as sanitation and hygiene*. Education on vaccinations given, and timing of the next visit, is already an essential element of good quality immunisation<sup>482</sup>; with implementation investigated further in the health services study (Chapter Seven). Including other topics of nutrition, child development and family disease prevention represents a call to *use immunisation sessions for individual and group education purposes*. This requirement is already well established in policy, but poorly so in practice (as seen in these data and in Chapter Seven). Their inclusion would add significant demands in skills, time and organization, as discussed below.

Screening for childhood illness is well established as part of immunisation sessions, and was reported relatively frequently. What women sought was *more thorough clinical checks*, and more ready access to treatment. For maternal illness, given the high prevalence of chronic infectious and nutritional morbidity,

adding screening services or follow-up of known problems would make a powerful addition to immunisation visits for many women.

Offering *family planning, and possibly sexual health counselling*, as an option at immunisation clinics is the final major integration request. It is notable that some women (around 4%) did report receiving this, as some reports note it as existing policy in selected facilities in PNG (see Section 2.4.6). This has high public health impact, given the ideal timing of immunisation clinics for contraception to delay the next pregnancy. The models of integration noted in Chapter Five (Section 5.3.4) offer options to be explored in ENB, discussed further below. Both family planning and illness care present new levels of integration challenge; like expanded education, they are dependent on staff skills and clinic capacity.

#### *Implications for who provides care*

No women in our study specifically envisaged the integration model of co-location of service providers that, as seen in Chapter Five, has been key to the integration of HIV and family planning services in other settings. Professional nursing staff are the backbone of ENB immunisation clinics, as detailed in Chapter Seven, and many of this cadre already provide family planning, illness care for women and infants, as well as health education in general. The difficulty, well recognised by women in this study, is the risk of staff overload, with possible longer wait times in clinic. Such concerns are common in other settings, including Ryman and colleagues' four country study,<sup>142</sup> which also noted an urban-rural divide in Mali wherein urban women preferred rapid services over protracted visits, while rural women were willing to stay for longer if comprehensive care was provided. This differentiation was not detected in ENB. Across the whole cohort, the desire for family needs to be met is balanced against the dislike of long waiting times and slow clinics. This suggests that integrating significant clinical care would require allocation of additional professional nursing staff, possibly with specialised training in the linked service, with a team or co-location approach. The exception may be for those

immunisation clinics that are seeing relatively few children; this is the case for a proportion of ENB clinics, as described in Chapter Seven.

In rural India,<sup>471</sup> successful integration of nutrition education required an extra non-vaccinating health worker. In that setting a trained lay health worker was dedicated to the education task, an approach also found successful for nutrition and family planning in Sierra Leone,<sup>339</sup> and for WASH in Kenya<sup>356</sup> (see also Section 5.3.5). The 'Village Health Volunteer' cadre has demonstrated similar capacity in a number of sites in PNG,<sup>225,483</sup> including in ENB and may play a critical role in this aspect of integration. Several decades of PHC evidence have demonstrated the contribution of trained lay health workers (often termed CHWs outside PNG) to immunisation coverage<sup>484</sup> and maternal and child health.<sup>114</sup>

#### *Implications for where and when services are delivered*

A critical constraint on family planning is sufficient privacy and lack of distraction to enable counselling. This could also apply to other individual health education, and likely some aspects of maternal illness care. Women's reports show that such privacy is commonly lacking and changes to the use of existing clinic rooms would be required, similar to that which has been undertaken in PNG over the past decade to facilitate HIV counselling and testing. Privacy has been a critical determinant of success elsewhere,<sup>333,334,477</sup> as discussed above.

Many women welcomed, and encouraged, expansion of the current practice of immunisation through community outreach clinics. As these are commonly in rudimentary shelters or open air, this would limit integration of additional services requiring privacy, or with significant equipment or commodity needs. Comments from women suggest some would be willing to give up substantial amounts of time to ensure a broader range of family needs were met, raising the possibility of tailoring centrally located care for women who travel long distances, perhaps on market days and sites. For both forms of service delivery, women repeatedly requested more reliable timing and notice.

Some aspects of illness care requested by women will not match well with the scheduled nature of immunisation services. Acute illnesses, such as pneumonia or diarrhoeal diseases in childhood, are not well managed at monthly

or less frequent routine clinics. Schedulable services are better suited to chronic illness management tasks such as clinical or POC test screening, follow-up after treatment (such as anaemia, obstetric complications, or RTIs), or to check for recurrences (such as with STIs). It is notable that many of these are more relevant to maternal than child ill health.

### *Implications for community engagement*

Many women's requests for information and education, on vaccination and other topics, highlight the need for stronger community engagement whether for immunisation or other services. Involvement of lay health workers (VHVs) drawn from local communities, as discussed above, provides a clear starting point for this, with examples from within PNG and internationally. The 'Missed Opportunities in Maternal and Infant Health' program<sup>485</sup> for four countries in sub-Saharan Africa saw the CHW as a bridge between community and health service, and a key element in building a platform for postpartum care that was structured around community demand. This approach to integrated services is echoed in many development initiatives assessed in the evidence review in Chapter Five (Section 5.3.5).

Engaging and educating clients as a form of integrated service may include making better use of unavoidable waiting times for group education. Assessments presented in Chapter Seven suggest that client engagement would benefit from better communication tools and education resources, such as job-aids, checklists and client-directed information products. Some of these have been demonstrated in ENB for antenatal education,<sup>486</sup> but not yet in infancy services. Topics like family planning, based on the results above, clearly need sensitive, well-planned products tailored to local sensitivities. Good formative evaluation for communication materials was important in Liberia<sup>334</sup> and Senegal.<sup>333</sup> Also in Senegal, Ideas42<sup>487,488</sup> used behaviour change theory and in-depth client research based on human-centred-design to develop materials adapted to the preferences of immunisation clinic clients, and front-line staff.

A key aspect of engagement discussed earlier in this section is the need to involve men, especially male partners, in a way that acknowledges the variety of



women's preferences on this. This may involve education sessions tailored to men, something that has proven successful in ENB for antenatal education, and tools oriented to men for discussion of family planning or sexual health from that source may be suitable to immunisation integration. Individual counselling, if pursued as an integrated service may also allow for involvement of men, especially if drawing on the evidence base<sup>489</sup> of interventions that can support communication and decision making for couples.

*Implications for broader health services and system*

Better integration of less complex commodity distribution at immunisation (vitamin A and anti-helminthic) depends more on supply-side issues of health worker practices or medical supplies reliability; topics investigated in the health services study (see Chapter Seven). Other commodity distributions targeting malaria control, would be welcomed by women, noting high recognition of the threat malaria poses, including intermittent preventive treatment of infants. Although proven in PNG,<sup>490</sup> this is not yet part of standard practice so its deployment raises a provincial or national policy question.

Illness care and family planning, as noted above, would require careful review of human resource allocations if integrated care is to be realistically attempted, with consideration of extra staff for busier clinics. Women's requests for treatment to be provided in clinic (rather than needing referral to private pharmacies, for example) and at lower cost, also raise broader system issues including the reliability of medical supplies, as well as budget allocations and supervision to enable PNG's policy for free PHC.<sup>242</sup>

Illness care also raises the challenge seen in women's requests for broader screening. Some screening tests (anaemia, malaria, syphilis, HIV) are already available, however the expanded suite of RTIs remains restricted to research programs at present. If, as seems likely, expanded screening for such common infections is judged as cost-effective,<sup>450</sup> this will become a subject of national policy discussion.

*Varied service offerings at different time points*

The trends over time clearly show a shift in women's priorities and preferences at different points in the life course; maternal health and illness feature more strongly in the early postnatal period, while child development looms larger from six months onwards. This could make a case for more differentiated routine care at different points in the life course, for example for clinics that address issues of both mother and early infancy in the first six months after childbirth offering a different range of services from those for mothers with older infants. The potential gains in this approach would need to be offset against the resources required, and the added programmatic complexity of specifying clinics as relevant to certain infant age ranges. The most important specialised service, in terms of promotion of maternal or child survival, and in improved development for the child, is that for the early postnatal period, as discussed below.

*Postnatal care needs special consideration*

The analysis in this section has focused on integration of other services with immunisation during infancy, that is, the post-neonatal period from one month and later. However, many women's responses also illuminated the pressing need for better routine postnatal care, especially in the first week after childbirth. Most women in this cohort delivered in a health facility and the high uptake of birth-dose vaccination against hepatitis B suggests this was well integrated into pre-discharge care in the facility. However many women's reports of services received suggest significant gaps in pre-discharge postpartum maternal health care and, after returning home, very few received routine checks. The, admittedly unrealistic, national newborn health policy<sup>268</sup> call for three routine checks in the first week of life is rarely followed. This misses opportunities to follow-up on the many postpartum complications or other illnesses that complicate women's early postpartum period, as well as assessing danger signs in the newborn infant. Further discussion of this critical window for more integrated preventive care for mother and baby is taken up in Chapter Seven.

#### **6.4.4 Limitations and strengths of the cohort study**

##### *Limitations and their mitigation*

A number of limitations need to be borne in mind when considering generalisability of these findings. The participants in this cohort are already health system users, given recruitment at ANC clinics, and showed higher uptake of facility-based childbirth and vaccination than background provincial or national rates. Thus responses may omit some socio-cultural or geographic barriers to care. This was mitigated partly by ensuring inclusion of small and rural facilities. Secondary analysis showed that balanced rural-urban representation was maintained up until the Six Month follow-up point, although at Twelve Months, when there had been greater loss to follow-up, there was a bias to more urban participants being retained. The findings are still felt to be representative of most women in ENB, given that administrative data showed coverage of over 80% of at least one ANC visit at the time of commencement. It is also noted that the range of responses reflected a healthy critique of health services and variety of comment on access barriers. Noting the varied views of women on the involvement of men in maternal and infant care, the omission of structured interviews with men, especially fathers, is also a limitation; their voice would be important to future research on this topic and they were omitted here simply because of constraints on research resources.

These data were collected in ENB province, and thus reflect the social and physical aspects of that setting; important given the intense diversity that characterises PNG. Potential applications of these findings, as discussed above, should consider the effect of local attitudes to issues such as family planning, and the fact that ENB health facilities are relatively more accessible when compared to the most remote settings in PNG.

The questions utilised here were part of a larger bio-behavioural questionnaire, administered through structured interview by local research officers. The research officers bring the perspective of professional science or

health care training to their interpretation and classification of women's responses. Social acceptability bias may also affect women's responses if they perceive research staff as allied with the health system. This was mitigated with the use of research officers fluent in Tok Pisin and local languages (where possible), and recruiting staff familiar with ENB communities wherever possible. Research staff were trained in interview skills and the use of non-judgemental encouraging probes; all were clearly identified as researchers distinct from and independent of usual health services. A further corrective was the inclusion of frequent additional 'open' questions throughout the interview (see question guide examples, Appendix 10.3.1), which were used to capture free text responses from women. Limited thematic analysis of these allowed cross-checking of the patterns of response recorded in structured interview responses. Although the study did not have a formal qualitative design, it is felt this approach did allow qualitative contributions; the usefulness of these questions was affirmed by the significant number and variety of open responses offered by participants.

Some responses on services provided and history of illness were dependent on women's recall, with the limitations that brings. This was countered with checking of home-based records ('Helti Mama Buk' and 'Helti Beibi Buk') wherever possible. Observation of clinic processes undertaken in the health services study (see Chapter Seven) also allowed cross checking of women's reports of services provided and their degree of integration.

### *Strengths*

A major strength of this study was the open design that was inclusive of most possible disease and health care priorities likely to affect women and families in this setting. Among the number of studies researching client perspectives on integrated services cited in this chapter and Chapter Five, relatively few<sup>127,142,444,468,469,477,487,488</sup> carefully examined client opinions on service delivery options. Of these, none apart from Ryman et al<sup>142</sup> assessed more than one option for a linked service. Others were restricted to a specific pre-identified integration priority such as HIV or family planning. The cohort study in this

research is, to our knowledge, unique in seeking women's preferences for integration with an open agenda for their suggestions.

Taking the 'woman's perspective' rather than a specific disease focus was a deliberate choice by the senior investigator team (which included the author of this thesis) to try to understand the latitude of health threats operating in ENB communities. This breadth of purpose rendered the study ideal for assessment of the potential of integrated services. In addition, there are few studies in PNG or similar settings that have taken on the arduous task of long-term follow-up of a complete cohort, including mother and baby dyads. This allowed tracking of reports, opinions and preferences through a critical phase of the life course, to determine which were sustained, and which varied in expression at different time points.

## 6.5 Conclusions, demand-side perspectives on integration

The need for integrated care is high, for mothers and their infants, in those attending immunisation sessions at ‘Well Baby Clinics’ in ENB. Nearly every family has important needs for health advice, education or follow-up of illness. When alternative routine care platforms are absent, the failure to consider these needs at immunisation clinics is a missed opportunity both for program reach, and for quality person-centred care.

Women clearly recognise their high-burden environment, proposing: integration priorities as illness care for both mother and infant; education on vaccinations, the growth and development of their baby and better nutrition for themselves; advice on disease prevention (with mentions of malaria, HIV, tuberculosis, sanitation and hygiene); as well as family planning and other sexual and reproductive health care. These requests amount to a call for comprehensive preventive health care oriented to the whole family. There is an additional pressing need to develop preventive care platforms to reach women in the first week after childbirth with postnatal care.

Women view any form of integration positively, although they offer valid concerns such as privacy or staff overload that will constrain good quality services under current clinic arrangements. When assessing the potential benefits of integration they privilege holistic care over efficiency; although savings in time and money are also important.

There are options for more integrated services that respond to women’s preferences even within current clinic arrangements, through better distribution of high impact commodities and better communications relevant to existing infant care services. Responding to broader requests addressing the needs of postpartum women will require additional human resources, enlistment of community-based lay health workers, more reliable supplies and innovative communications tools. Given the complexity and demands in time and skill that some of women’s requests entail, co-location of services with additional staff and site may represent the only feasible way to meet these. It is notable that

some women advocated for a ‘Well Woman Clinic’ to accompany that for their baby.

Woman-centred integrated postpartum care in LMICs will require new policy settings and dedicated resources. This starts with a re-orientation of health service priority setting to start with clients’ priorities and their preferences for service delivery, rather than the coverage targets of specific programs. While this is a significant investment, it is likely that planners and providers will benefit if they heed women’s desire to better understand public health rationales and interventions. Making services more responsive to community preferences may be one route to building the demand and confidence that immunisation and other programs need for their success.

As shown in Chapter Five, integrated services work best when resourced to provide holistic care, rather than being seen as a means to stretch scarce resources. For future developments in ENB, this raises important supply-side questions to complement the women’s perspective presented here. Chapter Seven presents the cross-sectional health services study, which includes assessment of how strong immunisation services currently are, observation of clinic services that may be compared to women’s report, and front-line health providers’ views on opportunities for more integrated care.

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## 7 HEALTH SERVICES FOR POSTNATAL AND INFANCY CARE IN EAST NEW BRITAIN PROVINCE, PAPUA NEW GUINEA

This chapter describes the two phases of the health services study, including some details on methods to complement Chapter Four. While aspects of the study extended beyond measures of integrated service delivery, the results and discussion in this chapter are focused on the study's implications for integrated delivery of immunisation and other services. There are five sections:

- Section 7.1 provides a description of the *overall health services study approach*, its two phases and their timing.
- Section 7.2 reports on phase one, *national and provincial consultations on immunisation services*, which helped frame the assessment of health services in ENB.
- Section 7.3 reports on the phase two, *in-depth assessment of routine immunisation* service provision.
- Section 7.4 reports the findings relating to integrated services delivery from the phase two in-depth services assessment and discusses the supply-side perspective on *integration with routine immunisation*.
- Section 7.5 covers routine preventive *postnatal care*, with findings and discussion on this topic from both phase one and phase two.

Section 7.3 has been expanded because of the significance of PNG's 2018 polio outbreak that took place following field data collection, but prior to completion of this thesis. An adaptation of this section was submitted to a peer review journal for publication<sup>461</sup> as:

Morgan, C.J., Saweri, O.P.M., Larme, N. Peach, E., Melepie, P., Au, L., Scoullar, M.J.L., Reza M.S., Vallely, L.M., McPake, B.I., Beeson, J.G. Strengthening routine immunization in Papua New Guinea: a cross-sectional provincial assessment of front-line services. *BMC Public Health* **20**, 100 (2020). <https://doi.org/10.1186/s12889-020-8172-4>

## 7.1 Health services study context, design and methods

### 7.1.1 Context, aims and objectives

This supply-side assessment of integrated services is nested within the *HMHB Health Services for Postnatal and Infancy Care study*. The full protocol for this study is at Appendix 10.1.5. This study aimed for better understanding of how health facilities interpret and implement national or provincial policy, and to identify areas for potential improvement. As discussed in Chapter Two (Section 2.4.5), integrated health care at *two points in the life-course* were seen as critically important. These are the *postnatal period* (care for both mother and baby in the first 28 days after birth), and *infancy* (the first twelve months after birth). The broader study aimed to inform the ENB provincial health authorities, and draw implications for national practice; with review of integrated services comprising one aspect among several.

The need to study *postnatal care* had been flagged by national newborn health advisors, and was reinforced by early findings from the HMHB Prospective Observational Cohort Study (see Chapter Six) of very low coverage of routine postnatal care. HMHB field team experiences with key MCH facilities in ENB suggested that routine postnatal checks were not happening through the first week after childbirth as envisaged by PNG's National Newborn Health policy.<sup>268</sup>

The study of *routine immunisation* was motivated by the desire to assess implementation of PNG's new strategy to strengthen immunisation services: termed the Special Integrated Routine EPI Program. This initiative<sup>277,283,491</sup> (see also Section 2.4.6 and Section 7.3 in this chapter) aimed to introduce new vaccines, improve local planning, intensify outreach, enhance information systems, and integrate other services with immunisation. Impetus for this strategy came from widespread concern at the country's persistently low vaccination coverage. PNG's resulting vulnerability had been seen in outbreaks such as measles<sup>252</sup>; and was borne out in the 2018 polio outbreak.<sup>253</sup> This major development prompted this thesis to include expanded discussion of routine immunisation findings, as presented in section 7.3 below.

In brief, the study *objectives* were to:

- measure preventive care infrastructure, equipment and supplies;
- assess health workers' knowledge and practices;
- assess health workers' opinions on health service organisation and delivery; and
- identify opportunities for improved quality and reach of care.

Specific *integration measures* were nested within the study design, as noted in Section 4.3.6. These address important questions on integrated service delivery in both the postnatal period and during infancy. These questions include: how well birth dose vaccination is integrated with routine postnatal checks; the status of new PNG policy on integrating other services with routine immunisation; and the feasibility of new forms of integrated services, including those emerging from early findings of the Prospective Observational Cohort Study (Chapter Six).

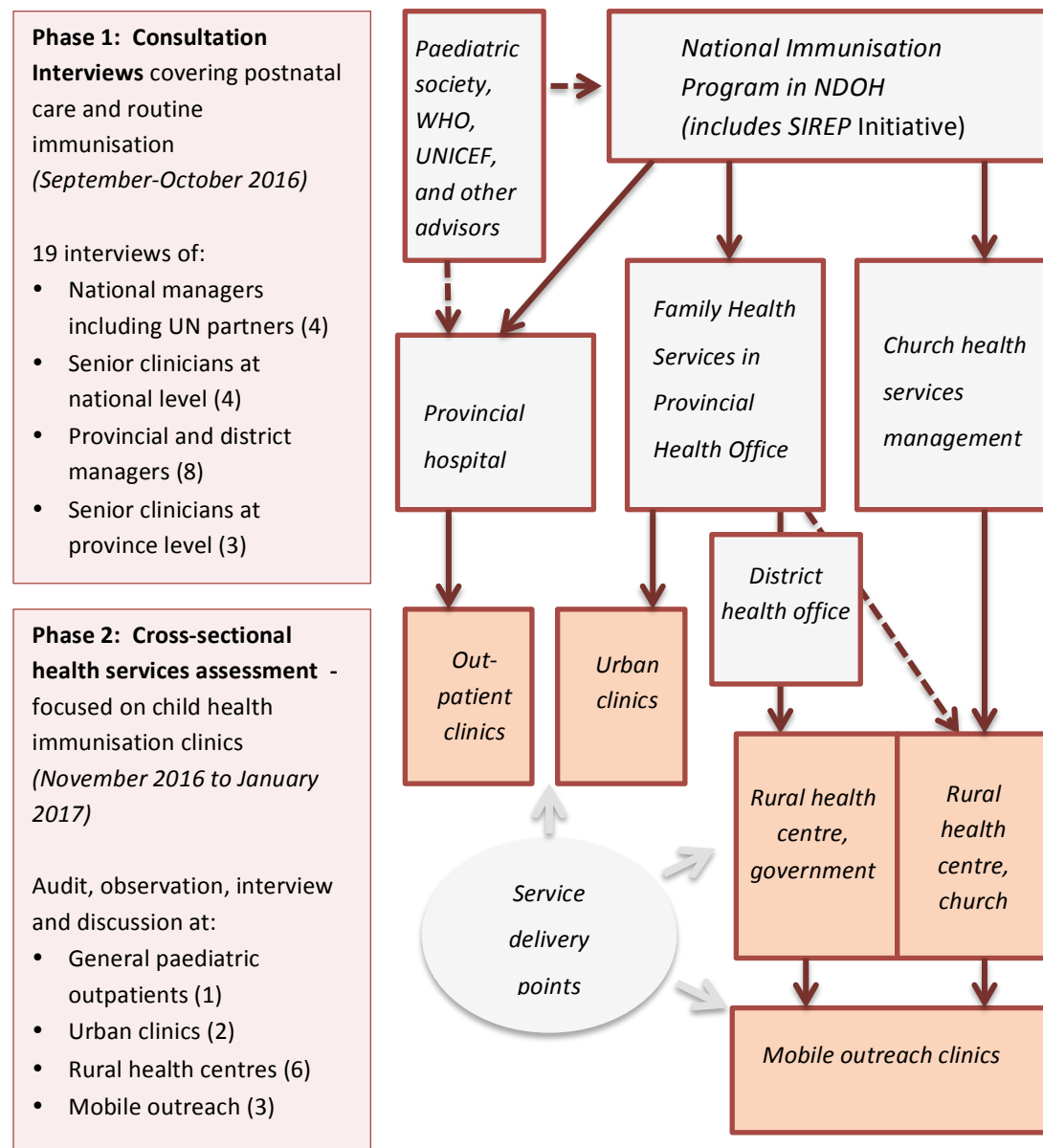
### **7.1.2 Study design and methods**

The study was designed to access key points of governance, policy and management of direct relevance to service delivery for immunisation or postnatal care; with levels and respondents also informed by this research's overall conceptual framework (Chapter Three, Section 3.1.4). The figure below maps the governance structures relevant to these services and shows how the two study phases capture data from the various levels involved. The first phase comprised consultation interviews with health managers at national provincial, and district levels. The second phase comprised a cross-sectional health services assessment of the five busiest health facilities in ENB (also partners in the HMHB Prospective Observational Cohort Study) and a selected group of smaller clinics and outreach points that are served by these facilities.

The health manager consultations (phase one) took place in September and October 2016. This was followed by rapid analysis of consultation interviews so as to refine the data collection tools for phase two. The phase two cross-sectional health services assessment of routine immunisation services took place from November 2016 to January 2017. A proposed phase two observational assessment of routine preventive postnatal care services proved impossible

because no services were in operation, although questions on postnatal care were included in health worker interviews as discussed in Section 7.5 below.

**Figure 15: Study phases in relation to governance of rural preventive health services**



Notes: The WHO, UNICEF offices in PNG, along with the specialist Paediatric Society provide the NDOH with key technical advice; and the Paediatric Society updates national standard treatment guidelines on a regular basis. SIREP refers to the Special Integrated Routine EPI Program introduced by the NDOH, with WHO support in 2015. 'Family Health Services' are units of national and provincial health governance that cover maternal and child health, immunisation and related services, especially as provided by smaller non-hospital facilities. 'Church Health Services' comprise a mix of denominations (largely Catholic Church Health Services in ENB) that provide approximately 50% of rural health care in PNG. Additional detail on health services structures is in Chapter Two.

### ***7.1.3 Approvals and relationship to other HMHB studies***

The study was approved by the PNG IMR Institutional Review Board (IRB: 1603), the PNG Medical Research Advisory Committee (MRAC: 16.22), the East New Britain Provincial Government (PEC: 12/2016), and The Alfred Hospital Ethics Committee, Melbourne (333/16). This study (also termed HMHB 2a) took place in 2016-17, timed to investigate supply-side perspectives to complement interim findings emerging from the HMHB Prospective Observational Cohort Study. A second HMHB study, conducted over 2019 to 2020, adds an investigation of inpatient care during pregnancy, childbirth and the early neonatal period (also termed HMHB Study 2b).

### ***7.1.4 Consultation methods for phase one***

Consultations with senior stakeholders, comprised a semi-structured interview administered to:

- Four national program managers, government, WHO and UNICEF
- Four senior clinicians working at national level
- Eight managers or coordinators at provincial or district levels
- Three clinicians working at provincial level.

The interview was administered as designed, with sections covering participant's opinions on the current status of immunisation services, other preventive services expected at the time of 'Well Baby Clinics', and their expectations of changes that might have resulted from implementation of the new SIREP strategy in a province such as ENB. Probes encouraged interviewees to reflect on the barriers or enablers to effective immunisation coverage, the contexts that determined these, and any underlying mechanisms behind barriers or enablers. The interview also covered postnatal care (see Section 7.4), including participant's understanding of current practices in routine postnatal checks, and barriers or enablers to implementation of national policy.

Interviews were either carried out by the author of this research or by other investigators (Ms Olga Saweri of PNG IMR, Dr Liz Peach and Ms Thalia Wat of Burnet Institute) that he had trained (see also Methods description in Section

4.4). Further details are provided in the study protocol (see Appendix 10.1.5). Dr M. Salim Reza of the PNG WHO office provided critical insights and connections to guide the phase one consultations and Mr Johnnie Arava, acting national EPI manager, provided access to national policy and planning documents. Mr Nicholas Larme, of ENB Provincial Government, provided access to provincial policy and planning documents, and identification of key informants within ENB. Thematic analysis of phase one consultations were devised and carried out by the author of this thesis, with review by other authors on the peer review publication arising (see Appendix 10.4.2) from this work. Tabulation of findings is also supplied at Appendix 10.4.1.

## 7.2 National and provincial perspectives on immunisation services, phase one findings

### 7.2.1 Consultation findings on new immunisation strategies

National managers readily described the new policy and strategies from 2015 that aimed to improve preventive services in infancy with a focus on immunisation. The acronym SIREP was coined to represent these; a term particularly used by WHO and NDOH respondents, but recognised by all interviewees from national to district levels. This program, as described in Chapter Two (Section 2.4.6), aimed to improve routine immunisation services from 2015:

*“What makes SIREP different from the current routine EPI program is that it will be implemented on a quarterly basis rather than on a monthly basis and it will be integrated with additional maternal and child health services. In addition, it is strengthened with intensified operational components necessary to ensure that the program is reaching every child and achieve high immunization coverage.” (National immunisation stakeholder)*

Some national stakeholders familiar with the national EPI strategy reported a distinction termed ‘SIREP Plus’ that emphasised the aim of introducing new vaccines such as measles and rubella combination (MR) and the inactivated polio vaccine, whose roll-out in settings such as PNG was a key accompaniment, from 2015 onwards, to the switch to newer oral polio vaccines.

*“SIREP Plus is the same as SIREP but will add delivery of supplemental vaccines and / or introduction of new vaccines within a given period of time of intensified activity. SIREP Plus ... will introduce MR and IPV vaccines in PNG”. SIREP Plus also includes Vitamin A and Albendazole alongside vaccination.” (National immunisation stakeholder)*

Interviews with national and provincial managers during Phase One demonstrated clear expectations on what should change through SIREP implementation, including that provincial, district and facility managers would have new micro-planning of outreach services (including quarterly timing), new

understanding of catchment populations to guide service planning, and that secondary training would have taken place within facilities. Provincial and district managers showed strong commitment to the concept as a path to renewal of service delivery, although not all had good awareness of the strategy. Those that did noted that repeated training and further funding was going to be needed. Some managers suggested that implementation through training, supply of new vaccines, and some funding support had commenced in ENB, but was not fully implemented.

### ***7.2.2 Consultation findings on current status of immunisation services***

National, provincial and district consultations also identified likely barriers to and enablers of immunisation service provision. Important barriers were listed as: insufficient funding by local health authorities, failures of supplies and equipment (including cold chain), difficulties in planning including outreach planning, gaps in staff knowledge and skills, and community attitudes or lack of knowledge. Two common mechanisms were mooted by central managers. One was poor management of all available resources (for example, accurate supply ordering or equipment renewal). The second was lack of awareness of the potential of non-government partners, or the existence of resources held by provincial or district governments, such as those in their Service Improvement Programs (sources of central and local governments' development funding). Conversely, a common enabler mentioned was strong local management, especially by creative and diligent local managers. Government resources were clearly acknowledged as insufficient in themselves, with most managers citing the need for church health services or private sector partners to support service coverage. Some noted that non-government health services having greater control over staff was a key enabling mechanism. One manager mentioned the potential to out-source service provision.

In keeping with the emphases in the SIREP strategy, reliable and effective outreach services were seen as a key enabler of access; recognising that many children would not be reached through fixed facilities alone. Poor understanding of populations to be reached, lack of resources dedicated to outreach services



and, to some extent, staff unwillingness to travel remotely, were all reported as mechanisms constraining outreach. Coordinated planning across programs, and between government and non-government providers were proposed to be likely contributors to successful outreach.

These expectations helped inform the structure of data collection tools in phase two (see Section 7.3), and the descriptions of barriers and enablers helped refine detailed hypotheses that the phase two assessments would test.

### ***7.2.3 Consultation findings relevant to integration of services***

National documents consulted for this study refer to integrated services as one aspect of SIREP (strictly speaking, 'SIREP Plus'),<sup>277</sup> and integration across programs is also promoted in the Ministerial Taskforce on Maternal Mortality<sup>84</sup> and the current National Health Plan,<sup>83</sup> as well as the Newborn Health Policy<sup>268</sup> (relevant to postnatal care, below).

Most managers offered strong support for the need for coordinated planning across MCH and EPI programs, which are often governed separately at national and district levels. All national-level interviewees endorsed the strategy of adding other services alongside immunisation services. Some respondents at provincial or district levels agreed, but others felt that this would not always be feasible or effective. When asked which services should be priorities, many managers cited family planning and nutrition services, some suggested tuberculosis, and some cited the SIREP priorities of vitamin A supplementation, and albendazole (for preventive treatment of helminths in children). National level respondents disagreed in opinions on the practice of integration in SIA campaigns. Several felt the planning of these had discouraged inclusion of non-immunisation services, while one informant suggested SIAs did allow integrated service delivery.

All respondents saw the rationale for integration of other services with immunisation as a mechanism for improved coverage, efficiency and use of scarce resources. No respondents suggested benefits of integrated services as including management of co-morbidity, responsiveness to family preferences or other demand-side perspectives. Apart from family planning services, all

examples managers provided, of services that could or should be offered alongside immunisation, were for the benefit of the child. Maternal illness management or support to maternal nutrition was not mentioned. This emphasis is in contrast to the preferences of women, reported in Chapter Seven, for maternal illness and other sexual and reproductive health care of a more complex nature; as such it may represent the clinical mindset of program specialists focused on coverage of their own particular priorities.

On probing, most respondents offered opinions on the potential for provision of immunisation during other child health services (the 'reverse' direction of integration). Most managers, and all clinicians, reported a strong sense that there are missed opportunities for immunisation when it is not being offered during clinical care of the sick infant or within general paediatric outpatient services. The exception was the birth-dose of hepatitis B vaccine, which was reported as being well integrated into early neonatal care when childbirth took place within a health facility (see also Section 7.4).

## 7.3 Routine immunisation services, phase two assessment

This section presents methods and findings from phase two of the HMHB health services study, with additional background and discussion to frame the findings in the context of PNG's 2018 polio outbreak. An adaptation of this section was submitted to BMC Public Health, published in 2019, as noted above.

### ***7.3.1 Routine immunisation challenges in PNG, and their relevance to polio, measles and other lapses in disease control***

The outbreak of polio in 2018, which came after the fieldwork for this cross-sectional assessment of routine immunisation services had been completed, is a clear product of sustained low coverage by PNG's routine immunisation services. This emphasized the need to see how routine systems could be improved, and also posed a challenging question familiar to fragile systems enduring a crisis. That is: how in the wake of a major, rapid emergency response to plan for long-term strengthening of routine systems. This is especially challenging when such systems have shown minimal improvement over the past 15 years (see Chapter Two). This cross-sectional assessment, conducted prior to the polio outbreak, provides data that, as well as providing a supply-side perspective on integration, can also demonstrate pathways to the long-term improvement of routine immunisation services that must complement emergency responses such as those for polio. One potential pathway under assessment here is the relevance and effectiveness of the government's SIREP strategy for immunisation service strengthening.

It is routine immunisation programs, rather than campaigns or emergency responses, that are most critical to the ambitious Global Vaccine Action Plan (2011-2020)<sup>37</sup> and its successor (see Chapter Eight). However routine coverage is not increasing as planned in many difficult settings challenged by expanding childhood cohorts, population displacement by conflict or natural disasters, and limited resources to overcome geographical and infrastructural challenges.<sup>166,492</sup> As noted in Chapter Two, measles had been suppressed by regular supplementary immunisation activities for eight years, but returned to

PNG in a major outbreak in 2014. Polio, after a twenty year hiatus, returned in 2018.<sup>280,281</sup> In that year, PNG was one of five countries experiencing outbreaks of circulating vaccine-derived poliovirus disease,<sup>281,282</sup> the rare mutated form that results from chronic under-immunisation with the oral poliovirus vaccine.<sup>257</sup> This has required one of PNG's largest public health emergency responses, led by the national government with support from Global Polio Eradication Initiative and other development partners.<sup>493</sup> In the short-term, the response entailed repeated SIAs (campaigns). Two national and three sub-national campaigns (none including ENB) in 2018 delivering only polio vaccine; and three national campaigns in the first half of 2019, delivering polio vaccine along with a mix of other vaccines and (in one) vitamin A supplements.<sup>494</sup> Development partners and government managers have also recognized the need for longer term plans for program reform, recognising that it is sustained gaps in routine immunisation services that are the primary cause of this form of polio.<sup>282</sup>

As discussed in Chapter Two and Section 7.2, PNG had in 2015 introduced the SIREP strategy to improve routine immunisation and reduce reliance on SIAs.<sup>283,491</sup> This sought to improve program performance amidst the major challenges facing PNG's health services such as a stretched health workforce, financial constraints, and dispersed rural populations with minimal road access.<sup>279</sup> SIREP had four priorities:

1. More efficient local planning based on locations of child populations;
2. Intensification of outreach services with realistic scheduling based on local resources;
3. Improved local information systems (including child health books); and
4. Staff training to support new vaccine introductions (most prominently Inactivated Polio Vaccine as well as pneumococcal and rubella vaccines).

SIREP also aimed to integrate other primary health care with vaccination, starting with limited curative care, and addressing malnutrition through

distribution of age-targeted vitamin A and anti-helminthic doses of albendazole.<sup>277</sup> SIREP attempted to merge the program intensification often seen in emergency campaigns<sup>277</sup> with internationally proven strategies for routine programming, such as those collated by WHO in “Reaching Every District (or Community)”<sup>423</sup> approaches and the Global Routine Immunization Strategies and Practices framework.<sup>495</sup> These innovations, emerging as the study methods were developed, informed our tools to investigate how routine immunisation in PNG might be improved, including consideration of the current status and future potential of integrated services.

### **7.3.2 Methods – cross-sectional assessment of routine immunisation services**

#### *Study concept and objectives*

This study adopted the conceptual framework introduced earlier in this thesis (Section 3.1.4) to review the likely influences on front-line service delivery and distinguish problems amenable to local change from those requiring central system reform. Study objectives were to measure current infrastructure, equipment and supplies for preventive care in infancy; assess what health workers know, think and do in relation to providing postnatal and infancy services; assess health workers’ responses to *SIREP* and other initiatives; and identify opportunities for health system strengthening and improved quality of care. We devised an evaluation framework that explicitly tested important elements of the SIREP strategy (as noted above), and that also referenced WHO standards for routine immunisation programs.<sup>298,495</sup>

#### *Study setting and timing*

As described in Chapter Four, the study setting is ENB, part of a large island in PNG’s north-east, whose population live in small towns and rural villages in highland and coastal topographies. Immunisation is usually provided through urban clinics, small rural health centres, scheduled outreach to community sites, and hospital children’s outpatients. ENB performs relatively better than other PNG provinces on some indicators (such as skilled attendance

at childbirth), but immunisation is similar to national estimates with 60% of children receiving DTP3 and 48% MCV1 in 2016.<sup>239</sup>

The author led a research team in the cross-sectional assessment of health facilities, staff and clients from November 2016 to January 2017, timed to follow the initial rounds of *SIREP* training and implementation. Sites surveyed comprised 12 clinics providing immunisation services, nine in fixed facilities and three community outreach sites. These were purposefully chosen as they are all linked to the health institutions also studied for the Prospective Observational Cohort Study. These sites provide approximately 80% of maternal and child health care in ENB.<sup>326</sup> Respondents for interview were chosen to provide a mix of seniority across front-line positions (Table 18, below) in these facilities.

#### *Data collection tools and ethical considerations*

Table 18 presents the mix of interview, focus group discussion, structured observation and records audit. All tools reflected our evaluation framework by incorporating items to test core elements of the *SIREP* strategy, PNG's national immunisation plans<sup>279</sup> and WHO standards for program monitoring,<sup>298</sup> refined through consultation with national and provincial health managers in phase one.

We also adapted WHO's 2015 Immunization Session Checklist<sup>298</sup> (see Figure 16 below) into a structured observation tool. This checklist is a streamlined quality improvement aid that was developed through consultation on the most common programmatic errors reported by senior immunisation managers working in settings in sub-Saharan Africa. Observation of patient flow and staff-patient interactions used a locally devised tool, similar to those used by the Integra Initiative<sup>9</sup> when researching integrated services.

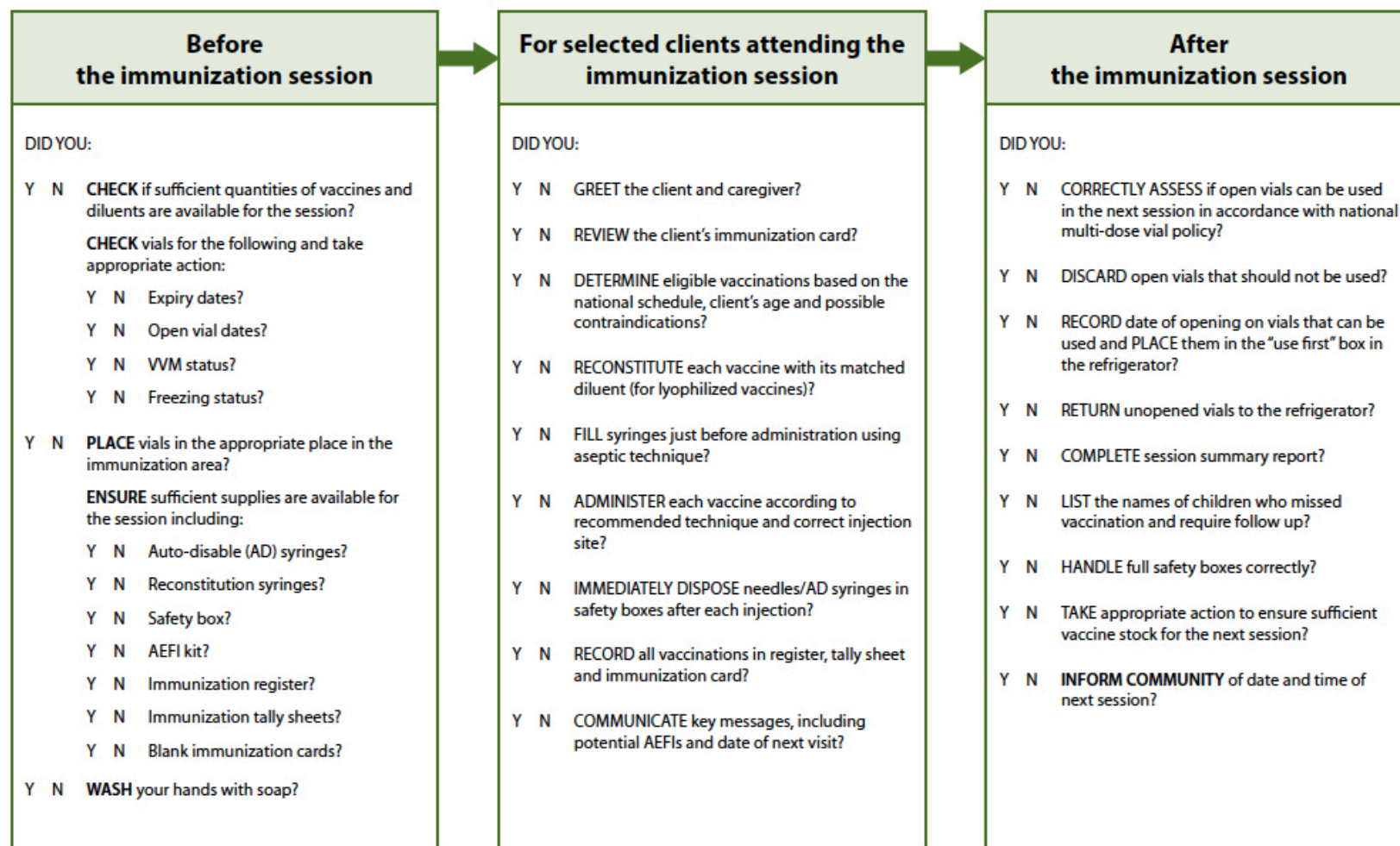
Data collection was carried out by trained local research officers, Ms Pele Melepie and Ms Lucy Au, using electronic tablets supplemented by paper-based note-taking. The author of this research, supported by Ms Olga Saweri and Dr Liz Peach, trained and supervised the research officers. The investigator team included policy-makers and managers at national (Dr M. Salim Reza, WHO PNG, and Mr Johnnie Arava, NDOH) and provincial levels (Mr Nicholas Larme).

However these investigators were excluded from front-line data collection or initial analyses, to avoid bias.

Research officers were trained in quantitative and qualitative data collection, including techniques to minimise social acceptability bias, and to assess and counter perceived power imbalance between themselves and interview subjects. All free-text interview responses were recorded verbatim, focus group discussions were documented by a dedicated note taker, and both were digitally recorded for cross-checking. Interviews were conducted in English and focus group discussions in Tok Pisin; both official languages of PNG. All participants provided written informed consent, with measures taken to ensure confidentiality.

**Table 18: Data collection, respondents and tools**

| <i>Study subjects</i>               | <i>Number</i> | <i>Details</i>                                                  | <i>Tools</i>                                                                                                                                                                        |
|-------------------------------------|---------------|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Primary health care staff           | 6             | HEO or Specialised Nursing Officer                              | Semi-structured <b>interviews</b> (mix of quantitative and qualitative fields)                                                                                                      |
|                                     | 6             | Nursing officer (NO)                                            |                                                                                                                                                                                     |
|                                     | 6             | Community Health Worker (CHW)                                   |                                                                                                                                                                                     |
| Family members                      | 67            | Caregivers of infants being vaccinated<br>66 female, 1 male     | Focus group <b>discussion</b> (10 groups)                                                                                                                                           |
| Health clinics and their operations | 9             | Child or family health clinic, static                           | <b>Audit</b> of infrastructure and equipment against PNG standards as described in national EPI plan <sup>279</sup> .<br><b>Observation</b> of general clinic procedures (12 sites) |
|                                     | 3             | Mobile child health clinics (run by staff from the above sites) | <b>Observation</b> using WHO Immunization Session Checklist (11 sessions)<br><b>Observation</b> of patient flow and staff-patient interactions (15 patients)                        |

**Figure 16: WHO Immunization Session Checklist**

Note: WHO Immunization in Practice (2015), Module 5, Figure 5.11, available at: [https://www.who.int/immunization/documents/IIP2015\\_Module5.pdf](https://www.who.int/immunization/documents/IIP2015_Module5.pdf)



### *Analysis*

Quantitative measures from audit, structured observation and interview elements (such as for knowledge) were reported as proportions with no further statistical manipulation, respecting the purposeful sampling in our design. Thematic analysis of qualitative data was carried out by the first author (after translation for focus group discussion data), then validated by Dr Liz Peach, Ms Olga Saweri, Ms Pele Melepia, and Ms Lucy Au (the latter two being native Tok Pisin speakers). After coding for themes predetermined in our conceptual framework and design, data were re-examined for emergent themes.

In 2017, for critique and validation, a detailed data report was provided to all investigators and a summary exposed to national and provincial stakeholders; this also allowed early dissemination of policy implications. Supplementary materials are provided at Appendix 10.4.1, detailing tables of themes derived from interview and focus group discussions. Following this, re-analysis led by the author of this thesis led to peer-review publication, with review of those interpretations provided by all authors on that publication (See Appendix 10.4.2).

### **7.3.3 Results – assessment of routine immunisation services**

Key findings from all data sources are summarised under six categories (Table 19) from our evaluation framework that combined priorities addressed by the national SIREP strategy,<sup>5,279</sup> WHO program advice<sup>298</sup> and the results of thematic analysis. Findings were additionally categorised as either local strengths or areas needing improvement, with decisions on this allocation being made by the research team. A comprehensive table of findings and coded themes is appended (Appendix 10.4.1).

**Table 19: Key findings from assessment of front-line immunisation services**

|                                                                                      | <i>Strengths in local systems</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <i>Opportunities for improvement in local systems</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Local service planning and delivery<br><i>Data sources: interview and audit</i>      | <ul style="list-style-type: none"> <li>Recent innovations recognised by most (14/18) staff: new vaccines or planning, with one mention of new quarterly outreach increasing efficiency</li> <li>Recent in-service training in SIREP reported by many (11/18) staff</li> <li>Static services available 5 days per week</li> <li>All clinics tallied vaccinations to report into national health information system</li> <li>82% of clinics conducted as planned (annual total of 109 implemented of 133 planned)</li> </ul>                        | <ul style="list-style-type: none"> <li>Outreach was limited – a minority (2/9) of static facilities used outreach with overnight stays for remote areas</li> <li>Outreach planning process not able to be described by half the staff, less than a quarter planned on population basis, no clinics used population data to estimate outreach supply quantities</li> <li>Many clinics with few patients: mean 17/clinic, IQR 3 – 26, maximum = 62</li> <li>Estimation of coverage impossible for more than half (10/18) staff due to lack of catchment data, only one clinic displayed coverage</li> <li>No clinics had lists of children overdue for vaccination, one third of clinics used child registers</li> <li>Local reasons for clinic cancellation were adverse weather, lack of transport or slow disbursement of funds</li> </ul> |
| Infrastructure and supplies<br><i>Data sources: interview, audit and observation</i> | <ul style="list-style-type: none"> <li>Most clinics had road access, with two outreach clinics on walking trails</li> <li>Water supply in nine (of 12) clinics and electricity in eight (of 9) static sites</li> <li>Functional injection equipment, safety boxes and weight scales in all clinics</li> <li>10 (of 12) clinics had appropriate, functioning cold chain equipment</li> <li>Supplies of all relevant vaccines (including IPV and PCV) and injection equipment present</li> <li>No expired or discontinued vaccines found</li> </ul> | <ul style="list-style-type: none"> <li>Eight (of 12) clinic sites needed renovation (by local standards), 9 (of 12) did not have usable toilets</li> <li>No clinics with kits for managing severe acute adverse events</li> <li>Cold storage monitoring inconsistent, no clinics with written temperature records</li> <li>Half the clinics had clear records of vaccine stock usage, not well reconciled with tallies of patients vaccinated, none able to match supply to population</li> <li>Recording forms did not clearly account for three new vaccines: IPV, PCV, MR</li> <li>Lack of important guidance documents: one (of 12) had an immunisation manual, and four had child health standard treatment guidelines</li> </ul>                                                                                                      |

Table continues below

**Table 19: Key findings from assessment of front-line immunisation services (continued)**

|                                                                                                                              | <i>Strengths in local systems</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <i>Opportunities for improvement in local systems</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Staff knowledge and staff practice during immunisation sessions</p> <p><i>Data sources: interview and observation</i></p> | <ul style="list-style-type: none"> <li>• More than half of staff could correctly cite recently introduced vaccines (11/18) and handling of lyophilised multi-dose vials (15/18)</li> <li>• Twenty staff (nurses and CHWs) across 12 clinics, vaccinating mean of 17 children per clinic falls within WHO maximums (30 per staff member<sup>298</sup>);</li> <li>• Core interactions (weight, screening and vaccination) done for 14 of 15 observed patients</li> <li>• Observation against WHO session checklist (see figure) shows key elements of safe injection in over 80% sessions</li> </ul> | <ul style="list-style-type: none"> <li>• Few staff could correctly cite: immunisation schedule (8/18), one national program target (3/18), storage temperature (6/18), interpret vaccine vial monitor display (3/18), or handling of liquid multi-dose vials (2/18)</li> <li>• Some important functions omitted in patient flow observations: educational interactions observed for just two of 15 patients, preventive care for women and AEFI monitoring observed in none</li> <li>• Waiting times in 15 patient flow observations were significant: mean 51 minutes arrival to final interaction (IQR 13-90, maximum 210)</li> <li>• Observation against WHO session checklist sessions shows gaps in preparatory checking of vaccines, client communication and AEFI observation, and (for less than 20%) in safe injection</li> </ul> |
| <p>Missed opportunities for vaccination</p> <p><i>Data sources: interview, audit and observation</i></p>                     | <ul style="list-style-type: none"> <li>• Most staff (13/18) stated they would open a multi-dose vial for just one patient</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>• Due vaccinations had been missed in 3 of 10 Child Health Record books</li> <li>• Reasons for missing vaccination included vaccine out of stock, clinic visit not for purpose of vaccination, or (for birth doses) childbirth in community</li> <li>• Two (of 15) observed patients were asked to return another day for vaccination</li> <li>• Thirteen (of 17 respondents) staff stated they would usually ask a sick child to return at another time for vaccination</li> </ul>                                                                                                                                                                                                                                                                                                                 |

*Table continues below*

**Table 19: Key findings from assessment of front-line immunisation services (continued)**

|                                                                                                                      | <i>Strengths in local systems</i>                                                                                                                                                                                                                                                                                                                                                                                                                | <i>Opportunities for improvement in local systems</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Integration of other services<br><i>Data source: interview and observation</i>                                       | <ul style="list-style-type: none"> <li>• All staff noted a policy of integrating other care and vaccination</li> <li>• Nine (of 18) staff cited at least one other care (usually childhood illness) regularly integrated</li> <li>• Child illness care available in nine (of 12) clinics</li> <li>• Child illness care accompanied vaccination in seven (of 15) observed patients</li> <li>• Weight measured in all observed patients</li> </ul> | <ul style="list-style-type: none"> <li>• Four (of 18) staff mentioned maternal health service as integration option</li> <li>• Three clinics (of 12) lacked supplies, or service organization, to integrate childhood illness care with vaccination</li> <li>• No observation of catch-up vaccination with children presenting for illness</li> <li>• Three (of 15) patients observed to receive feeding counselling, two to receive vitamin A, 1 to receive albendazole</li> <li>• No observations of maternal preventive care or counselling</li> <li>• Staff reported insufficient numbers as main constraint on integrated care</li> </ul>                                                                                                |
| Community engagement and family viewpoints<br><i>Data sources: interview, observation and focus group discussion</i> | <ul style="list-style-type: none"> <li>• Three (of 12) clinics provided verbal group health education alongside vaccination sessions</li> <li>• Three (of 18) staff reported support (for example food) provided by local communities</li> <li>• No fees for vaccines reported or observed and families did not report fees as barrier to vaccination</li> </ul>                                                                                 | <ul style="list-style-type: none"> <li>• No reported use of community-based trained lay health workers to help with organization, mobilization or education.</li> <li>• Six (of 12) clinics charged small administrative fees</li> <li>• Many families (6/10 groups) cited travel time, and transport costs, as significant constraints on timely attendance for vaccination</li> <li>• Many families (6/10 groups) sought more mobile clinics, more “on-demand” vaccination, and more reliable clinic timing</li> <li>• Some families (4/10 groups) sought more respectful staff-client interactions</li> <li>• No male family members were observed in attendance, staff cited embarrassment as a constraint on male involvement</li> </ul> |

Note: SIREP = Special Integrated Routine EPI Strengthening Program; IQR = Inter-quartile range; IPV = inactivated polio vaccine; PCV = pneumococcal conjugate vaccine; MR = measles-rubella vaccine; CHW = Community Health Worker; AEFI = adverse event following immunisation.

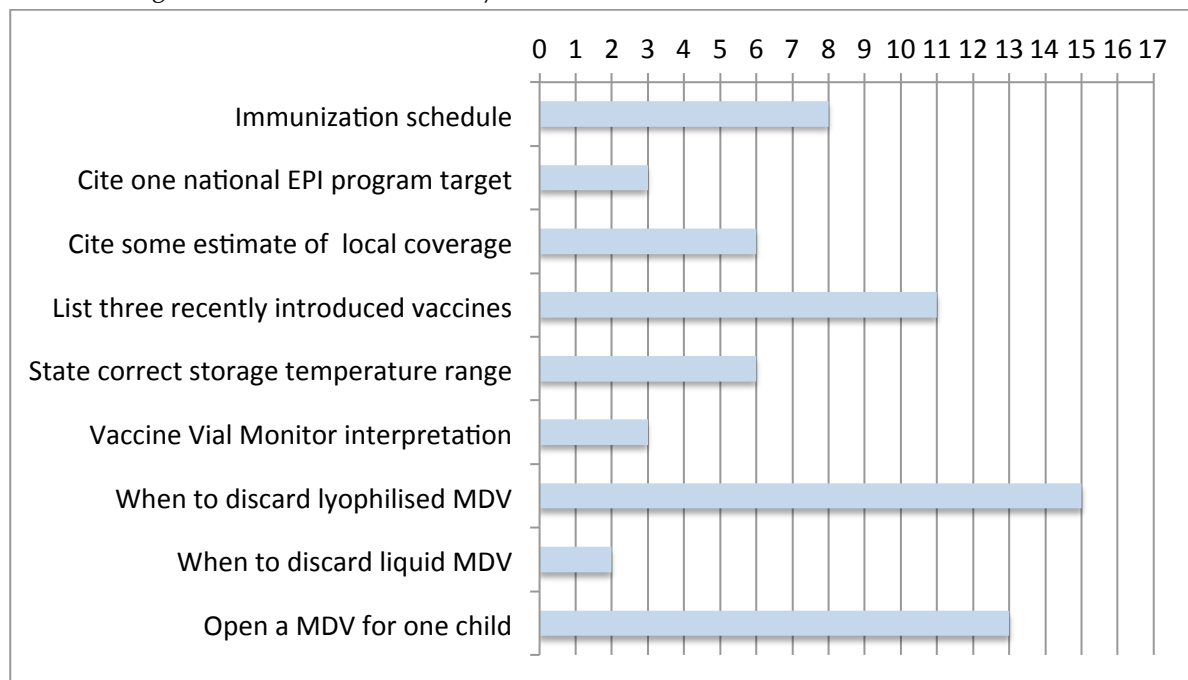
*Local service planning, infrastructure, supplies and staffing*

Local service planning findings demonstrated that services were largely provided as planned from static clinics and some outreach sites. Several key aspects of SIREP were not yet implemented. There was limited intensification of outreach, no selective targeting of population concentrations, and minimal systems for tracking and finding under-vaccinated children. Infrastructure and supplies review showed a functional level of infrastructure, equipment and supplies across almost all operating clinics, as judged against standards in the national EPI plan. New vaccines were being deployed in keeping with the *SIREP* strategy and, reassuringly, no expired or discontinued vaccines (such as trivalent oral polio vaccine) were found. However there were important unmet needs for renovation, equipment renewal, improved temperature monitoring, and availability of guidance documents. A significant gap was the absence of equipment to manage severe adverse events following immunisation (AEFI). Overall staffing was within WHO global standards for workload (30 vaccines per staff member<sup>298</sup>) at current levels of operation, noting a number of clinics with relatively few patients (25% seeing three or fewer).

*Staff knowledge and service delivery practices*

Selected staff knowledge elements from structured interviews are displayed in Figure 17 below.

**Figure 17: Selected Health Worker Knowledge Responses:** Count Of Respondents Whose Answer Aligned With National Policy, For 17 Health Workers

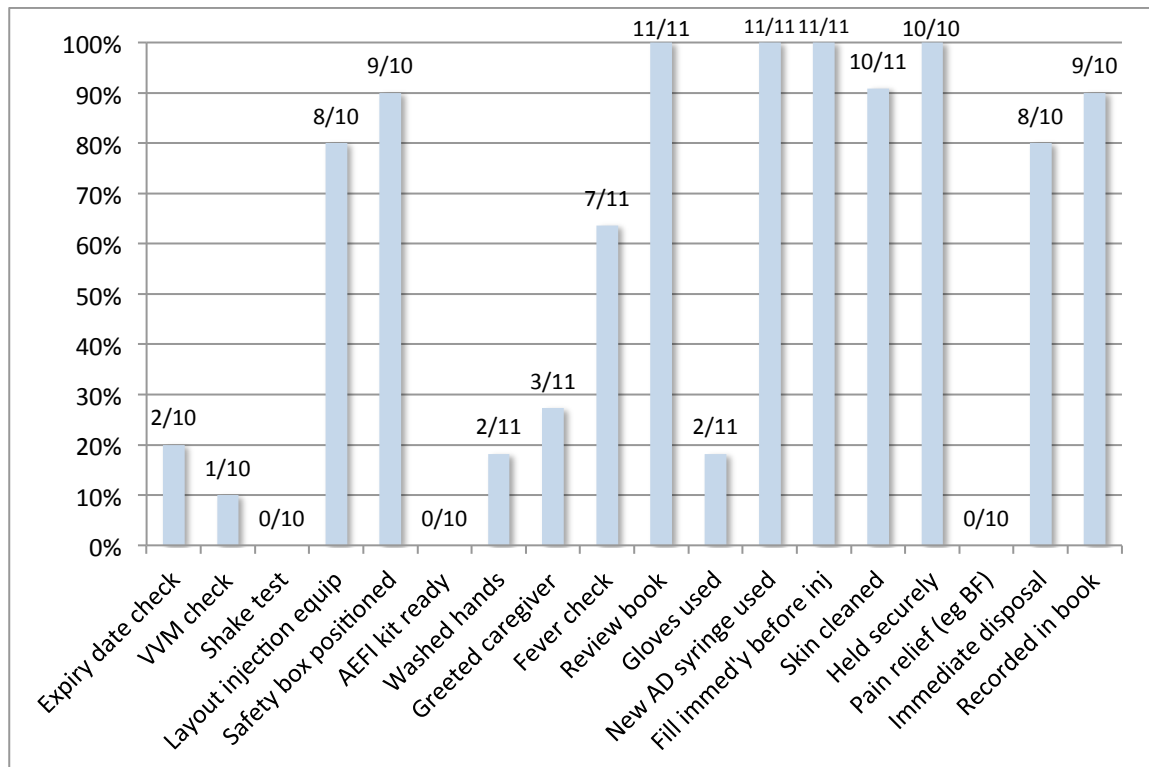


Note: EPI = Expanded Programme on Immunization (in PNG), MDV = multi-dose vial.

Knowledge responses are also incorporated into Table 19 above as well as Figure 17. Overall the assessment showed some staff recognising SIREP objectives, many staff understanding the essentials of safe and effective vaccination, and all staff reporting recent refresher training. Important knowledge gaps related to: vaccines given at birth or in the second year of life, the links between vaccination and disease control, and proper handling of liquid multi-dose vials (with the risk that usable vials would be unnecessarily discarded).

Results of structured observations obtained by applying the WHO Immunization Session Checklist (Figure 16) to 11 immunisation sessions are displayed below in Figure 18.

**Figure 18: Health worker practices assessed against the WHO Immunization Session Checklist**



Note: Structured observation of 11 immunization sessions, using categories from the WHO Immunization Session Checklist<sup>298</sup>. Not all practices could be checked in every session, hence denominators vary, as indicated in data labels. VVM = vaccine vial monitor; AD = autodisable; BF = Breast-feeding.

These were supplemented by structured observation of timing, flow and services received by 15 patients. Taken together, these observations demonstrated that while most staff provided a clean and effective vaccination injection, there were gaps in provision of education, counselling of families, AEFI readiness, and the checking of vaccines for heat or freezing damage. Several missed opportunities for vaccination were noted, along with inefficiencies in patient flow that are likely to inconvenience families; as listed in Table 19 above.

### *Community engagement*

As listed in Table 19, community engagement activities consisted of group education talks at one in four of the sessions we observed, but without use of pictorial, video, participatory, or take-home communication products. Local communities donated in-kind support to some clinics, but there was no structured engagement, nor use of trained community health volunteers. Small fees for attendance, but not for

specific vaccines, were seen in one third of clinic sessions, but were not reported as a major barrier to access. One male family member was observed as involved in one immunisation session. Community members reported lack of support from family members as an occasional barrier to vaccination.

#### *Locally generated ideas for improvement*

Locally generated ideas for improvement were derived from questions on local strengths and invitations to make suggestions; when prompted, all respondents (staff in interviews and community members in discussions) offered responses to one or both of these questions. Common ideas proposed by staff included more personnel, stronger support for transport needed to do outreach, better community engagement, more active community education, male involvement, and offering desirable extra services for both mother and baby. When asked to rank priorities, staff rated reliable vaccine supply and renewal of equipment and infrastructure as more important than staff numbers or staff knowledge. Care-givers sought more frequent, reliable and 'on-demand' services, especially outreach, noting travel time and costs as a common barrier to uptake.

#### **7.3.4 Discussion – strengths and weaknesses in ENB immunisation services**

This section of discussion considers findings relevant to routine immunisation in general, the interaction between routine services and emergency campaigns, and implications for local and central reforms. Section 7.4, below, includes discussion of findings relevant to the integration of other services with immunisation.

These findings depict an immunisation service with an operational level of staff, equipment and procedures at its service delivery points; but one that reaches just half to two thirds of its target population. The service strengths are similar to, or better than, many other sites in PNG,<sup>491</sup> and the service deficiencies are similar to those identified for other low- or middle-income settings.<sup>492</sup> These findings point to a range of immediate opportunities to improve coverage and strengthen local service quality. These are discussed below and, in Table 20, synthesised into ten recommended actions. By using an evaluation framework based on both PNG's SIREP strategy and WHO standards, it is possible to relate recommendations to what was included in



PNG's SIREP strategy (see also the list of SIREP elements in Section 7.3.1). Six of the ten proposed actions were also embedded in the SIREP strategy (and hence in national immunisation plans), but insufficiently resourced or implemented in our study setting. Particular resource gaps lie in resourcing for outreach. Four actions proposed go beyond the current SIREP strategy.

**Table 20: Recommended local actions to improve routine immunisation program coverage or quality, and potential contribution of emergency responses or campaigns**

| <i>Local actions already proposed in the PNG government's SIREP strategy</i>                                                                      | <i>Potential contribution of an emergency responses or campaigns</i>                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| <b>Local planning</b> based on populations rather than geography                                                                                  | Campaign coordinators help boost local routine planning capacity<br>Mapping child populations and data-sharing               |
| <b>Intensified quarterly outreach</b> focused on higher clinic numbers properly resourced and implemented                                         | Identify new outreach points, especially with population clusters,<br>Clarify options and costs for transport                |
| <b>System for tracking</b> unvaccinated children                                                                                                  | Mapping child populations and data-sharing                                                                                   |
| <b>Integrated SIAs</b> with additional vaccines, matching local priorities                                                                        | Involve district level in planning<br>Local flexibility in an expanded package of campaign services                          |
| <b>Supportive supervision linked to refresher training</b> including good communications and AEFIs                                                | Distribute resources to staff.<br>Use campaign monitoring to collect staff priorities for capacity development               |
| <b>Trained lay health workers</b> (health volunteers) to track births and children, support outreach clinics and promote uptake at static clinics | Campaign organisation that promotes local involvement<br>Leverage campaign supports to enlist long-term interest and support |
| <i>Local actions that go beyond the PNG government's SIREP strategy</i>                                                                           | <i>Potential contribution of an emergency responses or campaigns</i>                                                         |
| <b>Standardise every opportunity vaccination</b> , by policy, training and accessibility of vaccine supplies                                      | Not easily addressed by emergency responses or campaigns                                                                     |
| <b>Health communication</b> products and programs to educate families on the complete vaccine schedule                                            | Distribute family-oriented communications materials promoting catch-up vaccination                                           |
| <b>Test models of integrated services</b> , responsive to community preferences                                                                   | Not easily addressed by the emergency responses or campaigns                                                                 |
| <b>Review of staff roles and functions</b> to optimise allocations and workload                                                                   | Minimise incentives that discourage outreach as part of routine programs                                                     |

*Notes: SIA = Supplementary Immunisation Activity. AEFI = Adverse Event Following Immunisation.*

#### *Options for short-term improvements in existing services*

Within current resources, improvements in coverage should be achievable with a fuller implementation of the changes to local service planning envisaged in the *SIREP*

strategy. This builds on the number of clinics with few clients (25% with 3 or less), and the fact that most planning is not yet tuned to where the majority of children live. Other persisting gaps in knowledge and capacity that were prime targets of the *SIREP* strategy include improving catchment population data, increased frequency of service availability, a greater number of outreach points, and quarterly intensification of outreach. Change through improved local planning to reinvigorate outreach has proven successful in settings in Africa and Asia<sup>423</sup> that share similar burdens of disease and health system constraints to PNG. In past programmatic research in PNG, alongside the country's national coverage survey in 2004<sup>496</sup> similar potential gains were identified. Reinforcement of *SIREP* training, already well recognised by front-line staff, appears a helpful starting point, but with a stronger commitment of resources to enable outreach to take place and all staff. Such changes also meet many of the highest priorities expressed in group discussions by family members.

There are also opportunities for increased community engagement and mobilisation; through increased group and individual counselling in the vaccination encounter and the creation and provision attractive, durable, 'take-home' information products, aiming to build community demand for a timely, complete schedule of vaccination. Outreach can benefit from stronger, formalised involvement of local leadership, possibly with the deployment of trained lay health workers. Such community resources can also help register and track children needing vaccination. Improved health worker practices within immunisation sessions include better client communication and the institution of AEFI equipment and periods of observation (which also allows time for education). Managerial support, reliable supplies, and staff reminders could improve the practice of opening multi-dose vials even for one child. This mix of enhanced community engagement plus improved local planning has driven routine immunisation improvements in difficult settings in sub-Saharan Africa,<sup>299,497</sup> and vaccination support by trained lay health workers (VHVs), has been proven in PNG in the past.<sup>498</sup>

*Interactions between campaigns and the routine program*

PNG's 2018 polio outbreak necessitated a major two year emergency response, with national and sub-national campaigns initially for polio vaccination alone and later with other antigens, particularly measles-rubella, similar to previous SIAs in PNG.<sup>6,499</sup> Table 20 above, discusses where emergency responses or campaigns could synergise with the proposed actions to strengthen routine immunisation. In other settings, the 'micro-planning' used in polio and measles campaigns can inform local service planning.<sup>423</sup> Improved local service planning is a feature of PNG's *SIREP* strategy but was not fully implemented in this study site. Sharing of campaign coordination staff and systems to support local managers could help catalyse change by identifying new outreach sites, rebuilding local clinic registers and catchment descriptions, and setting benchmarks for sustainable, practical transport costs. Campaigns and emergency responses could also work for stronger community engagement, including communications with local leaders and trained health volunteers that advocate for long-term support to the continuing routine program. Other practical support could address the planning and information gaps noted in our study, by distributing Child Health Record Books, staff immunisation manuals, and other key knowledge resources needed by the routine program.

There is global evidence, especially for measles/rubella SIAs, that they can boost routine programs<sup>500</sup>; but only if they accommodate the needs of routine immunisation in the way they harmonise their planning, invest in suitably generic equipment, share staff and intelligence, use broadly supportive communications, and minimise unsustainable monetary incentives. PNG's past experience with SIAs suggest they had most success when they maximised district-level control of timing and operations, and of which package of services to integrate.<sup>278,501</sup>

*Longer-term issues for rebuilding immunisation services*

It is clear that changes limited to the front-line are insufficient and central reforms of management, a country-led technical advisory group, procurement and financing, and national re-equipping are also needed and have been repeatedly advised<sup>279,491,502</sup>; these were largely beyond the scope of this research. The assessment's

findings do illuminate the need for new thinking on the immunisation workforce. In interviews staff consistently mentioned lack of personnel as an important constraint on extending outreach or integrating new services, in contrast to our observations that staffing was more than adequate for the clinics actually operating. Expanding services will eventually require an expanded cadre of vaccinators, but this study suggests that prior to that there is a need to review the allocation of immunisation roles and responsibilities in pursuit of greater efficiency. This could be coupled with the reestablishment of commitment to the national immunisation program goals across all staff levels, as one contribution to a revitalisation of professionalism in routine immunisation cadres.

#### *Integration of other services with immunisation*

The SIREP strategy also called for integration of other services with immunisation and this was assessed in staff interviews, client FGDs and the structured observation of patient flow. These findings, and their interpretation, are presented in Section 7.4 below.

#### *Limitations and strengths of this assessment*

The sample for this phase two assessment was restricted to functioning services and families who were willing and able to use those services. As such, the assessment primarily relates to improving outcomes within existing services. Data collection took place over the fourth and first quarters of the year, when wet weather events could bias perceptions of access. Despite careful training in unobtrusive observation and non-leading interviewing, there may be some observer effect and/or social acceptability bias affecting the validity of our findings. Single author coding of themes in qualitative analysis increases the risk of bias. The mitigation was to critically reflect on the author's research and personal perspectives and carefully cross-check all inferences with local research staff, implementers and policy-makers. Study strengths include the assessment of a representative sample of functioning services, as well as the use of broader mix of methods and attempt at more detailed interviewing than is the norm in standard program evaluations.

### **7.3.5 Overall conclusion on strength of immunisation services**

This assessment of front-line immunisation services in rural PNG found opportunities to boost coverage and quality, even within current resources, especially through better population-based local planning, and stronger community engagement. Many, but not all, were contained in PNG's recent national strategy (*SIREP*) for routine program strengthening. The assessment findings call for increased resourcing of, and commitment to SIREP and additional interventions. These findings also suggest areas where vaccination campaigns, including emergency polio responses, can contribute to front-line routine immunisation services.

This cross-sectional health services assessment also provides a supply-side perspective on the current and potential levels of integration between immunisation and other services in ENB. These findings and their implications are discussed further in Section 7.4 below. This assessment also included data on routine postnatal care, which are presented and discussed in the Section 7.5 that concludes this chapter.

## 7.4 Supply-side perspectives on integrating immunisation and other health services

### 7.4.1 Results – interview, audit, and observation data relevant to integration

The cross-sectional assessment described above in Section 7.3 included a number of measures of integration (see also Chapter 4, Section 4.3.6) in staff interviews, structured observation of patient flow, and client group discussions.

Structured observations showed that vaccination was accompanied by another service approximately half the time; *checking of weight and assessment of childhood illness* being the two additional services commonly observed. This aligns with women's reports as presented in Chapter Six (Table 13, Section 6.3.3). Illness checks were reported in research observers' opinions as mainly oriented to pre-vaccination screening. In five of 15 patient flow assessments *vaccination was omitted because of reported illness* (although no illnesses comprised true contra-indications as recommended by WHO<sup>298</sup>). In one observation, vaccination was delayed because the health worker was reluctant to open a multi-dose vial. In several of these cases the child was referred to a different location and/or time for vaccination. Some capacity for child illness treatment was observed as available in all but one immunisation clinic; although two sites were observed to be out of stock of common childhood illness medicines.

Other preventive care infrequently included additional *nutritional advice*: in one instance an explanation of the weight-for-age chart was observed, and in two instances feeding advice was offered. As noted in Chapter Six, (Section 6.3.3) approximately 10% of women reported this at Six Month and Twelve Month interview time points. There were no instances of height measurement observed. Vitamin A distribution was observed in two of 14 patient-flow interactions and albendazole administration in one; similar in frequency to that reported by women in Chapter Six. There was one instance observed where a woman was given hygiene and nutrition advice that applied to both mother and baby. There were *no other instances observed of maternal preventive or curative health care*.

In a general hospital outpatient clinic there were *no instances observed where a child received vaccination as part of illness care*. This omission contravenes PNG's child health guidelines,<sup>503</sup> possibly made difficult in this site because routine immunisation was provided in a different site than the child outpatient clinic under observation.

At interview *most staff reported integration of other services with immunisation as important*. Of 17 health workers, when asked what additional services were in fact commonly provided alongside immunisation, nine said they checked for childhood illness, seven mentioned the child's weight, six said they counseled on hygiene, four mentioned family planning advice and one mentioned illness care for the woman. Of these, only checking of weight and screening for childhood illness were noted in observational data, as discussed above. The provision of illness screening may delay vaccination. Thirteen of 17 health workers stated they would usually ask a sick child to return for vaccination at another time, and several staff related this to the desire to avoid opening a multi-dose vial; an avoidance that also contravenes PNG's child health guidelines.<sup>503</sup>

The main constraint on provision of non-immunisation preventive care, according to staff interviews, was *shortage of staff numbers*. There were some mentions of insufficient staff time, but generally it was simply insufficient absolute numbers of staff to operate clinics that staff reported as the constraint.

Health workers in interview responded *positively about more integrated services in the future* as a means to improve preventive care reach. One staff member suggested re-designing outreach services so as to combine contraceptive distribution with immunisation. When asked about priorities for future integrated services *the most common additional services suggested were family planning and general family health education*. Less common services mentioned were care for infectious disease in the woman, such as sexually transmitted infections or tuberculosis, and support to improve infant feeding and nutrition. Several staff suggested drawing a stronger link between infancy services and antenatal services, especially in ensuring that the broad health education provided at some of the stronger antenatal services was also deployed in immunisation clinics.

Immunisation clinic clients in FGDs (almost all mothers) had suggestions for future integration. Similar to health care providers, there was a strong preference, mentioned in *a majority of client groups, for inclusion of family planning*. However, in contrast to health workers, other high priorities for clients were interventions to *promote women's health*, including preventive checks on *reproductive health* and care for *women's illnesses in the postpartum period*. Other desired services mentioned by clients attending immunisation clinics included care for sick children, advice on how to prevent childhood illness, and general health education for both mothers and fathers. These priorities compare closely with the more formal assessment in Chapter Six.

In open questions on what constitutes a good quality immunisation service, the majority of staff responses were on topics of effective vaccine handling and safe injection, while two of 17 staff mentioned the ideal of a broader 'Well Baby' service, with one of these also mentioning the potential for a mother to be checked as well. In discussing the reasons why more integrated services would be desirable, two key rationales were mentioned by both clients and health workers. Firstly, improving vaccination coverage by taking every opportunity to vaccinate, especially during sick child visits; and, secondly, reducing clients' costs in time, money, and inconvenience. Neither health workers, nor clients in group discussions, mentioned the possible rationale that integrated services may be important because of co-morbidity, or co-existing health needs in women and their infants.

#### **7.4.2 Discussion – current levels of integration in ENB immunisation services**

Our data suggest that the SIREP aspiration for greater integration of non-vaccine services (see Section 2.4.6 and 7.3 above) is seen only to a very limited degree. One policy priority in particular, distribution of vitamin A (as nutritional supplement) and albendazole (as preventive anti-helminthic treatment), was reported as important by many staff, but observation showed minimal implementation.

While measurement of a child's weight was commonly observed, it is debatable as to whether this truly represents an integrated non-vaccination service because it rarely led to counseling on feeding or other relevant action. Similarly, while observations found some assessment of childhood illness took place in vaccination



clinics approximately half the time, this often seemed more of a pre-vaccination screen than a true illness management service. This observation may help explain slightly conflicting findings reported from the cohort study in Chapter Six whereby many women reported receipt of child illness management, while at the same time many of the same women asked for more or better child illness care. In fact, the illness screen was observed to sometimes obstruct immunisation by providing a spurious reason to delay vaccination. False contra-indications resulting in missed opportunities for vaccination are common world-wide,<sup>32</sup> so it is not surprising to see them also expressed in ENB.

Overall, our assessment in fixed facilities and outreach clinics found a far more restricted range of integrated services than those that have been used in settings in sub-Saharan Africa that share similar constraints as ENB; as reviewed by Wallace and colleagues in 2012<sup>58</sup> (see Section 2.3.2) and in the systematic review in Chapter Five. Although there was mention in interview by staff of integration of services such as family planning, this was not observed in practice, and provincial or district consultations did not reveal concrete, active plans to enable this integration to take place. Family planning was named as a priority in SIREP documentation<sup>277</sup> however this seems rarely translated into practice. Earlier recommendations by PNG's Child Health Advisory Committee for regular intensified outreach to integrate immunisation, growth monitoring and family planning,<sup>278</sup> have also been found unrealised in this assessment.

Missed opportunities through failures to integrate vaccination into general child health services were also confirmed in observation of general child outpatients, the number of child health records where vaccinations were not up to date, and the reports of senior clinicians in phase one consultations. This is despite the fact that the need to check a child's vaccination status, a key step in WHO's integrated childhood illness management algorithm<sup>70</sup> (see also Section 2.3.4), is also reflected in PNG's adaptation of IMCI and paediatric guidelines.<sup>503</sup>

These lapses in integrated service delivery illustrate the two gaps discussed in Section 3.1.5 of this thesis. Firstly, practice clearly does not match policy, especially the policy expectations of SIREP or child health authorities. Secondly, the conflict

between interview findings and observed practice suggest there is a ‘know-do’ gap<sup>306</sup> in relation to provision of integrated services.

From interview data and phase one consultations, the major factor constraining provision of integrated services was reported as being lack of staff. In staff and manager discussions, this out-weighed other possible explanations such as deficiencies in planning, supplies, policy support or community expectation. However many of the clinics observed in this assessment saw relatively few clients, and all clinics met the minimum WHO requirements for immunisation clinic staffing. This level of staffing may also apply in many other provinces of PNG, given that one of the core reforms of the 2015 SIREP strategy aimed for more efficient deployment of staff by redirecting outreach to more frequently (for example, monthly or fortnightly) visit higher population sites, and less frequently (for example, quarterly) sites with fewer children. Our audits also found most clinics were equipped to manage at least childhood illness, suggesting that supply chain limits are less likely to be an over-riding constraint. Overall, our findings show very limited implementation of the modest policy recommendations for integrating other services. The potential for greater integration within the current program is discussed below.

#### **7.4.3 Discussion – implications for future integration in ENB immunisation services**

There needs to be a certain level of strength in routine immunisation if it is to be a productive platform for the integration of other services. This concern, and the linked apprehension that integrating into fragile services may weaken program performance, has been expressed in earlier international reviews<sup>58,137,139,140</sup> and characterizations such as Steinglass’ “*Routine immunization: an essential but wobbly platform*”.<sup>504</sup> While the in-depth assessment in Section 7.3 above shows some weaknesses in the ENB routine immunisation service, it also depicts a service that, for the population it reaches (approximately two thirds of that targeted), has key functions intact, and sufficient staff time and resources to provide at least some level of integrated services. The service has also successfully deployed three new vaccines;

significant in that introduction of new vaccines is a process that, like integration, requires a minimum level of system strength.<sup>292</sup>

Moreover, as discussed at the end of Section 7.3, there is scope to better implement some SIREP priorities and other locally feasible innovations that could both increase immunisation coverage and quality. If achieved, this improved program performance would also support the integration of additional high priority services. Specific prospects for integration are discussed below, organized by the categories of service delivery change in the conceptual framework developed for this research (Figure 5, Section 3.1.4). That is: changing *what* package of services are provided; *who* provides care and other *system supports*; *where and when* care is provided; *how users interact* with the service; and *engaging communities* differently. These categories also reflect the research and practice questions raised by the scoping review of integration evidence (see Section 2.3.5).

*What package of services to integrate:*

Only certain types of services are suitable for integration into new outreach clinics that are likely to be the first priority for service delivery scale-up. Supplementation of *vitamin A* remains warranted in settings such as PNG, and regular *anti-helminthic* treatment is at least worth consideration as an option,<sup>443,505,506</sup> so it is encouraging that delivery of both has proven feasible in SIAs in 2012<sup>278</sup> and to a limited extent in 2019.<sup>494</sup> However it is clear that other supports,<sup>140</sup> including information systems and supply chains as discussed below, are needed for these to be regularly available in outreach or fixed facility clinics.

Provision of *family planning advice* and distribution of *contraceptives* seems the highest priority for new services from this assessment. These were ranked highly by staff and clients in this health services study, as well as by the cohort described in Chapter Six, and experiences elsewhere have been discussed in the scoping review (Section 2.3.5), and the systematic review of Chapter Five. Experience internationally<sup>62,179</sup> shows that careful planning for optimal timing of both counselling and contraceptive provision is essential, although there are several points in the first year of life where postpartum family planning services match well with PNG's

immunisation schedule. The confirmation, from findings reported in Chapter Six, that this is indeed a sensitive topic that requires privacy and the provision for one-on-one counselling must be borne in mind; as well as the need to address the reservations of a minority (of perhaps 10%) of women attending immunisation clinics.

As well as family planning, routine *antenatal checks* and improved *growth monitoring* as part of intensified immunisation outreach were prime recommendations of the advisory group (as reported by Vince and others<sup>278</sup>) that contributed to the original concepts in the SIREP strategy. While there is minimal demonstrable implementation seen in the findings presented above, these aspirations are also reflected in manager consultations (Section 7.2) and staff interviews (Section 7.4.1). In some ways, promoting a comprehensive suite of growth monitoring and counselling on improved feeding and child development, offers one of the most coherent improvements, aligning powerful potential for improved infant well-being<sup>120</sup> with women's expectations and preferences, as seen in Chapter Six. Two interventions, antenatal checks and growth monitoring, are likely to be relevant to families with children in their second year of life<sup>414</sup>; an important age group for catch-up vaccination and booster doses of measles-containing vaccine currently not well addressed by either outreach or facility-based services.

This health facility assessment echoes the call for greater attention to *postpartum maternal morbidity*, both infectious and nutritional, that strongly emerged from the prospective observational cohort findings in Chapter Six. This request was reflected in this study in client views in FGDs, and by a small proportion of health managers and health providers. Although clearly important to family health and responsive to demand, interventions to address this are likely to be taxing to implement, and there are no current models to demonstrate this in PNG. There is some synergy with future staff and system supports that would be needed for other integrated interventions, as discussed below. Proposals for new models to test, that synthesise findings from Chapters Five and Six, are also discussed in Chapter Eight.

This supply side assessment elicited less on the potential for *malaria* or other disease control interventions, although distribution of ITNs and intermittent preventive treatment in infancy had been included in early SIREP documentation.<sup>277</sup>

IPTi at least is not widespread practice in PNG, and not anticipated in current national plans.<sup>507</sup> Internationally, as discussed in Chapter Five, delivery by means other than immunisation clinics have been seen as more productive for seasonal malaria control<sup>178</sup> or ITN distribution.<sup>391</sup>

#### *Staffing and other systems support*

A review of staff functions and tasks undertaken is likely to benefit immunisation in general, especially if additional skilled staff can assume vaccinator roles (as discussed in Section 7.3). Revision of task allocations may also benefit delivery of some integrated services; noting the relatively low vaccine numbers in clinics observed in this study. The infrequent observation of relatively straight-forward services such as vitamin A, anti-helminthic distribution, or growth monitoring suggests that there may be some expression of the ‘know-do’ gap.<sup>306</sup> As discussed in Section 3.1.5, attitudinal factors<sup>18,181</sup> are likely to constrain service delivery in addition to resources. Greater involvement of staff in local integration planning, as well awareness raising on the preferences of clients, may support additional motivation for implementation. PNG has seen success with improved implementation of birth-dose vaccination when staff were educated on underlying rationales<sup>508</sup> stressing its life-saving importance.

Provider incentives to motivate provision of more integrated care has so far not been seen in evidence reviews here (Chapter Five) or previously.<sup>58</sup> Broader evidence suggests such schemes’ success is highly dependent on design,<sup>509,510</sup> and unintended consequences may be seen in settings similar to rural PNG.<sup>511</sup> They are also highly dependent on effective support from health policy on other aspects of health financing, which in PNG are currently not targeting this approach.<sup>221,244</sup> For these reasons, the role of incentives in promoting supply-side changes for integration would require more detailed analysis and consultation before being proposed for PNG.

Noting that staff expressed positive opinions of integration at interview, some of the ‘know-do’ gap may be amenable to integration-specific point-of-care reminders, job aids, local training or supervisory inputs and policy reinforcement. One example on postpartum family planning from Senegal<sup>488</sup> has been designed with a strong emphasis

on the theory and practice of behaviour change (see also Chapter Eight). However high priority additional services such as family planning or maternal illness care are likely to add significantly to staff time commitments if done well.<sup>130,180</sup> From the analysis of successful integration models in Chapter Five, it seems likely that some form of co-location would be required, as discussed further in Chapter Eight.

While this assessment showed encouraging availability of supplies for non-immunisation services, this was not universal and increased integration of supply chain between vaccine and other family health commodities would need to be an explicit aspect of new attempts to integrate services, as has been found elsewhere.<sup>88</sup> Better use of existing information systems can accompany work on their much-needed overall improvement. Right now, population tallies for campaigns and home-based records can be better used for outreach planning, as noted above. A further innovation may be needed to better link antenatal registers with postpartum and child health registers to provide a more holistic picture of family health needs.

*Where and when: improved planning and more efficient outreach*

Improved planning of outreach sessions, with intensified outreach targeting higher population centres and a minimum frequency of quarterly elsewhere, as proposed under SIREP, seems an appropriate response to the low client numbers we observed in many of the clinic sites. This change will require major improvement in local service planning (often termed ‘micro-planning’); noting that our assessment (see Section 7.3) found a marked lack of effective pre-outreach planning with no attempts to document names, or even numbers, of children needing to be reached by a given outreach visits. Information collected for the 2018/19 emergency polio response campaigns (see Section 7.3.1) may assist with this planning. Emergency Operations Centres (EOC)<sup>494</sup> were established in most provinces and districts that, among other things, gathered detailed population information for campaign planning, that can potentially be used in more efficient outreach scheduling.

Better understanding of the community to be accessed, and expectation of greater coverage, can provide an opportunity for advance planning of new services to be offered alongside vaccination. This will need to go beyond emergency campaign

tallies and include a concerted attempt to rebuild child health registers by better utilisation of home-based records<sup>512,513</sup> for children and mothers. Health information integration is a critical contributor,<sup>458</sup> and it is worth noting that existing 'Helti Beibi Buk' records in PNG already integrate information on other services with that for vaccination. PNG is also currently establishing an electronic health information system based on portable electronic devices held at the clinic level. This is currently only to serve monthly tally functions, however with some adaptation could be extended to the construction of electronic child registers<sup>514</sup> that can aid in tracking those who are under-vaccinated. And, as noted in sections above, and below, community-based lay health workers can play a vital role in identifying children for vaccination.

Improved outreach planning is also likely to benefit fixed facility-based services through better understanding of the population catchment and clients to be tracked.

#### *Client interaction during service delivery*

The community discussion findings in this study, and the findings reported in Chapter Six, reflect a demand for integrated services that goes beyond distribution of commodities, prioritising relatively complex services such as maternal illness care, family planning counselling and provision, or childhood illness care. As well as new staffing and care models noted above, responding to this will need a different approach to staff-client interaction than that which was observed in this study. Even on immunisation topics, there was less communication than recommended in WHO standards<sup>298</sup> (Figure 16 in Section 7.3), whether through staff providing advice or clients seeking information. Specific tools to improve two-way communication have shown promise elsewhere, such as user-administered checklists<sup>426</sup> or aids to feedback,<sup>515,516</sup> and may represent useful supports to more integrated services in the future.

#### *Community engagement*

This assessment failed to find instances where community-based leaders or trained lay health workers (Village Health Volunteers) were specifically enlisted in support of routine immunisation services. This may be a potential resource, given that contributions from such groups were reported as important to the polio emergency response,<sup>494</sup> and have successfully combined vaccination with postnatal counselling in

a 2009 pilot in rural PNG.<sup>498</sup> As shown in Chapter Five, careful involvement of trained lay health workers can deliver counselling interventions alongside vaccination; as experiences in Sierra Leone<sup>339,356</sup> have shown. This can represent a form of co-location that helps protect staff time. As collated in a Cochrane review,<sup>484</sup> there is clear evidence over many decades for the role of community-based lay health workers in contributing to improved immunisation coverage. Finding community resources that can be harnessed to support the operations of both fixed and outreach preventive care services will be critical to renewal of immunisation services, and to any expansion of more integrated models of care.

Both staff and families mentioned the need for greater involvement of male care-givers in immunisation services. Their involvement in more integrated care is also likely to be important, especially considering services such as family planning, or broader family health education.<sup>489,517,518</sup>

More integrated care may also support immunisation strengthening if they are seen as more responsive to users' preferences. The increased acceptability of integrated services has been well-noted both in broader reviews of integration,<sup>6</sup> and of reasons for under-vaccination.<sup>166</sup> If integrated service provision prioritizes care that families want, this may help build demand for and confidence in immunisation services. It is notable that both providers and users, in interviews and discussion, saw integration as desirable largely on the grounds of improved efficiency in use of time and resources, for families and staff. The need for integration to provide more holistic care for all of a family's health needs, as an expression of good quality PHC<sup>48</sup> (and as discussed in Chapters Five and Six), is not yet widely recognised.

#### ***7.4.4 Conclusions - supply-side perspectives on integration in routine immunisation services***

The methods used in the health services assessment have proven helpful in exploring the current status and future potential of the integration of other services with routine immunisation. Informing interview and discussion guides with realist<sup>307,308</sup> and 'most significant change'<sup>310</sup> methodologies (see also Section 3.1.5) were helpful in detailing the nature of recent changes and what respondents valued. Some useful



contrasts emerged through the triangulation of interview with observation. In addition, the simplified patient-flow assessment tool, similar to those used by others<sup>9,90,169</sup> helped assess what new levels of integration may be possible. Adaptations of these methods could be employed to help monitor innovations that aim for more integrated care.

The discussion of the health assessment findings suggests that current levels of integration are well below the expectations of policy, plans and managers; and there are some opportunities to increase delivery of some core preventive services within current staff time and clinic capacity. However meeting the gaps in some of the higher priorities, such as family planning or maternal illness follow-up, will require introduction of new models of care, and tailoring these where appropriate to the new forms of intensified outreach that renewal of routine immunisation requires. Without such new models (see also Chapter Eight), there is a risk that simply asking staff to integrate more will limit population coverage in the way that has happened for routine immunisation until now. This would mean satisfactory quality care only for some, but no access for disadvantaged or remote communities.

## **7.5 Routine postnatal care findings from health services assessment and their implications**

In initial plans, it was hoped that this study would also include structured observation of the provision of routine preventive postnatal care for mother and baby; following either discharge from a health facility after childbirth, or after childbirth in the community. This expectation reflected PNG's 2014 Newborn Health Policy<sup>268</sup> which proposed that *“Every newborn baby should be followed up on day 1, 3 and 7, and 6 weeks after delivery”*; a policy that presumes either home visits or women attending outpatient clinics in health facilities for routine checks of their newborn. This proved impossible, because such routine checks are rare. For the same reason, analysis of postnatal care and its potential for integrated services was limited in the cohort study discussed in Chapter Six. The section below reviews data on routine postnatal care from both phases of the health services assessment and discusses their implications.

### **7.5.1 Consultation findings relevant to routine preventive postnatal care**

Interviewees at national and ENB provincial levels could not provide any examples of routine home visits, nor of outpatient clinics specifically for the postnatal period. Many managers noted that there is no separate postnatal care established within current preventive care services. Some managers reported that clinically responsive postnatal care would be offered in the event of illness in mother or baby, but that there was no designated access point for this. Families would need to present to emergency rooms (in hospitals) or standard outpatient services.

Most respondents volunteered topics relevant to the health of the newborn, rather than that of the postpartum mother; and most managers acknowledged routine preventive care for women at this point in the life course was not commonly provided. PNG does have ‘well woman clinics’ established at some provincial hospitals, however these seem oriented to reproductive health outside the postpartum period.<sup>460</sup>

Some managers mentioned that the only service available at present is early postnatal care obtained while inpatient following childbirth in a health facility. Most of those mentioning this also noted early discharge as a significant barrier. Neither the

Newborn Health Policy nor the recommendations from the Ministerial Taskforce on Maternal Mortality were found to specify a minimum duration of stay after childbirth.

Most managers, at all levels, reported that the provision of hepatitis B vaccine was well integrated into care in delivery rooms or postnatal wards for babies born in health facilities. A relatively high coverage with timely birth-dose vaccination was seen in the cohort of infants studied in Chapter Six (Section 6.3.3). Birth-dose vaccination is also included in a protocol for ‘babies born before arrival’ found in national guidelines.<sup>503</sup> No managers mentioned PNG’s 2009 district pilot (in East Sepik Province) of community-based birth-dose vaccination integrated with home visits for postnatal care.<sup>498</sup>

### ***7.5.2 Phase two findings relevant to routine preventive postnatal care***

In complement to the opinions regarding postnatal care captured from health managers in phase one (above), questions on this topic were also posed to health care providers and clients in phase two. Responses to these questions are also included in the data report at Appendix 10.4.1.

Interviews with the same front-line health workers described above in Section 7.3 confirmed the findings from consultations with managers in phase one. No staff reported any functional models of routine postnatal care checks, whether following childbirth in a health facility, after discharge, or after community births. No staff were aware of the recommendations in the national newborn health policy for at least three checks in the first week after birth, and from the evidence gathered here this policy seems unworkable in PNG in its current form. In structured interviews, one third of front-line health care providers suggested that the first routine check that is required would be at four weeks or later (that is: outside the postnatal period), at the time of the first infant vaccination visit.

After confirming that there were no routine dedicated outpatient or outreach services, respondents were asked to consider the potential for routine postnatal care. Most staff who provided comments on postnatal care, referred only to pre-discharge checks following childbirth in a health facility. Health worker interview data suggested that these inpatient pre-discharge checks are not always thorough and do not

commonly involve a structured checklist of routine preventive care. Interventions reported in structured interviews as forming part of these assessments included birth-weight measurement, checking for congenital abnormalities, birth-dose vaccination, hygiene advice and family planning advice. When asked about optimal timing of discharge after childbirth in a facility, two staff suggested 48 hours or more, six suggested 24 to 48 hours, and two suggested less than 24 hours.

The lack of reports of routine postnatal care beyond pre-discharge checks after facility-based childbirth meant that current constraints on postnatal care were difficult to derive from health worker interviews. Open questions to health workers on this topic suggested that important limitations on provision of routine postnatal care largely relate to staff shortages and the perception that routine outpatient or community-based postnatal checks were not needed. Also mentioned were distances and transport for community births, lack of dedicated clinic space, and one mention of obstructive institutional policies.

A minority of staff added, in open responses, detail on what was most important in postnatal checks should they be feasible. The most common emphases were advice on *personal hygiene, family planning, breast feeding, newborn vaccination* and some mentions of checks for *maternal bleeding or illness follow-up*. One respondent mentioned the use of postpartum iron supplementation to counteract the effect of blood loss. Two respondents mentioned the importance of education for male caregivers.

*Client opinions on postnatal care were difficult to elicit* in the ten FGDs held in phase two, due to caregivers' lack of familiarity with the concept of routine checks in the first weeks after birth. Most mentions in discussions of routine care at this point in the life course were of general health checks for mother and baby, review of maternal reproductive health, and of nutritional issues such as breast feeding. There were several mentions in different groups of the need to exclude maternal infections, and one mention of the need to check for anaemia following childbirth. Many groups discussed different types of maternal postpartum complications and said they would welcome better access to care for these. Two groups mentioned postpartum family planning services, in one adding the need to use local language (rather than Tok Pisin

or English) when discussing permanent contraception to ensure mothers understood the implications of this procedure.

*Few health workers were able to make suggestions for alternative mechanisms to provide routine preventive postnatal care, although one suggested that there is a need to push preventive care beyond hospitals to smaller clinics to enable easier access in the first weeks after childbirth. Three client groups proposed that health staff visit the community or homes of women in the period soon after childbirth.*

### **7.5.3 Conclusions on integration in routine postnatal care**

Overall, the *gap in provision of routine postnatal checks* for women or newborns represents a major missed opportunity to reduce mortality and morbidity at this critical point in the life-course.<sup>255,463</sup> The demand-side evidence in Chapter Six supports the finding from this supply-side assessment that any routine preventive care prior to the first vaccination visit is only available in the form of pre-discharge checks for women who deliver in health facilities. Further, both this assessment and the findings presented in Chapter Six suggest that such care is not meeting international<sup>233</sup> or national standards.<sup>503</sup> Regardless of integration considerations, this lapse in the continuum of care calls for renewed activity by policy-makers, obstetric and paediatric specialists, and health planners to adapt relevant examples from elsewhere<sup>372,519</sup> to the PNG context.

*Home visits* to provide both vaccination and postnatal care at community level have been demonstrated in a small pilot program in another province of PNG approximately 10 years ago.<sup>276,498</sup> This required a unique presentation of hepatitis B vaccine that could be administered by trained lay health workers<sup>175</sup> and managed for a period without access to refrigeration. The barriers to greater uptake of this approach included high costs of this form of the vaccine, and *reluctance to deploy volunteers* in this way. The findings from this assessment, however, do not provide strong encouragement for the feasibility of home visits from either health manager consultations or health provider interviews. It may be that the higher priorities for ENB are to continue to promote facility-based childbirth and work to improve the quality of integrated postnatal care provided to families in that forum. Some caregiver views in

this assessment sought home visits, but there were very limited data from this study. The Prospective Observational Cohort in-depth interviews provided better quality evidence on demand-side views, presented in Chapter Six. One more recent outcome of the research in this thesis includes a pilot program in ENB to test feasibility and acceptability of different models of postnatal care<sup>520</sup>; including home visits, enhanced pre-discharge counselling, and improved care-giver information materials (see also Chapter Eight).

The primary integration question is the degree to which *birth dose vaccination* is provided along-side early neonatal or postnatal care. Given the absence of routine postnatal care models, this question could only be tested for this research through the Prospective Observational Cohort study, as described in Chapter Six. Inspection of home-based records in that study shows that vaccination at birth against hepatitis B is well integrated into early pre-discharge postnatal care for those born in health facilities in ENB.

Vaccination is well integrated into managers' conceptualisations of potential future postnatal care, being frequently mentioned by all types of respondents. These views also included care for the women (in terms of illness follow-up, general reproductive health and family planning), as well as a desire to promote male partner involvement, both topics more often mentioned by front-line provider or care-giver respondents. It seems that some key integration themes that have emerged in the discussions above are more readily recognised at the peripheries of the health care system than in central planning.

## 8 FUTURE IMPLICATIONS FOR INTEGRATING OTHER SERVICES WITH IMMUNISATION

This chapter concludes the thesis by combining the findings presented above, with their implications for future work on integration, as it applies to immunisation and other routine preventive health care provided in the first years after childbirth.

Section 8.1 draws on Chapters Five, Six and Seven, synthesising the findings and expanding those discussions. Section 8.2 briefly describes current and planned contributions this research can make to integration research and policy, as supplement to the list of publications provided in the Preface. Section 8.3 presents a conclusion that summarises the implications for future directions in integrated services.

Section 8.1 returns to the overall *research objectives* (Section 3.2), to:

1. Review the current experiences of integrating immunisation and other services, globally and in PNG;
2. Quantify, in PNG, the current disease burden and health care needs that are relevant to integrated services;
3. Characterise opportunities for, and barriers to, new models of service delivery that promote greater integration, globally and in PNG; and
4. Estimate the potential impact (both positive and negative) of integrated services on intervention coverage and resources, client acceptance, equity of access, and quality of care.

The section below proposes expanded options to respond to the need and demand for integrated services, and considers how such changes could be made feasibly, acceptably and equitably. This section also presents means for monitoring the process of integration, and directions for future research.

## 8.1 New approaches to integration, globally and in PNG

### 8.1.1 *Current needs and experiences with integration, PNG and global*

#### *The need for integrated care in the first year after childbirth*

In rural PNG this research estimated that at least 89% of women had symptoms or signs (clinical or on POC screening test) of likely illness complicating pregnancy likely to extend through the postpartum period, including nutritional deficits, malaria, reproductive tract or other infections (Section 6.3.2). In addition, over the one to six months after childbirth when the primary series of post-neonatal vaccinations is scheduled, over 80% of families needed care for chronic illness or sought other preventive care, such as advice on family planning or maternal or infant nutrition.

This burden of morbidity on postpartum women and their infants, and requirement for other preventive care, is characteristic of many LMIC settings. Global estimates parallel those in PNG<sup>246</sup> for sexually transmitted infections and unwanted pregnancy,<sup>521</sup> childhood illness and undernutrition,<sup>522</sup> malaria,<sup>523</sup> or maternal undernutrition<sup>524</sup>; all often worse when experienced in combination.<sup>328,330,459</sup> They reinforce the need for integrated approaches at this point in the life-course, especially in settings of high mortality.

When offered the opportunity to suggest responses, women sought the holistic care of both mother and infant that evokes renewed descriptions of comprehensive PHC<sup>48</sup> and people-centred health services.<sup>74</sup> Front-line health workers observed and interviewed in ENB (Section 7.4.1), valued integrated services, but saw them more as pre-specified additions to vaccination, rather than comprehensive care.

Low levels of integrated service provision in ENB are failing to meet family needs, as seen in women's reports, clinic observations, or health care worker interviews, even for the prime policy targets of Vitamin A and anti-helminthic distribution. While weight and illness screening of infants was commonly done, these actions only infrequently translated into effective management, or counselling for the infant's growth or development. Consideration of women's need for illness follow-up, or for sexual and reproductive health care, including contraception, was extremely rare. Global reports also note low service coverage at this point in the life course in



LMICs. Similar gaps in coverage are evident for family planning, perinatal HIV screening or management of STIs,<sup>521,525</sup> intermittent preventive malaria treatment<sup>523</sup> (still not scaled up in PNG<sup>507</sup>), management of childhood illness or undernutrition,<sup>526</sup> promotion of optimal development,<sup>522</sup> or even the distribution of vitamin A.<sup>527</sup>

Low coverage with routine postnatal care is a distinct but related challenge. In global measures in LMICs it reaches far fewer than antenatal, childbirth or immunisation services.<sup>463</sup> In ENB, findings from women (Section 6.3.3), and health managers and frontline workers (Section 7.5) demonstrate extremely low coverage (11%) with the life-saving postnatal checks in the first week of life that are recommended by national<sup>268</sup> and international policy.<sup>255</sup>

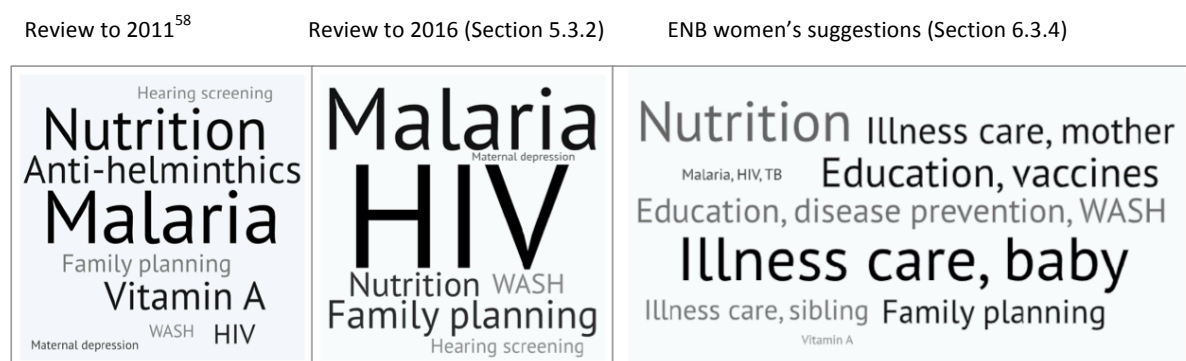
For women and infants in ENB, better integration of additional services at immunisation clinics could help to redress some of these gaps in provision of care.

*Women's priorities for integration go beyond policy and the existing evidence base*

Front-line staff in ENB (Section 7.4) and PNG policy<sup>277</sup> prioritise vitamin A, anti-helminthics, and possibly family planning.

The systematic review (2012-16) in this thesis documented 21 new integration experiences (Section 5.3.2) comprising interventions for HIV, malaria, family planning, nutrition and others; adding to the earlier reviews<sup>58,140</sup> up until 2011 (Section 2.3.2). Since 2016, most published experiences (incorporated into discussion sections of this thesis) have integrated HIV or postpartum family planning, with few on nutrition. The limitations on the systematic review timing, and plans for updating in 2020 are discussed below.

Women in ENB (Section 6.3.4) made some suggestions that mirrored published experiences, but many expressed additional priorities: maternal illness, childhood illness, and education on growth, development and preventive health. The graphic below, Figure 19, displays two differences in emphasis, firstly the trend over time across the reviews collating data to 2011 and then to 2016, and then the contrast between both reviews and women's suggestions.

**Figure 19: Word clouds of two integration reviews and ENB women's preferences.**

Note: word clouds generated from counts of program categories, at [www.wordart.com/create](http://www.wordart.com/create). Counts for 2011 and 2016 tallied numbers of studies captured by the two reviews. Counts for ENB women tallied the category of additional program suggested at Six Months, using data in Table 14 and Figure 13, Section 6.3.4.

### *Integrated services have some proven benefits, but implementation issues persist*

The analysis in Chapter Five (Table 5, Section 5.3.3) demonstrates that there are potential gains through integration of other services with immunisation. Gains are better for the linked service, with up to sevenfold expansion in access to HIV early infancy testing and treatment. There were also clear benefits for postpartum family planning, distribution of preventive malaria treatment in infancy and WASH. Only one study<sup>339</sup> provided encouraging evidence of integrating feeding counselling for improved childhood growth, when provided alongside both immunisation and family planning.

Not all were successful, with lack of benefit in some studies of family planning<sup>10</sup> and malaria control<sup>350</sup>; the reasons for which provide insights into what is required for successful integration as discussed below. Immunisation benefited in some experiences, especially when linked with highly valued commodities (ITNs,<sup>347</sup> hygiene products<sup>331,356</sup>) or services (malaria prevention,<sup>141</sup> nutrition<sup>339</sup>). Where there was failure to benefit, these were often due to specific barriers such as HIV stigma,<sup>340</sup> or implementation lapses such as ineffective counselling or inhibited referral.<sup>10,477,528</sup> In only a few was the process of integration itself the problem: seasonal malaria control for infants older than one year<sup>350</sup> (see below); or distribution of ITNs at scheduled clinics (where mass campaigns or other platforms than routine immunisation give better results<sup>389</sup>).

There was a paucity of controlled studies of broader integration approaches such as IMCI or community-based PHC that might respond to women's calls for holistic care. A number of PHC experiences do support integrated services (including vaccination) as a means to improve quality of care (see Section 5.3.6); and in Tanzania<sup>529</sup> integration in front-line services, with immunisation front and centre, made a key contribution to child survival through IMCI. However a Cochrane review<sup>109</sup> suggests the benefit is to other services rather than immunisation, with the integration of catch-up vaccination as part of childhood illness management being one of the less effective aspects of the IMCI approach. By contrast, a review of strategies to improve child health services<sup>15</sup> did note integration as one means to improve access. This study also attributed improvement to innovations in client communications, something that would be welcomed by women in ENB.

### 8.1.2 *New opportunities for integrating immunisation and other services*

A better understanding of the burden of co-morbidity and co-existing health care needs, as well as the suggestions of clinic users for which services to add, can help generate a demand-side rationale for how best to change service delivery arrangements. Such considerations can sit alongside the intent of health planners to increase coverage of pre-specified high impact interventions. In addition, the imbalance noted above, between needs, currently documented experiences and women's preferences, reveals significant gaps in three important areas. Firstly, in ensuring that *maternal health and nutrition* is addressed. Secondly, in taking up the challenge of *nutrition and development* for the infant. Thirdly, in action to reduce *missed opportunities for vaccination*.

The discussion below applies, where relevant, the typology of integration models that emerged from analysis in Chapter Five (see Figure 11). This typology acknowledges the call by Mayhew<sup>129</sup> and others, based on work in the Integra Initiative, to consider both *physical* integration and *functional* integration. The

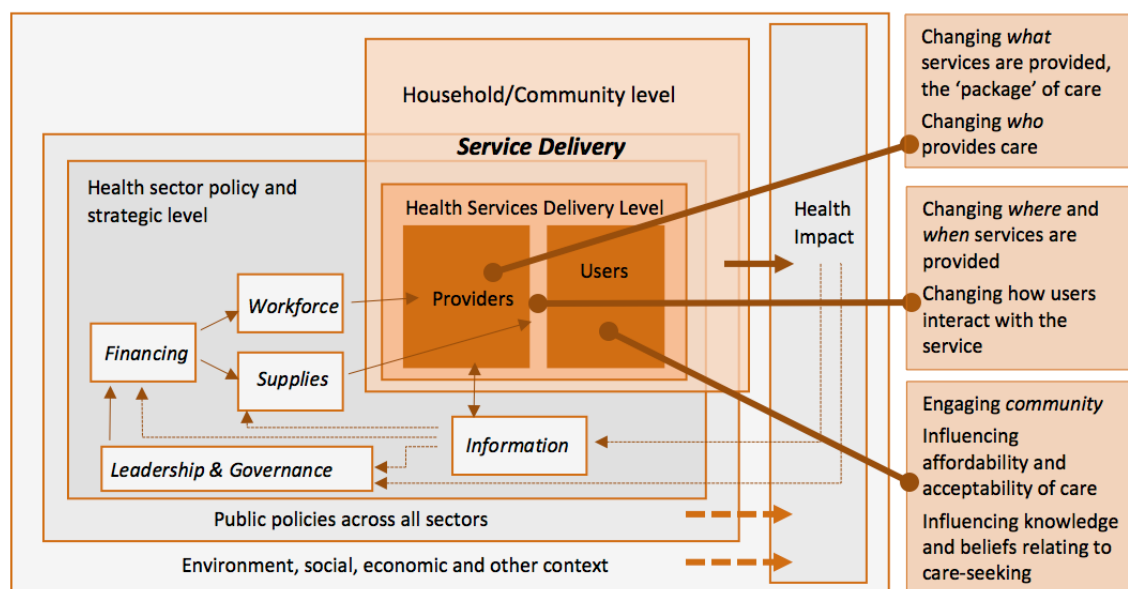
**Figure 11: Integration models**  
(from Section 5.3.4)

|                                                                                      |
|--------------------------------------------------------------------------------------|
| A: Extra <b>services</b> provided by vaccinating staff                               |
| B: Extra <b>counselling</b> provided by vaccinating staff                            |
| C: <b>Co-location</b> with extra services linked to immunisation place and time      |
| D: <b>Vaccination</b> by staff who are not usual immunisation providers              |
| E: <b>Immunisation counselling</b> by staff who are not usual immunisation providers |

typology used here has a tighter focus on practical elements of service delivery and demands placed on staff. The most important distinctions hinge on what is asked of the vaccinator: whether they are required perform extra clinical tasks (type A) or provide extra information (type B) during vaccination sessions; or whether other staff make these services available in a way that is facilitated by the immunization visit through co-location in time and place (type C). Less common typologies were those that sought to leverage non-immunisation platforms to vaccinate (type D) or promote vaccination (type E).

The following two sections are structured under categories of service delivery innovation drawn from the conceptual framework for this research (Figure 5, copied below, also in Section 3.1.4). The first category considers changes to *what* services can be provided.

**Figure 5: Conceptual framework for innovation in service delivery** (from Section 3.1.4)



Note: Adapted from Willey et al<sup>28</sup> and Hanson et al<sup>301</sup>

*What to integrate, the 'package' of care (top box in right hand column, Figure 5)*

The challenge posed in taking the client's (especially the woman's) perspective is how to give equal weight to both infant and maternal health needs when deciding on integration priorities. In part, this may require revising concepts of the postpartum period to extend beyond the traditional period of six weeks; extending the consideration of what is 'maternal health' to mirror the timeframe for postpartum

family planning (PPFP), by considering the mother's needs throughout the first twelve months after childbirth.<sup>530,531</sup>

*Postpartum family planning* has grown in evidence since 2012,<sup>334,333,393,394,33,92</sup> was a high priority for front-line health workers (Section 7.4) and senior child health advisors in PNG<sup>278</sup>, and frequently suggested by ENB women (Section 6.3.4), especially early in the postpartum period. It is already supported in immunisation policy<sup>277</sup>; so seems logical as the first choice for integration at immunisation clinics in PNG. Given its poor execution so far in most sites, future implementation will need to explicitly address the barriers and success factors documented in this research (see below), especially those that apply to 'Type C' co-location models.

*Integration of maternal illness follow-up*, based on data from Chapter Six (Section 6.3.2 and 6.3.4), could usefully address treatable reproductive tract infections, malaria, anaemia and undernutrition at least until six months after childbirth. No published LMIC experiences of this were found, so introduction in PNG or similar settings would be breaking new ground. It is acknowledged that this would be demanding of staff skills, time and additional screening tests. This may appear daunting, however enhanced screening and managing of reproductive tract infections is currently being trialled as an adjunct to ANC clinics in PNG<sup>450</sup>, meaning data on health system implementation requirements will be available by the end of 2020. A number of implementation issues, as discussed below, would be similar to those for integration of family planning. Other potential priorities include *tuberculosis*, given its importance in PNG and patchy program performance,<sup>532</sup> as well as screening for *high priority cancers* (such as cervical), as suggested globally,<sup>521</sup> and called for by some ENB women (Section 6.3.4.). 'Well Woman Clinics' with some of this spectrum of services exist in a very few sites in PNG<sup>460</sup>, but are not linked to the postpartum period or the schedule of immunisation clinics. Integration of maternal illness interventions is not documented in other LMIC settings; PNG's experience, if attempted, could be instructive for others.

*Nutrition* interventions are urgently needed, noting PNG's high and persistent prevalence of infant undernutrition<sup>213</sup> and the consequences of maternal undernutrition in these settings.<sup>459</sup> Integration of nutrition and HIV services was positive and cost-effective in Malawi and Mozambique.<sup>533</sup> Other experiences

integrating nutrition advice in Bangladesh and Vietnam<sup>534</sup> emphasised the importance of getting counselling right and linkages with mass communication approaches.<sup>535,536</sup>

The potential *combination of immunisation, nutrition counselling and family planning* services in the first postpartum months was well shown in Hodges and colleagues' study<sup>339</sup> in Sierra Leone (Section 5.3.2) and similar work in Kenya<sup>419</sup>; contributing to a global community of practice proposed in 2019 on integration of these three domains.<sup>537</sup> While welcomed by ENB women, it will need active planning and support in PNG, given low recognition and practice by front-line staff of nutrition counselling (Sections 6.3.3 and 7.3.3).

The impact on children could be extended greatly by *linking counselling on child development with nutrition, and into the second year of life*. Many ENB women asked for more general advice on child care and childhood development. This can draw on the strong evidence for combining better feeding with counselling on psychosocial stimulation, both having greatest impact across the early childhood years.<sup>481,538</sup> Integrated preventive care platforms in the second year of life<sup>414,539</sup> are essential to repeated doses of measles and other vaccines. There is opportunity to match a point in the life course where immunisation is weak<sup>263</sup> with a chance to maximise child growth and development, and extend women's access to reproductive and sexual health care.

*Integrating vaccination and child illness care*<sup>539</sup>, is a high priority for action<sup>540</sup> during infancy (noting the frequency of illness in ENB, Section 6.3.2). In PNG this requires better checking of vaccination status of sick children, as called for in global and local IMCI guidelines.<sup>480,541</sup> Conversely, bringing PNG's adaptation of IMCI sick child algorithms<sup>480</sup> into immunisation clinics will respond to the high proportion of mothers asking for more thorough assessments and effective child illness care at this time. This also applies to the second year of life; a time when Hanson and colleagues<sup>539</sup> found across 46 LMICs that 24% of children missed a chance for vaccination at a mix of well-child and sick-child visits. Given the limited published examples on interventions to redress *missed opportunities for vaccination* (see Section 5.4.6), such work may need explicit implementation research or development pilots in PNG, as it does globally.<sup>540</sup>

Most of the remaining *core set of high impact interventions*, discussed in Chapters Five, Six and Seven, will be beneficial in PNG, including vitamin A, antihelminthics,

and ITNs (as supplement to other distributions, especially when straightforward enough to suit Type A models of integration). Early postpartum care for *maternal and infant HIV* is important in PNG,<sup>542,543</sup> and dealing with issues of privacy and stigma below are prerequisite to integration attempts. However, neither *seasonal malaria chemoprophylaxis* nor IPTi are not currently recommended in PNG<sup>507</sup> and international experiences with the broader age group of SMC (three months up to five years) means community-based distribution trumps integration with immunisation clinics, for providers<sup>544-546</sup> and families.<sup>350,444</sup>

The next section discusses subsequent categories of the conceptual framework (see Figure 5), using them as a frame to explore issues of feasibility, acceptability and equity in future integration efforts.

*Who provides care – making integration relevant to front-line staff and local managers (top box in right hand column, Figure 5)*

Staff overload was a primary concern for women and front-line staff consulted in this research, seen too in analyses in Chapter Five, and many other studies of integration experiences.<sup>58,72,547,548</sup> The Integra experiences<sup>548</sup> found resourcing staff to work together, and empowering them to flexibly form teams and call on resources across programs is a key to successful integration. Type C *co-location models seem essential* for some additional services such as sensitive, professional counselling, or certain clinical skills (contraceptive device insertion for example), which apply to family planning, maternal illness (especially STIs or RTIs) and HIV care. This requires extra staff in a team approach,<sup>72</sup> particularly at larger facilities. Noting the proportion (about one quarter) of immunisation clinics in ENB with low client numbers, there may be some situations where a single staff member with multiple roles could undertake integrated care, assuming appropriate supports as discussed below. This is also subject, of course, to the realities that operate in settings such as rural PNG, where average staff-client ratios may mask other systemic problems, such as absenteeism, lack of a supportive team or days when staff are overwhelmed by unexpected influxes of clients. In all situations, success depends on ensuring staff are trained, made aware of the integration rationales (both client-service and program reach), and provided with

managerial and system supports noted below. Integration was less welcomed in PNG (Section 7.4.1) when seen as a way to do more with less.

Evidence collected in Chapters Five and Seven shows integrated services can achieve *efficiencies for health staff*. Issues relevant to front-line staff include support to integrated planning and supplies,<sup>345</sup> and streamlined consolidated reporting. Tools to encourage *health provider behaviour change* were important to successful integration experiences (Section 5.4.4), including job-aids to support counselling or checklists for good clinical assessments. These worked best if based on sound theory<sup>549</sup> or behavioural insights<sup>488</sup> and backed up by supportive supervision.<sup>86</sup>

*Task shifting to community-based lay health workers*,<sup>550</sup> was important across many integration experiences reviewed in Chapter Five<sup>339,351,350,352</sup> and by other researchers.<sup>142, 470,471,485</sup> Equivalent trained health volunteers have demonstrated roles in parts of PNG<sup>225,483</sup> but were rarely mentioned by women or frontline health workers in ENB. A cautionary note is also raised in the experiences with iCCM in sub-Saharan African settings such as Ethiopia<sup>160,375</sup> or Nigeria<sup>551</sup> where, despite their proven capacity to extend access to some MNCH care, immunisation did not always benefit. Greater support for their role would need to start at the policy level by including community-based staff (VHVs) in holistic workforce planning and focusing them on targeted roles<sup>552</sup> such as advocacy, education on specific topics (including nutrition and vaccination schedules), and commodity distribution. Evidence from Ethiopia, Kenya and Indonesia<sup>553</sup> shows this cadre are more cost-effective when properly integrated within a health team.

*Where and when integrated services are provided (middle box in right hand column, Figure 5)*

Most considerations above relate to *fixed facilities offering routine scheduled clinics*, often in central locations. Reports from ENB women, and others,<sup>554</sup> suggest that even if integrated services take longer, some travel to fixed sites is acceptable if thorough care is available. Perhaps new options for clinic timing (for example market days or extended hours) may help meet such community preferences.



*Improved planning for outreach* was sought by women and local managers in PNG,<sup>277</sup> looking for better reliability in timing, and optimising travel to higher population centres; both making integrated outreach more efficient. As noted in Section 7.3.4 expanding the reach of routine immunisation in PNG,<sup>461</sup> and similar settings,<sup>497,555</sup> requires intensified outreach. This is a core consideration for equity, as without outreach, more integrated care will only be available to those able to reach static clinics.<sup>556</sup> Type A and B integration models may be more suited to outreach,<sup>140</sup> and active planned support from community-based staff may enable educative services to accompany vaccination more efficiently in this setting.

*Campaigns or periodic intensification of routine immunisation* also offer proven means to improve equity of health care access,<sup>421,557</sup> and have shown capacity for Type A or Type B integration models for providing commodities such as vitamin A<sup>355</sup> or ITNs,<sup>547</sup> including in PNG.<sup>278</sup> Multi-country assessment of their role in ITN distribution<sup>389</sup> shows the process of integration is not a detractor from campaign success (although other factors do determine impact). Care is needed to ensure campaigns harmonise with routine services,<sup>421,500,558</sup> as presented in the analysis in Chapter Seven (Section 7.3.4).

*Innovations in vaccine delivery technology*, such as compact pre-filled autodisable injection devices<sup>175</sup>, with or without deployment of vaccines beyond the cold chain<sup>442,559,560</sup> have enabled greater reach into communities for vaccinations. This innovation has been shown previously in PNG as a means to enable trained lay health workers to integrate immunisation with postnatal care.<sup>498</sup> As work proceeds to license such approaches,<sup>442</sup> this may enable more frequent community-based provision of vaccination with other integrated services such as those for nutrition, family planning or postnatal care.

*How providers and clients interact in integrated services (middle box in right hand column, Figure 5)*

Close attention to the way providers and clients interact<sup>561</sup> provides possibly the most important insight into why integrated services succeed or fail. As displayed in the conceptual framework (Figure 5), this perspective entails seeing preventive health care

service encounters as a transaction in information, rather than a unidirectional transfer from provider to user. Women's calls for better quality information and education, increasing through the first year after childbirth (Section 6.3.4), confirm this aspect of demand.

Women in rural PNG privilege quality of care over savings in time and money, when ranking their interests in integrated services. Similar conclusions are drawn by others assessing quality of MNCH care,<sup>475,562</sup> including a study of community choices in South Africa<sup>554</sup> that concluded that women will tolerate “...a long waiting time, poor staff attitudes and lack of direct access to doctors if they receive the medicine they need, a thorough examination and a clear explanation”. Rural PNG women's quality concerns, like assessments in similar integration experiences,<sup>8,142,333,334,475,477</sup> are quite specific: privacy, time and expertise for good communications, thorough clinical assessments, and handling of local sensitivities to avoid stigma or embarrassment. Without these, referral for services such as family planning or follow-up of maternal illness may well be ineffective.<sup>469,477</sup>

Although lower-ranked by PNG women in this research, savings in time and money are valued through the need for fewer clinic visits when services are integrated, as seen in other studies.<sup>332,340</sup> Arranging efficient linkages between co-located services (such as signage, distances, opening hours), or ensuring efficiencies in staff processes for integration models Type A and B, are likely to improve acceptability and uptake.

As noted for health providers, more effective education interactions during integrated care can benefit when informed by behaviour change theory<sup>563,564</sup> in design of integrated counselling. There is good evidence from many family planning integration experiences,<sup>33,93,333,334,475,488</sup> SRH counseling,<sup>72,127</sup> and IMCI ‘Mothers Cards’,<sup>108</sup> that well designed counselling tools and practices play a critical role in efficacy. This applies also to integrated counselling for improved feeding for better nutrition.<sup>535,565</sup>

*Community engagement – making new service delivery responsive and acceptable (lowest box in right hand column, Figure 5)*

Many experiences reviewed in Chapter Five (Section 5.3.5), and other reviews<sup>33,39,58,72,137</sup> have noted the importance of *formative research to test community acceptability* of integration approaches. Going beyond specific questions of acceptability to seek women's opinions on what care should be integrated (Section 6.3.4) can be valuable to health policy and planning. In this research, seeking women's opinions in this way generated a mix of preferences that both overlapped and contrasted with those commonly proposed by health managers in PNG. Informing planning with community preferences,<sup>5</sup> especially when open to unexplored options, provides one means of community engagement to improve uptake of re-organised services. Community inputs on integrating services may be viewed as a complement to the growing evidence on participatory work for improved quality of care.<sup>184</sup> These efforts can also explore synergies of acceptability, for example where positive views on immunisation can enhance uptake of other care<sup>566</sup> or, as presented in Section 6.3.5, the willingness of some male partners to come to immunisation clinics provides opportunity for couples' SRH care.

Ensuring that any task shifting (see above) prioritises *lay health workers from the local community* is also a key mechanism for community engagement for integrated outreach services.<sup>95,97,116</sup> Analysis of the MNCH work of successful USAID MCHIP grantees<sup>88</sup> found community-oriented care most successful when integration of two or more interventions was combined with community level data collection, engaging local leadership and frequent personal contact with clients.

Extra efforts to encourage *community accountability* have improved immunisation uptake and client communications in Myanmar,<sup>426</sup> and service outcomes more broadly in development<sup>515</sup>; and innovative tools for this (such as 'u-Report for youth engagement<sup>522</sup>) are proposed for integrated MNCH. Women interviewed in ENB were progressively more willing to critique services through the first year postpartum (Section 6.3.5) and welcomed the opportunity.

Mechanisms for monitoring uptake and satisfaction with newly integrated services<sup>129,477</sup> are important to identify groups that may be reluctant to use the new

arrangements, as seen in the Tanzanian experience with HIV integration.<sup>332</sup> If there is a minority for whom new linkages such as family planning and immunisation would be a concern (as seen among a proportion of ENB women in Section 6.3.5), they may need to be explicitly addressed. Minimising disruption to clinic processes (see discussion on monitoring below) will also support acceptability. Monitoring uptake in general is critical to equitable coverage, identifying those unreached by immunisation,<sup>423</sup> especially noting the risk that more integrated services may reach less well to the most disadvantaged communities,<sup>187,567</sup> especially if confined to central facilities.<sup>556</sup>

*Broader health systems support to integration (central dark grey box in Figure 5)*

The systems elements in this research's conceptual framework (Figure 5) note the importance of support in governance, workforce, financing, supplies and health information. Topp and colleagues<sup>86</sup> review of systems implications of integrating services accords with this, noting that essential prerequisites include sufficiently functional frontline services, trained and motivated staff (as discussed above), and technical tools and equipment, as well as “*appropriately devolved authority and decision-making processes to enable frontline managers and staff to adapt integration*”. This last element is strongly echoed by Mayhew, Warren and colleagues’<sup>72,548</sup> analyses of HIV and SRH integration experiences.

It is clear that integrating other services with immunisation needs a certain level of strength in the existing immunisation platform<sup>504</sup>; and for ENB province in PNG there is encouragement that new approaches are feasible given the functionality observed (Section 7.3.3) and the high uptake of pentavalent vaccine in the cohort study (Section 6.3.3). Equity for immunisation and any future integrated services depends on greater outreach, as discussed above. *Management support* is important for routine operations, as seen in HIV and immunisation in Zambia.<sup>345</sup> It is also important for allowing adaptive organisational responses at the local level, as seen in Kenya,<sup>548</sup> that are needed for integrated service delivery. Local managers are critical, as well, to coordinating cross-program planning and referrals,<sup>132,333,334</sup> such as between HIV and family planning. Experiences in the Integra Initiative also suggested the value of simultaneous integration across a range of services.<sup>547</sup>

Ensuring *supplies* of vaccines and other commodities was a regular concern in ENB for women and frontline staff, as well as a key determinant of success across almost every integration experience reviewed in Chapter Five and in later publications. An assessment of integration in Kenya, highlighted the human factor in supply systems<sup>548</sup>: “*although structural factors like stock-outs, distribution of staffing and workload, rotation of staff can affect how integrated care is provided, all these factors can be influenced by staff themselves: both frontline and management*”.

*Health information systems*, including client-held records, can be a critical barrier to integration if they are fragmented or favour one service’s needs over another.<sup>341,439</sup> When well integrated they can advance community education and understanding of preventive care priorities.<sup>512,513</sup> Integration of tally sheets and reporting systems can also, as discussed above, help lighten staff loads.

Many women in ENB, both in interviews (Section 6.3.5) and focus groups (Section 7.3.3) cited *clinic fees* as a cause of dissatisfaction, but not, given their low absolute cost, a critical bar to accessing immunisation services. Care would be needed to ensure that adding new services did not impose administration or commodity fees that detracted from immunisation uptake. On *financing overall*, although the analysis of experiences in Chapter Five found few that measured costs, those that did found integration to be cost-effective (reflecting the high public health value of most services under consideration) and sometimes able to save program costs. Analysis in Kenya and Swaziland on HIV-SRH integration<sup>128</sup> showed that expected efficiencies through integration did not always materialise and that any supply-side economies of scale depend greatly on the mix of commodities, services and service providers (as discussed above). The major contributor to whether integrated services are less costly to health managers is likely to be decisions on workforce allocation. Many models (especially Type C) needed additional staff for co-located services, although those that maximised trained lay health workers in educative or other roles may have cost efficiencies. Le and colleagues’<sup>3</sup> broad review of integration initiatives concluded that “... *it is possible to integrate services in different human development contexts without incurring additional costs...*” but noted that “... *the improved outcomes shown were incremental rather than radical*”.

### 8.1.3 Achieving feasible and acceptable integrated services

As discussed in detail above, changes to make a feasible and acceptable package of integrated services available need to consider who provides integrated care, where and when it is provided, how users interact, how communities can be better engaged, and the broader system supports. This discussion also reviewed the determinants of successful integration that emerged from the systematic review (Section 5.3.5), as modified by findings presented in Chapters Six and Seven. A summary of the most important determinants of success are summarised in Table 21.

Careful matching of new interventions to be added is needed to ensure there is synergy in target populations (especially child age ranges), and that existing immunisation services are sufficiently established from supply and demand perspectives. Careful choice of integration model is needed to ensure tasks such as client counselling or clinical diagnosis receive due attention, or are provided for through additional staff that are co-located; task shifting of counselling or educational tasks to trained lay health workers may enable this. Many health workers in resource-constrained settings feel isolated and unsupported; integration reforms may represent an opportunity to build new teams

**Table 21: Determinants of success in integration experiences**

|                                            |
|--------------------------------------------|
| Match intervention and platform            |
| Sufficient strength in EPI                 |
| Match age range and family                 |
| Correct model, co-locate counseling        |
| Tailor intervention for campaigns          |
| Staff capacity and motivation              |
| Educate on rationale, consider incentives  |
| Training, on-site if possible              |
| Care with time, consider team approaches   |
| Job aids for counselling and quality       |
| Management and system support              |
| Cross-program planning and supervision     |
| Medical supplies reliability               |
| Infrastructure for privacy and client flow |
| Streamline reporting, joint tracking       |
| Integrate home-based records               |
| Monitor costs and savings                  |
| Community engagement                       |
| Plan with clients' preferences and needs   |
| Formative research on sensitive topics     |
| Optimise community-based worker roles      |
| High quality health communication          |
| Maximise savings on travel and fees        |
| Identify, address the concerned minority   |
| Include male partners and caregivers       |
| Community feedback, accountability         |
| Policy and governance                      |
| Policy commitments to integration          |
| Standing orders for linked services        |
| Harmonised development partners            |

that work together for mutual support and improved quality of care. As discussed in Chapter Five, most integration experiences to date have demonstrated the importance of a systems approach to ensure integrated supply chains, information systems and infrastructure support work together for the integrated service. The area that has arguably received least attention prior to this research is the need for community engagement, based on good formative research into the true burden of co-morbidity and the preferences of health service clients; reversing the usual program-driven imperatives for service reform so as to truly see the service from the client's perspective. Policy and leadership support are critical to any reform, and must be preceded by advocacy that highlights the aspirations of better quality and more client-centred approaches that should take priority over efficiency gains.

Overall, increased investment is likely to be needed in order to make more than incremental service delivery changes that more thoroughly respond to community preferences,<sup>561</sup> and that significantly improve quality of care. This may be justified by a broader perspective on cost-effectiveness that counts the benefits of improved uptake of preventive services, and increased confidence<sup>568</sup> generated by more comprehensive and responsive services.

#### ***8.1.4 Monitoring progress and future integration research***

*Monitoring progress when service delivery is changed to promote integrated services*

Sophisticated analysis of clinic usage and cost information in the Integra Initiative (HIV)<sup>129</sup> demonstrated that 'structural integration' (simply co-locating services, for example) does not guarantee receipt of integrated care by clients and that it is essential to also measure 'functional integration'. The integration typologies that emerged from the systematic review of this research (Section 5.3.4, Figure 11) attempt to combine both structures and functions to assist with categorisation of changes to service delivery.

As noted above, it is important to monitor changes to service delivery to identify unexpected difficulties for staff implementing, and barriers to uptake and access, including those that relate to community concerns such as stigma or embarrassment. Standard measures of coverage should be disaggregated to capture

changes for marginalised groups<sup>22,569</sup> reviewed to scan for such difficulties. Trends in service volumes (such as vaccinations given)<sup>334</sup> can also test for changes in service uptake, as well as for more general implementation problems. Measures more specific to the integration process include those examining disruptions to client flow<sup>9,90</sup> and prolonged consultation or clinic times.<sup>180,469,475</sup> Application of these has been useful in demonstrating declines over time or patchy implementation of integrated services.<sup>9</sup> Monitoring and research efforts will benefit from better documentation of the functional typologies of integrated services as discussed in Section 8.1.2 above.

Measurement is also a priority at national and global levels. Because greater integration of services was a key indicator in the Global Vaccine Action Plan<sup>570</sup> a concerted effort was made to include global reporting on integration progress. A suitable indicator was hard to achieve, mainly on measurability grounds, although later reporting was able to draw on concepts of co-coverage (clients' access to a suite of interventions) and composite indicators as used in MNCH that are more often applied to equity analyses.<sup>26,186,571</sup> Expanding on these to specifically test global progress in integration, using existing data sources where possible, will be important in the next phase of global planning for RMNCAH programs.<sup>27,190</sup> It will also be essential to global immunisation planning; noting the prominence of integrated services in Strategic Priority 4 (*"Life-course and integration"*) of the Immunization Agenda 2030.<sup>572</sup>

Also worth considering, in system-level measures, are the quality dimensions of client-oriented integration that is argued in this thesis. Leslie and colleagues<sup>573</sup> point to the need for better quality measures as a critical factor in progress to universal health coverage. In high-income settings the concept of *"integratedness"* is proposed as one dimension of health system strength,<sup>574</sup> although it is acknowledged that consensus on an agreed indicator is lacking. Integrated care is a dimension where learning between high-income settings and LMIC settings has merit<sup>50</sup>; particularly useful when viewing integration as a quality dimension of patient-centred, tailored and holistic care. This is the perspective that emerged from women's viewpoints in PNG, and which offers a means to build stronger connections between users and providers in health care, even where resources are short.



*Future research methods suited to integration initiatives*

Given the continuing need for evidence, while there are some aspects of integrated services suited to immediate scale-up in PNG, additional implementation research into, for example postpartum family planning and maternal illness care alongside immunisation, will be of value. Service delivery innovations will be more useful if drawing on established frameworks for implementation research<sup>575,576</sup> and those for health policy and systems research.<sup>82,552,577</sup> Systems oriented frameworks can be adapted to the processes of integrating services, such as that recently proposed by Topp and colleagues.<sup>86</sup> In assessing the policy relevance and systems implications of published experiences, the work of the Cochrane EPOC node<sup>302</sup> and the comprehensive framework derived from the Supporting Use of Research Evidence collaboration<sup>303</sup> has proven enduringly useful (see Section 4.2.3).

Integration-specific monitoring tools, as discussed above, such as measures of client flow and intervention delivery times, can be adapted to implementation research. The simplified patient-flow assessment tool used in this research (Section 4.3.5), similar to those used by others,<sup>9,90,169</sup> helped assess actual practices, with special attention to delivery of integrated services. The typology of integration models developed here may also complement that developed by the Integra Initiative<sup>129</sup> in research immunisation integration experiences.

Mixed methods, perhaps informed by complexity theory<sup>578</sup> will help analyse how different factors work together<sup>579</sup> in a particular service delivery context.<sup>577</sup> Mixed methods can also help assess underlying motivations and values to explain why policy may not be implemented or services not used as expected. Theories from realist inquiry<sup>307,308</sup> and ‘most significant change’<sup>310</sup> methodologies proved helpful for this purpose in the health services assessment presented in Chapter Seven.

Policy research will also need to include the roles of development partners. The themes and sub-Saharan African settings of the majority of studies available for review in Chapter Five likely reflect the priorities of key development partners such as USAID,<sup>88,89,361</sup> or the Bill and Melinda Gates Foundation,<sup>129</sup> as they aimed both to introduce more integrated services and to generate certain forms of evidence. More nuanced reviews, perhaps using realist synthesis methods,<sup>447,580</sup> may broaden the field

of view. One example could be study of middle-income Asian countries that are implementing integration initiatives, but with possibly less interest in the type of controlled studies that gain admission to standard systematic reviews.

Global development partners such as these can also play a role in supporting implementation research needed to advance the field of integration, especially noting its continuity priority in global strategies. Initiatives that combine development resourcing with a research-driven search for locally appropriate evidence can play a key role in taking up the challenges presented above; the Burnet Institute as a hybrid development agency and research institute has demonstrated this potential in the HMHB program in PNG. If such efforts are locally led and relevant to local realities, this can go a long way to overcoming the sometimes unwelcome politics that accompany foreign aid (as referred to briefly in Section 2.4.3).

A final methodological reflection from this research relates to the potential of new research tools to better bring community preferences for service delivery arrangements into health services research. As noted in Section 5.4.6, many acceptability studies focus on clients' views on pre-specified interventions, and also omit questions on client opinions for who, when, where, and what services may be provided. One way forward could be to adapt questions that relate to a service delivery framework, such as that developed for this research (Figure 5) for standard knowledge, attitude and practice surveys or use in participatory action research.<sup>581</sup> Going further, formal assessments of stated preferences,<sup>582</sup> such as discrete choice experiments,<sup>554</sup> may have application to better understanding community preferences for how services should be organised and made available. These advances would sit well within new moves to develop research frameworks to better investigate the dimension of responsiveness<sup>561</sup> as a health system characteristic that advances universal health coverage.

#### *Future research topics for integration of other services with immunisation*

Section 5.4.6 outlines some future research topics that emerged through analysis for the systematic review. Scanning of published literature since then confirms that these remain important gaps in the evidence base. One is in interventional studies

that aim to integrate immunisation into other services, including research to reduce *missed opportunities for vaccination*. A recent systematic review of missed opportunities<sup>583</sup> found only six interventions, all of which took place in a high-income country. When studying this, it will be important to research, for LMIC settings, how broader childhood illness care initiatives such as IMCI, and iCCM at the community level, can better promote catch-up vaccination.

Other evidence gaps (see also Section 5.4.6) of great importance are the study of how to integrate *nutrition, child development, family planning and immunisation* in infancy, and in *the second year after childbirth*. Establishing preventive care platforms at this point in the life-course is of prime importance to child and maternal health outcomes alike, and at present this evidence base is worryingly thin. The first two years after childbirth are also points where *women's ill health (including chronic infection or undernutrition)* can be prevented, monitored and managed to the benefit of both women and their families. As discussed above implementation research to pursue this would lead the way in making services at this point in the life course more responsive to women's needs.

## 8.2 Current and future use of this research

### *Limitations of this research*

Chapters Five, Six and Seven each discuss specific limitations of the research reported in those chapters. For the systematic review (Chapter Five), there are two key limitations to revisit. Firstly, the restricted time period up to 2016 omits the most recent evidence; the reason for this timing (to inform early work in this thesis) is discussed in Section 5.2.3. Scanning of literature since 2016 did reveal newer work on family planning and HIV; these have been incorporated into discussion sections in this thesis where appropriate, but are not yet formally reviewed. Updating and publication of this review is planned for 2020, as discussed below. The second limitation on the systematic review was the methodology employed, which restricted admissible publications and possibly missing some health system process findings, as alluded to in methodological discussions above.

For HMHB study findings the most important limitation to be borne in mind is the studies' restriction to one region, East New Britain Province. This is a province with relatively greater health service uptake than elsewhere in PNG; in less-advantaged parts of the country there may well be immediate overarching constraints, such as geographic inaccessibility, that must first be overcome before they can apply the considerations of integrated care discussed here. In addition, like all communities in such a diverse nation, ENB has its own cultural and social determinants on health understanding and usage; this means sensitivities such as those around family planning may apply differently in other provinces. However, it is arguable that the lessons from ENB on improving quality and responsiveness are likely to apply in most settings in PNG, especially as local health services mature.

### *Dissemination and uptake during the period of candidature*

A major area of learning through this research has been the *process of undertaking implementation research* in rural PNG; including contribution (see Section 4.4) to the establishment of a sustained, multi-partner research program capable of undertaking longitudinal cohort and interventional studies. Field operations for such research are challenging and time-consuming, with weather events, unreliable

infrastructure, fluctuations in staff capacity, and external emergencies all requiring flexibility in schedules and methods. The rewards have been great; especially the opportunity to see growth in local health research capacity, partnership with health managers and local governments, and in development of skills and analytic capacity of the PNG research team. Involvement of international research partners has been encouraging, but of arguably greater encouragement has been the engagement of local policy makers, the dedicated commitment of local research officers, and guidance received from collaborators in the PNG Institute of Medical Research and other PNG research leaders.

The HMHB program was established in ENB in 2014 and began its *discovery phase* in 2015 with the two studies reported in this research, emphasising the generation of evidence for immediate use in ENB as well as to inform health policy. This phase continues in 2020, with a health services study into *quality of childbirth care*.<sup>584</sup> The HMHB *intervention phase* commenced in 2018, overlapping the discovery phase, and includes an interventional study testing *improved quality and reach of postnatal care*, alongside introduction of umbilical chlorhexidine.<sup>520</sup> Both studies draw on methods and preliminary data generated by the research in this thesis.

*Local reporting of interim findings* in 2017, 2018 and 2019 took place to participating front-line health facilities and also at regular meetings of the ENB Provincial Health Authority's research advisory committee, established alongside the HMHB program to enable regular direct communication with health managers and policy makers. This mechanism led to calls for new interventions, such as that for postnatal care expansion, in part as reaction to interim findings from this research.

*Methods for service delivery assessment and analysis* developed through this research have contributed to other research or development initiatives in PNG and in other LMIC settings through the author's involvement during the period of candidature, including those noted in Table 22.

**Table 22: Research and development initiatives drawing on methods developed in this research**

| Detail                                                                                                                                                                                          | Timing      | Reference |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-----------|
| Health system implementation requirements of expanded point-of-care testing and treatment for STIs at ANC, the WANTAIM trial                                                                    | 2015 – 2020 | 450       |
| Health system implementation requirements of point-of-care HPV-DNA testing for cervical cancer screening in PNG                                                                                 | 2016-2020   | 585       |
| Multi-sectoral modelling of improvements for maternal and child nutrition in PNG                                                                                                                | 2019-2021   | 586       |
| Collaborative community checklists for immunisation in rural Myanmar, a feasibility and acceptability study                                                                                     | 2017-18     | 426       |
| Strengthening clinic level immunisation performance in Western Cape, South Africa                                                                                                               | 2015-19     | 587       |
| Stronger Surveillance and Systems Support for Rapid Identification and Containment of Resurgent or Resistant Vector Borne Pathogens in Papua New Guinea: STRIVE PNG                             | 2018-21     | 588       |
| Accelerating immunisation and other health systems strengthening in West Sepik Province, PNG, a development partnership initiative of Gavi and the PNG, Australian and New Zealand governments. | 2019-2021   | 589       |

Globally, some interim findings on integrating other services with immunisation have *contributed to immunisation policy discussions* through involvement by the author as a member then chair (until 2018) of the WHO Immunization Practices Advisory Committee<sup>91</sup> and related contributions to WHO, including: background documents for a 2016 national immunisation managers workshop in the African Region<sup>80</sup>; presentation to a meeting of technical staff of the Expanded Programme of Immunization (24<sup>th</sup> April 2017); and presentation at the Global Immunization Meeting, Kigali (26<sup>th</sup> June 2018). Additional contributions have been to a 2018 WHO global resource guide on integration in immunisation programs throughout the life-course,<sup>590</sup> and as a member of the small writing group responsible for one segment of the new global vaccine strategy, *Strategic Priority 4 Life-course and integration*, of the Immunization Agenda 2030 documents.<sup>572</sup>

#### *Future dissemination and use of this evidence in PNG and globally*

The immediate future use of the research from this thesis will be as an adjunct to the final analyses of HMHB biomedical data to link the evidence on multi-morbidity

with the service delivery experiences and preferences recorded in this thesis. These will continue to be fed back to local policy makers in ENB through their research advisory committee and through targeted policy forums and communications to national stakeholders in immunisation and family health. As discussed in Section 8.1.4, there may be scope for implementation research in PNG to investigate the feasibility, acceptability and costs of integrating family planning, nutrition and maternal health interventions with immunisation across the first two years of life.

Submissions to peer-review journals for publication are also planned for late 2020. This will include an update to the systematic review (as noted in Section 5.2.3) with increased involvement from colleagues in WHO, JSI and CDC prior to seeking publication. Additional reviews of integration experience, perhaps using alternative review methods as discussed above (Section 8.1.4), may be warranted to extract lessons on integration from efforts to advance universal health coverage. These proposals note the strong emphasis on integration in WHO's Framework on Integrated People Centred Health Services: it is a core element of advancing Strategies One (*“Engaging and empowering people and communities”*), Three (*“Reorienting the model of care”*), and Four (*“Coordinating services within and across sectors”*).<sup>74</sup>

#### *A comment on relevance to the outbreak of COVID-19*

The latter parts of this thesis were drafted in the shadow of the accelerating pandemic of infections caused by a novel coronavirus, termed COVID-19 by WHO.<sup>591</sup> In April 2020 PNG reported its first cases of novel coronavirus disease, COVID-19, with some occurring in ENB province; extending a state of emergency that is disrupting many routine services.<sup>592</sup> The ENB Provincial Health Authority requested informal access to data from all HMHB studies, including morbidity and service delivery data presented in Chapters Six and Seven, to add to their understanding of health system vulnerabilities and opportunities. Other evidence in this research relates to the important issue of maintaining essential services at a time when major emergency responses are being mounted.

The analysis presented in Chapter Seven and the publication arising<sup>461</sup> examines the interactions between routine services and emergency responses, the most recent of

which for PNG was required by their 2018 polio outbreak.<sup>280,281</sup> Evidence from the west African Ebola Virus Disease outbreak and its response<sup>593</sup> show a decline in maternal health care and immunisation service uptake with persisting consequences after the emergency resolved. PNG's extended state of emergency in mid 2020<sup>592</sup> is already disrupting services through travel bans, and more may come in 2021 if emergency campaigns need to resume, whether for measles, polio or new interventions to prevent COVID-19. An urgent priority is helping local health authorities adapt guidance<sup>594</sup> on maintaining routine immunisation and other core services. Integration efforts in this context will need to take account of short-term restrictions, the protection of staff, and also alignment with campaign delivery models.

This disruption will present a major challenge to the health systems in PNG,<sup>595</sup> as in similar settings, and service delivery models will need to evolve. Beyond the need to avoid damage to routine services' functioning,<sup>400,410</sup> there are ways that emergency responses can support the broader system<sup>500,501</sup> (see also Section 7.3.4). A recent review<sup>596</sup> recognised the issue of community trust during crisis as critical to an effective response, and a decline in families seeking care was a key mechanism of the Ebola-related coverage drop in west Africa.<sup>593</sup> In all times, but especially in emergencies, a system which has proven itself trustworthy and responsive to community preferences seems better placed to both serve its population and to benefit from community support when resources are stretched.



### 8.3 Conclusion, the future of integrating other services with immunisation

Integration of additional services with the childhood immunisation platform had been commonly proposed<sup>53,54</sup> as a means to increase coverage with high impact interventions, as well as benefit immunisation program performance. These calls have not diminished and are enshrined in the most recent,<sup>37</sup> and upcoming,<sup>572</sup> global immunisation strategies. Evidence reviews to 2011 led by CDC of immunisation integration experiences<sup>58</sup> had been positive, but cautioned against viewing this as universally beneficial, noting implementation difficulties in specific situations. This was echoed for HIV and SRH domains, with Church and colleagues<sup>8</sup> noting that *“the policy rhetoric of integration may be at odds with the complex service delivery reality in lower-income settings”*.

Through a systematic review and additional literature search, this research has documented the growth in evidence on generally successful controlled integration experiences, noting gains particularly for HIV, malaria, and family planning, as well as some nutrition interventions. Success is possible but implementation challenges persist, especially when client counselling and cross-program referral is involved, and some integration models are likely to work better than others for particular combinations of intervention.

This research’s unique demand-side investigation of what women in PNG would prefer when offered the prospect of adding new services to the immunisation visit brought new insights. Women’s preferences went beyond those of program planners to encompass maternal illness care, more comprehensive child illness care, and stronger health education on important disease threats, in addition to sexual and reproductive health care. Front-line health care providers echoed some of women’s priorities, such as family planning, but not all. Detailed concerns about privacy, embarrassment, distraction, potential staff overload, and other clinic processes, point to risks to be managed to ensure integration is successful and equitable in expanding access.

For PNG, and similar settings, there was a clear call to view integrating services as a shift to more holistic family-centred care, rather than a means to achieve

individual program coverage targets. This broadening of concepts of demand and acceptability accords with calls with SRH and HIV integration<sup>72</sup> to better emphasise the needs of key populations when planning changes to service delivery. It also evokes the people-centred PHC aspirations within universal health coverage.<sup>69,74</sup>

Priorities for integration with infant immunisation services in PNG should first focus on postpartum family planning. Further priorities are the inclusion of tailored screening for maternal illness (especially reproductive tract infections and malaria), and counselling for infant nutrition and development. In parallel, it is essential to improve the application of childhood illness management alongside vaccination, and vice versa. Inclusion of maternal and infant illness management will be difficult, but may play a critical part in making services more responsive and acceptable to women's preferences. Explicitly considering parents' preferences for care can be important to building a more acceptable health service that is more likely to benefit from sustained community support. There is hope that this may also increase demand for and confidence in the immunisation program.

This research has shown that detailed examination of integrated services for families, especially emphasising viewpoints of health care users, allows more sophisticated guidance to health planners who intend to re-organise service delivery to increase integration. Planners will also need to consider the way preferences vary through even this short snapshot of the life-course from mid-pregnancy through to one year after childbirth. It is appropriate that in WHO's Agenda 2030<sup>572</sup> plan for global immunisation that integration is closely tied to life-course vaccination; enabling those considering when, how and what to integrate with immunisation services to pay special attention to the differences between, say first year and second year of life needs in families.

The 2018 Assessment Report of the Global Vaccine Action Plan<sup>492</sup> concluded by stating:

*"The next chapter of immunization must also be one of integration, with immunization consolidating its position as a pillar of universal health coverage and primary healthcare, and contributing to the safer, healthier and more prosperous world envisioned in the Sustainable Development Goals."*

Integration of other services with immunisation in the first year after childbirth should be pursued primarily because it is the best way to meet the multiple health needs of families and individuals. It can also improve intervention coverage, and may in some settings save money. However, it is the needs and preferences of families and health service users that should be the first source of information for planners as to when and how integrated services are best deployed.

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## 10 APPENDICES

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## 10.1 Protocols and ethical approvals

### 10.1.1 Systematic Review – protocol

#### Integration of immunization services and other health services in low- and middle-income countries: protocol for an updated systematic review

<https://www.crd.york.ac.uk/PROSPERO/> [Last accessed 14 June 2019]

From: CRD-REGISTER [irss505@york.ac.uk](mailto:irss505@york.ac.uk)  
Subject: PROSPERO Registration message [45876]  
Date: 23 August 2016 at 7:01 PM  
To: [cmorgan@burnet.edu.au](mailto:cmorgan@burnet.edu.au)



Dear Dr Morgan

Thank you for submitting details of your systematic review *Integration of immunisation services and other health services in low- and middle-income countries: protocol for an updated systematic review* to the PROSPERO register. We are pleased to confirm that the record has been published on the database.

Your registration number is: CRD42016045876

You are free to update the record at any time, all submitted changes will be displayed as the latest version with previous versions available to public view. Please also give brief details of the key changes in the Revision notes facility. You can log in to PROSPERO and access your records at <http://www.crd.york.ac.uk/PROSPERO>

An email reminder will be sent to you on the anticipated completion date, prompting you to update the record.

Comments and feedback on your experience of registering with PROSPERO are welcome at: [crd-register@york.ac.uk](mailto:crd-register@york.ac.uk)

Best wishes for the successful completion of your review.

Yours sincerely

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PROSPERO is funded by the National Institute for Health Research and produced by CRD, an academic department of the University of York.

Email disclaimer: <http://www.york.ac.uk/docs/disclaimer/email.htm>

**Review title and time-scale**

|                 |                                                                                                                                                |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| Review title    | Integration of immunization services and other health services in low- and middle-income countries: protocol for an updated systematic review. |
| Start date      | 2 <sup>nd</sup> November 2015                                                                                                                  |
| Completion date | 30 <sup>th</sup> December 2016                                                                                                                 |

**Review team details**

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| Funding source                               | Dr Morgan is supported by a grant from the Australian National Health and Medical Research Council (GNT 1075065). The Burnet Institute acknowledges the support of the state government's Victorian Operational Infrastructure Support Scheme.<br><br>The funding sources have no role in the conduct of the study.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Conflicts of interest                        | None declared                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
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**Background and rationale**

|                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Background                | <p>The concept of integrated health services is not new, including early<sup>1</sup> and renewed<sup>2</sup> concepts of comprehensive primary health care. More integrated health services are often seen as means of providing better quality care with more efficient resource use. This is important everywhere, but especially for low- and middle-income countries. For immunization services, this is a topic of recurring interest, including a strong call made at the World Health Organization (WHO)'s influential Strategic Advisory Group of Experts meeting in April 2014<sup>3</sup> for stronger integration between immunization and reproductive, maternal, newborn and child health programs.</p> <p>Because immunization services are successful in reaching many families, delivery through this platform is frequently proposed as a means to improve access for other health care, for example the distribution of vitamin A, measures to prevent or control malaria<sup>4,5</sup>, management of HIV and related infections<sup>6,7</sup>, or family planning<sup>8</sup>, among others. Of the many usages of integration terminology, the concepts most relevant to this study are those defined by WHO<sup>9</sup> as: a) packages of care combining preventive and/or curative interventions and b) service-delivery points with multiple purposes and capacities.</p> <p>While more integrated services appear to be usually beneficial, there are concerns of adverse effects such as staff overload or exclusion of some clients. These warrant scientific study of coverage, quality, acceptability, complexity and unintended consequences<sup>10</sup>, especially in view of past weaknesses in the strength of evidence<sup>11-13</sup>.</p> |
| Rationale for this review | <p>An earlier systematic review examining health service changes that aimed for increased integration of immunization and other services (Wallace et al<sup>4</sup>) collated studies up until Feb 2011. This was published in a special supplement of the Journal of Infectious Diseases<sup>14</sup> with complementary reviews on topics such as integration of other services during immunization outreach sessions (Partapuri et al<sup>15</sup>) and new primary research on integration experiences.</p> <p>Since 2011 there has been an increase in publications dealing with integrated health services that include immunization. We propose a new systematic review, using an expanded but overlapping search strategy, which can update the previous review<sup>4</sup> with publications from 2011 onwards. We also intend to examine both studies collated by the previous review and those in this new review to assess whether there is sufficient concordance of design and outcome measures to undertake a meta-analysis of the effect of integration attempts on coverage. Lastly, we aim to document quantitative and qualitative information on barriers and enablers of integrated service delivery, and of any risks of adverse outcomes that require special monitoring and management.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

**Review Methods***Search strategy*



|                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Review questions | <p><i>Primary:</i> What change in coverage in linked RMNCH services and/or immunization is achieved with integration of health service delivery?</p> <p><i>Secondary:</i> What services and implementation arrangements have been used in integration experiences*?</p> <p>How do coverage changes and resource requirements vary by different service delivery models and intervention types?</p> <p>What are the benefits and risks to health service access and quality?</p> <p>*Explicit attempts to improve health services by integrating immunization and other care in service delivery</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Searches         | <p>The following databases were searched with combinations of the following terms:</p> <p>Immunization (immunis* immuniz* vaccine*)</p> <p>every opportunity, missed opportunity, co-coverage, codelivery, integration (integrat*, combin* package*, restruct*, reform, reorgan*)</p> <p>programs, services, delivery or care</p> <p>a broad range of other services (eg antenatal, malaria, vitamin A) previously identified to have been integrated with immunization services</p> <p>The following databases were searched on 13<sup>th</sup> May 2016 with no restrictions on language (although English will be used in data extraction) and with date restriction from 2011 to 2016. Search interface software is indicated where appropriate. Numbers of titles in parentheses are prior to removal of duplicates.</p> <p>Medline via Ovid (2918)</p> <p>Embase (Excerpta Medica Database) via Ovid (5756)</p> <p>CABI Global Health, Web of Knowledge via EBSCOhost (4190)</p> <p>CINAHL via EBSCOhost (774)</p> <p>Cochrane Central Register of Controlled Trials (905)</p> <p>Cochrane Database of Systematic Reviews and Other Reviews (40)</p> <p>Additional searches are made of grey literature databases, focusing on those held by agencies supporting health service improvement programs in low-income countries. These include: WHO: dedicated integration resource collation 2016, background papers for global strategies, manager training resources and guidance documents, health systems resource pages, WHO</p> |

|                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                   | Library Database (WHOLIS), Project Optimize, and advisory committees; UNICEF immunization, women's and children's health, and health systems resources; BASICS - <a href="http://basics.org">basics.org</a> ; Family Planning-EPI Integration working group <a href="http://www.fphighimpactpractices.org">www.fphighimpactpractices.org</a> ; Knowledge4Health; POPLINE; John Snow Incorporated, including ARISE program and Immunization BASICS; FHI - <a href="http://FHI360.org">FHI360.org</a> ; USAID supported programs (including MCHIP and MCSP resources pages)DfID clearinghouse of studies and evaluation reports Nigerian Urban Reproductive Health Initiative <a href="http://www.nurhitoolkit.org/">http://www.nurhitoolkit.org/</a>                                                                                                                                        |
| Search strategy                   | Search strategy and syntax available as separate file.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Condition or domain being studied | Vaccine-preventable diseases and disease control or health promotion targets of other preventive and curative health services during pregnancy, childhood and adolescence.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Population                        | The population to be studied is the health service clients in low- and middle-income countries as defined by World Bank classification in 2016. The emphasis is on immunization services provided during pregnancy, the postnatal period, infancy and childhood, and adolescence.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Intervention                      | Trials of health service improvement that explicitly attempt to achieve greater integration between immunization services and other services. The emphasis is on changes to service delivery arrangements, but may also include other local health system changes such as integrated planning, integrated health information management, or integration of local supply chains.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Comparator                        | Comparators are as defined in individual studies, usually either a) control sites with no or limited attempt to improve health services, or b) the situation prior to health service improvement efforts, or c) different integration strategies.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Types of study to be included     | <p>All study designs are admitted, providing they contain quantitative or qualitative measures of the outcomes or processes involved in increasing integration of services. Inclusion criteria are studies where</p> <p>One or more linked services and one or more immunization services were integrated during pregnancy, postnatally, in childhood (including first two years of life) and adolescents (including school years) as a function of health service innovation (noting this includes women of childbearing age and pregnant women); and Outcomes were measured in terms of coverage, access to care, quality of care and/or equity of access or coverage, for at least one service</p> <p>Exclusion criteria comprise:</p> <p>Integration outside the life course period in question</p> <p>Inadequate description of measurement methods, other study quality measures</p> |

|         |                                                                                                                                                                                                                                                                                                                      |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|         | <p>Integrated services that do not include immunization</p> <p>Studies with no relevance to low- or lower-middle income countries (studies from high-income countries may be included if they have data relevant to resource-poor settings such as studies including marginalised or disadvantaged populations).</p> |
| Context | The emphasis is on local (front-line) health services in low- and middle-income countries.                                                                                                                                                                                                                           |

***Data extraction, quality assessment and analysis***

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Primary outcomes      | <p>Immunization coverage or other measure of service uptake.</p> <p>Coverage, or other measure of service uptake, of associated intervention/s integrated with immunization.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Secondary outcomes    | <p>Identification of range of vaccines and range of associated interventions deployed in integration attempts.</p> <p>Quantitative and qualitative measures of feasibility, acceptability, equity of access and other potential benefits and risks associated with attempts to integrate services.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Analysis of subgroups | Two important modes of service delivery will be used to undertake sub-group analysis: delivery in campaigns (including supplementary immunization activities) and delivery by outreach services.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Data extraction       | <p>Two members of the research team (CM and JD) will independently screen by title, abstract and full text for eligibility and inclusion using databases generated by the EndNote reference manager software. A third reviewer (JB) will be available if needed a tie breaker. Both, with other team members assisting, will undertake data extraction. All the review team will have access to search databases and collections of excluded studies.</p> <p>The data extraction structure has been informed by the SURE Collaboration's guides to policy-relevant barriers and enablers (<a href="http://global.evipnet.org/SURE-Guides/">http://global.evipnet.org/SURE-Guides/</a>). Data extraction will cover the following categories (full structure available as separate file):</p> <p>Basic study information, population and comparator</p> <p>Integration intervention, service delivery option/s, additional service/s, program area, nature of integration change</p> <p>Outcomes primary and secondary, including coverage, other uptake measure, vaccinations provided, effects on feasibility or acceptability, costs, impact on organisation of services or supply chains</p> <p>Determinants of success and implementation considerations categorised by:</p> |

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                       | providers of care, recipients of care (including issues of equity and marginalisation), health system issues, and social or political constraints.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Quality assessment    | <p>Quality assessment will be conducted in step with data extraction. GRADE<sup>16</sup> will be used to assess evidence quality of effectiveness studies, classifying studies in four categories from High to Very Low. GRADE criteria to be scored comprise: selection bias, study design, confounders, blinding, data collection, withdrawals and dropouts, intervention integrity, and analyses.</p> <p>A modified checklist derived from the Critical Appraisal Skills Program (CASP)<sup>17</sup> will be used for quality of for qualitative data and qualitative studies. Our framework of seven categories will cover: appropriateness of qualitative research, clarity of study context, evidence of researcher reflexivity, clarity and appropriateness of sampling method, data collection method, analysis method, and whether the claims are supported by sufficient depth, detail and richness of data.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Synthesis of findings | <p>Both quantitative and qualitative data from included studies will be used to synthesis findings. The synthesis process will be led by one reviewer (CM) but receive input from the whole review team. Specific elements of the synthesis include:</p> <p>Very low quality will result in exclusion of studies from effectiveness analyses, and quantitative meta-analysis</p> <p>Meta-analysis will be attempted where studies prove to be sufficiently alike in setting and nature of integration attempt to be comparable in intervention design, and changes in intervention coverage, both immunization and linked intervention are available. This will examine relative and absolute differences in coverage between intervention populations and comparator populations and may need to group meta-analyses by study type: control vs intervention or pre-/post-intervention. Random effects modelling will be used to account for likely heterogeneity.</p> <p>Narrative reporting of qualitative data synthesis will be structured around SURE<sup>18</sup> guideline categories and also reflect on the findings of previous reviews.</p> <p>We will attempt to report our level of confidence in synthesis recommendations relating to quantitative measures by adopting GRADE for effectiveness studies. As implemented in SURE Collaboration guidelines<sup>18</sup> this will provide some narrative indication of our confidence in effectiveness conclusions (such that they can be readily adapted into guideline discussions) across the domains of study limitations, inconsistent results across studies, indirectness of the evidence, imprecision, and publication bias.</p> <p>Similarly, the updated CerQUAL<sup>19</sup> framework will be used to score confidence</p> |

|                     |                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     | in qualitative implementation considerations (barriers and enablers) across methodological limitations, relevance, coherence across studies, and adequacy of data.                                                                                                                                                                                                                   |
| Other procedures    | In general we will attempt to follow guidelines from Cochrane Effective Practice and Organisation of Care Group (EPOC). EPOC Resources for review authors. Oslo: Norwegian Knowledge Centre for the Health Services; 2013. Available at: <a href="http://epoc.cochrane.org/epoc-specificresources-review-authors">http://epoc.cochrane.org/epoc-specificresources-review-authors</a> |
| Dissemination plans | We aim to prepare a technical report suitable for reference by the WHO and other global agencies supporting immunization and related programs in low- and middle-income countries. We will also seek publication in a peer-reviewed journal dealing with global health.                                                                                                              |

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## **Data extraction structure**

### **Basic study information, population and comparator**

Author, date, abstract

Study design, control (if any)

Population and location

Timing of intervention and study

### **Integration intervention**

Immunization service delivery option/s – routine, intensified routine, campaign

Additional program area and service/s integrated

Nature of integration change in integrated service delivery

Extra services by immunization staff

Extra counselling by immunization staff

Co-location, linked timing of services

Immunization service by non-immunization staff

Immunization counselling by non-immunization staff

Nature of integration change other than service delivery

Integrated planning or policy, without integration of service delivery (eg joint disease control)

Integration of other health system elements with or without integration of service delivery

Community engagement, education, health promotion

Commodities, supply chain, logistics,

Health information, reporting and monitoring

Others: HR planning, policy development, financing and payment schemes

### **Outcomes**

Main outcome measures

Coverage – vaccine/s

Coverage – other service/s

Other outcome measures

Vaccinations provided

Other services utilization measures

Other population health outcome (mortality, morbidity etc)

Effects on feasibility for immunization and other program

Effects on acceptability for immunization and other program

Costs of intervention, ancillary costs

Effect on organization of immunization services

Effect on vaccine/supplies management, distribution and storage

### **Determinants of success and implementation considerations**

Implementation barriers or enablers (mainly qualitative, framework based on the SURE Guide

Checklist for identifying barriers to implementing a policy option and the SURE worksheet on equity considerations<sup>18)</sup>

Providers of care

- knowledge and skills;
- health worker cadres involved
- time issues
- quality of care
- attitudes regarding intervention acceptability, appropriateness,
- incentives or motivation to change behaviours
- attitudes regarding community trust and service credibility
- referral

Recipients of care

- Knowledge
- Attitudes to services and/or intervention, acceptability, trust
- Care seeking and healthy behaviours

- Travel and referral
- Marginalisation, equity of access

#### Health system issues

- accessibility of care, overall and among poor or vulnerable
- financial resources, procurement and payment
- human resources allocation
- clinical supervision and communications
- authority, delegations and accountability
- management and/or leadership, policy, norms and standards
- information systems,
- facilities and other infrastructure
- patient flow processes,
- procurement and distribution systems, incentives, bureaucracy, norms and standards;

#### Social and political constraints

- ideology,
- contracts, legislation or regulations,
- donor aid and development policies or issues,
- influential people,
- corruption,
- security and political stability.

### Search strategy and syntax for five databases

#### MEDLINE via OVID

- 1.(immunis\* or immuniz\* or vaccin\*)
2. (every opportunity or missed opportunit\* or co coverage or cocoverage or co delivery or codelivery or (composite adj4 coverage) or integrated package\*)
3. (program\* or service\* or delivery or care or healthcare or intervention\*)
4. (integrat\* or combin\* or bundl\* or packag\* or restructur\* or reform\* or reorgan\*)
5. (comorbidity or co morbidity or multimorbidity or multi morbidity or syndemic)
6. ((antenatal or postnatal or ante natal or post natal or post partum or postpartum or neonatal or reproductive health or reproductive healthcare or contracept\* or family planning or bednet\* or itn or net or nets or deworming or child health day or child health week or immunisation week or immunization week or filariasis or intermittent preventative or intermittent preventive or IPT or onchocerciasis or schistosomiasis or trachoma or "vitamin a" or pmtct or mother to child transmission or malaria or hiv or breast feeding or infant feeding or nutrition counselling or nutrition counseling or home based records or ((maternal or child) adj3 service\*) or (vitamin\* adj3 supplement\*)) and (program\* or service\* or delivery or care or healthcare or intervention\* or



restructur\* or reform or reorgan))

7. 3 adj3 4

8. 5 and 3

9. 1 and (2 or 7 or 8)

10. (1.ti,sw. or (1 adj5 3)) and 6

11. 9 or 10

12. Limit 11 to yr="2011-Current"

#### **EMBASE via OVID**

1.(immunis\* or immuniz\* or vaccin\*).ti,ab,hw,kw.

2. (every opportunity or missed opportunit\* or co coverage or cocoverage or co delivery or codelivery or (composite adj4 coverage) or integrated package\*).ti,ab,kw.

3. (program\* or service\* or delivery or care or healthcare or intervention\*).ti,ab,kw.

4. (integrat\* or combin\* or bundl\* or packag\* or restructur\* or reform\* or reorgan\*).ti,ab,kw.

5. (comorbidity or co morbidity or multimorbidity or multi morbidity or syndemic).ti,ab,kw.

6. ((antenatal or postnatal or ante natal or post natal or post partum or postpartum or neonatal or reproductive health or reproductive healthcare or contracept\* or family planning or bednet\* or itn or net or nets or deworming or child health day or child health week or immunisation week or immunization week or filariasis or intermittent preventative or intermittent preventive or IPT or onchocerciasis or schistosomiasis or trachoma or "vitamin a" or pmtct or mother to child transmission or malaria or hiv or breast feeding or infant feeding or nutrition counselling or nutrition counseling or home based records or ((maternal or child) adj3 service\*) or (vitamin\* adj3 supplement\*)) and (program\* or service\* or delivery or care or healthcare or intervention\* or restructur\* or reform or reorgan)).ti,ab,kw.

7. 3 adj3 4

8. 5 and 3

9. 1 and (2 or 7 or 8)

10. 1 and 6

11. 9 or 10

12. Limit 11 to yr="2011-Current"

#### **PubMed - EPUB AHEAD OF PRINT via OVID**

1. (immunis\* or immuniz\* or vaccin\*).mp.

2. (every opportunity or missed opportunit\* or co coverage or cocoverage or co delivery or codelivery or (composite adj4 coverage) or integrated package\*).mp.

3. (program\* or service\* or delivery or care or healthcare or intervention\*).mp.

4. (integrat\* or combin\* or bundl\* or packag\* or restructur\* or reform\* or reorgan\*).mp.

5. (comorbidity or co morbidity or multimorbidity or multi morbidity or syndemic).mp.

6. ((antenatal or postnatal or ante natal or post natal or post partum or postpartum or neonatal or reproductive health or reproductive healthcare or contracept\* or family planning or bednet\* or itn or net or nets or deworming or child health day or child health week or immunisation week or immunization week or filariasis or intermittent preventative or IPT or onchocerciasis or schistosomiasis or trachoma or "vitamin a" or pmtct or mother to child transmission or malaria or hiv or breast feeding or infant feeding or nutrition counselling or nutrition counseling or home based records or ((maternal or child) adj3 service\*) or (vitamin\* adj3 supplement\*)) and (program\* or service\* or delivery or care or healthcare or intervention\* or restructur\* or reform or reorgan)).mp.

7. 3 adj3 4

8. 5 and 3

9. 1 and (2 or 7 or 8)

10. 1 and 6 ( OR 1.ti,sw. and 6)

11. 9 or 10

12. limit 11 to yr="2011-Current"

#### **CINHAHL via EBSCOhost**

S1. (immunis\* or immuniz\* or vaccin\*)

S2. (every opportunity or missed opportunit\* or co coverage or cocoverage or co delivery or codelivery or (composite N4 coverage) or integrated package\*)

S3. (program\* or service\* or delivery or care or healthcare or intervention\*)

S4. (integrat\* or combin\* or bundl\* or packag\* or restructur\* or reform\* or reorgan\*)

S5. (comorbidity or co morbidity or multimorbidity or multi morbidity or syndemic)

S6. ((antenatal or postnatal or ante natal or post natal or post partum or postpartum or neonatal or reproductive health or reproductive healthcare or contracept\* or family planning or bednet\* or itn or net or nets or deworming or child health day or child health week or immunisation week or immunization week or filariasis or intermittent preventative or intermittent preventive or IPT or onchocerciasis or schistosomiasis or trachoma or "vitamin a" or pmtct or mother to child transmission or malaria or hiv or breast feeding or infant feeding or nutrition counselling or nutrition counseling or home based records or ((maternal or child) adj3 service\*) or (vitamin\* adj3 supplement\*)) and (program\* or service\* or delivery or care or healthcare or intervention\* or restructur\* or reform or reorgan))

S7. S3 N3 S4

S8. S5 and S3

S9. S1 and (S2 or S7 or S8)

10. S1 and S6

11. S9 or S10

12. Limit S11 to yr="2011-Current"

#### **CABI Global Health, Web of Science**

Limit results to 2011-2016 throughout

S1. (immunis\* or immuniz\* or vaccin\*)

S2. (every opportunity or missed opportunit\* or co coverage or cocoverage or co delivery or codelivery or (composite NEAR/4 coverage) or integrated package\*)

S3. (program\* or service\* or delivery or care or healthcare or intervention\*)

S4. (integrat\* or combin\* or bundl\* or packag\* or restructur\* or reform\* or reorgan\*)

S5. (comorbidity or co morbidity or multimorbidity or multi morbidity or syndemic)

S6. ((antenatal or postnatal or ante natal or post natal or post partum or postpartum or neonatal or reproductive health or reproductive healthcare or contracept\* or family planning or bednet\* or itn or net or nets or deworming or child health day or child health week or immunisation week or immunization week or filariasis or intermittent preventative or intermittent preventive or IPT or onchocerciasis or schistosomiasis or trachoma or "vitamin a" or pmtct or mother to child transmission or malaria or hiv or breast feeding or infant feeding or nutrition counselling or nutrition counseling or home based records or ((maternal or child) adj3 service\*) or (vitamin\* NEAR/3 supplement\*)) and (program\* or service\* or delivery or care or healthcare or intervention\* or restructur\* or reform or reorgan))

S7. #3 NEAR/3 #4 [note need to use complete search string]

S8. #5 and #3

S9. #1 and (#2 or #7 or #8)

10. #1 and #6

11. #9 or #10

### **10.1.2    *Prospective Observational Cohort Study – full protocol***

#### **RESEARCH PROGRAM TITLE:**

**Healthy Mothers, Healthy Babies – Study 1, Cohort Study**

#### **SPONSORED BY:**

The Burnet Institute, Papua New Guinea Institute of Medical Research and the University of  
Papua New Guinea

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**STATEMENT OF COMPLIANCE**

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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### Collaborators

*Collaborators will provide input to methods and analysis on specified subsections of the study and support synergies with other relevant studies.*

|                                                                                                                                                                  |                                                                 |
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| <b>Prof Stephen Rogerson</b> , Peter Doherty Institute, University of Melbourne<br><b>Prof Beverley Biggs</b> , Peter Doherty Institute, University of Melbourne | <i>Nutrition, malaria and other infections in pregnancy</i>     |

**SIGNATURE PAGE**

The signatures below document the approval of this protocol and the attachments, and provide the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality and according to local legal and regulatory requirements and to the principles outlined in the ICH guidelines.

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**GLOSSARY OF ABBREVIATIONS AND TERMS**

|         |                                                |
|---------|------------------------------------------------|
| ANC     | Antenatal care                                 |
| BMI     | Body Mass Index                                |
| CI      | Co-investigator                                |
| CHW     | Community Health Worker                        |
| CRF     | Case report form                               |
| CRP     | C-reactive protein                             |
| DNA     | Deoxyribonucleic acid                          |
| EENC    | Early Essential Newborn Care                   |
| ELISA   | Enzyme linked immunosorbant assay              |
| ENB     | East New Britain province                      |
| FP      | Family Planning                                |
| G6PD    | Glucose -6-phosphate dehydrogenase             |
| Hb      | Haemoglobin                                    |
| HBsAg   | Hepatitis B surface Antigen                    |
| HIV     | Human Immunodeficiency Virus                   |
| HPV     | Human Papilloma Virus                          |
| HSV-2   | Herpes Simplex Virus -2                        |
| HEO     | Health Extension Officer                       |
| HMHB    | Healthy Mothers Healthy Babies (this program)  |
| LBW     | Low birth weight (<2.50kg)                     |
| LLIN    | Long-lasting insecticidal nets                 |
| LMP     | Last known menstrual period                    |
| MDG     | Millenium Development Goal                     |
| MMR     | Maternal mortality rate                        |
| MNH     | Maternal and Newborn Health                    |
| MNCH    | Maternal, Newborn and Child Health             |
| MUAC    | Mid Upper Arm Circumference                    |
| MTB/RIF | Multi drug resistant tuberculosis / Rifampicin |
| NDOH    | National Department of Health                  |
| PCR     | Polymerase Chain Reaction                      |
| PHO     | Provincial Health Office                       |
| PI      | Principal Investigator                         |

|        |                                                       |
|--------|-------------------------------------------------------|
| PNC    | Postnatal care (of mother and baby)                   |
| PNG    | Papua New Guinea                                      |
| PNGIMR | Papua New Guinea Institute for Medical Research       |
| POC    | Point of care                                         |
| PPH    | Post-partum haemorrhage                               |
| RBC    | Red blood cell                                        |
| RBP    | Retinol Binding Protein                               |
| RDT    | Rapid Diagnostic Test (for malaria)                   |
| RMNCH  | Reproductive, Maternal, Newborn and Child Health      |
| SIN    | Study Identification Number                           |
| SMAHS  | School of Medicine and Allied Health Sciences at UPNG |
| SOVS   | Self-Obtained Vaginal Swab                            |
| SRH    | Sexual and Reproductive Health                        |
| STI    | Sexually Transmitted Infection                        |
| sTfR   | Serum Transferrin receptor                            |
| TB     | Tuberculosis                                          |
| UI     | Urinary Iodine                                        |
| UTI    | Urinary tract infection                               |
| UPNG   | University of Papua New Guinea                        |
| WHO    | World Health Organization                             |

## LAYMANS PROTOCOL SUMMARY

The Healthy Mothers Healthy Babies (HMHB) research program uses five different studies to investigate problems and potential solutions for improved care of mothers and babies during pregnancy, childbirth, and shortly after birth; as well as specific aspects of the reproductive health of young men and women. This will take place in East New Britain Province (ENB) of Papua New Guinea (PNG), focusing on health facilities and the communities they serve, in the districts of Rabaul, Gazelle and Kokopo.

This protocol describes **Healthy Mothers Healthy Babies Study 1, Cohort Study**. An overview of all five proposed studies will be described here to show how they are linked and complement each other. Separate protocols and ethics applications will be submitted for each.

Firstly, this **observational cohort study** will select women attending antenatal care in five health facilities (two hospitals and three health centres), interview them, collect samples for laboratory tests, check on outcomes at birth, and follow their progress through to twelve months after birth. The interview will ask them about previous pregnancies, symptoms of illnesses that may be present in mother or baby, and their plans, knowledge, opinions and experiences of accessing health care.

The laboratory tests will measure markers of nutrition and various infections important in pregnancy (but not HIV). If they have signs of specific illnesses complicating pregnancy, the standard recommended treatment and follow-up will be undertaken.

This study combines description (observing what happens with women and their babies) with some analysis. Analysis will look for relationships between the presence of complicating illnesses during pregnancy and outcomes for mother and baby at birth, and during the first year of life. The analysis will also examine the relationship between usage of health services before and during pregnancy, and usage in the first month and year after birth.

Secondly, a **health services study** will assess the current levels and standards of care in the study health facilities, and work with staff in selected health facilities to trial different ways to improve quality of care for women and children.

Thirdly, a **community survey**, taking place after studies 1 and 2, will visit selected villages to interview women, families, community leaders, and men. This will balance information obtained through health facilities. The interviews and discussion will cover women's previous births, pregnancies, knowledge, opinions and experiences of gaining access to good quality health care.

Fourthly, a **young people's study** will be conducted to assess knowledge, opinions and experiences related to accessing good quality reproductive health information and services. This information will be gathered through interviews and discussions with young people (males and females) and other community members in rural and urban settings.

Finally, a **modelling study** will take the results from the earlier studies and enter them into computer software that incorporates information from successful programs elsewhere in PNG and other countries. This analysis will estimate the expected costs and reductions in death and disease that might be achieved through changes to care before and after childbirth. This will aim to identify strategies to improve perinatal care for better maternal and newborn health outcomes, and strengthen disease control, targeted to populations with limited access to health services.

The PNG Institute of Medical Research (PNGIMR) is conducting studies in other provinces in PNG with different populations, who have different health status and lower levels of access to health services, compared with ENB. These studies have some similarities to HMHB Studies 1 to 4. The collaboration between PNGIMR and Burnet Institute will facilitate future comparisons between these studies, enabling an analysis based on provinces with different health indices.

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## 1.0 INTRODUCTION

This observational cohort study takes an integrated approach to understanding important questions across the life-course of pregnancy, the postnatal period and infancy in PNG. It looks firstly at the interactions between multiple important diseases that complicate pregnancy and their relationship to maternal and infant outcomes, and secondly at family experiences of care and the predictors of optimal utilisation of health services through this period.

### 1.1 Background

#### *Health system in Papua New Guinea*

Health care in PNG has always been challenged by its unique mix of diverse populations, rugged geography and constraints in infrastructure, especially in rural and remote areas. However, PNG is currently undergoing significant transition in its overall economy, as resource extraction industry revenues increase funds available to the government for public services. This comes at a point when for nearly two decades, health service delivery to rural or urban poor communities is acknowledged to have remained static or even deteriorated in some cases,<sup>1</sup> especially in regards to maternal and newborn health.<sup>2</sup>

The PNG health system follows a decentralized model, in which a National Department of Health (NDOH) provides policy, standards and monitoring oversight, as well as specific centrally administered public health services such as medical supplies and immunization programs. PNG's 22 provinces are responsible for health service provision through three levels of care: provincial and district hospitals (although not present in all districts), health centres and sub-centres (with limited inpatient and delivery care), and community-based 'Aid Posts' or Community Health Posts. Medical professionals are usually located only at hospital level, with nurses and PNG-specific cadres of Health Extension Officers (HEO) and Community Health Workers (CHW), a professional cadre in PNG, at hospital and peripheral facilities.

National health planners<sup>1</sup> are grappling with a number of implementation questions. These questions include: the degree to which services can usefully be made available at new peripheral facilities (Community Health Posts); the best balance of interventions delivered by outreach compared to fixed facilities; the optimal utilisation of a variegated but numerous cadre of village health volunteers; how to better partner with non-state providers of health care; and how to improve community acceptability and affordability of services. This latter question is especially important given the mandate to implement the new Free Primary Health Care and Subsidised Specialist Services policy from 2014 onwards. New government commitments to improved information for health policy, including the use of research, are seen in the National Health Research Policy.<sup>3</sup> This has resulted in PNG's first national health and HIV research agenda,<sup>4</sup> which is notable for its focus on questions of health service implementation, and for its recognition of the pressing need to develop national capacity in health services research.

#### *Maternal and newborn health care in PNG*

Globally, maternal and newborn mortality remains unacceptably high. Over a quarter of a million maternal deaths occur annually, with 99% of this burden carried by developing countries.<sup>5</sup> The focus placed on maternal mortality by the Millennium Development Goals (MDG) has lead to



significant progress in some countries. However, the MDG target of reducing the maternal mortality ratio (MMR) by 75% from 1990 levels by 2015 is unlikely to be achieved. In Papua New Guinea (PNG) estimates of MMR vary widely, however the latest national estimates are high: between 500 and 733 deaths per 100,000 live births.<sup>6</sup> The most common direct and indirect causes of maternal mortality have been well described globally, and the limited evidence available in PNG suggests that the causes of death are similar, with Post-Partum Haemorrhage (PPH), eclampsia and sepsis being the major contributors.<sup>7,8</sup>

Recently there has been a global call to action to save newborn lives. Whilst impressive progress has been made to reduce the under 5 mortality rate across the world, neonatal mortality has been alarmingly slow to improve. Globally, close to 3 million babies die in the first month of life, with 1 million dying on their first day. In PNG, it is estimated that nearly 5000 newborns die annually, with over a third of these not surviving beyond day one. Based on international estimates, up to two thirds of these deaths could be prevented with basic but effective interventions.<sup>9</sup> Research specifically into newborn outcomes in PNG is limited, however concerning deficiencies in newborn care capacity in PNG hospitals has been described.<sup>10,11</sup> Government assessments suggest that high priorities accord with the international data, namely addressing newborn sepsis, prematurity and other causes of Low Birth Weight (LBW), and reducing newborn intrapartum deaths due to obstructed labour.

#### ***Health service research questions for MNCH health care in PNG***

In most areas of PNG, life-saving health services are often under-utilised or accessed later than is ideal. Contributing factors include physical access difficulties, financial barriers for families, lack of understanding of the need for supervised childbirth, as well as other cultural factors (such as lack of partner support or preference for traditional childbirth arrangements<sup>12</sup>). Studies in Madang and Goroka have highlighted that the majority of women who die as a result of childbirth come from rural areas.<sup>7,8</sup> These and other studies highlight the importance of investigating options for improved community engagement in the provision of Maternal, Newborn and Child Health (MNCH) care.

In addition to the direct influence care quality has on patient outcomes, deficient quality of care can also reduce health service utilisation in pregnancy and childbirth.<sup>4</sup> Studies in PNG, both published<sup>7,8</sup> and a range of presentations at the annual medical symposium, highlight the importance of improving quality of care.<sup>13</sup> International attention has been given to standardising quality expectations for current approaches to antenatal care,<sup>14</sup> intrapartum care,<sup>15</sup> and recent updates to care for the newborn, expressed in the Early Essential Newborn Care (EENC) package.<sup>16,17</sup> Limited evidence is available on how to do this in PNG,<sup>10,18,19</sup> and it is crucial to make use of this to understand family experiences of care, how these affect their future care-seeking decisions, and the predictors of optimal utilisation of services. This forms a complement to quality improvement work with health staff and services, and will remain an important research area even after physical, financial, and social accessibility of services is improved.

Another important health service question for MNCH in PNG is the potential to increase coverage by integration of other services, such as immunisation or family planning, with MNCH service provision. Specific questions apply to integration in the postnatal period, for example the optimal

timing of family planning advice and services, or the provision of vaccinations at birth against tuberculosis (TB) and hepatitis B. One experience in PNG<sup>20</sup> suggests that integration of birth-dose vaccination with postnatal care can increase coverage of interventions in both community and health facility settings. Questions of integration of services also apply to disease control initiatives, including those for Human Immunodeficiency Virus (HIV), malaria and TB. Because MNCH services are often the primary point of women and children's access to the health system, they are often seen as points for dissemination, for example of Long-Lasting Insecticidal Nets (LLINs) or additional TB services.<sup>21</sup> However, optimal approaches are unknown, and international evidence on health service integration shows both positive and negative effects,<sup>22</sup> suggesting that careful implementation research is needed to assess when and how it is likely to be successful. A better understanding of family experiences of care is important to complement other health services research in this area.

### ***Family planning and reproductive health.***

Supporting women and couples to plan for healthy timing and spacing of births is a cost-effective approach to reduce maternal and infant mortality and has proven benefits for gender equality, educational attainment and poverty reduction.<sup>23,24</sup> Increasing family planning coverage and improving adolescent sexual and reproductive health are key targets of the PNG National Health Plan 2011-2020.<sup>1</sup> Use of modern methods of contraception among married women aged 15-49 in PNG is among the lowest in the region and has increased only modestly since 1996 (from 20% to 24% in 2006). Contraceptive prevalence has declined in that period in the Islands region, with the poorest access among young, less educated and rural women.<sup>2</sup> The most recent national estimates suggest that less than half the demand for family planning is currently being met, with at least a third of married women who want to limit childbearing not using any family planning method.<sup>2</sup> Subsequently, over 50% of births in PNG are in an avoidable 'high risk' category, occurring to women at the extremes of maternal age, high parity, or spaced less than 24 months. Further research is required to understand family experiences and decision-making concerning contraceptive use, particularly in the postpartum period. Such information is essential in order to help understand predictors of optimal utilisation of reproductive health services, and seek opportunities to improve uptake of reproductive health services.

### ***Specific diseases likely to complicate pregnancy in PNG***

In PNG maternal morbidity, mortality and newborn health is further complicated by a complex interaction between the normal state of pregnancy and common diseases that may also be present. Anaemia, malnutrition, Sexually Transmitted Infections (STIs) and malaria are common amongst pregnant women in PNG, with each independently affecting maternal and newborn outcomes. Emerging evidence suggests the interaction between these factors is complex and important, raising important questions (discussed below) for routine care in pregnancy and infancy. Additionally, the influence of other infectious diseases in pregnancy, such as STIs and TB, is not well documented in PNG. There are very few studies globally that have examined co-infection of malaria and STIs in resource-constrained settings similar to PNG,<sup>25</sup> and no published studies in PNG, although the high prevalence of both diseases in PNG suggest co-infection is likely. There is a need to understand the degree to which STIs coexist with malaria, the degree to which common

infections co-exist with micronutrient deficiencies, and the impact multiple co-morbidities in pregnancy has on mothers and their infants.

**Anaemia** continues to be a widespread public health issue in PNG<sup>26</sup> where overall prevalence is approximately 55%, substantially higher than the globally estimated prevalence of 38%.<sup>27</sup> Anaemia is especially common in coastal regions such as Madang, where it affects up to 90% of pregnant women<sup>1</sup> and is associated with poor outcomes for both mother and child, such as PPH, iron deficiency and LBW.<sup>7,28</sup> International estimates suggest that at least 50% of anaemia in pregnancy is treatable with iron supplementation, and WHO recommends iron supplementation in areas where anaemia prevalence is high,<sup>29</sup> noting the benefits for improved birth weight.<sup>30</sup> PNG also has significant prevalence of genetic anaemias, such as alpha thalassaemia<sup>31</sup>: this is more common in malarious areas and anaemia interactions with malaria are discussed below.

**Malaria** continues to be an important cause of morbidity and mortality in pregnant women and children in PNG.<sup>32</sup> It is estimated that over 90% of the population is at risk of malaria, and more than half of the population live in areas with high transmission.<sup>33</sup> The introduction of LLINs have coincided with a significant reduction in parasitemia rates, however rates remain as high as 7% in the Islands and Mamose regions.<sup>34</sup> Recent gains in malaria control, achieved through the delivery of LLINs and improved diagnosis and treatment, seem fragile in the light of findings from several populations internationally, indicating that rebound increases in malaria are occurring in many populations after improvements in malaria control.<sup>35</sup> Recent studies have also suggested that rebound increases in malaria are occurring in some regions of PNG (data presented at the PNG Medical Symposium, Lae, 2013). Research into malaria prevention, control, and treatment continues to be a pressing need.

**Anaemia and malaria** are known to interact in pregnancy and childhood. Concerns regarding potentially harmful malaria-iron interactions<sup>36</sup> question the appropriateness of iron supplementation guidelines in malaria-endemic areas. This relationship is complicated by the fact that malaria is also a significant cause of anaemia and that iron deficiency can be protective against high-density parasitaemia or placental malaria.<sup>37,38</sup> Genetic causes of anaemia, such as alpha thalassaemia also interact and may reduce the severe anaemia related to malaria.<sup>31</sup> Better defining the interactions between anaemias in pregnancy in malaria endemic regions, and outcomes in mothers and their infants, is important to developing suitable evidence-based interventions.

**Malnutrition** inflicts a large burden on populations throughout PNG, particularly for young children and women of reproductive age, with PNG now experiencing a dual burden of under-nutrition and obesity.<sup>39</sup> Under-nutrition is known to increase the risk of, and exacerbate, infection in infants and young children, and can be associated with up to 35% of under five deaths.<sup>40,41</sup> In coastal areas, stunting occurs in about 50% of children under 5 years; a third of children are underweight, and one in five experience wasting.<sup>40</sup> In infants, malnutrition is also associated with lower education, and the risk of developing metabolic diseases in adulthood, thereby linking nutritional deficiencies with slow socioeconomic development.

There is a strong body of evidence demonstrating that a life cycle approach to understanding nutrition is crucial, with infant nutrition not only heavily influenced by in-utero factors, but by the health of the mother well before conceiving. Malnutrition in expectant mothers is associated with complicated deliveries, LBW babies and subsequent delays in infant cognitive development. The

National Nutrition Survey in 2005<sup>39</sup> demonstrated a significant burden of micronutrient deficiencies in women of reproductive age. However, the full extent of micronutrient deficiencies and the impact on maternal and child health is unknown.<sup>42,43</sup> Recent studies of pregnant women in Madang Province found that women with iron deficiency were less likely to deliver a newborn with LBW because of a protective effect on malaria (Fowkes, Beeson, et al., unpublished data). The limited data suggest the interaction between micronutrient deficiencies (especially iron), and infections (malaria and others) is important in PNG and requires further research to understand the coexistence in mothers, the additional impact on maternal, newborn and infant outcomes, and to identify appropriate management strategies.

**Tuberculosis.** In 2012 there were an estimated 8.6 million new cases of TB globally and 1.3 million deaths.<sup>44</sup> The TB epidemic is a major health problem in PNG - the third highest overall cause of death and the leading cause of in-hospital death, admission and bed stays.<sup>1</sup>

TB is a major cause of maternal and child mortality, and most commonly affects women in their reproductive years. In 2012, TB killed 410 000 women worldwide, placing it amongst the top 3 causes of death for women.<sup>44</sup> Despite this, the true burden of active and latent TB in pregnant and post-partum women is unknown as few national TB programs collect data or report pregnancy-specific outcomes. TB in pregnancy usually presents in the third trimester and has been associated with increased risk of LBW, prematurity, intrauterine growth restriction, and fetal death.<sup>45</sup> In HIV-infected women, TB in pregnancy is associated with maternal death, infant mortality and increased likelihood of transmission of HIV to the infant.<sup>46,47</sup> In HIV-uninfected women, pregnancy is associated with an increased risk of TB compared to risk for non-pregnant women of similar age.<sup>48</sup> If infected with *Mycobacterium tuberculosis*, infants are at very high risk of developing severe, disseminated forms of TB such as TB meningitis.<sup>49</sup> Effective preventive therapy is readily available to reduce the risk of TB in infants born to mothers with perinatal TB. While this is universally adopted as policy, it is rarely implemented in practice.<sup>50</sup>

**Hepatitis B** infection in pregnancy is important because chronic infection may lead to liver cancer or liver failure in the mother and/or (later in life) her newborn: WHO estimates that globally around 360 million people are chronically infected and at risk of developing life-threatening liver diseases.<sup>51</sup> In settings such as PNG there is significant risk of perinatal infection of the newborn, and infection early in life carries greater risk of chronic infection. PNG has adopted the WHO recommendation of vaccination within 24 hours of birth<sup>52</sup>, however timely coverage, at 30%,<sup>52</sup> remains insufficient to control transmission. A recent hepatitis B sero-survey shows that prevalence remains higher than national targets, and some provinces, especially in the islands region, have especially high prevalence (WHO PNG Country Office, Immunization staff personal communication). Research into experiences of vaccination can illuminate options to both improve vaccination coverage and benefit other immediate postnatal care (East Sepik).

**Sexually Transmitted Infections (STIs)** have alarmingly high prevalence in PNG and community based surveys show rates are among the highest in the Asia Pacific.<sup>53</sup> Although there is some regional heterogeneity, *Chlamydia trichomatis*, *Neisseria gonorrhoeae*, Syphilis, Herpes Simplex Virus (HSV), and *Trichomonas vaginalis* (TV) are common, with one of these occurring in approximately 20-25% of women.<sup>53-56</sup> Human papilloma virus infection also poses a significant public health threat in this population.<sup>57</sup> A study of coastal women in Madang, demonstrated that

more than a quarter of pregnancies had at least one STI, of which 20% of infected women had two or more concurrent infections.<sup>58</sup> Other preliminary findings indicate even higher rates: 44% of pregnant women had at least one STI, of which 80% were asymptomatic (A Vallely, personal correspondence). Bacterial Vaginosis (BV) is known to be associated with poor pregnancy outcome, however the burden of BV in PNG is not well understood with only three studies reporting on BV prevalence.<sup>53</sup> Our research will determine the prevalence of BV in ENB and evaluate the impact of BV on pregnancy outcomes. Appropriate treatment of BV is currently unclear.<sup>59</sup> This study will inform the development of appropriate clinical guidelines for the diagnosis and management of BV in pregnancy.

The HIV epidemic in PNG was previously thought to be a generalised epidemic with predictions made in 2004 that prevalence would increase rapidly and mimic the rapid spread of the epidemic in Sub-Saharan Africa. However, more recently the understanding of the epidemic in PNG has been better informed by increased testing throughout the country, particularly in antenatal clinics. The epidemic is now described as a concentrated epidemic with key populations and geographical areas affected. The estimated overall adult prevalence is between 0.6-0.9% with prevalence in the islands regions at 0.6%.<sup>60,61</sup> In ENB, voluntary testing and counseling is available in multiple locations throughout the province and is actively encouraged as part of routine antenatal care (ANC). Given the low prevalence of HIV, and presence of accessible routine testing for HIV, this study will not include HIV testing.

Controlling STIs is complicated by the fact that infections are frequently asymptomatic or non-specific in women, and diagnostic services are limited, leading to persistent progression and transmission. If left untreated STIs can have severe and long-term consequences for both the mother and her offspring, including infertility, premature delivery, LBW, still births, ectopic pregnancy, congenital syphilis, and meningitis.<sup>62</sup> In addition to many STIs remaining asymptomatic and the significant stigma and fear attached to seeking treatment, management of STIs in PNG is hampered by a lack of appropriate national testing and surveillance programs. Innovative strategies may include rapid point of care tests, which overcome many of the financial, technical, and access barriers. In order to respond appropriately, operational research is needed to identify and inform national policies on evidence-based, locally appropriate, and effective measures to combat the STI epidemic in pregnancy.

### **Group B Streptococcus**

In high-income countries, GBS has been identified as a significant cause of neonatal sepsis, mortality and morbidity, as well as being a cause of peri-partum infection in the woman<sup>63</sup>. GBS prevalence in high income countries can be as high as 30% with half of newborns born to these women becoming colonised either prior to, during or after delivery. For those newborns colonised there is a high risk of sepsis, pneumonia and meningitis with devastating consequences. Screening of women antenatally and treatment of GBS positive women in labour with intra-partum antibiotics (IAP) 4 hours prior to delivery is routine practice in many countries. This has reduced early onset neonatal GBS sepsis by 75% and reduced the GBS case fatality rate from 50% to 4-15% depending on the setting, however there has been no impact on late onset GBS sepsis<sup>63</sup>. In Kenya GBS was identified as the second most common cause of bacteraemia in children under 2 months of age and the most common gram-positive organism in children under 7 days<sup>64</sup>. Despite the potential

importance of this organism, very few studies on GBS have been done in developing countries with the little data available mostly coming from India, China and Sub-Saharan Africa. Published reviews of GBS in developing countries have found no studies from the Pacific as of 2012, nor have we been able to identify any published studies from PNG or the Pacific since this time<sup>65-68</sup>. Understanding if GBS carriage is common in pregnant women in this study would provide the first insights into whether this issue needs to be further explored in PNG and if routine surveillance and treatment should be considered.

Both internationally and in PNG, there are serious gaps in our understanding of how various prevalent disease processes interact during pregnancy, and of optimal models of providing and seeking health care in response. This is what drives our proposal for an integrated, longitudinal study of diseases, outcomes and health service utilization at this critical point in the life cycle.

## **1.2 Research program location**

This research program is being established in Gazelle, Kokopo and Rabaul Districts of East New Britain Province (ENB), PNG. ENB is located in the New Guinea Islands region and has a population of 271,252. ENB is typical of much of PNG in terms of both disease profile and geography. Although a smaller island than the PNG mainland, New Britain has both a mountainous interior with some communities only accessible by walking tracks, and a string of coastal villages whose only access is by canoe or small boat. There is relatively good road access for the most densely populated districts of ENB.

Burnet Institute has been working in ENB for more than five years on improved services for pregnancy care, prevention and treatment of STIs, and the home-based management of malaria. This has involved close interaction with provincial health authorities, support to first-line health facilities, and the establishment of volunteer networks for community education and mobilisation. Many of the questions posed in the five HMHB studies, including this Cohort Study, have emerged directly from these experiences and the suggestions of local health staff and their managers.

ENB reports a high burden of malaria (at 385 presentations per 1,000 population)<sup>69</sup> TB and other respiratory infections, STIs (based on local facility reports), and malnutrition. This disease burden is similar to many other sites in PNG, although there is currently a relatively low burden of HIV infection.<sup>69</sup> Hepatitis B prevalence is reported as higher than most provinces in PNG (personal communication, WHO Country Office).

Overall health service utilisation in pregnancy and childbirth is higher in ENB than elsewhere in PNG, as is the case for most provinces in the Islands Region. ENB reports a relatively high coverage of facility-based childbirth (hospital or health centre) at 86% and at least one antenatal care visit is reported to occur for 100% of pregnant women.<sup>69</sup> Immunisation performance is close to national average, with coverage of third dose of pentavalent vaccine variously reported at 77% in 2012<sup>69</sup> and 60% in a recent independent review.<sup>52</sup> Reporting of health outcomes is less consistently available, although the average or high prevalence of infectious diseases suggests that preventive control measures are not reaching all they should. In terms of other outcomes: LBW is reported as 4% of births (national average is 9%), while case fatality rates reported by the Paediatric Society at the provincial hospital (Nonga Base), for 2011 are 7.3% for all paediatric admissions and 8.2% for

neonatal admissions – close to, or slightly below the median across reporting hospitals. These outcome measures (based on very incomplete data) are likely to be underestimates, especially for rural facilities. This lack of outcome data is one gap our research program intends to address.

While it is important to question and test the reports of high utilisation, this does suggest that ENB is a site where questions of morbidity within pregnancy can be investigated, at least initially, within a cohort of pregnant women presenting for ANC, with reasonable expectation that these women will be representative of the health facility's catchment area. This is also a setting where research into families' experience of health care can investigate the determinants of care-seeking related to quality of services from the client perspective. These determinants may be different, and possibly more helpful to study, in ENB as compared to a setting (such as other provinces in PNG) where major physical barriers to access are an over-riding reality. Follow-up of the reported 14% of women who in ENB do not seek facility-based childbirth after ANC will be especially relevant to identifying ways of overcoming barriers to accessing health care. Study of a cohort in a higher utilisation setting also enables the tracking of families' intended and then actual care-seeking decisions, including issues of timeliness of utilisation, opportunities for integrated care through the life course, and the predictors of optimal care-seeking.

Complementary studies in the HMHB program (see overview below) will provide opportunity to examine care-seeking from a community perspective, through a community survey that can re-examine the reportedly high health facility utilisation, and a health services study that will link client perspectives with that of health staff and managers. In addition, the partnership with PNGIMR, and with other collaborators listed, will enable ready comparison of this study's findings with work in other provinces of PNG where health service utilisation rates are significantly lower.

### **1.3 Overview of Healthy Mothers Healthy Babies research program**

The overall HMHB program aims to define the major causes of poor maternal, newborn, and child health, and to identify feasible, acceptable and effective interventions and service delivery strategies to improve reproductive, maternal, neonatal and child health (RMNCH) outcomes in PNG. There are **five program objectives**:

1. Identify and quantify major causes of morbidity in mothers, newborns and infants attending health care facilities, and the relationship of morbidity in pregnancy to predicting poor pregnancy outcomes for mother and infant;
2. Identify key determinants of current maternal, newborn and child health care utilisation, patterns (such as timeliness and completeness) of utilisation through pregnancy and the first year of life, and the predictors of optimal utilisation of health services for MNCH;
3. Evaluate RMNCH services and identify strategies to improve services aimed at reducing morbidity and mortality;
4. Examine sexual and reproductive health knowledge, attitudes, practices and outcomes among young people;
5. Identify strategies to improve RMNCH care, and strengthen disease control, targeted to populations in PNG with varying levels of access to health services.

These five program objectives will be addressed by five separate but complementary studies each with study-specific research objectives. The emphasis is on the generation of evidence that has

immediate use in ENB in improving services, and that can inform future health policy in PNG and similar settings. This requires a research program with an operational and implementation focus. HMHB will use predominantly quantitative methods supplemented by qualitative approaches to explore specific themes in these objectives. The five distinct studies will receive separate analysis and contribute to an integrated interpretation.

Throughout the HMHB program a strong focus on capacity development will be maintained. This will occur on multiple levels, including training for local research staff, mentoring of local researchers to undertake discrete research elements, as well as facilitating and providing technical input for research and quality improvement activities at the health facility and at the provincial level.

The timeframe for the five HMHB studies is 2015 to 2020; with Study 1 commencing in 2015 and Study 2 commencing in 2016, Study 3 and Study 4 in 2017, and Study 5 in 2017 or 2018.

The current protocol presented below includes Study 1 only. Separate protocols for Studies 2, 3, 4, and 5 will be prepared and submitted for ethics review.

### ***Study 1 – Cohort Study***

Study 1 is a prospective longitudinal descriptive study with nested analysis, which we refer to as the “Cohort Study”. It will combine both descriptive and analytical components. This longitudinal study is the focus of this protocol and will address program objectives one and part of objective two; complemented by Study 2 to address health service delivery questions and Study 3 to provide additional community data on care-seeking and health service utilisation. Study 1 will recruit a cohort of 700 pregnant women attending their first antenatal clinic in three levels of sentinel health facilities. Health facilities chosen will be those that have the highest utilisation rate for childbirth services, across both urban and rural settings.

The measures involved in this study outlined below are in addition to the usual health care provided at ANC as prescribed by clinic protocols and in accordance with national guidelines. At recruitment participants will provide blood samples, and be interviewed on their reproductive history, as well as health care experiences, intentions and preferences, and will be asked to provide a vaginal swab (self-obtained) and urine sample. Further interview, measurements, and follow up will occur at the time of delivery (including births within and outside facilities), and at 4, 8 and 12 weeks, 6 months and 12 months post-partum, including limited laboratory testing of newborn and mother in this period.

This study aims to quantify the major causes of poor health in pregnant women (including nutritional deficiencies, anaemia, and major infections), and identify major preventable causes of LBW, and assess complications of delivery and the perinatal period. Analysis will also assess interactions between co-morbidities during pregnancy and the relationship to outcomes for mother and baby at birth, and during the first year of life. The study will also examine the patterns of health care utilisation during pregnancy, and in the postnatal period and infancy. This will be used to identify predictors of optimal and sub-optimal care-seeking and health service utilisation.

### ***Study 2 – Health Services Study***



A detailed separate protocol will be submitted for this study. The Health Services Study will primarily address program objective three and also complement the client perspectives obtained in Studies 1 and 3. It focuses on evaluating currently available RMNCH services and describing health worker knowledge, attitudes and practices; as well as establishing prospective audits of deaths and other strategies for health system strengthening and improved quality of care. This study will also link with other health development support being provided to the provincial health office by various partners.

### ***Study 3 – Community Study***

This study will address research program objectives 2 and 3 using a community-based survey whose design will be informed by Studies 1 and 2. It will interview women, who have recently been pregnant, from selected community sites, enrolling both women who have and have not used health services. Other community groups (including community leaders and men) will participate in focus group discussions. A detailed protocol for this study will be developed separately, based on early findings in the Cohort Study.

### ***Study 4 – Young Peoples Study***

HMHB program objective four will be addressed by a mixed methods study with young people recruited from both rural and urban communities. Appropriate participants (including the age range) and topics will be determined through local consultation during study design. Analysis will emphasise the implications for comprehensive and culturally appropriate strategies for improving SRH service utilisation and outcomes. A detailed protocol for this study will be prepared separately.

### ***Study 5 – Impact and Implementation Modeling***

HMHB program objective five will be addressed via a desk review of RMNCH service options, analysis of feasibility and acceptability data gathered during Studies 1 – 4, and follow-up interviews with policy-makers and health managers at national, provincial and health facility levels. Potential service innovations will be subjected to cost and impact modeling using internationally standardised software packages.

## **1.4 What this research adds**

The cohort study described in this research protocol addresses major gaps in our knowledge of maternal and newborn health in PNG. Particularly, the burden of major causes of morbidity in pregnant women, major preventable causes of LBW and their subsequent impact on newborn weight and infant growth, and knowledge of the predictors of and barriers to health care utilisation by pregnant women and new mothers.

Very few longitudinal descriptive studies of cohorts of pregnant women have been performed in PNG. A longitudinal study following women through pregnancy and to one year after birth provides a powerful opportunity to identify major predictors of LBW and poor infant outcomes. This type of study can also determine the longitudinal patterns of health care utilisation by families during pregnancy and early childhood. This will provide insight into new interventions during pregnancy

that could improve outcomes, as well as ways to optimise service delivery through the antenatal, postnatal and infancy periods.

Little is known about interactions between major morbidities and their combined impact on LBW or other pregnancy outcomes where the prevalence of many important causes of LBW is high. Many women will have multiple co-morbidities; therefore assessing these together in the same woman is important. For example, malaria, nutritional deficiencies, and some STIs (such as BV and TV) are major causes of LBW, however very few studies in any resource-poor settings have assessed multiple major causes of LBW within the same cohort. This is an important novel aspect to this study. Additionally, most cohort studies have followed pregnant women only to childbirth, in order to assess birth weight and complications of delivery. A further novel aspect of this study is to follow infants until 12 months of age in order to assess how nutritional deficiencies during pregnancy and LBW impact on growth and health of infants. In addition, we will evaluate health care utilisation by mothers to identify barriers and enablers to access, and evaluate how new interventions can be implemented to maximize gains in health outcomes.

Data on micronutrient deficiencies in resource-poor settings during pregnancy is lacking, particularly how these impact on birth weight, and newborn and infant growth. Our unpublished data from Madang Province demonstrated iron deficiency to be very common (70%) in pregnant women, however similar data is lacking from ENB or other sites in PNG. Data on zinc deficiency and vitamin A deficiency in pregnant women in PNG are limited, despite their public health importance. Currently in PNG, iron and folate are routinely given to pregnant women. However, this study may identify other micronutrient deficiencies that impact on pregnant women and their children that would warrant future investigation as to how appropriate nutritional supplements can maximize the improvements in maternal and infant health.

This cohort study forms Study 1 of the HMHB research program. Other components of the HMHB research program (addressed in subsequent protocols) will address other major knowledge gaps across several broad areas:

- The determinants of utilisation of RMNCH care, including perceived and actual quality of care, collected across one health system with the inclusion of both demand- and supply-side perspectives;
- The relationship between families' intended plans for RMNCH care, their actual experiences of health care and pregnancy outcomes, so as to understand the predictors of timely complete utilisation of care;
- Young peoples' and other stakeholders' perspectives on SRH, including utilisation on essential family planning services, in the study sites in PNG;
- Facility based measures of RMNCH morbidity and mortality, monitoring of improvements in quality and how these can improve utilisation of RMNCH care, including the testing of focused operational research into quality improvement;
- Evidence-based estimates of the feasibility, acceptability, impact and costs of different health service delivery models, that may be tested through future implementation research or health services development, for stronger implementation of national health policies in RMNCH;

- Experience and mentoring for emerging researchers from ENB health facilities, UPNG SMHS and PNGIMR.

The proposed research addresses eight (priorities 1,2,3,7,8,11,16,19) of the top 20 priorities in PNG's new national health and HIV research agenda.<sup>70</sup> The range of academic and government collaborators will enable engagement with important research and policy questions in PNG (see also section on Dissemination of Findings below), and assist the development of national capacity in operational, implementation and health systems research (see also section on Capacity Development, below).

Findings from these studies will be valuable for informing national policy on management and prevention of major causes of maternal and infant morbidity and death, and will be used to inform the development of novel interventions for maternal and infant health in PNG, or a package of interventions, and identify ways to improve the access to and quality of RMNCH.

## **2.0 COHORT STUDY OBJECTIVES**

### **2.1 Research Objectives**

#### ***Primary research objectives***

1. Determine the prevalence of nutritional deficiencies, anaemia, and major infections (including malaria, STIs and TB) among pregnant women attending antenatal care
2. Identify major preventable causes of low birth weight, with a particular focus on the impact on birth weight of nutritional deficiencies, anemia, and major infections (including malaria, STIs, and TB)
3. Determine the impact of infections (including malaria, STIs, and TB), nutritional deficiencies and anemia during pregnancy on newborn weight (at 1 month), and infant growth (at 6 and 12 months)

#### ***Secondary research objectives***

1. Identify key determinants of maternal, newborn and child health care utilisation through pregnancy and the first year of life, and the predictors of optimal utilisation of health services for MNCH
2. Determine the prevalence of adverse pregnancy outcomes (including deaths, stillbirths, miscarriage, and complications such as pre-eclampsia, postpartum haemorrhage or serious infections), and their predictors
3. Determine whether interactions between comorbidities and/or risk factors impact on birth weight, anaemia, neonatal and infant weight, and other pregnancy or infant outcomes
4. Determine the relationship between birth weight and subsequent newborn weight and infant growth (at 6 and 12 months)
5. Identify factors contributing to anaemia among pregnant women and infants
6. Establish women's knowledge and attitudes regarding pregnancy and newborn danger signs, and pregnancy-related morbidities, family planning and sexual risk behaviours, and RMNCH service provision

7. Assess uptake of and adherence to iron and folate supplementation, immunisations, intermittent treatment for malaria, and use of LLINs during pregnancy, the postnatal period and infancy
8. Identify host factors that influence the risk of, or susceptibility to infectious diseases

## **2.2 Primary and Secondary Outcome Measures**

### ***Primary Outcome Measures***

- Presence of
  - Micronutrient deficiencies (defined by laboratory testing, including iron studies, vitamin A, zinc and others)
  - Malaria (by PCR, blood smear and RDT)
  - STIs (including bacterial vaginosis, trichomonas vaginalis, chlamydia, gonorrhea, syphilis, determined by laboratory testing)
  - Tuberculosis (diagnosed clinically with laboratory confirmation where possible), Hepatitis B carriage (laboratory antigen testing)
- Hemoglobin level (measured by Hemocue)
- Birth weight measured within four days of birth
- Newborn and infant weight, height and head circumference at 1, 6 and 12 months

### ***Secondary Outcome Measures***

- Presence of maternal or newborn death, miscarriage, stillbirths, pre-eclampsia, post-partum hemorrhage, other serious complication (reported by trained delivery attendant)
- Presence of morbidities amongst newborns and infants, including malaria (by PCR, blood smear and RDT), anaemia, and micronutrient deficiencies, serious infection or other serious illness (as reported by health worker or medical records)
- Health service utilisation (including preventive care such as family planning or LLINs) prior to and during pregnancy, and the predictors of timely complete utilisation of care postnatally and in infancy
- Women's knowledge and attitudes regarding pregnancy danger signs and pregnancy-related morbidities, and family planning and sexual risk behaviours
- Women's reported experiences of quality of care and preferences for alternative forms of service delivery
- Knowledge amongst pregnant women regarding family planning, pregnancy and childbirth complications, and routine care through pregnancy, postnatal and infancy periods
- Knowledge amongst pregnant women regarding TB, including determinants of TB infection, symptoms, treatment and outcomes
- Knowledge regarding malaria, including impact of disease on pregnancy and newborns, prevention and treatment

- Women's views on feasibility and acceptability of existing or potential interventions to address nutritional deficiencies, causes of anaemia, malaria, TB, STIs and other infections in pregnant women and newborns
- Number of doses (reported or documented) of iron and folate, and antimalarials taken during pregnancy
- Genetic markers of susceptibility to malaria and other infections, with a particular focus on RBC polymorphisms and haemoglobinopathies.
- Household characteristics outside health service utilisation, including housing, water and sanitation, and wealth, in those for whom growth measures are taken at age six months and twelve months.

### **3.0 METHODOLOGY**

#### **3.1 Study Design Overview**

This protocol comprises Study 1 of the Healthy Mothers Healthy Babies research program. It is a prospective longitudinal descriptive study, with nested analysis, recruiting 700 pregnant women attending their first ANC, following them from first ANC visit through to delivery and up to 12 months post partum. All families will receive normal antenatal care, delivery care, post natal care and childhood care from their health facility, in accordance with PNG national guidelines.

At recruitment during the first ANC visit, following eligibility screening and informed consent, women will complete a baseline assessment through interview, examination and laboratory testing. Subsequent data collection, by interview, examination and laboratory testing of mother and her infant, will take place at:

- delivery;
- later immunisation visits (4, 8 and 12 weeks post partum);
- 6 months post partum; and
- 12 months post partum.

Women who deliver outside a health facility will be followed up within two weeks of childbirth, and more restricted laboratory testing undertaken.

Sample size calculations aim to enroll 700 women who present to first ANC appointment prior to 27 weeks gestation (end of second trimester), in order to measure the primary research questions. Enrolment will be open to other women attending at later gestations during the study period, to allow assessment of the secondary research objective and related questions.

#### **3.2 Site characteristics and selection**

East New Britain Province is made up of four districts with a total population of 271,252, mainly located in Gazelle, Rabaul and Kokopo districts. This study will restrict its analysis to these three districts. Each district is divided into Local-Level Government areas (LLGs) and, within these, Wards (the smallest unit of governance) that each comprise two to four villages represented by a single Ward Councillor.

The provincial hospital is Nonga General Hospital, which comes under the direct management of the National Department of Health (NDoH). The Provincial Health Office (PHO) and the district health administrations are responsible for all other health facilities in the province, including both

government and church run services. In ENB there are two hospitals (Nonga and a Catholic run hospital), one urban clinic, 12 health centers, 15 sub-centers and 85 aid posts.<sup>71</sup>

This study will enroll women who are representative of the population of women attending health facilities for ANC in ENB (noting that the province currently reports very high rates of coverage with at least one ANC) so as to describe the burden of disease confronting health services at this point in the life cycle. The study also aims to examine birth and infancy outcomes in relation to this burden, and to understand issues of quality of health care throughout pregnancy, postnatally and in infancy. This requires study sites that have high rates of utilisation for child-birth care, and a mix of rural and urban catchments.

Health facilities and their catchment areas reviewed for inclusion in this study included the two largest hospitals in major towns, and the busiest health facilities providing childbirth services in the rural areas of the three districts selected for this research. The sentinel sites were selected to include the 5 busiest facilities based on the number of deliveries per year. It is noted that other complementary studies within the HMHB program will allow for cross-checking of findings with those families that do not use health services. Also, other HMHB studies and work by partners such as PNGIMR, will allow contrasting analysis with facilities and communities that do not have such high health service utilisation rates, in ENB and elsewhere in PNG.

Based on current information obtained from the Provincial Health Office, the study is planned to be conducted in:

- Nonga Hospital,
- St Mary's Hospital,
- Keravat rural hospital,
- Paparatava Health Centre and
- Naparpar Health Centre.

### **3.3 Study Population – inclusion, exclusion and recruitment**

This study aims to recruit women of any gestation who are attending their first ANC for that pregnancy.

#### ***Inclusion Criteria***

- Pregnant woman attending her first ANC for the current pregnancy
- 16 years or older
- Attending ANC at a participating health facility, and resident within the formal catchment area of the facility
- Willing and able to participate and provide informed consent

#### ***Exclusion Criteria***

- Unable to understand or provide informed consent
- Intention to relocate to a non study area during the study period
- Previous attendance at ANC at another facility during this pregnancy

#### ***Participant recruitment and consent***

Health facilities in ENB divide their ANC into different days for whether the patient is attending for the first time or a repeat visit. The number of women attending their first ANC on one of these days varies across different health facilities, however generally the number is greater than 10, with some

clinics seeing 50 women in a morning. For those clinics that have less than 10 women attending their first ANC in a day, all women who meet eligibility criteria will be invited to participate. At clinics where there are a larger number of women (average of more than 10), enrolment of eligible first ANC attendees will be randomised, using a formula that incorporates the time available to each researcher and the number of women attending the clinic.

A sign written in both English and Tok Pisin will be located at the clinic registration area that will provide an explanation of the study activities and purpose. Potential participants will be screened to ensure they are eligible to be included in the study. Eligible women will then be provided with a written plain language study information brochure in Tok Pisin regarding the study, including an explanation of the voluntary nature of participation and what will be asked of those who choose to participate. Female literacy in Kokopo, Rabaul and Gazelle districts is estimated to be 85-95%.<sup>72</sup> Therefore, all women will be given the option to read the documents themselves, or have it read to them by the researcher.

Verbal confirmation of comprehension will be obtained, allowing adequate time for questions, and the participant asked to sign a written consent should they choose to participate. If the woman is illiterate, then she will be asked to provide a thumbprint in place of a signature, and a witness will be present during the verbal consent process and also required to sign the consent. Participants will be free to choose not to answer any question they do not feel comfortable answering, and advised that they are free to discontinue participation at any point should they wish to do so.

### **3.4 Study Procedures**

Eligible women will be invited to enroll in the study during routine outpatient sessions for first ANC at the five study sites. In addition to the research assessment they will also proceed through normal antenatal care at that clinic site, in accordance with PNG national guidelines. The outcomes of antenatal care will also be noted in research records.

#### ***Baseline assessment***

At recruitment, following informed consent, enrolled women will complete a baseline assessment consisting of: a structured interview, physical examination, providing a urine sample and two vaginal swabs (either self-administered or performed by a trained health worker), and allow the appropriately trained research staff to obtain a 10mls blood sample via venepuncture. The baseline examination will document: routine ANC measurements (e.g. blood pressure, fundal height), Mid Upper Arm Circumference (MUAC), and Body Mass Index (BMI). At baseline enrolment an estimated gestation will be made, based on Last Menstrual Period (LMP) and fundal height, and the estimated date of delivery recorded.

The structured interview (see appendix) will cover demographic details, reproductive and pregnancy history (including spontaneous and induced abortion, stillbirth, and previous obstetric complications), past utilisation of services (including past preventive care such as family planning, LLIN use), experience of accessing the current services, plans for future health service utilisation, and preferences for alternative forms of health services.

Blood samples will be tested at the point of enrolment for hemoglobin (Hemocue) and malaria (by RDT) later tested for iron deficiency (serum ferritin, serum Transferrin Receptor (sTfR)), C reactive

protein, (CRP)), micronutrient deficiencies (including, serum retinol, Retinol Binding Protein (RBP), zinc and others as indicated [e.g. vitamin C, magnesium, copper]), malarial antibodies, malaria PCR and light microscopy, and syphilis (RPR and THPA tests; rapid test- included as part of routine antenatal care), and evidence of vaccine preventable infectious diseases (hepatitis B surface antigen (HBsAg), measles antibody), glycosylated haemoglobin (HbA1C), glycated albumin, random glucose or other markers for diabetes. Also to be examined at later testing are growth factors and cytokines that impact on birth weight, and genetic polymorphisms that may influence risk of malaria and other infectious pathogens (e.g. red blood cell polymorphisms), or pregnancy outcomes. The urine sample will be used for dip-stick urinalysis and later urinary iodine (UI). The first vaginal swab will be tested on site in ENB for chlamydia, gonorrhoea and trichomonas using the Point of Care (POC) GeneXpert platform, or laboratory-based PCR off-site. The second vaginal swab will be used to prepare a smear for subsequent diagnosis of bacterial vaginosis in a specialized diagnostic laboratory, and then stored for reference testing for Chlamydia, Gonorrhoea and Trichomonas Vaginalis. Dried blood spots will be collected for G6PD testing and antibody extraction. Additional detail on specimen collection, laboratory testing and specimen storage is described below.

In addition researchers will ask a number of questions to actively identify any woman with symptoms consistent with malaria, TB or an STI. Appropriate treatment will be provided for those with malaria, and STI treatment will be provided as per national guidelines for syndromic management. Any woman identified to have an STI following testing of vaginal swabs using GeneXpert will be treated promptly if not already receiving appropriate syndromic management. If the use of GeneXpert is unavailable, testing for STIs will be conducted offsite. In this instance, testing and results may be delayed by a number of months. Any women identified with an STI within six months through offsite testing of swabs, who did not receive appropriate treatment based on symptoms, will be followed up and treatment provided, together with counseling and partner treatment provided as per national guidelines.

For those women with symptoms consistent with TB, national guidelines will be followed, and appropriate referral provided to facilitate investigation such as smear microscopy, and treatment. Any referral or transport costs incurred, as a result of this baseline assessment, by the woman to have further investigation or treatment will be paid for by the study. Women who have evidence of a UTI on urine dipstick will be provided appropriate treatment and advised on when or if they should represent to the health facility should their symptoms persist.

### ***Delivery assessment***

The health facility will notify the research team if and when each study participant presents for delivery. The research team will be (at the minimum) in twice weekly communication with each facility in order to maximize notifications of study participants attending for delivery. A member of the research team will visit the facility as close to delivery as possible and document: maternal and newborn outcomes (based on interview and review of health facility records), newborn birth weight, Apgar score, estimated gestation and vaccination status. This will ideally occur within 48 hours of delivery, with an outside limit of two weeks. A postnatal venous blood sample will be collected from the mother for haemoglobin testing, later testing of antibodies, malaria by PCR and light microscopy, micronutrients or RBC genotypes in plasma, serum or cell fractions, glycosylated



haemoglobin (HbA1C), glycated albumin, random glucose or other markers for diabetes. A vaginal swab will be obtained (either self obtained or by health practitioner) for all women, this will include 2 vaginal swabs for STI and other genital infections and a rectovaginal swab for Group B *Streptococcus* (GBS). A malaria RDT will be performed for all participants. A heel prick blood sample will be collected from the newborn for haemoglobin and micronutrient testing, as well as antibodies to malaria and other vaccine preventable infections. Research staff or health facility staff will be trained to collect a placental blood or a 5-10g placental tissue sample at delivery, which will be tested for evidence of placental malaria (see laboratory methods).

Active follow-up of women who do not attend for delivery by the expected date will be pursued through telephone and contact with local health staff. If the woman has delivered at home, the research team will make community visits, aiming for a home visit within four days of birth but with an outside limit of two weeks. On home visits, blood (but not placental) samples will be collected. It is acknowledged that active follow-up at this point and later in the life course will influence care-seeking behavior, and this will be accounted for in the analysis process.

### ***Post partum assessments***

Women and their newborns will be followed up at 4 weeks post partum to capture any late maternal or neonatal morbidity and mortality events. This will take place in conjunction with the first immunisation visit (which is scheduled at this age in PNG) where possible. These women will be seen either at the health facility or, should they not attend, a research team member will actively follow them up at their residence within two weeks. They will be interviewed regarding experiences of illness in mother or newborn, experiences of health services, plans for future health service utilisation (including preventive care such as family planning and routine care of the infant), and preferences for alternative forms of health service utilisation. The infant's growth will be assessed for weight and height. A maternal blood sample (finger prick and dry blood spot) will be taken at this visit, and tested for anaemia, haemoglobin levels, malaria PCR and micronutrient deficiencies. If the woman previously tested positive for a treatable STI, she will be offered re-testing and treatment. At 2 and 3 months post delivery, attendance at a health facility for infant immunisations will also be documented by interview, client-held records and clinic registers. Should the participant not attend at either of these 2 and 3 month visits, they will not receive a community visit. A diagnosis of maternal TB at any point will lead to assessment of the infant for TB and provision of treatment or preventive treatment as per PNG guidelines.

Two further opportunistic health facility assessments, or community visits will be conducted: firstly between 6 and 7 months, and then at between 12 and 13 months after delivery. Women will be interviewed regarding any current symptoms for themselves or their infant, experiences of illness in mother or newborn, experiences of health services, utilisation of routine services such as vaccination and family planning, plans for future health service utilisation (including preventive care such as family planning and routine care of the infant), and preferences for alternative forms of health service utilisation. The infant's growth and development will be assessed, including weight, height, head circumference and developmental milestones. A double finger or heel prick will be performed to obtain 400 microlitres of capillary blood from infants. Venepuncture will be performed on women to collect venous blood if possible; alternatively double finger pricks will be used to collect blood. Both maternal and infants sample will be tested for haemoglobin, malaria

PCR, micronutrients, and malaria antibodies and evidence of other vaccine preventable infections (eg HBsAg). Maternal venous samples will also be tested for glycosylated haemoglobin (HbA1C), glycated albumin, random glucose or other markers for diabetes. At 6 months, all women will be asked to provide two self-obtained vaginal swabs to be tested for STI and genital infections, any woman who tests positive will be actively followed up and treatment facilitated (provided the GeneXpert machine used at our lab in Kokopo is operational, if it is not, testing may not be possible for a number of months, making follow up of these women potentially infeasible). At 12 months, any woman who has previously tested positive for a treatable STI will be offered repeat testing. For infants at 12 months, additional consent will be requested for a nasopharyngeal swab to facilitate pneumococcal surveillance. If the assessment suggests presence of disease, the mother or infant will be supported in seeking care at their first line health services. As above, it is acknowledged that this may affect care-seeking behavior and this will be accounted for in data analysis.

### **Summary of data collection points**

An overview of assessments and data to be collected is tabled below. More detailed descriptions of laboratory testing is provided in the section below on specimen collection and handling.

**Table 1: Summary of data collection points**

|                             | <b>Mother (enrolment)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                    |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| <b>ANC1<br/>(Enrolment)</b> | Baseline interview and medical notes<br>Anthropometry<br>TB and other symptom screen<br>Routine ANC care (physical examination, fundal height)<br>Fingerprick blood test for syphilis rapid test (coordinated with other routine ANC test)<br>Venepuncture (plasma, serum, cell fraction) for: <ol style="list-style-type: none"> <li>1. Haemoglobin</li> <li>2. Malaria blood smear &amp; malaria RDT</li> <li>3. Micronutrients</li> <li>4. Dried blood spot for G6PD and antibodies</li> <li>5. RPR for those who test anti-TPsyphils rapid test positive</li> <li>6. Later testing</li> <li>7. Markers of diabetes</li> </ol> Urine sample for: <ol style="list-style-type: none"> <li>1. Dipstick (protein, leucocytes, nitrites)</li> <li>2. Iodine</li> </ol> Vaginal swabs: <ol style="list-style-type: none"> <li>1. STIs by GeneXpert testing (CT/NG and later TV)</li> <li>2. Smear for bacterial vaginosis</li> </ol> Stored specimen for possible testing of HPV, other infections |                                                                                                                                    |
|                             | <b>Mother (follow-up)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Newborn and Infant (follow-up)</b>                                                                                              |
| <b>Delivery</b>             | Baseline interview and medical notes (including malaria episodes, iron supplementation, any STI/TB or other treatments), complications.<br>Pregnancy outcome, morbidity and mortality record                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Apgar score<br>Anthropometry (weight, height, HC)<br>Sex<br>Finger/heel prick for haemoglobin, micronutrients and other infections |

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                         |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                             | <p>Venepuncture (plasma, serum, cell fraction) for:</p> <ol style="list-style-type: none"> <li>1. Haemoglobin</li> <li>2. Malaria blood smear (&amp; RDT if symptomatic)</li> <li>3. Later testing of antibodies</li> <li>4. Markers of diabetes</li> <li>5. Placental blood +/- tissue for malaria</li> </ol> <p>Swabs:</p> <ol style="list-style-type: none"> <li>1. Vaginal swabs for STIs &amp; other genital infections</li> <li>2. Rectovaginal swab for GBS</li> </ol> |                                                                                                                                                                                                                                                                                                                         |
| <b>4 weeks postpartum</b>   | <p>Interview for morbidity/mortality, health service utilization</p> <p>Blood sample (venous or finger prick) for haemoglobin, micronutrients, malaria PCR</p> <p>Re-testing for treatable STIs offered.</p>                                                                                                                                                                                                                                                                  | <p>Anthropometry (weight, height, HC)</p> <p>Blood sample for haemoglobin, micronutrients and other infections</p>                                                                                                                                                                                                      |
| <b>8 weeks</b>              | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Immunisation data                                                                                                                                                                                                                                                                                                       |
| <b>12 weeks</b>             | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Immunisation data                                                                                                                                                                                                                                                                                                       |
| <b>6 Months post partum</b> | <p>Interview for morbidity/mortality, health service utilization</p> <p>Venepuncture, or finger-prick blood for haemoglobin, micronutrients and malaria, antibodies to infections and markers of diabetes</p> <p>Swabs:</p> <ol style="list-style-type: none"> <li>1. Vaginal swabs for STIs &amp; other genital infections</li> </ol>                                                                                                                                        | <p>Anthropometry (weight, height, HC)</p> <p>Developmental data</p> <p>Heel prick for:</p> <ol style="list-style-type: none"> <li>1. Haemoglobin</li> <li>2. Micronutrients</li> <li>3. Malaria PCR</li> <li>4. Hepatitis B surface antigen</li> <li>5. Antibodies to malaria and other infections</li> </ol> <p>1.</p> |
| <b>12 Months</b>            | <p>Interview for morbidity/mortality, health service utilization</p> <p>Hemacue</p> <p>Re-testing for treatable STIs offered.</p>                                                                                                                                                                                                                                                                                                                                             | <p>Anthropometry (weight, height, HC)</p> <p>Developmental data</p> <p>Heel prick for:</p> <ol style="list-style-type: none"> <li>1. Haemoglobin</li> <li>2. Micronutrients</li> <li>3. Malaria PCR</li> <li>4. Hepatitis B surface antigen</li> <li>5. Antibodies to malaria and other infections</li> </ol>           |

### 3.6 Study timeline

The table lists this Cohort Study timetable.

**Table 2: Timeline for Study 1.**

|                              |                                                                                                                                                                     |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>2014</b>                  |                                                                                                                                                                     |
| <b>February</b>              | New Research Program Manager appointed                                                                                                                              |
| <b>March</b>                 | Drafting of study protocol                                                                                                                                          |
| <b>April-July</b>            | Stakeholder / Partner review of study protocol in Kokopo and Port Moresby<br>Confirming Partners<br>Confirming study investigators<br>Finalise study protocol       |
| <b>July - August</b>         | Ethics submission (PNG & Melbourne)                                                                                                                                 |
| <b>August - September</b>    | Advertising and interviewing for staff<br>Community engagement and permissions<br>Health facility engagement and permissions<br>Ethics approval (PNG and Melbourne) |
| <b>October - December</b>    | Training of staff<br>Testing of Study 1 tools                                                                                                                       |
| <b>2015</b>                  |                                                                                                                                                                     |
| <b>January</b>               | Begin Study 1 enrollment                                                                                                                                            |
| <b>February - March</b>      | Ongoing Study 1 enrollment<br>Interim analysis once 350 women enrolled                                                                                              |
| <b>April</b>                 | Completed Study 1 enrollment<br>Ongoing Cohort follow up                                                                                                            |
| <b>May – June</b>            | Analysis of baseline assessment data<br>Ongoing Cohort follow up                                                                                                    |
| <b>June - October</b>        | Ongoing Cohort follow up                                                                                                                                            |
| <b>November</b>              | Analysis of delivery data                                                                                                                                           |
| <b>September – July 2017</b> | Ongoing Cohort follow up                                                                                                                                            |

### **3.7 Data collection and data management**

#### ***Data linkage***

Specimens and data collected in this project will be linked to the related Healthy Mothers Healthy Babies studies detailed in subsequent protocols. In addition, future laboratory or epidemiological studies may be conducted on the specimens and data collected from those participants who specifically consent to this. Potential future tests are made clear in the consent form in an opt in format, and will not include testing for HIV.

#### ***Preparation for data collection***

Field survey tools will be validated over several weeks prior to study commencement in consultation with the local advisory group. Data collectors will be trained over a three-week course on informed consent, interview style and review of supporting clinical data available (collected from participant health books or hospital records). Source documents for the study include

- Field log book charting enrolment and on-going participation in cohort study
- Case Report Forms (CRFs) completed by field team (scheduled and non-scheduled)
- Health Centre log books
- Participant's personal health books
- Infants personal health books
- Health Centre documents of illness and treatment history of participants
- Laboratory worksheets documenting evaluation of blood or sputum, smears, tissue, swabs or DNA.
- Adverse event forms
- Morbidity episode detection

#### ***Data collection***

Following eligibility screening and informed consent study participants will be allocated a unique Study Identification Number (SIN), this will be used to identify all specimen samples and questionnaires relating to that participant to ensure data are de-identified. A separate file will link the SIN to participant identification details to ensure that any required follow up of results is possible.

Study participants will complete an interviewer-administered structured questionnaire. All interviewers will be research staff appropriately trained in interview techniques particularly when dealing with sensitive health topics, confidentiality and ethical considerations in research. Particular focus will be given to how to appropriately deal with, and discuss sensitive health topics and interacting with adolescents. Responses will be recorded on a de-identified standardised electronic or paper questionnaire sheet. Each form will be checked for completeness by the research coordinator or supervisor. If corrections are required, the incorrect entry will be crossed out with a single line with the correction printed adjacent, initialled and dated. Any requested information that is not obtained should have an explanation noted on the CRF.

For laboratory work conducted at Burnet Institute (East New Britain, and Melbourne) or PNGIMR, separate laboratory databases will be created, cleaned and linked to the main database, as appropriate.

### ***Data management***

Data handling and database management will take place in Burnet Institute facilities in Kokopo under the supervision of the research coordinator and database manager. The research coordinator will design electronic survey tools systems using software such as QDS, REDcap or MDS, for use on compatible data collection tools.

An independent data clerk will enter data into electronic form. Entries will be cross-checked and cleaned, and combined with cleaned electronic captured records under the supervision of site investigators. All data collected will be entered onto a computer and backed up into a centralised digital folder at the end of each day. All computers will be password protected and only accessible to the research team. The centralised backup will be password protected, regularly backed up, and only accessible to the research program manager and named study investigators. All data forms will be stored in a secure locked filing cabinet in the Kokopo Burnet Institute Office and accessible only to the research program manager. Any personally identifying documents, including the file linking participant identification with their allocated SIN will be stored in a separate locked filing cabinet and accessible only to the research program manager and Principle Investigators.

### ***Data analysis***

The dedicated computer database (noted above) will use Microsoft Access or similar software that is able to export reports for data analysis. A Burnet Institute statistician, Mr Paul Agius, will provide expert advice on analysis procedures prior to database construction; this process will also inform the construction of final electronic data collection forms. Our expected sample size (discussed in the section below) is designed to provide sufficient power to detect postulated associations in our primary endpoints using appropriate tests for statistical significance, reporting 95% confidence intervals. Mr Agius will work with other study investigators on the use of STATA (StataCorp, USA) to conduct initial descriptive analyses of prevalence and tests for differences in sub-groups, as indicated in our primary and secondary research outcome measures. Addressing these measures will also entail application of appropriate univariate and multivariate analyses, including the identification of predictors of different outcomes or care practices at birth or in infancy, and adjust for potential confounders.

Qualitative data will be captured through questions with open fields in the data collection tools (see appendix), recorded by interviewers in English or Tok Pisin, and an English version entered into the computer database. These will provide triangulation of quantitative findings, as well as additional explanatory data likely to be helpful in hypothesis generation for future studies. Reliability of the qualitative data will be assured through careful collection, collation and a transparent replicable approach to analysis. Thematic coding will address previously identified themes that have guided the data collection tool construction, as well as an active search for new themes emerging from a consolidated review of the qualitative data. After themes are established (based on a preliminary review of a subset of records), all coding will be done by at least two

researchers, aiming for independent review followed by consensus through discussion. We will endeavor to be reflexive, in particular to observe and document any interviewer or analyst bias that may be operating, with special attention to any that may arise from the interviewer-client relationship. Themes will be derived through hand-coding, supported by qualitative analysis software (NVivo, QSR International).

### ***Access and retention of source documents***

At the end of the study the final database and data for analysis will be maintained at Burnet Institute and PNGIMR. Electronic and hard copies of study records will be maintained for at least ten years following the conclusion of the study. Interested participants may access their personal records at anytime. Only authorized research staff will have access to records, and strict privacy and confidentiality to participant records applies.

### **3.8 Statistical Considerations – Sample Size**

This study aims to recruit 700 women of all gestations into the study who will participate in the baseline survey and health seeking questionnaire. Women who meet the inclusion criteria for the cohort study will be followed up through delivery (primary research questions) and for one year post-partum in the first year of life (secondary research questions). The enrolment sample size calculation is based on detecting clinically meaningful differences in birthweight (primary outcome) between women with and without malaria, STIs, TB, anaemia, iron deficiency, micronutrient deficiencies and detecting significant interactions between co-morbidities. In sample size calculations, power has been conservatively set to 90%.

Recent data from Burnet on iron deficiency and malaria prevalence in pregnant women (Madang Province; Fowkes, Beeson, et al., unpublished) was used to base our sample size calculations. Recent research in PNG has shown a mean (SD) birth weight of 2736 grams (475) in iron replete pregnant women from Madang province (Beeson, Fowkes, unpublished data). Table 3 shows the range of sample sizes to detect a difference of between 100-200 grams between groups at 90% power with 5% two-sided significance assuming a ratio of 0.43 (~ 30% will be iron replete, 30% Plasmodium spp. Positive, 30% STI positive (based on Beeson, Fowkes, unpublished data from Madang province; and experience in PNG (Vallely et al) is that 30% sits well within the prevalence range for different STIs from various community surveys in women). A sample size of 700 pregnant women (or 500 after anticipated loss to follow-up or excluding women over 27 weeks at enrolment) is well powered to give good precision of estimates of the prevalence of major causes of disease in pregnant women, including nutritional deficiencies, anaemia, and infections. An interim analysis will be conducted following the enrolment of 350 women to review the study's sample size and power calculations based on the primary objectives.

Primary analysis of the association between morbidities and birth weight will include women enrolled in their 1<sup>st</sup> or 2<sup>nd</sup> trimester only (up to 27 weeks). Exploratory analyses will be performed that includes all women regardless of their gestation to evaluate any effect of gestation on the association between morbidities and birth weight.

**Table 3: Range of Sample Sizes**

| +-----+ |       |      |     |     |        |       |      |      |      |     |  |
|---------|-------|------|-----|-----|--------|-------|------|------|------|-----|--|
| alpha   | power | N    | N1  | N2  | nratio | delta | m1   | m2   | diff | sd  |  |
| -----   |       |      |     |     |        |       |      |      |      |     |  |
| .05     | .9    | 1130 | 790 | 340 | .43    | 100   | 2736 | 2836 | 100  | 475 |  |
| .05     | .9    | 934  | 653 | 281 | .43    | 110   | 2736 | 2846 | 110  | 475 |  |
| .05     | .9    | 786  | 549 | 237 | .43    | 120   | 2736 | 2856 | 120  | 475 |  |
| .05     | .9    | 670  | 468 | 202 | .43    | 130   | 2736 | 2866 | 130  | 475 |  |
| .05     | .9    | 578  | 404 | 174 | .43    | 140   | 2736 | 2876 | 140  | 475 |  |
| .05     | .9    | 504  | 352 | 152 | .43    | 150   | 2736 | 2886 | 150  | 475 |  |
| .05     | .9    | 444  | 310 | 134 | .43    | 160   | 2736 | 2896 | 160  | 475 |  |
| .05     | .9    | 394  | 275 | 119 | .43    | 170   | 2736 | 2906 | 170  | 475 |  |
| .05     | .9    | 351  | 245 | 106 | .43    | 180   | 2736 | 2916 | 180  | 475 |  |
| .05     | .9    | 315  | 220 | 95  | .43    | 190   | 2736 | 2926 | 190  | 475 |  |
| .05     | .9    | 285  | 199 | 86  | .43    | 200   | 2736 | 2936 | 200  | 475 |  |
| +-----+ |       |      |     |     |        |       |      |      |      |     |  |

From this estimated sample, it is expected that approximately 15% will be recruited >27 weeks and approximately 15% will be lost to follow-up or not have birth weight measured within four days of delivery and will subsequently be excluded from birth weight analysis resulting in ~500 women included in the birth weight study. This will provide at 90% power with 5% two-sided significance to detect a minimum difference between groups of 150 grams or greater (Table 1). Given the estimated sample size, we expect the study to have 90% power with 5% two-sided significance to detect a small effect size (Cohen's effect-size measure  $f=0.14$ ) in an interaction term from a two-way analysis of variance approach.



## **4.0 LABORATORY METHODS**

### **4.1 Specimen collection, storage and shipment**

Specimens will be transported at regular intervals from participating sites to laboratory facilities in ENB for processing and storage. Delivery and receipt of samples will be documented in sample log-books, and processed according to standard operating procedures.

All human specimens received in the laboratory will be labeled with a code to preserve confidentiality, and will be logged in paper or electronic databases prior to processing. As noted below, investment in partner laboratories in ENB will be pursued to maximize the amount of testing that can be done in ENB (see section below).

For specific tests that require testing outside ENB, samples will be stored initially at facilities in Kokopo at  $-20^{\circ}\text{C}$ , or room temperature for blood spots, and subsequently samples will be shipped to the IMR (Madang and Goroka), or the Burnet Institute for sample testing. Samples will be securely stored at these locations at  $-70^{\circ}\text{C}$ . All specimens leaving ENB will be cross-checked and logged out, prior to shipment. Shipments will be undertaken in accordance with the international air transport association guidelines, contracting local and international specialized courier companies, where appropriate.

### **4.2 Laboratory evaluations and assays**

#### ***Detection and quantitation of malaria infections***

Blood smears will be prepared from all blood samples and will be read by two independent microscopists following standard methodology.

- a) Thick and thin smears (in duplicate) will be prepared on each participant in the study at recruitment and delivery by trained field staff. Blood smears will be evaluated for the presence of asexual parasites under oil immersion by at least two independent trained microscopists. Smears will be examined over enough fields to include a total number of 200 leukocytes. Results are expressed as number of asexual parasites/ul (assuming 8000 leukocytes/ul blood). In case of discordance in species or positivity, or parasite counts deviating more than ten fold, a third read will be performed.
- b) PCR detection of parasitaemia and determination of all *Plasmodium* species will be performed using DNA will extracted from blood using widely established methods.<sup>73</sup>

Analyses will use both PCR and smear definitions of malaria infection.

#### ***Placental Pathology***

If feasible, placental blood samples or small placental tissue biopsies (up to approximately 10 grams in size) will be collected from a subset of women after delivery. Blood samples will be collected into tubes for cryopreservation, and used to prepare smears and filter-paper blood-spots. Full thickness tissue biopsies will be collected into formalin and subsequently processed for histology using standard procedures. Sections of placenta will be cut onto slides and will be stained with haematoxylin and eosin. Slides will be examined by light microscopy to classify placentas as (1) no infection (2) acute infection (parasites but no malaria pigment) (3) chronic infection (parasites plus

malaria pigment (4) past infection (pigment, no parasites). Two readers will examine all sections and discrepancies will be resolved by a third consensus read.

### ***Measurement of antibodies to malaria***

- Enzyme immunoassays – sera will be tested for the presence of antibodies to peptides or recombinant proteins corresponding to specific malaria antigens, or using whole parasites, using standard methods.<sup>74</sup> This will include antibodies (Ig isotypes and IgG subclasses) to all malaria parasite life-stages, and different *Plasmodium* species, but will primarily focus on *P. falciparum* and *P. vivax*. For reference, samples may also be tested for antibodies to other infectious pathogens that are common in the community (e.g. causes of pneumonia, hepatitis B, and others), or tested for vaccine-induced antibodies (e.g. measles, tetanus, and others). Samples will not be tested for HIV antibodies.
- Flow cytometry – antibodies to parasite surface antigens can also be measured by flow cytometry in vitro. Parasites are incubated with sera, and using a flow cytometer, the average amount of antibody bound measured, giving a semi-quantitative indication of amount of antibody in individual sera.<sup>75</sup>
- Functional activity of antibodies – antibodies will be tested using in vitro assays that measure their functional activity against malaria parasites. This includes i) the ability of antibodies to inhibit parasite growth and replication in vitro, which is an established assay of immunity; ii) the ability of antibodies to opsonize parasites and promote their phagocytosis and killing by immune cells (including mononuclear cells and neutrophils, dendritic cells, NK cells), iii) the ability of antibodies to opsonize parasites and promote the deposition of complement in vitro; iv) the ability of antibodies to inhibit the adhesion of parasites to endothelial cells in vitro, v) the ability to inhibit the function of specific malaria virulence proteins in vitro; and other assays of antibody function if relevant.

### ***Characterising genes expressed by malaria parasites***

Among a subset of women with malaria infection, we will examine the presence of polymorphisms in specific genes that are relevant to immunity or malaria virulence using DNA purified from blood samples.<sup>76</sup>

### ***Testing for STIs***

Presence of common STIs will be tested using vaginal swabs (see below) and blood sample for rapid test of syphilis.

Serum will be tested for serological evidence for suspected cases of active syphilis using commercially-available kits (THPA and RPR tests, POC).

During the commencement of this study, the intention is to introduce GeneXpert testing for chlamydia and gonorrhea to facilitate more rapid diagnosis of STIs and improve treatment. Current studies are underway to validate the GeneXpert testing for *trichomonas vaginalis* (TV), and it is hoped that once this is available it can also be used to in this study. We will house a GeneXpert machine at one clinic location. Specimen processing and testing will use standard operating procedures based on those successfully established in the NHMRC TTANGO trial in remote Aboriginal communities in Australia, and will be adapted for use in PNG.

Samples from all women enrolled in the study, and those sampled at delivery and 6 months post partum (at all clinics) will be batch-tested for STIs each week using GeneXpert and standardized procedures to ensure quality control. If the cartridge required for TV testing is not yet available, specimens will be stored for later testing. Results from testing will be recorded in a study register/recording log. Quality control will be conducted by including positive and negative quality control samples to test after every 30 POC tests, and the results will be regularly reviewed by the study co-ordinator.

Women who test positive for an STI and who have not already received appropriate treatment as per the syndromic management of STIs will be provided with a diagnosis of STIs within a week of sample collection and treatment provided. If there is a delay in obtaining and installing a GeneXpert at the study site, all samples will be stored and subsequently tested as soon as access to the machine is available and results provided as indicated above. Additional testing of samples for STIs by standard PCR-based diagnostics, either in Melbourne or PNGIMR-Goroka, may be performed to supplement data obtained using GeneXpert.

### ***Specimen collection***

Participants will be asked to collect two self-obtained mid-cavity vaginal swabs (SOVS); a previous PNG IMR study found that women preferred this approach. Study staff will explain to patients how to collect the swabs. Specimens will be self-collected by patients in a private space made available at the clinic and these will be handed back to the study staff. At delivery an additional rectovaginal swab will be collected. All specimens will be labelled with the unique SIN for that patient. One swab will be used for STI diagnosis using GeneXpert; the second swab will be used to prepare a smear on a microscope slide for subsequent diagnosis of bacterial vaginosis, and stored for possible subsequent testing for STIs by PCR, depending on results from the implementation of GeneXpert-based testing (PCR testing may include gonorrhea, chlamydia, trichomonas, Mycoplasma, and HPV). Swabs will be collected at enrolment, delivery and post partum visits to test for STI and other genital infections.

### ***Specimen storage***

All specimens for GeneXpert testing will be transferred into GeneXpert transport tubes to ensure stability in case of delays in testing. The research nurse or technician will test specimens at least weekly using the GeneXpert to enable results and treatment to be provided to the patient and her partner as soon as possible. Should any delays in testing be anticipated (for example, because of high patient load or machine malfunction), specimens will be stored in the GeneXpert transport medium which preserves specimens for a month, should further delays be expected specimens will be frozen. Testing will be prioritised based upon the order in which patients are seen in the clinic.

### ***Diagnosis of TB:***

Sputum samples collected subsequent to clinical screening of pregnant women will be tested for TB at Nonga Base Hospital according to current protocols. Any presumptive or confirmed case will be treated according to the 2012 PNG Adult Standard TB Treatment Manual. Samples may also be tested using the GeneXpert MTB/RIF test once this becomes available during the course of the

study. A bacteriologically confirmed case of TB will be indicated by positive smear microscopy or GeneXpert MTB/RIF. Phenotypic drug susceptibility testing will be performed as per national guidelines and may be performed on additional samples. DNA may also be extracted from sputum samples to detect TB by standard PCR methodologies, or to test for the presence of drug-resistance genotypes (by established PCR, RFLP or genome sequencing methods), which will provide data to inform public health policy on TB management.

#### ***Host blood genetic analysis using blood samples.***

Blood samples from women and children will be typed for red blood cell polymorphisms, and other relevant polymorphisms, that are associated with changes in risk of malaria illness in PNG (these include South East Asian Ovalocytosis, Glycophorin C, alpha-thalassaemia, and others).<sup>77</sup> Red cell counts will be performed on peripheral blood samples using a coulter counter, or similar device (e.g. Scepter hand-held counter), where available. In addition, blood samples may be tested for G6PD deficiency using commercially available or in-house tests on filter paper samples.

#### ***Assessing micronutrient deficiencies***

Serum or plasma from peripheral blood samples from women and infants will be tested for micronutrient deficiencies using commercially available kits. These assays are typically performed in a 96-well plate format. Initially, studies will assess levels of iron (including ferritin, C reactive protein, transferrin receptor, hepcidin), zinc, and vitamin A (retinol and retinol binding protein), as these are common nutritional deficiencies that impact on maternal and child health. Studies will then be expanded to include additional micronutrients (e.g. Vitamin C, magnesium, copper), as well as other markers of nutrition (e.g. serum albumin) will be measured depending on clinical and laboratory data from the study. A small volume of midstream urine sample will be tested for dipstick analysis at point of recruitment, and aliquoted and stored at -20C for further testing of iodine levels.

#### ***Antibodies to other infections or vaccine-induced antibodies.***

Sera or antibodies extracted from filter paper will be tested for the presence of antibodies to a number of other infectious pathogens that are common in the community (e.g. causes of pneumonia (S. pneumonia, RSV, TB, Hib), hepatitis, CMV, EBV, dengue and other arboviruses (e.g. chikungunya), and others), or tested for vaccine-induced antibodies (e.g. measles, tetanus, hepatitis B, and others).<sup>78,79</sup> Samples will not be tested for HIV antibodies under the study protocol. We note that this is included in routine antenatal care in accordance with the PNG national guidelines, in approved counseling and testing locations in ENB.

#### ***Cytokines and growth factors***

In serum or plasma samples, we will measure cytokines and growth factors that are associated with LBW or under-nutrition (e.g. TNF-alpha, IFN-gamma, insulin-like growth factors).<sup>80</sup> These are measured in a 96-well plate format using commercially available kits or reagents.

### **4.3 Laboratory testing sites.**

#### ***Laboratory studies in East New Britain***

The ability to perform sample testing in ENB will be dependent on the availability of laboratory space and equipment and appropriately trained staff. During the course of this project, we intend to work with local organisations to help develop capacity and training in laboratory studies. We anticipate developing capacity for processing, performing standard ELISA assays and some micronutrient assays using commercially available kits (e.g. ferritin) during the course of this project.

#### ***Laboratory studies at IMR***

Depending on the availability of staff and facilities at the IMR and agreement from the Director, a range of laboratory studies will be performed at the IMR. This includes light microscopy, ELISA for antibodies to malaria, PCR detection of Plasmodium infection, PCR detection of STIs, evaluating micronutrient deficiencies using available kits. We will co-ordinate with the IMR Director, Unit Heads (e.g. vector-borne diseases, infection and immunity, sexual and reproductive health) and key IMR personnel to identify studies to be performed at IMR and opportunities for training of IMR staff.

#### ***Laboratory studies at Burnet Institute***

Because of the limited facilities in East New Britain, many of the laboratory studies will need to be performed at the Burnet Institute, requiring the shipment of samples to Melbourne. Studies will include analysis of malaria infection, analysis of malaria antibodies and antibodies to other common infectious diseases, measuring micronutrients and other markers of nutrition, testing for STIs including bacterial vaginosis microscopy, PCR of specific genes and gene sequencing, and placental histopathology analysis. However, we aim to identify staff from local organisations in ENB and staff at the IMR who could travel to Melbourne to develop and expand their laboratory skills, especially in the most clinically-relevant assays for PNG (e.g. assays of micronutrients, STI diagnosis) that can then be transferred to PNG laboratories.

## **5.0 OTHER CONSIDERATIONS**

### **5.1 Capacity Development**

Significant research capacity development is built into the broader HMHB program of five studies. This includes: investment in local laboratory and biomedical research capacity in East New Britain under Study 1; inclusion of obstetric or paediatric registrars and other local clinical staff in aspects of Study 2 (Health Services) and Study 3 (Community Survey); inclusion of national and local clinicians in Study 4 (Young Peoples Study); and inclusion of health planners at provincial and national level in Study 5 (Impact and Implementation Modeling).

This is signaled in the range of co-investigators from UPNG and local health institutions who will work alongside investigators from PNGIMR and Burnet Institute, gaining experience in the detailed design and implementation of research activities with direct clinical or policy relevance.

Throughout the course of these studies, the PIs will involve PNG staff and students to further

develop their scientific experience, skills, and qualifications. In particular, staff and students will be involved in i) performing immunological assays on samples, ii) analysis and interpretation of results, and iii) the presentation and publication of research findings. The PIs will work with staff and students during the drafting of any publications to further develop their writing and analytical skills. Staff and students will be encouraged to present relevant aspects of these studies at local and national scientific meetings in PNG, and overseas where appropriate. Selected staff and/or students from PNG will be provided with opportunities for further training at the Burnet Institute in Melbourne.

The local and national advisory boards also play a key role in guidance and dissemination (as noted below) and we expect that this will also build provincial and national capacity in the use of research to inform policy and practice.

Research for this Study 1 (Cohort Study) will invest in laboratory infrastructure in clinical institutions in Kokopo and Rabaul, aiming to maximize the local conduct of laboratory tests (as noted elsewhere) including new techniques such as technology for rapid conduct of full-blood counts. This will include additional training of laboratory staff, with complementary benefits for their clinical work. The program will also recruit and train local research assistants who will gain skills in quantitative and qualitative research methods as applied through the research cycle, including data collection and data management, as well as analysis and interpretation.

Burnet Institute's involvement in development projects, and other research, in ENB and nationally, also enable HMHB to link with other capacity development activities including those building provincial capacity for disease control and improved quality of RMNCH care, and those building national capacity in the governance and direction of national research priorities.

## **5.2 Ethical Considerations**

This is an observational study and is not trialing any intervention. The main considerations are to minimise distress or discomfort when sensitive or sad topics are discussed, avoid stigma and maintain confidentiality if sensitive illnesses are revealed, and the need to ensure that standard health care obtained by participants is not compromised, and where possible is enhanced.

### ***Provincial and District Engagement***

Prior to the commencement of the study, appropriate permissions will be sought from both the Provincial Government and Provincial Health Advisor, as well as from the relevant district authorities. Following these permissions, each health facility will be approached and participation requested through their administrative channels.

### ***Community Engagement***

At the beginning of the study, the research team will undertake consultation workshops in the participating Wards. These will address the study purpose, procedures, use and dissemination of information and expected benefits and potential risks. Community leaders, community members, and young people will be invited to attend. At this time, the Ward Councillor will be asked to give formal consent for the Ward to participate in the study. Consent forms and community information will be provided in written form in Tok Pisin and English, and will also be provided verbally by

research staff. The Ward Councillor will be asked to sign his or her name and will be provided with a printed copy of the information form. This community consent will provide permission for the community to engage in the proposed research, however further individual consent will be required prior to enrolling each participant.

### ***Informed consent***

The key issues here are a) to ensure that consent is administered in a way that accounts for differences in language, education, and perceived obligations to health staff; and b) that participants understand the scope of what they are consenting to.

Informed written consent will be obtained from each participant prior to enrolment in compliance with International Convention on Harmonisation and Good Clinical Practice guidelines. A patient information brochure will be displayed during ANC clinics when enrolment is occurring, this will be in both English and Tok Pisin. PNG is a linguistically diverse country and Tok Pisin can vary between provinces; so our current translation (see appendix) will be checked with local health partners in ENB to ensure the wording is appropriate. Additionally, if local partners feel it is appropriate, the information brochure will also be made available in the relevant local language ('tok ples'). Verbal information will also be provided to women as they register for the clinic to ensure those who are not literate understand the study is occurring and that they may be asked to participate.

Information materials also provide for two avenues within PNG through which concerns or complaints can be raised, one of which is independent of the project.

Local research staff trained in sensitive interview techniques will administer consent following screening for eligibility. Research staff will be explicitly distinct from standard clinic services and it will be made clear that refusal will not affect health care provision. It will be made clear to women that they choose to participate voluntarily, that they will not be paid for participation, and that they are free to discontinue participation at any time.

Consent will only be obtained after participant comprehension is checked with a series of questions. The participant information brochure will be in plain language and will clearly state exactly what is required of the participant. This includes outlining the number of encounters with the researchers a participant is likely to have, the time each encounter is expected to take, the number and nature of all samples to be obtained and the tests to be performed on each, the expectation that after delivery both the mother and the infant will be followed up at defined intervals, permission to follow her up at her place of residence should she not come to the health facility, and that the mother and infant will have tests performed at certain follow ups. A clear explanation of potential future tests will be provided and why these may occur. Women are free to choose not to have future tests performed, and the consent form will have an opt-in component for this aspect.

### ***Interviews and confidentiality***

Interviewers will be trained in sensitive interview techniques and required to monitor for distress or discomfort if difficult topics such as previous deaths or pregnancy loss are raised. They will pause, and if necessary cease the interview if participants are distressed or wish to withdraw. If counseling is required, they will help arrange this within the capacity of the local health service. Participants

will be made aware that those in the clinic waiting area will be able to see that she has chosen to consent to the study given the open nature of such areas, however interviews will be conducted in private away from others. Participants will also be made aware that research staff will need to retain her name and residence to allow for follow-up. Confidentiality of test results and other findings will be maintained through the use of Study Identification Numbers rather than names within project databases. Participants will be made aware of the fact that data from this study may be used in comparisons with other HMHB studies, but that their names will not be recorded in such comparisons. Research staff will be instructed in data handling to maintain confidentiality of findings and special arrangements, described above, will be in place to ensure data security. Testing done after the follow-up period will be anonymous and not linked to participant names or residence.

***Including women between 16 and 18 years of age***

This study will include women over the age of 16. As the proposed study poses minimal risk to participants, and support procedures are in place to address any distress that may arise, parental consent will not be sought for participants under the age of 18. Interviewers will ask standardised questions of all adolescent participants under the age of 18 to ensure that they understand the purpose of the research, their role, and that their involvement is entirely voluntary to assess competency to consent. The decision not to obtain parental consent is based on advice from local partners taking into account the legal and cultural context, previous research experience with young people in Papua New Guinea, and is informed by a review of the international literature relating to parental consent in adolescent sexual health research. The general age of consent to sex in PNG is 16 for both males and females, although is as young as 12 if there is no more than a two-year age difference between partners. The age of consent for an HIV test without requiring parental consent is 13, in recognition of the mature minor.<sup>81 76</sup>

It has been argued that research into adolescent health, particularly sexual health, has been hampered by difficulties surrounding parental permission and that mandatory requirements for parental consent may be inappropriate.<sup>82-84</sup> Psychological research has indicated that adolescents aged 14 years and over have the capacity to make informed decisions and consent to participate in research similar to adults.<sup>85-88</sup>

The Guidelines for Adolescent Health Research: A Position Paper from the Society for Adolescent Medicine suggest that behavioural research and confidential surveys generally pose minimal individual risk for adolescents and may provide benefits in terms of increased self-awareness, knowledge, understanding and decision-making capacity.<sup>86</sup> They also suggest that for research of low risk, such as anonymous surveys, informed consent of the adolescent can be substituted for parental consent. They and other authors have highlighted that it may not be reasonable to require parental consent in some circumstances (including sexual health research), that it may not be in the young person's best interest to demand parental consent, and that local contexts need to be taken into consideration.<sup>82,85</sup>



***Testing, provision of results and health care***

Participants will undergo a number of tests, some of which are of a sensitive nature (such as STIs) and a number require treatment should the woman be found to have a positive result. Illnesses such as malaria, anaemia or TB, will have timely diagnosis as part of study procedures and women will be supported to receive standard care through their health facility. If interview or symptom screen reveals another illness requiring treatment, research staff will help the woman seek this, through normal health services available at the time the illness is revealed.

***STI treatment and management***

The implementation of GeneXpert testing for STIs will provide the opportunity for timely provision of a diagnosis and optimal treatment for women attending ANC. Using the approach of centralized testing of vaginal swabs for STIs using GeneXpert, we intend to provide participants with results of their tests within 1 week of sample collection. If logistics allow, we will attempt to provide results within a shorter time period. This is greatly improved on the current situation in which only syndromic management of STIs is available. The research nurse will report the STI test results to each individual patient and explain what they mean. Patients will be offered treatment, or modification of any existing treatment, if they have a positive result. For contact tracing of partners of patients with a confirmed STI (CT, NG or TV) will follow standard national guidelines for STI contact tracing.

Testing for BV cannot be performed on the GeneXpert and is not currently available in ENB. As such, swabs will be shipped to Melbourne for testing by established procedures with appropriate quality control. Screening and treatment of BV will not be offered to patients as it is not currently part of national treatment guidelines, and is not supported by international consensus.<sup>59</sup>

The project plans to test for signs of hepatitis B infection in the mother and infant; however this will be done after completion of follow-up and thus it will be impossible to provide these results to individual participants; this will be made clear during consent procedures. It is currently not national policy to screen women for hepatitis B during pregnancy, although it is policy that all newborns receive a birth-dose of vaccine, which is efficacious in interrupting perinatal transmission. The project, through linked health system strengthening activities, will be supporting efforts to maximize the coverage of birth-dose vaccination, including for research participants. The sero-prevalence in this cohort will also help inform national and provincial planning as to whether routine testing should be introduced in pregnancy.

**5.3 Governance Procedures**

The research team in ENB will be overseen and managed by the Research Program Manager, and supported through dedicated Burnet Institute administration and office in Kokopo. The Program Manager will report directly to the Principal Investigators (PIs) on at least a weekly basis. The Program manager is an employee of the Burnet Institute, which provides professional support and line management through one of the PIs. Other PIs are employed by and responsible to the Burnet Institute and PNGIMR respectively. PIs will be in regular contact and there will be a PIs meeting once a month to review progress. The local team and all PIs will construct a quarterly report on

progress, to be provided to all Co-Investigators (CIs), a Local Advisory Panel and a National Advisory Panel.

A Local Advisory Panel, as detailed above, will be established with the Provincial Health Advisor, Mr Nicholas Larme, as its chair. This group will meet quarterly, facilitated by the Research Program Manager. This group will provide advice to the research program on provincial health policy, on changes that may affect the research and on the regular progress reports provided.

A National Advisory Panel will also receive quarterly reports and will meet once a year, with chair responsibilities shared between NDOH and UPNG. This group will also provide advice to the research program on health policy, on changes that may affect the research, and on the regular progress reports provided.

The PIs will be jointly responsible for study quality and procedures, and for appropriately involving CIs in their respective areas of expertise. The first PI-Beeson will have overall responsibility for the conduct of the study. PI-Beeson, PI-Pomat and PI-Scoullar will have special responsibility for research work towards the first research objective and PI-Morgan, PI-Siba and PI-Scoullar will have special responsibility for research work towards the second and third research objective.

#### **5.4 Reporting Adverse Events**

As this is an observational study we do not expect participants will be at significant risk of adverse consequences in the short or long term due to the study. However, possible clinical adverse events will be evaluated by the study clinician, and classified according to NIH Division of Microbiology and Infectious Diseases rating:

- Grade 1 (mild, self limited (<48 hours), no intervention required).
- Grade 2 (moderate: some limitation in activity, some assistance possibly required; no or minimal medical intervention required).
- Grade 3 (severe: marked limitation in activity; some assistance usually required; medical intervention required; hospitalization possible).
- Grade 4 (life-threatening: extreme limitation in activity; significant assistance required, significant medical intervention required; hospitalization probable).
- Grade 5 adverse event results in death

#### ***Compliance and protocol deviations***

The protocol and standard operating procedures will be followed for the duration of the study, with adherence maintained by the research coordinator and principal investigators. No deviations are permitted, without ethics committee review and approval. In the event of an unintended deviation, the deviation will be logged, and study supervisor will inform PIs on the nature of the deviation, and if indicated protocol amendments will be sought.

Any unforeseen event resulting from this research program will be referred to the Principal Investigators. After review, the PIs will report serious adverse events or breaches of protocol to the National, Local, or Australian advisory committees, and to the PNG IMR Internal Review Board or PNG NDOH Medical Research Advisory Committee if indicated.

### **5.5 Dissemination Of Findings**

Progress and technical reporting will be provided annually to the two levels of advisory board: local in ENB province, and national in Port Moresby. This will enable scanning for relevant changes in the program environment or health policy, and also provide opportunity for appropriate levels of sharing of interim results, where they are relevant to local stakeholders. Annual reporting to participating health facilities, and communities in their catchment areas (including study participants) will also take place with the support of these bodies.

The research methods and findings will have a primary audience within PNG, through dissemination at the annual PNG Medical Symposium and, especially for health system findings, through the annual National Health Conference; access to this latter forum to be mediated by the government staff named as co-investigators and on advisory boards. The PNGIMR, Burnet Institute and UPNG institutional connections to policy and plans of government agencies and international development partners will also enable sharing of interim and formal findings with policy-makers. It is planned to use tailored communication products, such as policy briefs, to help communicate the policy implications of study findings.

Study findings and analysis will be tested and refined through submission to international peer-review biomedical journals dealing with maternal and perinatal infections and nutrition, and with the provision of health services in pregnancy, the postnatal period and childhood, as well as the PNG Medical Journal. These peer-reviewed findings will form the basis for evidence-based policy communications noted above. Journals with an Open-access policy will be prioritized for publication of findings.

Copies of publications will be archived and made available at Burnet Institute and PNGIMR. Findings from the studies will also be presented and appropriate international and national conferences. No findings will be presented or published without the agreement of all principal and co-investigators involved. In particular, the investigators will actively seek to involve the PNG staff and students as co-authors in all publications, and as lead authors when possible.

### **5.6 Budget statement**

The budget for this study and other linked HMHB studies is provided by philanthropic support, the Burnet Institute and NHMRC grants.

It is expected that the initial set up budget will be \$320,000 AUD, followed by \$520,000 AUD in 2015.

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### **10.1.3 *Prospective Observational Cohort Study - data collection tools and patient information and consent forms.***

#### **A1: OUTLINE OF DATA COLLECTION TOOLS**

Note: tools provided here are in outline format to allow for ethical review prior to formatting into electronic or paper-based data collection tools. It is expected that field testing will require some change to sequencing, question wording, and listing of interviewer-identified closed responses. Field testing will not result in the addition of new topics without further reference to ethics review.

##### **A.1.1 Baseline Assessment at first Ante-natal Care (ANC) visit**

###### **Introduction**

Researcher and study introduction: sequence of questions, measurements, tests and follow-up at birth and after.

Consent procedures, including discussion of confidentiality, options to decline some questions and options to withdraw.

###### **Note**

Estimated time for interview - 1 hour

Closed ended questions in normal font, open ended questions in *italics*.

- **Name and residence / location information linked to SIN on separate form**

#### **1. Demographics**

**1.1** Woman's age, marital status, occupation, education, birth province

**1.2** Husband/partner's education and occupation

#### **2. Reproductive history**

**2.1** Total number of all pregnancies

**2.2** For each pregnancy, including this pregnancy:

- 2.2.1** age at pregnancy,
- 2.2.2** pregnancy intention / planning (wanted, mistimed, unwanted)
- 2.2.3** pregnancy outcome type (live birth, still-birth, miscarriage, abortion),
- 2.2.4** estimated gestation at outcome,
- 2.2.5** place of outcome,
- 2.2.6** type of delivery,
- 2.2.7** sex of baby (if known)
- 2.2.8** complications at outcome

**2.3** Number and ages of children alive, number and ages at death of children who have died

**2.4** Ever use of family planning (age when FP first used,, number of children already born when first used, methods ever used (modern and traditional)

**2.4.1** Barriers to access FP closed list, *open field*

**2.5** Reason for never use of modern contraception

2.6 Were you using FP when you got pregnant with this pregnancy? (method)

***Other questions regarding this pregnancy***

2.7 Last menstrual period

2.8 Obstetric complication symptom screen – note on clinic follow-up if present

2.9 Costs of ANC1

2.10 Use of LLINs

2.11 Other routine preventive care prior to ANC1

**3. This pregnancy – other illnesses**

3.1 Any curative care prior to ANC1

3.2 Fever/night sweats, if yes number of days, prior treatment

3.3 Cough, if yes number of days, infectious contacts (inc TB), prior treatment

3.4 Weight loss

3.5 Genital discharge, sores (type), abdominal pain (site), if not covered under 3.3

3.6 Other illness, *open response*

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**Note:** physical examination and testing may interrupt at this point if needed.

**4. Future care planning** [open questions, interviewer assigns responses to closed list]

4.1 Plan for future ANC visits, place, attendant

4.2 Plan for childbirth care, place, attendant

4.3 Plan for postnatal care, first two days, first week, first month (including first immunisation)

4.4 After this pregnancy, would you like to have another child? Yes/No

4.4.1 If yes, how long would you like to wait before the birth of another child?

4.5 Do you intend to use a family planning method? Yes/No

4.5.1 If yes, which method? closed list, *open field*

4.5.2 If no, why? Closed list, *open field*

4.6 Woman's expectations of health and risk during and after pregnancy

4.7 Emergency referral plan, pregnancy, labour, post natal, closed list, *open field*

4.8 Knowledge of danger signs in pregnancy before labour, closed list plus *open field*  
(vaginal bleeding, severe abdominal pain, fever, foul smelling discharge,

racing heart, breathlessness, very tired, looking pale, severe headache, blurry

vision, swelling, unconscious or fits, not feeling foetal movements)

4.9 Knowledge of danger signs during childbirth, closed list plus *open field*

4.10 Knowledge of danger signs during postnatal period, mother closed list plus *open field*

- (heavy bleeding, severe abdominal pain, fever, foul smelling discharge, severe headache, difficulty breathing, feeling weak, unconscious or fits, swollen red tender breasts)

4.11 Knowledge of danger signs during postnatal period, newborn closed list plus *open field*

- (trouble feeding, vomiting everything, fits, lethargy, unusually cold, hot/fever, difficult/fast breathing, umbilical redness, multiple skin pustules, red swollen eyes with discharge, yellow coloured skin/eyes)
- 4.12 Knowledge of common infections, malaria, other febrile, tuberculosis
- 4.12.1 Common presentations
  - 4.12.2 Modes of spread
  - 4.12.3 Implications for pregnancy
- 5. Attitudes to care** [open questions, interviewer assigns responses to closed list]
- 5.1 Attitudes relating to this visit
- 5.1.1 Reason for choosing ANC1 at this facility
  - 5.1.2 Husband/partner attending ANC1
- 5.2 Barriers to ANC in this pregnancy, closed list plus *open field*
- 5.3 Barriers to childbirth care in this pregnancy, closed list plus *open field*
- 5.4 Expected barriers to postnatal care in this pregnancy, closed list plus *open field*
- 5.5 Has access to ANC, childbirth care or PNC changed in past five years? *How*
- 5.6 What enables access to routine ANC, childbirth care and PNC, *open field* and interviewer probe/nomination from closed list on:
- 5.6.1 Type of provider – person, position
  - 5.6.2 Place and timing
  - 5.6.3 Decision making in home and community
  - 5.6.4 Funding, source and availability
  - 5.6.5 Transport, type and availability
- 5.7 What enables access to emergency referral, *open field* and interviewer probe/nomination from closed list on:
- 5.7.1 Type of provider – person, position
  - 5.7.2 Place and timing
  - 5.7.3 Decision making in home and community
  - 5.7.4 Finances, source and availability
  - 5.7.5 Transport, type and availability
- 5.8 Additional care preferences not currently available – pregnancy and co-morbidities
- 5.8.1 Provider
  - 5.8.2 Place and timing
  - 5.8.3 *Open field*
- 6. Physical examination and testing**
- 6.1 Weight, height, BMI, BP
  - 6.2 MUAC
  - 6.3 Fundal height
  - 6.4 Any current other illness? E.g. fever, lower respiratory infection

**Note:** If unwell and not already seen by clinic, may require referral for further history, examination and investigation as required.

- 6.5 Blood drawn for study investigations
- 6.6 Urine sample for routine and study investigations

6.7 Sputum smear, if indicated

6.8 Other testing indicated through ANC

### **A.1.2 Assessment of mother and infant at birth**

#### **Introduction**

Researcher and study re-introduction: sequence of questions, measurements, tests and follow-up after this.

Consent procedures, including discussion of confidentiality, options to decline some questions and options to withdraw.

#### **Note**

Estimated time for interview and measurements – 30 minutes

Closed ended questions in normal font, open ended questions in *italics*.

#### **1. Identifier and location**

**1.1** Record Study Identifier

**1.2** Location of interview

**1.3** Date of birth, date of interview

**1.4** Infant alive yes/no (*some subsections will be skipped if infant not alive*)

#### **2. Birth outcome and current health status**

2.1 Single or multiple birth, sex/es

2.2 Live-birth, still-birth, miscarriage. Estimated gestation – by records/maternal

2.3 Estimated gestation at birth

2.4 Place of birth – allow multiple if referral (level and outcome)

2.5 Attendant/s at birth – specify for each level

2.6 Birth complications (noting report by records or maternal)

2.6.1 PPH (how measured), retained placenta, labour > 24 hours, fits, hypertension, instrumentation/breech/surgery (CS), newborn resuscitation, other complication or intervention/treatment

#### **3. Future care planning – intended postnatal checks (first month)**

3.1 Timing, staff and place of checks

3.2 Expected services (unprompted, from closed list) including

3.2.1 Maternal nutrition, hygiene, feeding advice, social support, other

3.2.2 Newborn hygiene, warmth, vaccination, other

#### **4. Measurements**

4.1 Newborn

4.1.1 Birth-weight

4.1.2 Length, Head circumference

4.1.3 Apgar (if recorded)

4.1.4 Gestational assessment

- 4.1.5 Heel prick
- 4.2 Mother
  - 4.2.1 Venepuncture
  - 4.2.2 Placental blood or tissue
- 5. **Early postnatal complications** (only if more than 24 hours since birth)
  - 5.1 Postnatal maternal: sepsis (WHO syndromic definition), STI (syndromic), cough, fever/night sweat, other infection, bleeding, treatments (specify, including depression), admissions
  - 5.2 Postnatal newborn: sepsis (WHO syndromic definition), feeding problem, other infection, treatment/s, admissions
  - 5.3 Knowledge of danger signs during postnatal period, mother & newborn, closed list plus *open field*

**Note:** If unwell and not already attended to, may require referral for further history, examination and investigation as required.

#### **A.1.3 Assessment of mother and infant at 4 weeks post partum**

##### **Introduction**

Researcher and study re-introduction: sequence of questions, measurements, tests and follow-up after this.

Consent procedures, including discussion of confidentiality, options to decline some questions and options to withdraw.

Review completeness of A1.2 Birth assessment, in case catchup is needed.

##### **Note**

Estimated time for interview - 1 hour

Closed ended questions in normal font, open ended questions in *italics*.

#### **1. Identifier and location**

- 1.1 Record Study Identifier
- 1.2 Location of interview
- 1.3 Date of birth, date of interview
- 1.4 Infant alive yes/no (*some subsections will be skipped if infant not alive*)
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#### **2. Birth outcome (only if not already collected)**

- 2.1 Single or multiple birth, sex/es
- 2.2 Live-birth, still-birth, miscarriage. Estimated gestation – by records/maternal
- 2.3 Place of birth – allow multiple if referral (level and outcome)
- 2.4 Attendant/s at birth – specify for each level
- 2.5 Birth complications (noting report by records or maternal)
  - 2.5.1 PPH (how measured), retained placenta, labour > 24 hours, fits, hypertension, instrumentation/breech/surgery (CS), other complication or intervention

### 3. Postnatal care and health status

#### 3.1 Postnatal checks

- 3.1.1 Timing, place of checks, by who

#### 3.2 Postnatal illness

- 3.2.1 Postnatal maternal: sepsis (WHO syndromic definition), STI (syndromic), cough, fever/night sweat, other infection, bleeding, treatments (specify, including depression), admissions
- 3.2.2 Postnatal newborn: sepsis (WHO syndromic definition), feeding problem, other infection, treatment/s, admissions

#### 3.3 Postnatal Routine

- 3.3.1 Breastfeeding, additional feeds, problems
- 3.3.2 Thermal control practice
- 3.3.3 Vaccination – BCG, hepatitis B, and timing, record or report
- 3.3.4 Use of LLINs, when/who
- 3.3.5 Use of micronutrients mother, other preventive medicines mother/baby

### 4. ANC received

#### 4.1 Antenatal care (ANC) use

- 4.1.1 Place, attendants, number/gestation/timing of visits
- 4.1.2 Care items received (closed list based on WHO quality checklist, includes emergency planning, vaccination, nutritional supplementation, weight, IPTp, urine testing)
- 4.1.3 IPTp yes/no
  - 4.1.3.1 If yes, name of medicine used and number of doses
- 4.1.4 Fefol yes/no
  - 4.1.4.1 If yes, how many doses received
- 4.1.5 Costs of ANC1, at facility, transport
- 4.1.6 Number of visits attended by husband/partner

#### 4.2 Use of LLINs, micronutrients (number/type)

#### 4.3 Other routine preventive care after ANC1

#### 4.4 Complications prior to delivery (during ANC period)

- 4.4.1 Admissions
- 4.4.2 Treatments
- 4.4.3 Symptom screen: fever, cough (duration/timing), STI syndromic

### 5. Experience of care [open non-leading questions, interviewer assigns responses to closed list]

#### 5.1 Experience of ANC

- 5.1.1 Reason for main choice of ANC facility (advisor, past experience, geography, *open*)
- 5.1.2 Satisfaction with ANC care
- 5.1.3 Reasons for (dis)satisfaction – closed list with *one open field*

#### 5.2 Experience of PNC

- 5.2.1 Reason for main choice of PNC facility (advisor, past experience, geography, *open*)

- 5.2.2 Satisfaction with PNC care
- 5.2.3 Reasons for (dis)satisfaction – closed list with *one open field*
- 6. **Future care planning** [open non-leading questions, interviewer assigns responses to closed list]
  - 6.1 After this pregnancy, would you like to have another child? Yes/No
    - 6.1.1 If yes, how long would you like to wait before the birth of another child?
  - 6.2 Do you intend to use a family planning method? Yes/No
    - 6.2.1 If yes, which method? closed list, *open field*
    - 6.2.2 If no, why? Closed list, *open field*
  - 6.3 Emergency referral plan, sickness in infancy, closed list, *open field*
  - 6.4 Knowledge of common infections, malaria, other febrile, tuberculosis
    - 6.4.1 Common presentations
    - 6.4.2 Modes of spread
    - 6.4.3 Implications for pregnancy
- 7. **Future care preferences**
  - 7.1 Has access to ANC, childbirth care or PNC changed in past five years? *How*.
  - 7.2 What enables access to routine **ANC** *open field* and interviewer probe/nomination from closed list on:
    - 7.2.1 Type of provider – person, position
    - 7.2.2 Place and timing
    - 7.2.3 Decision making in home and community
    - 7.2.4 Funding, source and availability
    - 7.2.5 Transport, type and availability
  - 7.3 What enables access to routine **childbirth** care *open field* and interviewer probe/nomination from closed list on:
    - 7.3.1 Type of provider – person, position
    - 7.3.2 Place and timing
    - 7.3.3 Decision making in home and community
    - 7.3.4 Funding, source and availability
    - 7.3.5 Transport, type and availability
  - 7.4 What enables access to routine **PNC**, *open field* and interviewer probe/nomination from closed list on:
    - 7.4.1 Type of provider – person, position
    - 7.4.2 Place and timing
    - 7.4.3 Decision making in home and community
    - 7.4.4 Funding, source and availability
    - 7.4.5 Transport, type and availability
  - 7.5 What enables access to **family planning** *open field* and interviewer probe/nomination from closed list on:
    - 7.5.1 Type of provider – person, position
    - 7.5.2 Place and timing
    - 7.5.3 Decision making in home and community
    - 7.5.4 Funding, source and availability
    - 7.5.5 Transport, type and availability
  - 7.6 Barriers
    - 7.6.1 to ANC in this pregnancy, closed list plus *open field*
    - 7.6.2 to childbirth care in this pregnancy, closed list plus *open field*
    - 7.6.3 to postnatal care in this pregnancy, closed list plus *open field*
    - 7.6.4 to family planning in past, closed list plus *open field*
  - 7.7 What enables access to **illness care**, including emergency referral, *open field* and interviewer probe/nomination from closed list on:



- 7.7.1 Type of provider – person, position
- 7.7.2 Place and timing
- 7.7.3 Decision making in home and community
- 7.7.4 Funding, source and availability
- 7.7.5 Transport, type and availability
- 7.7.6 Differences for mother or infant
- 7.8 Combining services [open non-leading questions, interviewer assigns responses to closed list, *three open fields in this section*]
  - 7.8.1 What services could be combined for easier care,
    - 7.8.1.1 Pregnancy
    - 7.8.1.2 Postnatal one month
    - 7.8.1.3 With immunization visits in infancy
    - 7.8.1.4 With other visits
  - 7.8.2 If yes, what difficulties would combining services pose
    - 7.8.2.1 Closed list: time, quality, acceptance, other, *open*
  - 7.8.3 If yes, what benefits
    - 7.8.3.1 Closed list: time efficiency, cost saving, co-morbidity, other, *open*
  - 7.8.4 Other feasibility of combining services
    - 7.8.4.1 Place, attendant
    - 7.8.4.2 *Open field on feasibility and acceptability of combining services*
- 7.9 Additional care preferences not currently available – pregnancy and childbirth
  - 7.9.1 Provider
  - 7.9.2 Place and timing
  - 7.9.3 *Open field*

## 8. Physical examination and testing

- 8.1 Infant weight, length, head circumference
- 8.2 Infant heel prick for haemoglobin, micronutrients
- 8.3 Maternal blood drawn for haemoglobin, micronutrients, malaria PCR
- 8.4 Maternal sputum, if indicated

**Note:** If unwell and not already attended to, may require referral for further history, examination and investigation as required.

### A.1.4 Assessment of mother and infant at 6 months post partum

#### Introduction

Researcher and study re-introduction: sequence of questions, measurements, tests and follow-up after this.

Consent procedures, including discussion of confidentiality, options to decline some questions and options to withdraw.

Review completeness of A3 Postnatal assessment, in case catchup is needed. Consider review of family planning questions (2.4, from Baseline Assessment).

#### Note

Estimated time for interview - 45 minutes

Closed ended questions in normal font, open ended questions in *italics*.

## 1. Identifier and location

- 1.1 Record Study Identifier

- 1.2 Location of interview
- 1.3 Date of birth
- 1.4 Infant alive yes/no (*some subsections will be skipped if infant not alive*)

## 2. Maternal/infant health status

- 2.1 Number, date and age of **infant** illness/es
- 2.2 If any, for each report
  - 2.2.1 Type closed list with multiple responses, *open field*: (cough, diarrhoea, fever, feeding problem, skin rash, *other*)
    - 2.2.1.1 If cough or diarrhoea: duration
  - 2.2.2 Treatment site (aid post, CHP, SC, HC, hospital, private, traditional, *other*)
  - 2.2.3 Admission yes/no, if yes: site (aid post, CHP, SC, HC, hospital, private, *other*)
  - 2.2.4 Outcome (home well, home sick, death)
- 2.3 Number, date of **maternal** illness/es
  - 2.3.1 Number of illness/es
  - 2.3.2 If any, for each report
    - 2.3.2.1 Type closed list *open field*: (cough, diarrhoea, fever, breast-feeding problem, *other*)
      - 2.3.2.1.1 If cough: duration
    - 2.3.2.2 Treatment site (aid post, CHP, SC, HC, hospital, private, traditional, *other*)
    - 2.3.2.3 Admission yes/no, if yes: site (aid post, CHP, SC, HC, hospital, private, *other*)
    - 2.3.2.4 Outcome (home well, home sick, death)
- 2.4 Other serious family illness or death
  - 2.4.1 *Open field*, date of incident

## 3. Family and health care received

- 3.1 Family care routine
  - 3.1.1 Infant feeding: breast yes/no, any other foods yes/no, if yes, age started
  - 3.1.2 Use of LLINs, when/who
  - 3.1.3 Use of micronutrients mother, other preventive medicines mother/infant
- 3.2 Immunization visits
  - 3.2.1 For each visit:
    - 3.2.1.1 Date, Place, By who, Immunizations received
    - 3.2.1.2 Other service received for infant closed list, *open field* (vitamin A, LLIN, other micronutrient, nutrition counseling, development counseling, *other*)
    - 3.2.1.3 Other service received for mother: closed list, *open field* (LLIN, micronutrient, nutrition counseling, family planning counseling, *other*)

## 4. Experience of care [open non-leading questions, interviewer assigns responses to closed list]

- 4.1 Experience of immunization visits
  - 4.1.1 Reason for main choice of health facility (advisor, past experience, geography, *open*)
  - 4.1.2 Satisfaction with care during these visits - rating
  - 4.1.3 Reasons for (dis)satisfaction – closed list with *one open field*

- 4.2 Experience of illness visits (for up to three most recent visits)
  - 4.2.1 Reason for main choice of health facility (advisor, past experience, geography, *open*)
  - 4.2.2 Satisfaction with care during these visits - rating
  - 4.2.3 Reasons for (dis)satisfaction – closed list with *one open field*
- 5. **Future care planning** [open non-leading questions, interviewer assigns responses to closed list]
  - 5.1 After this pregnancy, would you like to have another child? Yes/No
    - 5.1.1 If yes, how long would you like to wait before the birth of another child?
  - 5.2 Do you intend to use a family planning method? Yes/No
    - 5.2.1 If yes, which method? closed list, *open field*
    - 5.2.2 If no, why? Closed list, *open field*
  - 5.3 Emergency referral plan, sickness in infancy, closed list, *open field*
  - 5.4 Knowledge of common infections, malaria, other febrile, tuberculosis
    - 5.4.1 Common presentations
    - 5.4.2 Modes of spread
    - 5.4.3 Implications for pregnancy
  - 5.5 Intention to use FP postpartum and preferred method for future use
- 6. **Future care preferences**
  - 6.1 Has access to routine child health care in the first year of life changed in past five years? *How*.
  - 6.2 What enables access to routine care? *open field* and interviewer probe/nomination from closed list on:
    - 6.2.1 Type of provider – person, position
    - 6.2.2 Place and timing
    - 6.2.3 Decision making in home and community
    - 6.2.4 Funding, source and availability
    - 6.2.5 Transport, type and availability
  - 6.3 Has access to family planning services changed in past five years? *How*.
  - 6.4 What enables access to **family planning** *open field* and interviewer probe/nomination from closed list on:
    - 6.4.1 Type of provider – person, position
    - 6.4.2 Place and timing
    - 6.4.3 Decision making in home and community
    - 6.4.4 Funding, source and availability
    - 6.4.5 Transport, type and availability
  - 6.5 Barriers
    - 6.5.1 to routine child health care in the first year of life, closed list plus *open field*
    - 6.5.2 to family planning in past, closed list plus *open field*
  - 6.6 What enables access to **illness care**, including emergency referral, *open field* and interviewer probe/nomination from closed list on:
    - 6.6.1 Type of provider – person, position
    - 6.6.2 Place and timing
    - 6.6.3 Decision making in home and community
    - 6.6.4 Funding, source and availability
    - 6.6.5 Transport, type and availability
    - 6.6.6 Differences for mother or infant
  - 6.7 Combining services [open non-leading questions, interviewer assigns responses to closed list, *three open fields in this section*]
    - 6.7.1 What services could be combined for easier care,
      - 6.7.1.1 Pregnancy

- 6.7.1.2 Postnatal one month
- 6.7.1.3 With immunization visits in infancy
- 6.7.1.4 With other visits
- 6.7.2 If yes, what difficulties would combining services pose
  - 6.7.2.1 Closed list: time, quality, acceptance, other, *open*
- 6.7.3 If yes, what benefits
  - 6.7.3.1 Closed list: time efficiency, cost saving, co-morbidity, other, *open*
- 6.7.4 Other feasibility of combining services
  - 6.7.4.1 Place, attendant
  - 6.7.4.2 *Open field on feasibility and acceptability of combining services*
- 6.8 Additional care preferences not currently available – pregnancy and childbirth, child health, family planning, illness care
  - 6.8.1 Provider
  - 6.8.2 Place and timing
  - 6.8.3 *Open field*
- 7. Physical examination and testing**
  - 7.1 Infant weight, length, head circumference
  - 7.2 Infant heel or finger prick for haemoglobin, micronutrients, malaria PCR, hepatitis B surface antigen, antibodies to malaria and other infections
  - 7.3 Maternal blood drawn for haemoglobin, micronutrients, malaria PCR, antibodies to infections
  - 7.4 Maternal sputum, if indicated
  - 7.5 Administration of minimal set of standardized questions for parental report on infant development
- 8. Household amenities and services**
  - 8.1 Main source of drinking water (piped house/communal, well protected/unprotected, surface water lake/river/spring, rainwater)
  - 8.2 Toilet facility flush/VIP/ pit with slab/pit without slab/ closet over sea or water/ no toilet
  - 8.3 Does your household have electricity/ radio / TV/ Refrigerator/ Motor vehicle/ Phone
  - 8.4 How many rooms in your household are used for sleeping?
  - 8.5 How many people sleep at your house?
  - 8.6 What type of fuel does your household mainly use for cooking?
    - Gas/electricity/firewood/ kerosene/saw dust/ charcoal
  - 8.7 Main material of floor? Marble/ceramic, floor tile, concrete/brick, wood, bamboo/palm, earth/sand, other

**Note:** If unwell and not already attended to, may require referral for further history, examination and investigation as required.

#### **A.1.5 Assessment of mother and infant at 12 months post partum**

##### **Introduction**

Researcher and study re-introduction: sequence of questions, measurements, tests and follow-up after this. Consent procedures, including discussion of confidentiality, options to decline some questions and options to withdraw. Review completeness of A3 Postnatal assessment, in case catchup is needed. Consider review of family planning questions (2.4, from Baseline Assessment).

**Note** Estimated time for interview - 45 minutes Closed ended questions in normal font, open ended questions in *italics*.

**1. Identifier and location**

- 1.1 Record Study Identifier
- 1.2 Location of interview
- 1.3 Date of birth
- 1.4 Infant alive yes/no (*some subsections will be skipped if infant not alive*)

**2. Maternal/infant health status**

- 2.1 Number, date and age of **infant** illness/es
- 2.2 If any, for each report
  - 2.2.1 Type closed list with multiple responses, *open field*: (cough, diarrhoea, fever, feeding problem, skin rash, *other*)
    - 2.2.1.1 If cough or diarrhoea: duration
  - 2.2.2 Treatment site (aid post, CHP, SC, HC, hospital, private, traditional, *other*)
  - 2.2.3 Admission yes/no, if yes: site (aid post, CHP, SC, HC, hospital, private, *other*)
  - 2.2.4 Outcome (home well, home sick, death)
- 2.3 Number, date and date of **maternal** illness/es
  - 2.3.1 Number and age of illness/es
  - 2.3.2 If any, for each report
    - 2.3.2.1 Type closed list *open field*: (cough, diarrhoea, fever, breast-feeding problem, *other*)
      - 2.3.2.1.1 If cough: duration
    - 2.3.2.2 Treatment site (aid post, CHP, SC, HC, hospital, private, traditional, *other*)
    - 2.3.2.3 Admission yes/no, if yes: site (aid post, CHP, SC, HC, hospital, private, *other*)
    - 2.3.2.4 Outcome (home well, home sick, death)
- 2.4 Other serious family illness or death
  - 2.4.1 *Open field*, date of incident

**3. Family and health care received**

- 3.1 Family care routine
  - 3.1.1 Infant feeding: breast yes/no, any other foods yes/no, if yes, age started
  - 3.1.2 Use of LLINs, when/who
  - 3.1.3 Micronutrients mother, other preventive medicines mother/infant
- 3.2 Immunization visits
  - 3.2.1 For each visit:
    - 3.2.1.1 Date, Place, By Who, Immunizations received
    - 3.2.1.2 Other service received for infant closed list, *open field* (vitamin A, LLIN, other micronutrient, nutrition counseling, development counseling, *other*)
    - 3.2.1.3 Other service received for mother: closed list, *open field* (LLIN, micronutrient, nutrition counseling, family planning counseling, *other*)

**4. Experience of care** [open non-leading questions, interviewer assigns responses to closed list]

- 4.1 Experience of immunization visits

- 4.1.1 Reason for main choice of health facility (advisor, past experience, geography, *open*)
- 4.1.2 Satisfaction with care during these visits - rating
- 4.1.3 Reasons for (dis)satisfaction – closed list with *one open field*
- 4.2 Experience of illness visits (for up to three most recent visits)
  - 4.2.1 Reason for main choice of health facility (advisor, past experience, geography, *open*)
  - 4.2.2 Satisfaction with care during these visits - rating
  - 4.2.3 Reasons for (dis)satisfaction – closed list with *one open field*
- 5. Future care planning** [open non-leading questions, interviewer assigns responses to closed list]
  - 5.1 After this pregnancy, would you like to have another child? Yes/No
    - 5.1.1 If yes, how long would you like to wait before the birth of another child?
  - 5.2 Do you intend to use a family planning method? Yes/No
    - 5.2.1 If yes, which method? closed list, *open field*
    - 5.2.2 If no, why? Closed list, *open field*
  - 5.3 Emergency referral plan, sickness in infancy, closed list, *open field*
  - 5.4 Knowledge of common infections, malaria, other febrile, tuberculosis
    - 5.4.1 Common presentations
    - 5.4.2 Modes of spread
    - 5.4.3 Implications for pregnancy
  - 5.5 Intention to use FP postpartum and preferred method for future use
- 6. Future care preferences**
  - 6.1 Has access to routine child health care in the first year of life changed in past five years? *How*.
  - 6.2 What enables access to routine care? *open field* and interviewer probe/nomination from closed list on:
    - 6.2.1 Type of provider – person, position
    - 6.2.2 Place and timing
    - 6.2.3 Decision making in home and community
    - 6.2.4 Funding, source and availability
    - 6.2.5 Transport, type and availability
  - 6.3 Has access to family planning services changed in past five years? *How*.
  - 6.4 What enables access to **family planning** *open field* and interviewer probe/nomination from closed list on:
    - 6.4.1 Type of provider – person, position
    - 6.4.2 Place and timing
    - 6.4.3 Decision making in home and community
    - 6.4.4 Funding, source and availability
    - 6.4.5 Transport, type and availability
  - 6.5 Barriers
    - 6.5.1 to routine child health care in the first year of life, closed list plus *open field*
    - 6.5.2 to family planning in past, closed list plus *open field*
  - 6.6 What enables access to **illness care**, including emergency referral, *open field* and interviewer probe/nomination from closed list on:
    - 6.6.1 Type of provider – person, position
    - 6.6.2 Place and timing
    - 6.6.3 Decision making in home and community
    - 6.6.4 Funding, source and availability
    - 6.6.5 Transport, type and availability
    - 6.6.6 Differences for mother or infant

6.7 Combining services [open non-leading questions, interviewer assigns responses to closed list, *three open fields in this section*]

6.7.1 What services could be combined for easier care,

6.7.1.1 Pregnancy

6.7.1.2 Postnatal one month

6.7.1.3 With immunization visits in infancy

6.7.1.4 With other visits

6.7.2 If yes, what difficulties would combining services pose

6.7.2.1 Closed list: time, quality, acceptance, other, *open*

6.7.3 If yes, what benefits

6.7.3.1 Closed list: time efficiency, cost saving, co-morbidity, other, *open*

6.7.4 Other feasibility of combining services

6.7.4.1 Place, attendant

6.7.4.2 *Open field on feasibility and acceptability of combining services*

6.8 Additional care preferences not currently available – pregnancy and childbirth, child health, family planning, illness care

6.8.1 Provider

6.8.2 Place and timing

6.8.3 *Open field*

## **7. Physical examination and testing**

7.1 Infant weight, height, head circumference

7.2 Infant heel or finger prick for haemoglobin, micronutrients, malaria PCR, hepatitis B surface antigen, antibodies to malaria and other infections

7.3 Maternal blood drawn for haemoglobin

7.4 Maternal sputum, if indicated

7.5 Administration of minimal set of standardized questions for parental report on infant development

## **8. Household amenities and services**

8.1 Main source of drinking water (piped house/communal, well protected/unprotected, surface water lake/river/spring, rainwater)

8.2 Toilet facility flush/VIP/ pit with slab/pit without slab/ closet over sea or water/ no toilet

8.3 Does your household have electricity/ radio / TV/ Refrigerator/ Motor vehicle/ Phone

8.4 How many rooms in your household are used for sleeping?

8.5 How many people sleep at your house?

8.6 What type of fuel does your household mainly use for cooking?

Gas/electricity/firewood/ kerosene/saw dust/ charcoal

8.7 Main material of floor? Marble/ceramic, floor tile, concrete/brick, wood, bamboo/palm, earth/sand, other

**Note:** If unwell and not already attended to, may require referral for further history, examination and investigation as required.

## A2: STUDY INFORMATION BROCHURE

### A.2.1 English Study information brochure

#### HEALTHY MOTHERS HEALTHY BABIES

#### STUDY 1 – COHORT STUDY

#### STUDY INFORMATION BROCHURE

##### Why is this study being done?

This study aims to measure the diseases or pregnancy complications experienced by mothers and their infants in East New Britain Province (ENBP), as well as the existing factors that are both protective and predictive of a risky pregnancy, including health care utilization. In this study we will invite pregnant women aged 16 years and over, attending health facilities to participate in research that aims to improve future health services, to help improve the health of mothers and their babies.

##### How many people will participate in the study?

This study intends to recruit a sample of 700 pregnant women from Antenatal Clinic (ANC) at a number of different health facilities in ENB.

##### What is involved in the study?

For those who choose to participate, participation will involve:

- **Answering questions** about:
  - Current and past pregnancies, sexual and reproductive health history (including pregnancies, stillbirths, spontaneous and induced abortion, complications of pregnancy, newborn outcomes, Sexually Transmitted Infections (STIs));
  - Current or past symptoms (e.g. fever, cough, weight change, vaginal discharge, vaginal ulcers or other lesions);
  - Past use of health services and opinions on current health services including health workers attitudes, behaviours and clinical practice
  - Intended future use of health services including ANC visits, childbirth, and care of the infant after birth;
  - Financial situation and health care related costs incurred;
  - Previous behavior with newborns who became unwell, and intended behavior with this pregnancy;
- **Allow an assessment** of nutrition through Mid-Upper Arm Circumference (MUAC), and Body Mass Index (BMI) (measurement of weight and height) in addition to routine ANC measurements
- **Allowing blood samples** to be taken as per the study protocol (at 1<sup>st</sup> ANC, delivery (placental sample), and 1, 6 and 12 months after childbirth for the mother and infant;
  - Maternal blood will be tested for anaemia, iron deficiency, malaria parasites and malarial antibodies, micronutrient deficiencies (vitamin A, zinc), inflammatory marker (CRP)



- Infections prevented by vaccination like hepatitis B and measles
- Placental blood will be tested for evidence of placental malaria
- Infant blood will be tested for anaemia, micronutrient deficiencies
- **Providing a mid-vaginal swab** (this is self-administered with a pictorial guide provided to assist); or performed by a trained health worker.
  - Vaginal swabs to be tested for STIs (chlamydia, gonorrhoea and trichomonas vaginalis);
- **Providing a urine sample**, to be tested for evidence of infection (dipstick), and urinary iodine;
- **Allowing follow up** of pregnancy, childbirth and infant outcomes (answering questions around the time of childbirth, and at 1,2,3,6 and 12 months post delivery);
- **Allowing access to medical information**, as documented in health facility files and patient booklets.
- **Testing for HIV will NOT be done** as part of this study, although women are encouraged to seek routine care for this through their clinic.

#### How long will participant be in the study?

Participants will be involved from the time of their first ANC visit, until the infant is 12 months old.

#### What information and test results will participants receive?

- Information on malaria, anaemia and STIs will be made available to participants soon after testing.
- If other questions reveal serious illness in the mother or baby, then they will be helped to seek care within the ENB services
- Participants in the study will receive information on the progress and results of the research on a regular basis, through the ENB health services.

#### What about confidentiality?

All researchers will be appropriately trained in ethical standards relating to participant confidentiality. Participants will be issued a unique Study Identification Number (SIN), this will be used to identify participant questionnaires to ensure that no personally identifying information is recorded on the questions, samples or results pertaining to the participant. A separate sheet will match SINs with participant names so as to ensure appropriate treatment and follow up can be provided for those who are diagnosed with an STI.

#### What are the risks in participating?

Risks relating to questions:

- The questionnaire will cover some topics that are of a sensitive nature (previous pregnancy outcomes (including stillbirth, abortion, newborn outcomes) and STIs). Some participants may find these questions uncomfortable or upsetting. Researchers will be appropriately trained in how to deal with these topics in a sensitive manner, and it will be made clear to participants that they are free not to answer any particular question they would prefer not to. It will also be made clear that should they want to withdraw participation at any point they are welcome to do so.

Risks relating to blood samples:

- Having a blood sample taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which tissue is taken could become inflamed. Some people may feel faint when having blood taken, and may occasionally faint. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.

Risks relating to urine samples:

- Providing a urine sample is a simple procedure that is not associated with any risks other than splashing or contamination of the hand with urine. Appropriate handwashing facilities will be available.

Risks associated with providing a high vaginal swab:

- A self administered high vaginal swab may be associated with some mild discomfort. In rare circumstances, it may cause some mild bleeding that would be self-limiting.

Risks relating to confidentiality:

- Every effort will be taken to ensure confidentiality of participant information. However, due to the nature of the clinic environment, it is likely that others waiting at the clinic will be able to see who chooses to participate as it is likely they will be seen to go and talk with the researchers. However, questionnaires will be conducted in an area that will allow a discussion to be conducted in a confidential manner, and absolute privacy will be provided during procedures (blood sampling, provision of urine and upper vaginal swab).
- Every effort will be made to ensure the document linking SINS to participant personal information is kept confidential; this will be locked in a separate cabinet with access restricted to the research manager. However there is a small risk that access could be obtained to this information (e.g. robbery or break-in).
- This study is linked to other studies of health issues and health services in ENB and some data from this study will be used to check the results of other research. Patient names will NOT be used when linking to other studies.

#### What are the benefits in taking part in the study?

Specific benefits to the participant:

- Active case finding of TB through referral of those women who meet clinical criteria for TB. Women will be referred for diagnosis and management as per national guidelines, any transport costs associated with this referral will be covered by the research team.
- Diagnosis and treatment of STIs will be provided at no cost to the participant.
- Diagnosis of malaria and anaemia, allowing referral for treatment of these

Broader benefits to health facilities, communities and East New Britain Province (ENBP):

- Participating health facilities will benefit from some updated equipment where required (baby scales, adult scales, adult height measures, tape measures). They will also benefit from the study information that will be fed back to them at completion of the research.
- Communities and ENBP will benefit greatly from the improved understanding of factors contributing to maternal and newborn health in the province, and enablers and barriers to accessing health care.

What options do participants have?

Participation in this research is entirely voluntary. Meaning, that any women invited to participate has the right to say no, and the right to withdraw from the study and decline further participation at any point.

What is the cost of participating in the study?

Those who choose to participate in this study will not face any additional financial costs. Those who participate will be met at the facility which they have selected to attend. If participants do not attend their follow up visits (scheduled as per national guidelines), researchers will follow them up at their residence at a time that is convenient for them.

What rights do participants have?

- Participants have the right to withdraw participation at any point.
- Participants have the right not to answer a question.
- Participants have the right to refuse blood tests, or refuse to provide a vaginal swab.
- Participants have the right to request for their information.
- Participants have the right to refuse stored samples to be tested in the future.

Will samples be stored and used for future studies?

Wherever possible samples will be tested in ENBP. Samples we expect to be able to test in ENBP province include:

- Vaginal swabs for STIs using the geneXpert machine
- Urine sample for evidence of UTI (dipstick) and urinary iodine
- Blood sample: Haemoglobin (Hb), C-Reactive Protein (CRP) and malaria RDT

Should it not be possible for these to be tested in ENBP, the samples will be shipped to an IMR laboratory or Melbourne, Australia for later testing. Results of these tests will not be able to be passed back to individual participants:

- Blood sample: serum ferritin, serum Transferrin Receptor (sTfR), serum retinol, Retinol Binding Protein (RBP), zinc and malarial antibodies.
- Placental sample: malarial antibodies
- Tests for exposure to hepatitis B and measles

Blood samples will be stored at the Burnet Institute laboratory in Melbourne, Australia. If the participant provides consent to do so, these samples may undergo future testing for biomedical markers relevant to maternal and child health.

How will my information be used?

Information collected from this study will not have identifying information, after collection it will be recorded in a group data set, analysed and interpreted. The results of this study will be made available to participants at the completion of the study and will also be used to develop policy recommendations. It is anticipated the results of the study will be submitted to peer-reviewed

medical journals and presented at conferences as well as used in other forums to disseminate the findings (e.g. teaching).

Who do participants contact if they have questions or problems?

Participants can inform the researcher who recruited them and conducted their questionnaire if they choose (names and contact details will be provided at recruitment), or they can contact Dr Michelle Hendel, the Research Program Manager and Principal Investigator, by email: [michelle.hendel@burnet.edu.au](mailto:michelle.hendel@burnet.edu.au), or at the Burnet Institute office in Kokopo (+675 9828610, or dicigel 72892558).

If participants wish to talk to an independent person they can contact XXXX

### A.2.2 Tok Pisin Study information brochure

#### HELTİ MAMA HELTİ BEBİ

#### WOK PAINIM AUT – Pat Namba 1

#### TOKSAVE PEPA

##### Wanem bikpela tingting bihain lon dispela wok panim aut?

Bikpla tinting istap bihain long dispela wok painim aut. Em long skelim sik na hevi ol mama igat bel save bungim wantaim ol pikini bilong ol insait long East New Britain Provins. Na tu long lukluk igo insait long sampela samting we em inap long halivim na daunim hevi bilong ol belmama long:

- taim ol igat bel.
- taim bilong karim pikinini long hausik o klinik bilong belmama.

Long dispela wok painim aut bai mipela askim ol mama husat i save go long hausik o klinik long halivim mipela painim aut sampla rot long mekim helt servis i kamap gut long ol mama na pikinini.

##### Haumaspela lain manmeri bai stap insait long dispela wok panim aut?

Long dispela wok painim aut bai igat olsem 700 belmama long klinik bilong belmama insait long ENB.

##### Wanem samting istap insait long dispela wok pinim aut?

Ol lain mama igat tingting long halivim dispela wok painim aut bai wokim wanem?

- **Bai tok aut long:**
  - Stori bilong bel mama igat nau na bipo, long taim bilong mama igat bel (pikinini dai insait long bel, mama i karim taim em ino redi (9 Mun), rausim pikinini taim mama ilaikim bel em igat long em na sik bilong kuap *[STIs]*).
  - Hevi bilong nau na bipo long sait bilong skin i hat, kus, skin i lus, susu long rot bilong karim, sua long rot bilong karim na ol narapela mak nabaut long hap bilong karim.
  - Pasin bilong yusim hausik bipo na wanem tingting yu gat nau long servis yu lukim na kisim wantaim pasin bilong wokmanmeri insait long hausik o klinik.
  - Wanem sampela samting yu laik lukim kamap long sait bilong bel mama klinik, taim bilong karim, na lukaut bilong pikinini bihain tasol long karim.
  - Siat bilong moni. Em orait wantaim yu kam long hausik em olsem wanem.
  - Pastaim pasin bilong yu taim pikinini igat bikpela hevi o sik na wanem tingting yu gat nau wantaim dispela bel.
- **Bai givim tok orait** long panim aut tu long wei bilong kaikai tru long mak bilong makim namel han *[MUAC]*, na sais bilong bodi *[BMI]* makim bilong hevi bilong bodi na longpela bilong bodi. Na tu olgeta mak belmama klinik i save makim olgeta taim olgeta belmama i kam.
- **Tok orait long kisim blut** olsem istap insait long wok painim aut pasin (long namba 1 taim belmama kam long belmama klinik, long taim bilong karim *[delivery]* long lukim bilum bilong pikinini *[placenta sample]*). Na tu kisim blut bilong mama na bilong bebi bilong em long 1pela, 6pela, na 12pela mun bihain long mama karim bebi;

- Testim blut bilong belmama long sik bilong blut is sot [*anaemia*], long iron, long binatang bilong malaria, na long vitamin, na long sampela narapela ol mak bilong sik [*inflammatory marker*].
- Sik wei tambu sut isave pasim olsem hepatitis B na sik mesel.
- Testim blut bilong bilum bilong pikinini long sik malaria.
- Testim blut bilong pikinini long sik bilong blut i sot na long vitamins.
- **Kisim na givim kan wara bilong belmama.** Dispela em belmama yet bai kisim na givim. Bai igat tok skul bilong kisim dispela kan wara.
  - Dispela kan wara ol bai testim long sik bilong kuap olsem klamidia, [*Chlamydia*], Konoria [*gonorrhea*] na trikomonas [*trichomonas*].
- **Kisim na givim liklik pispis** long testim long mak bilong sik [*infection and urinary iodine*].
- **Tok orait long bihainim mama igat bel** [*pregnancy*], mama karim pinis [*childbirth*], na wanem samting i kamap long pikinini (ansarim askim long taim bilong mama i karim, na long 1 mun, 2 mun, 3 mun, 6 mun na 12 mun bihain).
- **Tok orait long kisim haus sik rekot** we ol i lukautim na long rekot bilong sikmanmeri.
- **Long testim HIV bai NOGAT** long dispela wok painim aut, olsem na ol meri bai mas go long haus sik o klinik we ol i save go olgeta taim long em long kain halivim.

Long haumas mun bai ol lain mama istap insait long dispela wok painim aut?

- Ol lain belmama we bai istap long dispela wok painim aut bai stat long numba 1 taim ol igo long belmama klinik igo inap long bebi em i 12 mun.

Wanem kain toksave na wok painim aut resol bai ol belmama i kisim?

- Toksave long sik malaria na blut i sot ol bai kisim hariap long haus sik/ klinik we ol igo long em. Ol narapela sik olsem sik bilong kuap [*STIs*] bai kisim longpela taim liklik.
- Sapos ol narapela askim i sowim olsem mama o bebi bilong em igat bikpela hevi bai mipela halivim long painim halivim yet insait long ENB helt servis.
- Ol lain mama we istap insait long dispela wok painim aut bai kisim toksave klostu klostu long ol lain bilong ENB helt servis.

Wanem ol sampela samting we iken kamap olsem birua o bikpela bagarap?

*Ol sampela hevi wei ken kamap long ol askim:*

- Sampela askim bai karamapim sampela bikpela het tok we i ken mekim skin i kirap (olsem hevi bilong igat bel o karim pikinini - bebi dai insait long bel [*still birth*], lusim pikinini long blut [*abortion*]), sampela samting long siat bilong sik wei ol liklik pikinini iken bungim [*new born outcomes*], na sik bilong kuap [*STIs*]. Sampela lain mama bai painim ol kain askim long ol dispela het tok i hevi tumas, olsem na mipela bai mekim klia olsem sapos ol sampela askim em i hevi em ol NOKEN wari long ansarim na tu ol iken lusim namel sapos ol INO laik long stap insait moa long dispela wok painim aut.

*Wanem ol sampela samting we iken kamap olsem birua o bikpela bagarap long sait bilong kisim blut:*

- Taim bilong kisim blut iken kamapim pen o sua. Sampela taim rop bilong blut iken solap, o blut iken bung insait long rop bilong karim blut, o long hap ol ikisim hap met bilong bodi

iken kamap ret. Sampela bai pilim ai i raun long taim bilong kisim blut na tu ol iken ai raun na pundaun. Sampela hevi i no save kamap planti taim tumas ol inap kisim liklik sik o ol inap lusim liklik blut. Sapos wanpela long ol dispela kain hevi em bai kamap igat pinis gutpela we tru long tritim em.

*Wanem ol sampela samting wei iken kamap long siat bilong kisim pispis:*

- Long kisim na givim pispis em ino hatpela samting we nogat hevi o biruap tasol long taim bilong kisim em iken kapsait long han na mekim han i smel. Bai igat hap bilong wasim han istap.

*Wanem ol sampela samting wei iken kamap long sait bilong kisim kan wara:*

- Long kisim kan wara antap tru insait long kan bai ken gat liklik pan. Na sampela taim em bai igat liklik blut we i ken kamap tasol klostu em bai pinis.

*Wanem ol sampela samting we iken kamap long sait bilong givim tok orait:*

- Olgeta rot bilong kisim tok orait long ol lain meri long dispela wok painim aut bai mipela bihainim gut. Na tu mipela no inap tokaut long narapela manmeri wanem toktok belmama i mekim na long wanem narapela kain save belmama i givim na ol save mipela i kisim long testim blut o wara bilong belmama. Tasol long sait bilong klinik nau em bai hevi liklik bilong wanem bai igat ol lain meri i wet long klinik na ol bai lukim husat nau istap insait long dispela wok painim aut wantaim ol woklain we bai askim ol askim bilong painim aut.
- Dispela wok painim aut em bai bung wantaim ol narapela wok painim aut long hevi bilong sik na helt servis insait long ENB na sampela pepa wok long dispela wok painim aut bai ol yusim bihain taim. Nem bilong ol sikmanmeri bai inonap kamap taim mipela tingting long lukluk long narapela wok painim aut.

Wanem sampela gutpela samting bai mipela kisim long dispela wok painim aut?

*Sampela gutpela samting ol lain manmeri istap insait long dispela wok painim aut iken kisim:*

- Ol lain husat bai stap beksait tru long wok bilong sik TB long painim na salim ol meri igo long hausik na bai ol woklain bilong hausik bai mekim bikipela wok painim aut na givim marasin bilong sik TB, istap bihainim nasinol kaidelain bilong depatmen bilong helt, long sait bilong baim kar long kisim ol meri igo long hausik bai ol lain igo pas long dispela wok painim aut bai baim rot bilong ol.
- Wok painim aut bilong sik na givim marasin long sik bilong kaup (STIs) em bai pirie yu INONAP baim marasin.
- Wok painim aut bilong sik malaria na blut i sot na salim ol igo long hausik o klinik long kisim marasin

*Sampela gutpela samting bai kamap long hausik, klinik, komuniti na ENB provins:*

- Ol hausik na klinik husat istap insait long dispela wok painim aut bai kisim ol masin bilong wok (olsem skel bilong bebi, skel bilong ol bikipela man/meri, samting bilong makim longpela bilong ol manmeri na tap masar [tape measure]). Na tu olsem bai yupela ikisim ol luksave toktok istap insait long dispela wok painim aut taim em ipinis olegta insait long 12 mun.
- Ol lain komuniti na ENB provins olgeta bai kisim gutpela tingting insait long pasin bilong lukautim meri igat bel wantaim bebi long hausik na klinik na ol sampela samting we iken halivim na inonap stopim ol mama long go long painim o kisim dispela halivim long hausik/klinik.

Wanem sampela kain tingting ol lain meri husat istap insait long dispela wok painim aut bai igat?

Long yu istap insait long dispela wok painim aut em yu yet na laik blo yu. Em olsem ol meri we yu bai istap insait long dispela wok painim aut igat rait long tok NOGAT, na tu yu gat RAIT long lusim na ino stap moa insait long dispela wok painim aut.

Olsem wanem long tok itru insait long wok painim aut?

Ol lain bai go pas long dispela wok painim aut bai kisim wanpela skul long halivim ol long dispela wok painim aut long sait bilong wok tru tasol. Ol lain meri husat bai stap insait long dispela wok painim aut bai kisim namba long mekim ol yet ihait, wei ol narapela wok manmeri bilong hausik inonap save long name bilong ol.

Wanem nau em sampela samting iken kamap long dispela wok painim aut?

Husat yu bai stap insait long dispela wok painim aut mas tingim olsem yu INONAP baim wanpela samting. Yu husat bai stap insait long dispela wok painim aut bai go long klinik we yu yet i mekim long go long em. Yu husat meri ino kamap long ol dispela klinik ol woklain bilong dispela wok painim aut bai kam long hap bilong yupela taim yupela i givim tok orait.

Wanem kain rait ol lain meri igat?

- Ol lain meri igat rait long lusim sapos ol INO laik long stap insait moa long dispela wok painim aut.
- Ol lain meri igat rait long NOKEN bekim bek ol askim.
- Ol lain meri igat rait long tok NOGAT long kisim blut tes, o tok NOGAT long kisim na givim kan wara long wok painim aut.
- Ol lain meri igat rait long tokim ol wokmanmeri long toksave long dispela wok painim aut long ol.
- Ol lain meri igat rait long tok NOGAT long putim ol blut o kan wara istap na bihain bai ol iken wokim wok painim aut ken long bihain taim.

Olsem wanem long blut na kan wara we bai ol iputim istap long wokim wok painim aut ken long bihain taim.

Long sait bilong sekim blut na kan wara ol bai traim long wokim olgeta dispela wok painim aut tasol insait long ENB provins. Ol lukim olsem planti test ol inap wokim long ENB provins yet:

- Sekim kan wara long sik bilong kuap *[STIs]*.
- Sekim pispis long sik bilong rot bilong pispis *[UTI and urinary iodine]*.
- Sekim blut haumas blut bodi igat *[Hb]* na sekim blut long binatang bilong malaria *[malaria RDT]* na long narapela mak bilong sik *[C-Reactive Protein]*.

Sapos ol INONAP long wokim dispela pat bilong wok painim aut insait long ENBP, ol dispela blut na kan wara bai ol i salim igo long IMR long Goroka o Melbourne long Australia long ol sekim bihain taim. Sapos ol mas mekim olsem, ol INONAP toksave bek long wanem istap insait long dispela pat bilong wok painim aut:

- Long blut wok painim aut sapos binatang bilong malaria bin stap, na tu long planti ol mak bilong sik na strong bilong blut *[serum ferritin, serum Transferring Receptor (sTfR), serum retinol, Retinol Binding Protein (RBP), zinc]*.
- Long blut long bilum bilong pikinini, wok painim aut sapos binatang bilong malaria bin stap.



- Wok painim aut sapos ol inap long kisim sik hepatitis na sik mesel.

Ol blut bilong wok painim aut bai ol ilukautim long Burnet Institute long hap bilong lukautim blut long Melbourne, Australia. Sapos ol lain meri itok orait long ol woklain long sekim ol dispela blut ken bai ol iken mekim.

Husat wokmanmeri bai ol lain meri i painim ol sapos ol igat askim o hevi?

Ol lain meri iken tokim ol woklain manmeri husat i kisim ol na askim ol long askim ol dispela askim istap insait long dispela wok painim aut sapos ol laikim (Nem na adras na fone numba bai ol igivim long taim bilong kisim ol meri long dispela wok painim aut o ol iken painim Dr. Michelle Hendel husat igo pass long dispela wok painim aut long fone numba: (0675) 9828610, o dicigel 72892558 na email: [michelle.hendel@burnet.edu.au](mailto:michelle.hendel@burnet.edu.au)

**APPENDIX 3: CONSENT FORM****A.3.1 English Consent Form****HEALTHY MOTHERS HEALTHY BABIES****STUDY 1 – COHORT STUDY**

&lt;List of collaborators&gt;

&lt;Principal Investigators&gt;

East New Britain Province, Papua New Guinea

**SIGNATURE FORM**

***Confirm if participant has been informed about the research study and voluntarily agree to participate; received the study information brochure; asked any questions about the study that s/he may have; and that the information given has permitted him/her to make a fully informed and free decision to participate in the study.***

***Clarify that the participant does not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have.***

***If participant can not read and write, an independent witness to the consent process will participate in all the consent process (ensure that participant has fully understood the purpose of the research project) including signing and filling the consent form on behalf of the participant.***

\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_

Signature of participant

Date

\_\_\_/\_\_\_/\_\_\_

***Samples that will be used in future studies related to the current study must be consented for.***

(Eg, if you would like to give us permission to use your specimens for future studies related to our current study then please indicate this by ticking the box below and write your initials on the line next to it)

|  |  |
|--|--|
|  |  |
|--|--|

\_\_\_\_\_

If participant is illiterate, a witness is required

\_\_\_\_\_

Name of witness

Date

\_\_\_/\_\_\_/\_\_\_

\_\_\_\_\_

Signature of Witness

**This consent was obtained by:**

\_\_\_\_\_/\_\_\_\_/\_\_\_\_  
Printed Name of Person Obtaining Consent                      Date

\_\_\_\_\_  
Signature of Person Obtaining Consent  
(Must be an individual who has been designated)

\_\_\_\_\_/\_\_\_\_/\_\_\_\_  
Signature of Study Co-ordinator (Affirming that                      Date  
informed consent has been obtained)

**A.3.2 Tok Pisin Consent Form****HEITI MAMA HELTI BEBI****WOK PAINIM AUT – Namba 1**

<Nem bilong ol lain man/meri long halivim>  
 <Manmeri we bai go pas long dispela wok painim aut>  
 East New Britain Provins, Papua Niugini

**PEPA LONG PUTIM HAN MAK**

Askim sapos ol lain meri i bin tok orait long stap insait long dispela wok painim aut na tu sapos ol ikisim toksave long pepa. Askim ol sapos ol igat sampela askim ol ilaik askim na sapos nogat; ol i hamemas long ol toksave ol ikisim long stap insait long dispela wok apainim aut.

Tokaut na tok klia long ol belmama olsem ol rait bilong em olsem belmama em istap yet. Na tu ol woklain bilong wok painim aut na ol lain husat i wok long halivim o sapatim dispela wok painim aut inonap tok “em rong o hevi bilong ol belmama tasol”: ol bai kamap wantaim sampela rot bilong stretim dispela hevi o wok bagarap we em kamap long mekim dispela wok painim aut.

Sapos ol lain meri husat INO save long rit na rait bai kisim wanpela manmeri long witnisim dispela pasin bilong tok orait long dispela wok painim aut long putim han mak bilong tok orait long husat bai stap insait long wok painim aut.

\_\_\_\_\_  
 Raitim nem bilong meri:

\_\_\_\_\_  
 Putim han mak

\_\_\_\_/\_\_\_\_/\_\_\_\_  
 de

Blut na wara mipela i laik yusim long mekim sampela test long bihain taim. Ol mas givim tokorait pastaim mipela inap yusim ken lkong bihain taim.

Sapos yu givim tokorait long mipela long yusim blut na wara bilong yu long mekim sampela test long bihain taim, putim mak long bokis “Yes”. Sapos yu no wanbel putim mak long bokis “No”. Long hapsait putim mak bilong yu.

|    |   |
|----|---|
| es | o |
|----|---|

Sapos dispela meri INO save rit na rait, bai em i mas kisim wanpela narapela manmeri long pulapim dispela pat tambilo

\_\_\_\_\_  
 Nem bilong witnis

\_\_\_\_/\_\_\_\_/\_\_\_\_  
 de

\_\_\_\_\_  
 Han mak bilong witnes

This consent was obtained by:

\_\_\_\_\_/\_\_\_\_/\_\_\_\_  
Printed Name of Person Obtaining Consent      Date

\_\_\_\_\_  
Signature of Person Obtaining Consent  
(Must be an individual who has been designated)

\_\_\_\_\_/\_\_\_\_/\_\_\_\_  
Signature of Study Co-ordinator (Affirming that      Date  
informed consent has been obtained)

**APPENDIX 4: CLINIC SIGN****A.4.1 English Clinic Sign****HEALTHY MOTHERS HEALTHY BABIES****STUDY 1 – COHORT STUDY****CLINIC SIGN**Why is this study being done?

This study aims to measure the diseases or pregnancy complications experienced by mothers and their infants in East New Britain Province (ENBP), as well as the existing factors that are both protective and predictive of a risky pregnancy, including health care utilization. In this study we will invite pregnant women aged 16 years and over, attending health facilities to participate in research that aims to improve future health services, to help improve the health of mothers and their babies.

How many people will participate in the study?

This study intends to recruit a sample of 700 pregnant women from Antenatal Clinic (ANC) at a number of different health facilities in ENB.

What is involved in the study?

For those who choose to participate, participation will involve:

- **Answering questions**
- **Allow a physical assessment**
- **Allowing blood samples**
- **Providing a mid-vaginal swab**
- **Providing a urine sample**
- **Allowing follow up until your baby is 1 year old**
- **Allowing access to medical information**
- **Testing for HIV will NOT be done**

How long will participant be in the study?

Participants will be involved from the time of their first ANC visit, until the infant is 12 months old.

What information and test results will participants receive?

- Information on malaria, anaemia and STIs will be made available to participants soon after testing.
- If other questions reveal serious illness in the mother or baby, then they will be helped to seek care within the ENB services
- Participants in the study will receive information on the progress and results of the research on a regular basis, through the ENB health services.

What about confidentiality?

All researchers will be appropriately trained in ethical standards relating to participant confidentiality. Participants will be issued a unique Study Identification Number (SIN), this will be

used to identify participant questionnaires to ensure that no personally identifying information is recorded on the questions, samples or results pertaining to the participant. A separate sheet will match SINS with participant names so as to ensure appropriate treatment and follow up can be provided for those who are diagnosed with an STI.

What options do participants have?

Participation in this research is entirely voluntary. Meaning, that any women invited to participate has the right to say no, and the right to withdraw from the study and decline further participation at any point.

What is the cost of participating in the study?

Those who choose to participate in this study will not face any additional financial costs. Those who participate will be met at the facility which they have selected to attend. If participants do not attend their follow up visits (scheduled as per national guidelines), researchers will follow them up at their residence at a time that is convenient for them.

What rights do participants have?

- Participants have the right to withdraw participation at any point.
- Participants have the right not to answer a question.
- Participants have the right to refuse blood tests, or refuse to provide a vaginal swab.
- Participants have the right to request for their information.
- Participants have the right to refuse stored samples to be tested in the future.

Will samples be stored and used for future studies?

Wherever possible samples will be tested in ENBP. Samples we expect to be able to test in ENBP province include:

- Vaginal swabs for STIs using the geneXpert machine
- Urine sample for evidence of UTI (dipstick) and urinary iodine
- Blood sample: Haemoglobin (Hb), C-Reactive Protein (CRP) and malaria RDT

Should it not be possible for these to be tested in ENBP, the samples will be shipped to an IMR laboratory or Melbourne, Australia for later testing. Results of these tests will not be able to be passed back to individual participants:

- Blood sample: serum ferritin, serum Transferrin Receptor (sTfR), serum retinol, Retinol Binding Protein (RBP), zinc and malarial antibodies.
- Placental sample: malarial antibodies
- Tests for exposure to hepatitis B and measles

Blood samples will be stored at the Burnet Institute laboratory in Melbourne, Australia. If the participant provides consent to do so, these samples may undergo future testing for biomedical markers relevant to maternal and child health.

How will my information be used?

Information collected from this study will not have identifying information, after collection it will be recorded in a group data set, analysed and interpreted. The results of this study will be made

available to participants at the completion of the study and will also be used to develop policy recommendations. It is anticipated the results of the study will be submitted to peer-reviewed medical journals and presented at conferences as well as used in other forums to disseminate the findings (e.g. teaching).

Who do participants contact if they have questions or problems?

Participants can inform the researcher who recruited them and conducted their questionnaire if they choose (names and contact details will be provided at recruitment), or they can contact Dr Michelle Hendel, the Research Program Manager and Principal Investigator, by email: [michelle.hendel@burnet.edu.au](mailto:michelle.hendel@burnet.edu.au), or at the Burnet Institute office in Kokopo (+675 9828610, or dicigel 72892558).



#### A.4.2 Tok Pisin Study Clinic Sign

### HELTİ MAMA HELTİ BEBİ

#### WOK PAINIM AUT – Pat Namba 1

##### TOKSAVE PEPA

#### Wanem bikpela tingting bihain lon dispela wok painim aut?

Bikpla tinting istap bihain long dispela wok painim aut. Em long skelim sik na hevi ol mama igat bel save bungim wantaim ol pikini bilong ol insait long East New Britain Provins. Na tu long lukluk igo insait long sampela samting we em inap long halivim na daunim hevi bilong ol belmama long:

- taim ol igat bel.
- taim bilong karim pikinini long hausik o klinik bilong belmama.

Long dispela wok painim aut bai mipela askim ol mama husat i save go long hausik o klinik long halivim mipela painim aut sampla rot long mekim helt servis i kamap gut long ol mama na pikinini.

#### Haumaspela lain manmeri bai stap insait long dispela wok painim aut?

Long dispela wok painim aut bai igat olsem 700 belmama long klinik bilong belmama insait long ENB.

#### Wanem samting istap insait long dispela wok painim aut?

Ol lain mama igat tingting long halivim dispela wok painim aut bai wokim wanem?

- **Bai tok aut**
- **Bai givim tok orait**
- **Tok orait long kisim blut**
- **Kisim na givim kan wara bilong belmama.** Dispela em belmama yet bai kisim na givim. Bai igat tok skul bilong kisim dispela kan wara.
- **Kisim na givim liklik pispis**
- **Tok orait long bihainim mama igat bel** [*pregnancy*], mama karim pinis [*childbirth*]
- **Tok orait long kisim haus sik rekot** we ol i lukautim na long rekot bilong sikmanmeri.
- **Long testim HIV bai NOGAT** long dispela wok painim aut

#### Long haumas mun bai ol lain mama istap insait long dispela wok painim aut?

- Ol lain belmama we bai istap long dispela wok painim aut bai stat long numba 1 taim ol igo long belmama klinik igo inap long bebi em i 12 mun.

#### Wanem kain toksave na wok painim aut resol bai ol belmama i kisim?

- Toksave long sik malaria na blut i sot ol bai kisim hariap long haus sik/ klinik we ol igo long em. Ol narapela sik olsem sik bilong kuap [*STIs*] bai kisim longpela taim liklik.
- Sapos ol narapela askim i sowim olsem mama o bebi bilong em igat bikpela hevi bai mipela halivim long painim halivim yet insait long ENB helt servis.
- Ol lain mama we istap insait long dispela wok painim aut bai kisim toksave klostu klostu long ol lain bilong ENB helt servis.

Wanem ol sampela samting we iken kamap olsem birua o bikpela bagarap?

Ol sampela hevi wei ken kamap long ol askim:

- Sampela askim bai karamapim sampela bikpela het tok we i ken mekim skin i kirap (olsem hevi bilong igat bel o karim pikinini - bebi dai insait long bel [*still birth*], lusim pikinini long blut [*abortion*]), sampela samting long siat bilong sik wei ol liklik pikinini iken bungim [*new born outcomes*], na sik bilong kuap [*STIs*]. Sampela lain mama bai painim ol kain askim long ol dispela het tok i hevi tumas, olsem na mipela bai mekim klia olsem sapos ol sampela askim em i hevi em ol NOKEN wari long ansarim na tu ol iken lusim namel sapos ol INO laik long stap insait moa long dispela wok painim aut.

Wanem sampela kain tingting ol lain meri husat istap insait long dispela wok painim aut bai igat?

Long yu istap insait long dispela wok painim aut em yu yet na laik blo yu. Em olsem ol meri we yu bai istap insait long dispela wok painim aut igat rait long tok NOGAT, na tu yu gat RAIT long lusim na ino stap moa insait long dispela wok painim aut.

Olsem wanem long tok itru insait long wok painim aut?

Ol lain bai go pas long dispela wok painim aut bai kisim wanpela skul long halivim ol long dispela wok painim aut long sait bilong wok tru tasol. Ol lain meri husat bai stap insait long dispela wok painim aut bai kisim namba long mekim ol yet ihait, wei ol narapela wok manmeri bilong hausik inonap save long name bilong ol.

Wanem nau em sampela samting iken kamap long dispela wok painim aut?

Husat yu bai stap insait long dispela wok painim aut mas tingim olsem yu INONAP baim wanpela samting. Yu husat bai stap insait long dispela wok painim aut bai go long klinik we yu yet i mekim long go long em. Yu husat meri ino kamap long ol dispela klinik ol woklain bilong dispela wok painim aut bai kam long hap bilong yupela taim yupela i givim tok orait.

Wanem kain rait ol lain meri igat?

- Ol lain meri igat rait long lusim sapos ol INO laik long stap insait moa long dispela wok painim aut.
- Ol lain meri igat rait long NOKEN bekim bek ol askim.
- Ol lain meri igat rait long tok NOGAT long kisim blut tes, o tok NOGAT long kisim na givim kan wara long wok painim aut.
- Ol lain meri igat rait long tokim ol wokmanmeri long toksave long dispela wok painim aut long ol.
- Ol lain meri igat rait long tok NOGAT long putim ol blut o kan wara istap na bihain bai ol iken wokim wok painim aut ken long bihain taim.

Olsem wanem long blut na kan wara we bai ol iputim istap long wokim wok painim aut ken long bihain taim.

Long sait bilong sekim blut na kan wara ol bai traim long wokim olgeta dispela wok painim aut tasol insait long ENB provins. Ol lukim olsem planti test ol inap wokim long ENB provins yet:

- Sekim kan wara long sik bilong kuap [*STIs*].
- Sekim pispis long sik bilong rot bilong pispis [*UTI and urinary iodine*].

- Sekim blut haumas blut bodi igat [*Hb*] na sekim blut long binatang bilong malaria [*malaria RDT*] na long narapela mak bilong sik [*C-Reactive Protein*].

Sapos ol INONAP long wokim dispela pat bilong wok painim aut insait long ENBP, ol dispela blut na kan wara bai ol i salim igo long IMR long Goroka o Melbourne long Australia long ol sekim bihian taim. Sapos ol mas mekim olsem, ol INONAP toksave bek long wanem istap insait long dispela pat bilong wok painim aut:

- Long blut wok painim aut sapos binatang bilong malaria bin stap, na tu long planti ol mak bilong sik na strong bilong blut [*serum ferritin, serum Transferring Receptor (sTfR), serum retinol, Retinol Binding Protein (RBP), zinc*].
- Long blut long bilum bilong pikinini, wok painim aut sapos binatang bilong malaria bin stap.
- Wok painim aut sapos ol inap long kisim sik hepatitis na sik mesel.

Ol blut bilong wok painim aut bai ol ilukautim long Burnet Institute long hap bilong lukautim blut long Melbourne, Australia. Sapos ol lain meri itok orait long ol woklain long sekim ol dispela blut ken bai ol iken mekim.

Husat wokmanmeri bai ol lain meri i painim ol sapos ol igat askim o hevi?

Ol lain meri iken tokim ol woklain manmeri husat i kisim ol na askim ol long askim ol dispela askim istap insait long dispela wok painim aut sapos ol laikim (Nem na adras na fone numba bai ol igivim long taim bilong kisim ol meri long dispela wok painim aut o ol iken painim Dr. Michelle Hendel husat igo pass long dispela wok painim aut long fone numba: (0675) 9828610, o dicigel 72892558 na email: [michelle.hendel@burnet.edu.au](mailto:michelle.hendel@burnet.edu.au)

#### 10.1.4 *Prospective Observational Cohort Study - ethical approvals*



### Government of Papua New Guinea Medical Research Advisory Committee

National Department of Health

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WAIGANI 131, NCD  
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Phone: + (675) 301 3650  
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FILE: 54-6-2  
DATE: 10/11/2014

Dr. Michelle Hendel  
PNGIMR  
P.O.Box 60  
GOROKA 441  
Eastern Highlands

Dear Dr. Michelle Hendel

Your proposal "Health Mothers, Healthy Babies Study I, Cohort Study," by Michelle Hendel" has been reviewed by the Medical Research Advisory Committee (MRAC). **The committee approved your proposal and registered it as MRAC No. 14.27**

MRAC would like to thank you for your submission and looks forward to the successful implementation of your study.

Investigators are reminded of the importance of keeping relevant authorities including the MRAC on the progress of and outcomes of their study.

Best Wishes.

Dr. Urarang Kitur  
MRAC Chairman

**ETHICS COMMITTEE CERTIFICATE OF APPROVAL**

*This is to certify that*

**Project No:** 348/14

**Project Title:** Healthy Mothers Healthy Babies – Study 1 Observational Cohort

**Principal Researcher:** Professor James Beeson

**Protocol Version 2.1 dated:** 4-Aug-2014

**Participant Information Sheet Version 1.1 dated:** 4-Aug-2014

**Consent Form Version 1.1 dated:** 4-Aug-2014

*was considered by the Ethics Committee on **28-Aug-2014**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **26-Sep-2014***

---

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

***The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of***

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

***Additionally, the Principal Researcher is required to submit***

- A Progress Report on the anniversary of approval and on completion of the project (*forms to be provided*);

The Ethics Committee may conduct an audit at any time.

**All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).**

**The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).**

**SPECIAL CONDITIONS**

None

**SIGNED:**

**Professor John J. McNeil  
Chair, Ethics Committee**

***Please quote project number and title in all correspondence***

**10.1.5 Health Services for Postnatal and Infancy Care Study – full protocol****Healthy Mothers Healthy Babies, Study 2a****Version 2: 25<sup>th</sup> July 2016****SPONSORED BY:**

The Burnet Institute, Papua New Guinea Institute of Medical Research and the East New Britain Provincial Administration.

**RESEARCH TEAM:****Principal Investigators**

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Nicholas Larme, *East New Britain Provincial Health Office*

Olga Saweri, *PNG Institute of Medical Research (PNG IMR)*

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Johnnie Arava, *Acting Manager for Immunization, NDOH*

Robert Power, *Burnet Institute*

**FUNDING SOURCE**

Private funding provided to the Burnet Institute for the collaborative Healthy Mothers Healthy Babies research program.

**CONFIDENTIALITY**

This document is confidential and the property of the Macfarlane Burnet Institute for Medical Research and Public Health and the Papua New Guinea Institute for Medical Research. No part of it may be transmitted, reproduced, published, or used without prior written authorization from the institution.

**STATEMENT OF APPROVAL AND COMPLIANCE**

This document is a protocol for a clinical research study. The study has been approved by the PNG IMR Institutional Review Board (IRB: 1603), the PNG Medical Research Advisory Committee (MRAC: 16.22), the East New Britain Provincial Government (PEC: 12/2016), and The Alfred Ethics Committee, Melbourne (333/16). The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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## PROTOCOL SUMMARY

**Weaknesses in health care services**, on top of the extra illness burden suffered by mothers and babies, contribute to the unacceptably high rates of death and disease seen in Papua New Guinea (PNG), including the province of East New Britain (ENB), where this study is set. A strong mix of preventive and treatment care services is needed to ensure the health of mothers, and of newborns and infants. This includes good quality routine care during pregnancy (antenatal care), skilled management of childbirth, availability of emergency care if a complication or illness occurs, special care in vulnerable first month after a childbirth (the **postnatal** period), and effective routine care (including vaccinations) as well as illness care during the first years after a childbirth (the **infancy** period).

The **Health Services for Postnatal and Infancy Care study** (HMHB Study 2a) is the first of two linked studies conducted as part of the larger Healthy Mothers Healthy Babies research program based in ENB. Both studies aim to use high quality research tools to evaluate currently available services for reproductive, maternal, newborn and child health (RMNCH) care in ENB province, comparing them to national policies and international standards. **This Study 2a focuses on services for the mother and baby during the postnatal and infancy periods**, that is: from one hour after birth until 12 months after birth. A later study will provide a complementary perspective: the Pregnancy, Childbirth and Newborn Services Study (HMHB Study 2b).

This study will:

- measure current infrastructure, equipment and supplies for care in pregnancy, childbirth and throughout infancy in health facilities,
- assess what health workers know, think and do in relation to providing postnatal and infancy services;
- assess health workers' preferences for changes to the way health services are organized – these changes will include those introduced by the government in 2015 and other potential changes that have been proposed in other countries similar to PNG; and
- identify immediate and medium-term opportunities for health system strengthening and improved quality of care.

This study will survey the five busiest health facilities providing postnatal care in ENB and a selected group of smaller clinics and outreach points that are served by these facilities. This survey is planned to take place in mid-2016, with analysis and conclusions completed by the end of 2016. This will help design the second health services study on pregnancy and childbirth care (Study 2b) late in 2016.

The study will be conducted by the Burnet Institute, the PNG Institute of Medical Research, and the East New Britain Provincial Health Office. Additional advice is provided by the University of PNG, the National Department of Health (NDOH), the PNG office of the World Health Organization, the University of Melbourne and other Australian research institutions with experience in PNG. The study is funded from private donations provided to the Healthy Mothers Healthy Babies research program, as well as using internal resources of the institutions involved.



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**Advisory Panel – Local**

*To comprise representatives from Nonga General Hospital, Catholic Health Services, and Family Health Services in PHO. This will mirror the Local Advisory Panel that is already established as part of Healthy Mothers Healthy Babies, Study 1, in Kokopo.*

**Advisory Panel – National and international**

**Professor Beverley-Ann Biggs**, Head, International and Immigrant Health, Department of Medicine, University of Melbourne

**Dr Angela Kelly-Hanku**, Lead, Sexual and Reproductive Health, PNG IMR and Senior Research Fellow, School of Public Health and Community Medicine, University of NSW

**Associate Professor Stanley Luchters**, Head, Women's and Children's Health Team, Centre for International Health, Burnet Institute and School of Public Health and Preventive, Monash University

**Associate Professor Mark Stooze**, Head, HIV Research and Head, Justice Health Research, Centre for Population Health, Burnet Institute

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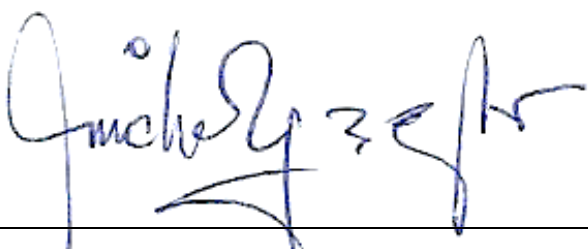
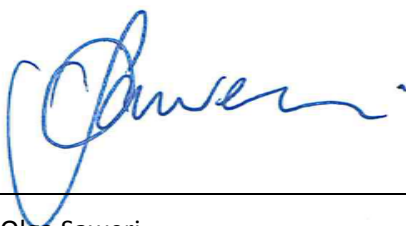
**Dr William Lagani**, Manager, Family Health Services, National Department Of Health

### Training

All project staff will receive appropriate training on protection of human subjects and ethical conduct, in accordance with good clinical practice guidelines. Research and field staff will receive training in consent, standard operation procedures for data collection and handling, and community engagement.

### SIGNATURES

The signatures below document the approval of this protocol and the attachments, and provide the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality and according to local legal and regulatory requirements.

|                                                                    |                                                                                                                      |       |            |
|--------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|-------|------------|
| Principal investigator (Burnet Institute)                          |                                                                                                                      |       |            |
| Signed:                                                            |                                     | Date: | 09/03/2016 |
|                                                                    | <b>Name:</b> Christopher Morgan<br><b>Title:</b> Principal Fellow, Centre for International Health, Burnet Institute |       |            |
| Principal investigator (East New Britain Provincial Health Office) |                                                                                                                      |       |            |
| Signed:                                                            |                                   | Date: | 09/03/2016 |
|                                                                    | <b>Name:</b> Nicholas Larmer<br><b>Title:</b> Provincial Health Advisor, East New Britain Provincial Health Office   |       |            |
| Principal investigator (PNG Institute of Medical Research)         |                                                                                                                      |       |            |
| Signed:                                                            |                                   | Date: | 09/03/2016 |
|                                                                    | <b>Name:</b> Olga Saweri<br><b>Title:</b> Senior Scientific Officer, PNG Institute of Medical Research               |       |            |

**GLOSSARY OF ABBREVIATIONS**

| <b>ABBREVIATION</b> | <b>TERM</b>                                                                                                                     |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------|
| ANC                 | Antenatal care                                                                                                                  |
| CBD                 | Community Based Distributor (of health products)                                                                                |
| CHW                 | Community Health Worker (a professional cadre in PNG)                                                                           |
| ENB                 | East New Britain (province)                                                                                                     |
| EENC                | Early Essential Newborn Care                                                                                                    |
| EPI                 | Expanded Programme on Immunization                                                                                              |
| HEO                 | Health Extension Officer                                                                                                        |
| HIV                 | Human Immunodeficiency Virus (infection)                                                                                        |
| HMHB                | Healthy Mothers Healthy Babies (multi-institutional research program based in East New Britain province)                        |
| MMR                 | Maternal Mortality Ratio                                                                                                        |
| NO                  | Nursing Officer                                                                                                                 |
| PHO                 | Provincial Health Office                                                                                                        |
| PNC                 | Postnatal care                                                                                                                  |
| PNG                 | Papua New Guinea                                                                                                                |
| PNG IMR             | Papua New Guinea Institute of Medical Research                                                                                  |
| SIREP               | Special Integrated Routine EPI Strengthening Program (SIREP and SIREP Plus: a government package for improved service planning) |
| STI                 | Sexually Transmitted Infection                                                                                                  |
| TB                  | Tuberculosis (infection)                                                                                                        |
| UPNG                | University of PNG                                                                                                               |
| USAID               | United States of America's Agency for International Development                                                                 |
| VBA                 | Village Birth Attendant                                                                                                         |
| VHV                 | Village Health Volunteer                                                                                                        |
| WHO                 | World Health Organization                                                                                                       |

## 1. INTRODUCTION AND RATIONALE

### 1.1.1. General health service issues in Papua New Guinea

In many areas of Papua New Guinea (PNG), life-saving health services are often difficult to access, not optimally utilized, or do not properly meet family health needs. Contributing factors include PNG's unique mix of diverse populations, rugged geography, and limited transport and infrastructure, especially in rural areas(1, 2). As well as these physical access difficulties, health care access is constrained by limits on human and other resources for health services, financial barriers, lack of understanding of the need for medical care, as well as other cultural factors (such as lack of partner support or preference for traditional arrangements(3)).

For many years, PNG's health system has responded through deploying **auxiliary cadres** of health worker (HEOs, nurses and CHWs) in smaller, more peripheral health facilities, and the provision of **health services at community level** through Aid Posts and mobile outreach clinics. However recent government and research analyses acknowledge that health service delivery to rural or urban poor communities has remained static or deteriorated (1, 4), including those for maternal and child health(5).

There is a critical need, across the health services, to find new ways to **make services more accessible and affordable** for communities. This is especially relevant to the 2014 enactment of the Free Primary Health Care and Subsidised Specialist Services legislation; a policy that is proving difficult to implement(6, 7) such that user fees remain common. A second critical need is to **measure and improve quality of care**. This is particularly important in the provision of maternal and newborn health care services, where increased coverage without increased quality has been shown to fail to improve survival of mothers or newborns(8, 9).

Health planners in PNG are grappling with **important implementation questions** including: how to overcome fragmentation across differing management of hospital, rural and public health services; how to ensure proper placement of well-trained staff; which services should be provided at the most peripheral levels (health posts or community outreach patrols); and how different services to families could best be planned, coordinated and resourced(1, 4). Health managers also recognize the 'know-do' gap in health care provision; that is: even with sound policy and evidence-based planning, a range of factors make it commonplace for policy to not be put into practice, or health plans to not be implemented as designed. These factors are likely to arise both internally within health teams and externally from their operating environment, however they are not well documented by health research in PNG.

### 1.2. Health service issues for postnatal and infancy care

Access to **good quality health care in the postnatal period** (first month of life) is critical to preventing maternal and newborn deaths, especially in the first days immediately after childbirth, when close to 50% of maternal or newborn deaths occur(10). Reaching mothers and babies with preventive care, and emergency treatment if needed, at this point in time has proven very difficult at global levels (11, 12) and in PNG(13, 14). Coverage with early postnatal care (that is: care in the first two days after birth, the recommended standard(15)), is currently not measured in PNG, but is

thought be at low levels for both home births and facility births, the latter because many mothers leave a health facility very soon after childbirth.

Quality of care for mothers, newborns and children has a direct effect on patient outcomes; in addition, **deficient quality of care can also discourage health service utilization**(16). Studies in PNG, both published(17, 18) and presentations made to the annual medical symposium, highlight the importance of improving quality of care. International efforts are increasingly defining standards for quality care. Those for newborn care, in the Early Essential Newborn Care (EENC) package(11) build on earlier guidance for postnatal care(19). Limited evidence is available on how to implement this in PNG(13, 20, 21), and it is important to measure current practices and assess future potential for quality improvement with health managers and providers.

Attempts to **improve organization and management of services** raise specific challenges at this point in the life course including: how to reach mothers and newborns following a home birth through facilities or home visits(22); how to provide postnatal care to women who have a facility-based childbirth but who return home very early after birth; how best to partner with VHVs (where they are active); what mix of preventive and treatment services can be provided by community outreach; and how best to plan outreach services so they optimize coverage with efficient use of resources, especially where transport is difficult.

Other important health service questions for postnatal and infancy care relate to **the potential of integration of different services to increase coverage**. First is the question of how immunization can be integrated with other maternal, newborn or child health services, or with other disease control services such as those for Human Immunodeficiency Virus (HIV), malaria and TB (23). Routine immunization services in the infancy period are scheduled for ages one, two, three, six and nine months in PNG. While these services do themselves require strengthening to improve vaccination coverage, they are also an established aspect of PNG's routine preventive health services on which other services could leverage.

Specific questions apply to **integrating health services in the postnatal period**. Services here need to consider combining advice on feeding, nutrition, hygiene and danger signs, with discussions on family planning, and with provision of the birth-dose of vaccinations against tuberculosis (TB) and hepatitis B. One experience in PNG(24) suggests that integration of birth-dose vaccination with postnatal care can increase coverage in both community and health facility settings. **During infancy** (the first year of life), additional questions include how to improve routine immunization coverage and reverse recent declines (25), and whether it is feasible to deliver other high priority interventions for nutrition, disease control, family planning or illness management at the same service points. PNG does not yet have a standardized policy on preventive services in the **second year of life** however this time point will become increasingly important to provide booster doses of new vaccines, interventions for child nutrition and psychosocial development and support to families aiming to space children and improve sexual and reproductive health.

However, **optimal approaches to integrating health services are not well described**(26), and **international evidence on health service integration shows both positive and negative effects**(27), for example the additional burden placed on staff if they are expected to provide an expanded range

of services. This suggests that careful implementation research is needed to assess when and how more integrated care, and/or other improved service planning initiatives, are likely to be successful. The PNG National Department of Health recently introduced a new national strategy for preventive care in the first year of life, focused on improved immunization services, termed the 'Special Integrated Routine EPI Strengthening Program' **SIREP and SIREP Plus**(25). This proposes improved planning of outreach services based on population density, introduction of new vaccines, and integration of other nutrition and disease control interventions with the immunization platform. This was introduced across the country in 2015, it is timely to assess its feasibility, acceptability and field implementation in the context of these broader health services research questions.

### 1.3. What this research adds

The PNG government's **National Health and HIV Research Agenda**(28) **sees a clear role for health services and implementation research**. Our research aims to examine the delivery of health services in the first year after birth, from the postnatal period onwards; a linked future study under HMHB will examine pregnancy, childbirth and newborn care. By detailed study of services in ENB, this health services study aims to provide:

- **Better understanding of how health facilities interpret and implement national and provincial health policy**, including:
  - Current infrastructure, equipment, plans, staffing patterns, and service delivery patterns (including balance of fixed and outreach),
  - How closely organization and management of postnatal and infancy care services match current policy and plans (including SIREP);
  - Characterisation of the obstacles within health teams, and in their operating environment, that constrain proper implementation;
  - How health teams describe and value aspects of good quality and effective health care services.
- **Potential areas for improvement** in policy and practice, including:
  - Immediate needs for strengthening infrastructure, equipment and other health system elements;
  - Opportunities for greater integration of immunization and other services that match and extend national policy;
  - New options for organizing service delivery;
  - Potential for new incentives, partnerships or other responses to internal and external constraints on quality service provision.

The research will draw on **sound theory-based methods**, including realist evaluation(29) and innovative qualitative research techniques, which are more robust than many approaches commonly used in PNG. This will include careful definition of national policy expectations, comparison with international norms, and theory-development consultations. The consultations, involving the research team, advisors and senior health managers, will develop theories of how varying context, mechanisms or understanding of outcomes may explain difficulties in provision of good quality health care(30, 31). This application of internationally recognized research methods will give our data collection tools a higher likelihood of detecting valid causes of deficiencies in implementation, such as the 'know-do'

gap(32). The research aims to promote active participation by health managers and staff within ENB and provide health service research experience for emerging researchers in PNG.

This research sits within the overall Healthy Mothers Healthy Babies (HMHB) research program and complements other studies addressing related research gaps including:

- Quantification of the burden of diseases (nutritional and infectious) that complicate normal pregnancy and postnatal periods in PNG, the interactions between them and their relationship with pregnancy outcomes;
- Women's experiences of and preferences for health care;
- How adolescents and other young people can gain better access to health services, including sexual and reproductive health services.

The broader HMHB program addresses eight of the top 20 priorities in PNG's national health and HIV research Agenda(28). A wide range of collaborators enables engagement with important research and policy questions in PNG, and assists the development of national capacity in operational, implementation and health systems research.

#### **1.4. Research program location and context**

The HMHB research program is established in East New Britain Province (ENB), PNG. It covers three of the provinces four districts, Gazelle, Kokopo and Rabaul Districts, where the majority of the ENB population lives. ENB is located in the New Guinea Islands region and has a population of over 270,000. The province is typical of much of PNG in terms of both disease profile and geography. A high burden of malaria, TB and other respiratory infections, STIs and malnutrition exists, although prevalence of HIV infection is relatively low(33). The island of New Britain's mountainous interior has some communities accessible only by walking tracks, and coastal villages whose only access is by water. In contrast with most of PNG, there is relatively good road access for the most densely populated districts(34).

ENB province has two large hospitals (Nonga General Hospital and a Catholic run hospital in Vunapope), a rural hospital, several urban clinics, 12 health centers, 15 sub-centers and 85 aid posts. The provincial hospital, Nonga General Hospital, is managed by the National Department of Health (NDOH). The Provincial Health Office (PHO) and the district health administrations are responsible for all other health facilities in the province, including both government and church run services. Catholic and other church health services provide approximately one third of the rural health services in the province. The province was selected based on its burden of disease, population size and the location of the Burnet Institute's field office, as well as the previously established relationships with the provincial health authority.

ENB is reported as being one of six provinces whose expenditure on health is at the higher end of the national range, that is: closer to what is required(35), and is also seen as having relatively better provision of outreach services for family health(4). ENB has a higher coverage of facility-based delivery and antenatal care (ANC) than other provinces: supervised delivery coverage was 86% in 2013 and 70% in 2014, while ANC coverage was 81% in 2014. However ENB's reported coverage with infant vaccines is no better than the national average, at approximately 50% coverage for those vaccines administered between three and nine months of age (33).



The contrast between the relatively high uptake of pregnancy care compared with the lower coverage of immunization suggests that it is likely that innovation in the organization of health services could improve access to postnatal and infancy care. The fact that transport is relatively good, and that provincial government funding of health is higher than other provinces means that health service solutions discovered in ENB are likely to be more sophisticated, and possibly more informative to health policy, than those required for settings with a poorer operating environment. ENB solutions will need to go beyond the broad-brush remedies of improving transport and allocating more funds to health that are the necessary starting point for many other parts of PNG. To this is added a high level of interest in health systems research on the part of the ENB provincial health authorities. These factors make ENB an excellent setting for this health services research.

## 2. RESEARCH AIMS, OBJECTIVES AND OUTCOME MEASURES

### 2.1. Research aims and objectives

The research aims, objectives and outcome measures below relate to a specific set of health services: those for **provision of preventive and treatment care in the postnatal and infancy periods**, in selected health facilities and community outreach services in ENB. As noted above, the goal of this research is to provide a better understanding of how health facilities interpret and implement health policy, and identify potential areas for improvement.

The **research aims** to:

1. Evaluate current provision of postnatal and infancy health services compared to national and provincial policy, and to international good practice;
2. Identify opportunities to improve quality, efficiency and coverage of postnatal and infancy services for better health of post-partum mothers and their babies, and for stronger disease prevention and control.

In support of this, the specific **objectives** are to:

1. Document current infrastructure, equipment, staffing patterns, service plans, and service activity;
2. Assess adherence to national and provincial policies (including SIREP) for planning, providing and monitoring health care to families during the postnatal and infancy periods;
3. Assess the efficiency, coverage and quality of current service provision, including aspects of staff-client interactions;
4. Measure the degree to which postnatal and infancy services are integrated, including integration between immunization and other family health or disease prevention and control measures, and the integration objectives of SIREP;
5. Describe health staff explanations of implementation deficiencies and possible responses, including staff motivations and values, and external factors in the operating environment;
6. Describe expectations of post natal and infancy services from the user's perspective
7. Identify and describe opportunities for improvements in policy, governance and management, service planning, service delivery, and monitoring, generated by health managers, health care providers, and by comparisons with international practice.

These objectives **complement those of other HMHB studies**. **HMHB Study 1**, a longitudinal observation of a cohort of pregnant women through pregnancy, childbirth and infancy, provides mothers' perspectives on health services and how they might be improved. These data will be available to expand and validate the findings of this study. The **HMHB Pregnancy, Childbirth and Newborn Services Study** (HMHB Study 2b) will have some overlap with the current study in addressing the newborn period. To manage the overlap, this Study 2a will not examine immediate newborn care at childbirth (less than 1 hour of age), and, when assessing other aspects of newborn care (in the first 28 days of life), will only examine routine preventive care such as birth-dose

vaccination, but will not undertake detailed assessment of other aspects of quality of newborn care in health facilities.

## 2.2. Outcome measures

The research objectives above will be addressed through the following outcome measures. The subsequent section of this protocol describes the study methods to generate these measures.

1. Definition of current national and provincial policy expectations (including SIREP) for the range of services to be provided to families in the first year after childbirth, compared to international good practice for similar settings;
2. Quantification of current infrastructure, equipment and supplies for childbirth, postnatal and infancy care, benchmarked against defined policy expectations;
3. Description of postnatal and infancy care service planning and delivery in terms of
  - a. timing - frequency, and period after birth that services are offered,
  - b. locations (fixed and outreach) and range of services offered at each location,
  - c. staffing levels, consistency and turnover,
  - d. client costs, and
  - e. utilisation by families – numbers, coverage and timeliness;
4. Assessment, by interview and observation, of health care providers'
  - a. knowledge and practices in postnatal care, including routine preventive care for mothers, newborns and infants, and clinical treatment care for post-partum mothers and infants, benchmarked against international and national quality standards; and
  - b. management, governance, supervision, monitoring and reporting;
5. Current service integration (including SIREP objectives), including:
  - a. coordination (vertical integration) of information and care between postnatal and infancy services with antenatal and delivery services;
  - b. description of which non-immunization services are currently offered with routine immunization services, their relative coverage and uptake, and health worker opinions on benefits and risks of currently integrated services;
6. Collation of health managers' and health care providers' opinions on what constrains implementation, especially constraints that mean services do not match policy and standards, including:
  - a. external constraints in the operating environment,
  - b. infrastructure, equipment and commodities,
  - c. issues of governance, supervision, staff management,
  - d. motivations, incentives, health team functioning,
  - e. financial issues for providers and clients,
  - f. recent changes in policy and planning;
7. Identification, by health managers', providers' and clients' opinions, and researcher observation, of new options for governing, organizing and delivering postnatal and infancy services to improve access and/or quality, including:
  - a. governance, management and supervision of facilities, staff and supplies,

- b. the balance of fixed and outreach services,
  - c. management of fees and charges,
  - d. monetary and non-monetary incentives for providers and clients,
  - e. new opportunities for organizing service delivery or staff deployment
  - f. how specific policy initiatives, such as Free Primary Health Care and SIREP are working in practice;
8. Identification, by health managers', providers' and clients' opinions, and researcher observation, of the likely feasibility and acceptability of more integrated preventive services immediately after birth and in the first year of life, including family planning, to address a broader range of family health needs;
  9. Identification of likely future challenges to health services planning for family health.

### 3. METHODOLOGY

#### 3.1. Study Design Overview

This is a cross-sectional health services assessment, using mixed-methods, of a purposeful sample of postnatal health facilities and outreach services in ENB. The consultations, tools development and data collection will take place in two phases.

##### Phase 1:

An essential initial step is the definition of national policy expectations (cross-checked against international standards), and the use of robust evaluation methods to develop possible theories for implementation deficiencies that can focus and guide the data collection tools. This includes:

- Collation and analysis of:
  - national policies and standard treatment protocols relevant to postnatal and infancy care, and SIREP documentation;
  - cross-referenced against international recommendations from WHO, UNICEF and tools available from partners within the Partnership for Maternal, Newborn and Child Health (<http://www.who.int/pmnch/>) and the USAID Maternal and Child Survival Program.
- Consultation with national and provincial policy-makers to:
  - review documents above and define a concise description of what is expected of facilities and staff;
  - gather possible explanations for deficiencies in service delivery;
- Discussion among the investigator team, using approaches based on realist evaluation theory and application of new qualitative research methods, to adapt standard health service tools for audit, observation and interview so as to focus them on possible explanations for service delivery problems likely to be operating in ENB.

##### Phase 2:

- At a single time-point for each facility carry out:
- Audit of infrastructure, equipment and supplies
- Observation of health service administration, procedures, and patient flow
- Observation of health care provider practices
- Interview of health care providers on knowledge and attitudes regarding current and potential future postnatal and infancy health services
- Interview of health managers relevant to the service providers
- Review of the facilities' health service records over the past twelve months, including a review of the facility's intended population catchment
- Confirmatory group discussion with family health service clients<sup>1</sup>

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<sup>1</sup> Note that the HMHB Observational Cohort Study (Study 1) currently underway is also collecting detailed information on mothers' experiences of and preferences for health services – data that will also be available for correlation and validation of this study's findings during analysis.

The second phase of the study also adapts international frameworks for assessing health service quality and health service capacity derived from the sources noted under phase one. Facility visits will be supplemented by a review of medical supply logistics and management within the province.

### **3.2. Site selection and study population**

#### **Health facility site selection**

Study site selection aims to allow assessment of busier providers of services in the three districts of ENB (Gazelle, Kokopo and Rabaul) where the HMHB program is established. This study will include the five health facilities that were selected for the HMHB Observational Cohort Study (Study 1) in 2014, on the basis that they managed the highest numbers of deliveries in that year. These facilities comprise:

- Nonga General Hospital,
- St Mary's Hospital, Vunapope,
- Keravat Rural Hospital,
- Paparatava Health Centre, and
- Naparpar Health Centre.

A further sample of outreach services that are supported by these facilities will be selected in discussion with the ENB Provincial Health office, using purposeful sampling that aims to include:

- Two fixed site outpatient-only clinics, including two urban clinics,
- Four or five outreach clinics, based at either aid posts or in community locations – as provided by the facilities above; and
- If feasible, one site in Pomio District.

Sites will be purposefully selected to include relevant staff who have been covered by the nationally-sponsored training on SIREP that was conducted in 2015 or 2016

It is noted that all of the five main health facilities support a variety of outreach services for postnatal and infancy care, as directed by the Provincial Health Office, mainly for the provision of childhood vaccinations.

#### **Study population**

A total of approximately 20 health managers to be interviewed and will include

- all managers within the PHO (such as the Family Health Services coordinator) with responsibility for planning postnatal care, immunization, family planning, nutrition and related services;
- other health leaders within the province responsible for the provision of postnatal services, including those involved in training service providers;
- managers of relevant medical supply services;
- director of Catholic Health Services, and/or relevant delegate;
- two district health managers;

- one or two managers from each main facility, with responsibility for planning postnatal, immunization child health, or reproductive health services.

All health care providers responsible for postnatal or preventive care during infancy on the day of assessment at a facility will be invited to take part in interview and observation. Preventive care during infancy refers to any preventive service offered to families during the first twelve months after childbirth. These are primarily immunization services, but may also include services for child growth and nutrition, family planning and reproductive health, or disease control services offered at this point in the life course. These participants are expected to comprise between 15 and 20 health care providers, a mix primarily of NOs and CHWs, with some HEOs. Three or more medical officers, based at the two larger hospitals may also be eligible.

As discussed below under ethical considerations, operating procedures will assure confidentiality and study participants will not be individually identifiable.

### **3.3. Study procedures**

#### **Site visits and participant recruitment**

Consultation with provincial and district management will identify most appropriate days for assessment at each site; aiming for assessment when routine preventive infancy services are being actively offered, for example: an immunization outpatient clinic or mobile outreach clinic point. If specific days are designated for outpatient postnatal care, then facilities will be visited at that time as well.

All regular providers of postnatal or preventive services (as noted above) will be invited to participate, using consent procedures discussed under Ethical Considerations (below). If health managers identify a health care provider who is an important and regular provider of such services as being absent on the day of assessment, arrangements will be made to interview and observe that provider at a later time.

Each site visit will be conducted by a study research officer (locally hired) and one or more investigators, who will divide responsibility for site visit tasks between them.

Following introductions and consent, the research team will conduct:

- audit of infrastructure and review of facility records,
- observation of patient flow and handling,
- observation of between one and three client encounter/s, and
- interview of health care providers.

Health managers (as identified above) will be interviewed at a time and private location convenient to them.

#### **Avoidance of bias**

Several steps will be taken to minimize bias in health manager or health care provider responses. These include:

- emphasising confidentiality and the study procedures that aim to prevent health provider responses, or observed behaviour, from influencing professional relationships;
- ensuring that researcher-participant relationships are closely observed, and research tasks assigned so that data collection is not biased by these relationships, especially with respect to the role of investigator/s who hold positions in PNG health management;
- sequencing site visit tasks to avoid contamination, for example conducting observation prior to interview;
- some elements of data collection tools, such as the Most Significant Change questions in interviews are expected to prove more effective at eliciting valid responses, when coupled with good interview technique.

In addition, the mixed methods, and multiple data sources will be used to triangulate findings. All fixed facility sites are well-known to the HMHB team through the conduct of HMHB Study 1, and staff involved in that study will be consulted to help identify whether the visit of researchers through this Study 2a has generated un-characteristic levels of activity at study facilities. In further triangulation, wherever possible, outcome measures will be assessed by both qualitative and quantitative means, interview responses will be compared with observation and facility records review, and local records and responses will be compared with provincial health information sources.

It is acknowledged that these methods can only mitigate, not eliminate, potential sources of bias, and the considerations of likely observed bias and reflexivity noted above, will be made explicit in the documentation of data analysis and interpretation.

### **Data collection procedures and tools**

As noted above, phase one of the study uses document review and manager consultations to develop policy-relevant theory-focused tools for audit, observation and interviews. The Annexes to this protocol provide an outline of the expected scope these tools. The tools will draw on national policy and procedures, as well as international sources, including:

- WHO standards for immunization services, including a new Immunization Service Quality Checklist being pioneered by WHO HQ EPI section;
- United Nations Commission on Life-Saving Commodities for Women and Children
- WHO/UNICEF standards for postnatal care offered in facilities and in the community;
- WHO Consultation on Improving measurement of the quality of maternal, newborn and child care in health facilities;
- WHO/UNICEF Integrated Management of Childhood Illness standards for equipment, infrastructure and post-training health care worker practices;
- The Columbia University's Averting Maternal Death and Disability Program's checklist for health facility readiness to provide routine and emergency care;



- The USAID Maternal and Child Survival Program (formerly MCHIP) resources for capacity and quality care assessment in resource-constrained settings;
- New work on integration monitoring indicators developed by the Family Planning-Immunization Working Group sponsored by USAID.

**Audit of facility or outreach clinic point** will comprise a checklist of minimum infrastructure (such as clean water), equipment and supplies based on national standards and the above sources. As regards equipment, the checklist will distinguish between items that are functional or non-functional, and items that are in active use or unused. Supplies assessment will include review of stock-outs that can also be compared to national health information monthly reports on stock-outs.

**Observation of health service administration, procedures, and patient flow** will be against a standardized set of parameters that allow the research to categorize the way the site registers patients, sequences clinical tasks, manages waiting times, and provides for follow-up and tracking of clients, including provisions for comparing actual activity with that predicted from understanding of patient registers and/or the sites's catchment.

**Observation of health care provider practices** will address routine immunization services, routine preventive postnatal care services, client counseling, and opportunistic management of illness. Dependent on the site, they may also include nutrition assessment and counseling or family planning and reproductive health counseling. These will use a study-specific standardized checklist, drawn from the resources noted above and modified to fit national policy needs. They will also be modeled on rapid competency assessment tools used by members of the research team in the past that have proven feasible for assessment of staff in rural clinics in PNG.

**Interview of health care providers** will be conducted using a study-specific semi-structured interview format addressing the outcome measures listed above relating to knowledge and attitudes regarding current and potential future postnatal and infancy health services. These items will comprise a mix of quantitative closed responses and qualitative free text responses. They will explicitly address the constraints on proper implementation of services in line with policy and standards, encouraging reflection across the domains specified in the outcome measures above. Questions regarding observed changes in health services will also use a modified version of the Most Significant Change technique<sup>2</sup> to help assess the participant's underlying values relevant to health service delivery.

**Interview of health managers** relevant to the service providers will be conducted by the research team using a study-specific semi-structured interview format addressing the outcome measures listed above relating to recent, current and future health service planning. These items will comprise a mix of quantitative closed responses and qualitative free text responses. They will explicitly address the constraints on proper implementation of services in line with policy and

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<sup>2</sup> Most Significant Change is a qualitative research technique in which respondents are asked to describe significant changes, to rank changes to identify the most significant, and to describe why they view changes as significant and why some rank as more significant than others. These rationales for significance and ranking are the primary items of analysis, and can help reveal underlying values that are important to the respondent and which may play a role in future behavior change.

standards, encouraging reflection across the domains specified in the outcome measures above. Questions regarding observed changes in health services will also use a modified version of the Most Significant Change technique to help assess the participant's underlying values relevant to health service delivery.

**Review of the facilities' health service records** will examine postnatal and infancy service delivery over the past twelve months, a review of the facility's intended population catchment, and a researcher assessment of likely catchment coverage by the facility's various modes of service delivery.

Electronic tablets running Mobile Data Studio software (or similar electronic data capture software) will be used to administer interviews, enter extracted data from records review, and score checklists for audit and observation. These have proven feasible in HMHB Study One, and help improve inter-observer reliability while also eliminating the need for manual data entry. Because they can only handle very short forms of qualitative data entry, interviews will also be recorded and the research team will use complementary paper-based notebooks to allow capture of longer free-text responses. Whilst the electronic tablets have been robust, a paper version of interviews will also be prepared and available for use should there be unforeseen problems arising with the use of electronic tablets.

**Group discussion with family health service clients** will be conducted to help confirm and validate other conclusions. This discussion will focus on client preferences for organization of clinics and other aspects of service delivery, including current and potential integration of services. This will be a convenience sample of mothers and other care-givers accessing family health services on the day of assessment. The sampling and scope of these discussions recognize that the HMHB Observational Cohort (HMHB Study 1) is also currently collecting more detailed information on mothers' experiences of and preferences for health services; these data will be available to support qualitative analysis from this Study 2a.

### 3.4. Study timeline

Applications for ethical approval PNG and Australia are planned for March 2016. Assuming approval, the following timeline is planned:

- April-May 2016: refinement of detailed tools and procedures (consistent with ethics applications) based on initial consultations
- June 2016: research officer recruitment, training and field-testing
- July – September 2016: data collection, over six weeks
- September – December 2016: analysis will be conducted, coordinated with completion of data collection
- January – March 2017: circulation of drafts and report.

### 3.5. Data handling and analysis

#### Data management

Data handling and database management will take place in Burnet Institute facilities in Kokopo under the supervision of the HMHB Research Project Manager (also an investigator on this study) and office database manager. Quantitative data, and some short forms of qualitative data, will be managed through the Mobile Data Studio software database extensions and maintained in this and in Microsoft Excel formats. All data collected will be entered onto a computer and backed up into a centralised digital folder at the end of each day. All computer files will be password protected and only accessible to the research team. The centralised backup will be password protected, regularly backed up, and only accessible to the database manager and named study investigators. All paper-based data forms and recordings of interviews will be stored in a secure locked filing cabinet in the Kokopo Burnet Institute Office and accessible only to the HMHB Research Project Manager and database manager.

### **Data analysis**

Computerized data reports will be exported from the dedicated computer database (noted above) using Mobile Data Studio or Microsoft Excel in forms suitable for analysis in STATA (StataCorp, USA) or an equivalent statistical software package. A Burnet Institute statistician will provide expert advice on analysis procedures prior to database construction; this process will also inform the construction of final electronic data collection forms. The statistician will work with other study investigators on the use of Stata (or equivalent) to conduct descriptive analyses, as indicated in our research outcome measures. Addressing these measures will also entail application of appropriate univariate and multivariate regression models to investigate associations between quantitative measures. An *a priori* comparison framework based on international evidence and national/provincial policy will be established for use in identification of gaps in service delivery.

Qualitative data will be captured through questions with open fields in the data collection tools and recorded by interviewers in English or Tok Pisin, with an English version transcribed and entered into the computer database. Additional qualitative data will be gathered through focus group discussions of mothers and other care-givers at each clinic point assessed. These will provide triangulation of quantitative findings, as well as additional explanatory data likely to be helpful in hypothesis generation for future studies. Reliability of the qualitative data will be assured through careful collection, collation and a transparent replicable approach to analysis. Thematic coding will address previously identified themes that have guided the data collection tool construction, as well as an active search for new themes emerging from a consolidated review of the qualitative data. After themes are established (based on a preliminary review of a subset of records), all coding will be done by at least two researchers, aiming for independent review followed by consensus through discussion.

We will endeavor to be reflexive, in particular to document any interviewer or analyst bias that may be operating, with special attention to any that may arise from the interviewer-participant relationship. Themes will be derived through hand-coding, supported by qualitative analysis software (such as NVivo, QSR International).

**Access and retention of source documents**

At the end of the study copies of the final database and data for analysis will be maintained at the Burnet Institute and in secure data storage at PNG IMR. Electronic and hard copies of study records will be maintained for at least ten years (or other timing if designated by ethical requirements or following discussion with colleagues and/or stakeholders in PNG). At ten years after the conclusion of the study a decision will be made through consultation regarding extended data storage or destruction of data. This will use Burnet Institute archival resources. Only authorized research staff will have access to records, and strict privacy and confidentiality to participant records applies, including those provisions noted under Ethical Considerations (below).

#### **4. OTHER CONSIDERATIONS**

##### **4.1. Ethical considerations**

This is an observational study and is not trialing any intervention. The topics for interview or observation are consistent with those that would be a common subject of health management discussions. The main considerations are to minimize distress or discomfort when sensitive topics are discussed, and maintain confidentiality to ensure participants can provide information without fears that it may affect their professional relationships.

Ethical approval is sought through the Institutional Review Board of the PNG IMR, and through them the PNG national Medical Research Advisory Committee. Approval is also sought through the Alfred Health Human Ethics Committee in Melbourne, a requirement for the Burnet Institute.

##### **Informed consent**

The key issues being managed by the study's informed consent procedures are a) to ensure that consent is administered in a way that accounts for differences in position, education, and perceived obligations to health managers and other staff; and b) that participants understand the scope of what they are consenting to.

Informed written consent will be obtained from each participant prior to enrolment. A participant information brochure will be provided to accompany the consent process. Because participants are professional health care providers or managers, it is judged that English versions will suffice, however this will be reviewed during field testing. Consent will only be obtained after participant comprehension is checked with a question based on the information brochure. This brochure will be in plain language and will clearly state exactly what is required of the participant.

Information materials also provide for two avenues within PNG and Australia, as required by relevant ethics approval processes, through which concerns or complaints can be raised, one of which is independent of the project.

Local research staff will administer consent following screening for eligibility. Research staff will be explicitly distinct from standard health management structures and it will be made clear that refusal will not affect professional relationships. Participants will also be free to discontinue participation at any time.

##### **Interviews and confidentiality**

Interviewers will be trained in sensitive interview techniques and required to monitor for distress or discomfort. They will pause, and if necessary cease the interview if participants are distressed or wish to withdraw. If counseling is required, they will help arrange this within the capacity of the local health service. Participants will be made aware that others in the facility may be able to see that he/she has chosen to participate given the open nature of many health facilities, however interviews will be conducted in private away from others.

Participants will not be identified by name in interview and observation records. Care will be taken in analysis and reporting to avoid descriptions that could otherwise identify individuals; in

particular, if a facility has only one staff member with a particular level of training then a more generic term will be used for either the facility or the health worker level, depending on context. For example: rather than a report specifying a data source as 'HEO, Kerevat' (which could indicate a specific individual) the report may note 'health care provider, Kerevat' or 'HEO, fixed health facility', depending on the point being made. If a particularly sensitive topic is reported that is likely to affect professional relationships, additional care will be taken to avoid geographic or other markers that may inadvertently identify the participant.

Focus group discussions with groups of mothers or other care-givers at each clinic point will not be subject to audio or video recording, and names of individual participants will not be noted in note-taking or other data collection of these discussions, apart from the recording of names on consent forms.

The record of consenting participants, and their consent forms, will be kept in a locked filing cabinet in the HMHB offices in Kokopo, accessible only to the HMHB Research Project Manager and HMHB Database Manager. No other study documentation will record participants' names, and participants will be referred to only by an assigned Study Identification Number. For data analysis, only non-identifiable data collection forms and databases will be used.

### **Provincial, district and community engagement**

Appropriate permissions have already been awarded from the ENB Provincial Government, in their approval of the broader HMHB research program (which included the plans for this study). Close involvement, and consultation from the Provincial Health Advisor (PHA) has already been obtained to help assure compliance with local norms. Similar consultation will be pursued with the relevant district authorities and church health services. Following these permissions, each health facility will be approached and participation requested through their administrative channels.

On the day of assessment, verbal announcements and an information poster will inform community members and health service clients about the study. This information will emphasize the fact that the study is the work of independent researchers, that no criticisms of service quality are implied by the research, and the research will not hinder normal patient care. It is noted that this study is taking place in the same patient catchment areas as the first HMHB study, which has already undertaken significant community engagement including consultation workshops in the participating Wards, formal assent from Ward Councillors, and frequent community information sessions regarding broader HMHB research.

### **4.2. Governance and study management**

The first principal investigator, Dr Morgan, will have overall responsibility for the conduct of the study. The three principal investigators will jointly comprise the study management group and will be responsible for:

- Field testing and finalisation of data collection tools;
- Development of Standard Operating Procedures for data collection, data management, stakeholder communication and other study procedures;

- Training of research staff;
- Reporting to co-investigators and advisory groups;
- Monitoring and responding to adverse events; and
- Finalisation of analysis and reporting for dissemination (see below).

One co-investigator, Dr Peach, also works as the HMHB Research Project Manager based in the Burnet Institute office in Kokopo, East New Britain. As such, Dr Peach will have additional responsibility, alongside the Principal Investigators, in:

- Supporting training of research staff;
- Monitoring conduct in line with Standard Operating Procedures;
- Monitoring and responding to adverse events.

All **co-investigators** have had input into the study design, and will support finalization of data collection tools following field testing. This group will receive monthly updates on progress during the period of data collection and analysis. Individual co-investigators will contribute to analysis in specific areas of expertise and to the final report.

One principal investigator, Mr Larme, will lead the formation of a **local advisory panel**, comprising representatives from Nonga General Hospital, Catholic Health Services, Family Health Services in the Provincial Health Office, and other appropriate stakeholders. This group will receive quarterly updates on progress, and meet once at study commencement and once to support dissemination. This group will also facilitate reporting of progress and findings to the Provincial Government. The **national/international advisory panel** has been circulated with the proposed study protocol and will have opportunity to review finalized data collection tools. This group will receive quarterly updates on study progress, and meet once to support dissemination of findings at the national level in PNG.

In addition to dissemination procedures noted below, the final report will be made available, through the Burnet Institute's governance structures, to the private funding sources supporting the HMHB program. The private funding sources have no role in determining the nature of the data collection or interpretation of study findings, and all communications and resources are managed in compliance with Burnet Institute procedures, noting the institute's compliance as both a medical research institution and a development agency accredited with the Australian government.

#### **4.3. Reporting adverse events**

As this is an observational study we do not expect participants will be at significant risk of adverse consequences in the short or long term due to the study. However, possible clinical adverse events will be evaluated by the PI, and classified according to NIH Division of Microbiology and Infectious Diseases rating:

- Grade 1 (mild, self limited (<48 hours), no intervention required).
- Grade 2 (moderate: some limitation in activity, some assistance possibly required; no or minimal medical intervention required).
- Grade 3 (severe: marked limitation in activity; some assistance usually required; medical intervention required; hospitalization possible).

- Grade 4 (life-threatening: extreme limitation in activity; significant assistance required, significant medical intervention required; hospitalization probable).
- Grade 5 adverse event results in death.

**Compliance and protocol deviations**

The study procedures outlined in this protocol will be followed for the duration of the study, with adherence maintained by the investigators, one of whom is also the HMHB Research Project Manager, who has oversight of the HMHB office and staff in Kokopo. No deviations are permitted, without ethics committee review and approval. In the event of an unintended deviation, the deviation will be logged, and all PIs will be informed on the nature of the deviation. PIs will then determine appropriate action, which may include seeking a protocol amendment and/or notifying ethics authorities in PNG and Melbourne.

Any unforeseen event resulting from this research program will be referred to the Principal Investigators. After review, the PIs will report serious adverse events or breaches of protocol to the National/International or Local Advisory Panels, and to the PNG IMR Internal Review Board or PNG NDOH Medical Research Advisory Committee if indicated.

**Capacity development**

Significant research capacity development is built into the broader HMHB program, including: investment in local laboratory and biomedical research capacity in ENB, involvement of PNG researchers, health planners and clinicians wherever possible. In this study this is signaled in the range of investigators who will work alongside investigators from PNGIMR and Burnet Institute, gaining experience in the detailed design and implementation of a health service research activities with direct policy relevance.

This study may be suited to national staff members or postgraduate students undertaking research degrees. The study team will actively support opportunities for masters, honours or other higher degree students, and the Burnet Institute and PNG IMR will work together to identify sources of funding or other resources needed. Such involvement could build skills and experience in data analysis tasks, the interpretation of results, and the presentation and publication of research findings.

The local and national advisory boards also play a key role in guidance and dissemination (as noted below) and we expect that this will also build provincial and national capacity in the use of research to inform policy and practice.

This study will also recruit and train local research officers who will gain skills in quantitative and qualitative research methods as applied through the research cycle, including data collection and data management, as well as analysis and interpretation.

The study's institutional sponsors' involvement in development projects and other research, in ENB and nationally, also enables HMHB to link with other capacity development activities including



those building provincial capacity for disease control and improved quality of RMNCH care, and those building national capacity in the governance and direction of national research priorities.

#### **4.4. Dissemination of findings**

##### **Dissemination**

A provincial dissemination plan will be designed in conjunction with the PHA, and national, with NDOH. The aim is to provide analysis and reporting tailored to policy and practice at both levels. The strong interest of the Provincial Government in this, and other HMHB research activities, helps provide a conduit to local policy-makers. Facility managers will receive draft and final findings, including an opportunity to clarify at the draft stage.

The research methods and findings will have a primary audience at national levels in PNG, through dissemination at the annual PNG Medical Symposium and, especially for health system findings, through the annual National Health Conference; access to this latter forum to be mediated by the government staff named as investigators or advisors. The PNGIMR, Burnet Institute, NDOH, WHO and UPNG institutional connections to policy and plans of government agencies and international development partners will also enable sharing of interim and formal findings with policy-makers. It is planned to use tailored communication products, such as policy briefs, to help communicate the policy implications of study findings.

##### **Publication**

Study findings and analysis will be tested and refined through submission to international peer-review journals dealing with the provision of health services in the postnatal period and childhood, as well as the PNG Medical Journal. Copies of publications will be archived and made available at Burnet Institute and PNGIMR. Findings from the studies will also be presented at appropriate international and national conferences. No findings will be presented or published without the agreement of all principal and co-investigators involved. In particular, the investigators will actively seek to involve the PNG staff and students as co-authors in all publications, and as lead authors when possible.

#### **4.5. Other research outcomes**

It is anticipated this research will afford health staff the opportunity to contribute ideas to implementation arrangements for the practice of new policy. Provincial health authorities and facility managers will receive data and analysis helpful to improved postnatal and infancy service planning. Details of service arrangements may also be helpful to other research (including HMHB studies) and development activities in PNG. Two specific outcome areas are built into this study design:

##### **Focused quality improvement actions**

The study aims to highlight immediate opportunities for health system strengthening. These are focused on individual health facilities where rapid analysis highlights low-cost, feasible actions that

can be implemented quickly, including actions to improve the quality of care, organisation of services, staff practices, investigation of adverse outcomes, or community acceptability and access. Under the HMHB program, further funding is being sought so that, rather than simply recommending such changes, HMHB staff can continue working with facility staff to define the change they seek, develop an innovation plan, and test the innovation by measuring changes in health facility processes or outcomes. If funding is obtained, this process may commence in 2017 and extend for up to twelve months in any specific facility.

#### **Longer-term health system strengthening**

Medium and longer-term opportunities for stronger systems, or innovations worth testing, are drawn out from the Health Services Study's overall analysis. These findings will firstly be presented in forums within ENB, hosted by the provincial health office, and in PNG, targeting the 2017 national medical symposium and other national forums such as the annual health services conference. These will help make lessons learnt tightly applicable to PNG contexts. Findings will also be published in the international health systems literature.

By involving senior government and non-government health planners from the outset, longer-term implications of the findings will be used to examine potential system changes. These may include large-scale innovations in terms of new interventions or new ways to organise health care, that could be trialled in future health systems research in PNG.

#### **4.6. Budget statement**

Funds for this study are derived from private funding provided to the Burnet Institute for the collaborative Healthy Mothers Healthy Babies research program. These funds are managed by the Burnet Institute in compliance with accepted accounting procedures, noting that Burnet Institute is a fully accredited with the Australian government as a health development non-government organization; a process that includes regular scrutiny of the institute's financial management procedures. The budget provided will cover the costs of:

- Local research staff, travel to research sites, and research tools deployment;
- Inputs from international and national (PNG IMR, NDOH, UPNG) researchers for development of research tools, data collection oversight, analysis and documentation; and
- Dissemination of findings in provincial and national forums.

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## **ANNEX 1: OUTLINE OF DATA COLLECTION TOOLS**

As noted in the main body of the protocol, data collection tools will be refined and developed as the key output of phase one of the study, based on local consultations making use of realist evaluation theory and qualitative research techniques.

The tools provided here are in outline format to allow for ethical review. The outlines below provide a description of the scope of topics to be included; if the necessary scope extends beyond this, an ethics amendment will be sought. Copies of finalized tools that are the output of Phase 1 of the study will be provided to ethics committees for their records, prior to deployment.

Data collection tools will also be subject to formatting into electronic or paper-based data collection tools. It is expected that field-testing will require some change to sequencing, question wording, and listing of interviewer-identified closed responses.

### **Health manager and service provider interviews**

Phase one activities will generate tools that aim to assess knowledge and attitudes, including detection of underlying values, motivations and understanding of context, mechanisms of change and outcomes that are likely to determine future behavior. Questions regarding observed or proposed changes in health services will use a modified version of the Most Significant Change technique and other tools generated through phase one activities including realist evaluation and new qualitative methods. These will help assess the participant's underlying values relevant to health service delivery.

Scope of the interview tool will include:

1. Position, experience, and role (ensuring non-identifiable)
  - 1.1. Professional training, type and duration of services
  - 1.2. Current role in the health system
  - 1.3. Current and usual duties in relation to postnatal
  - 1.4. Gender, basic education and family situation
2. Understanding of national and provincial policy and constituents of quality care
  - 2.1. Required services at time points throughout first year after childbirth
  - 2.2. Service planning and monitoring ideals and sources of guidance
  - 2.3. Service delivery quality ideals and sources of guidance
  - 2.4. Levels and types of integration of various services
  - 2.5. Recent changes noted, nature and purposes
  - 2.6. Desired health service outcomes in current planning
3. Reports on current practices
  - 3.1. Service planning, supervision, management and monitoring
  - 3.2. Balance of outreach and fixed facility services
  - 3.3. Service delivery practices – single and multiple function, integrated services
  - 3.4. Utilisation by families, including timeliness and continuity
4. Opinions on constraints on coverage, utilisation or quality
  - 4.1. Contextual factors constraining service coverage, utilisation or quality
  - 4.2. Internal team, management or governance factors
  - 4.3. Factors in the enabling environment, supplies, supports and tools
  - 4.4. Financial factors for health staff or clients
  - 4.5. Constraints on integrated services, SIREP implications

- 4.6. Most important constraints and likely mechanisms of action for constraints
- 5. Review of health service and contextual changes and outcomes
  - 5.1. Recent changes in social, cultural, economic or physical context
  - 5.2. Recent changes in management, planning, monitoring, delivery or utilization, including specific review of SIREP
  - 5.3. Recent changes in intended or unintended health service outcomes
  - 5.4. Ranking of most significant changes or outcomes and reasons for ranking
- 6. Suggested improvements
  - 6.1. Potential enablers in context, health teams and management, enabling environment and support services
  - 6.2. Potential of different service planning, including integrated services and varying modes of outreach
    - 6.2.1. Specific note on family planning and immunization service integration
  - 6.3. Potential for stronger implementation of SIREP and other recent proposals
  - 6.4. Short-term improvements, intended outcomes and mechanisms of effect
  - 6.5. Longer-term improvements, intended outcomes and mechanisms of effect
    - 6.5.1. Includes emerging issues such as services through later phases of the life course

### **Clinic observation**

Observation of clinic function will examine both health provider practices and patient experience, flow and outcomes. Phase one activities will generate a study-specific standardized checklist, drawn from international and national policy resources noted in the protocol (Section 3.3) and modified to focus on national policy expectations. They will make use of lessons learned in rapid competency assessment tools used by members of the research team during the national Women's and Children's Health Project (1998-2004).

The scope of checklists for clinic observation will include:

- 1. Observation of health service administration, procedures, and patient flow, distinguished for postnatal care services, immunization clinics, and other family health clinics in the first year after childbirth
  - 1.1. Registration and tracking of clients, comparisons with expected catchment
  - 1.2. Sequence, timing (including wait time) as clients process through services
  - 1.3. Staff allocation for clinical and support tasks
  - 1.4. Preparation and service delivery timing and site
  - 1.5. Discharge and follow-up
  - 1.6. Disposals of waste and other equipment tasks
- 2. Observation of health care provider practices with abbreviated competency-oriented checklists tailored to postnatal care services, immunization clinics, and other family health clinics, including:
  - 2.1. Routine preventive postnatal care services and counseling,
  - 2.2. Routine immunization service,
  - 2.3. Nutrition assessment and counseling
  - 2.4. Disease prevention counselling and supplies, including insecticide-impregnated bed nets

- 2.5. Family planning and reproductive health counseling.
- 2.6. Responsive management of selected illness, such as suspected sepsis, pneumonia, diarrhoea, fever
- 2.7. Other preventive family clinic service defined in national policy expectations

#### **Audit and records review - facility or clinic outreach point**

This will document current infrastructure, equipment, staffing patterns, service plans, and service activity by walk-through and direct observation, and review of health facility service delivery records such as register books and tally sheets. No information identifying clients or staff will be collected. The final tool will be based on phase one study activities, including manager consultation and review of international standards (as noted in the main protocol, eg Section 3.3, p.19) and national policies. Scope of the facility audit will include:

1. Physical locations and buildings available for the delivery of antenatal, delivery, and routine postnatal services
  - 1.1. Bed numbers, rooms, privacy, materials
  - 1.2. Fitted and temporary services
  - 1.3. Facilities available to patients receiving these services including access to toilets, cooking, cleaning, other daily life services, waiting areas, companion areas
  - 1.4. Intended and actual patterns of use, including whether these locations are physically separate, overlapping or multi-use areas
  - 1.5. Transport access
2. Staffing for the delivery of the ANC, delivery and postnatal services
  - 2.1. Numbers and skill levels
  - 2.2. Availability and rostering
  - 2.3. Functional allocations
3. Service planning
  - 3.1. Methods for determining catchment, postnatal and through infancy
  - 3.2. Records of catchment, coverage and activity levels over previous 12 months
  - 3.3. Outreach planning, support and implementation over previous 12 months
4. Equipment available in each location, distinguished by status of repair and level of current or recent usage
  - 4.1. Support equipment including hand sanitisation, appropriate waste disposal, availability of appropriate safety equipment for health workers and other essential equipment
  - 4.2. Clinical equipment for management of routine and illness management during antenatal, obstetric, postnatal care, and infant clinic care.
  - 4.3. Essential medicines, including those reviewed in the 2013 medical supplies survey and others defined during phase one consultations
  - 4.4. Supply chain management and logistics strategies, routine and during interruptions
5. Essential clinical and support services
  - 5.1. Reliability of electrical and water supply and other utilities
  - 5.2. Availability and reliability of oxygen supply

**Group discussion with clients**

These group discussions will be focused on describing expectations of postnatal and infancy services from the user's perspective, as well as opinions on potential improvements. Other client perspectives will be available to the research team from analysis of HMHB Study 1, observational cohort study, that is following individual pregnant women from first antenatal care through to 12 months after childbirth. Phase one activities for this study 2a will apply innovative qualitative methods to generate a group discussion methodology to cover the following scope of topics:

1. Understanding and expectations of postnatal care
  - 1.1. Timing and range of services, including mother and newborn
  - 1.2. Rationale for care at this point
  - 1.3. Context and service organisation, constraints and enablers
    - 1.3.1. Mechanisms by which they act
  - 1.4. Expectations of outcomes for baby, mother, other family members
2. Understanding and expectations of postnatal care
  - 2.1. Timing and range of services for infant, mother, other family members
  - 2.2. Rationale for care at this point
  - 2.3. Context and service organisation, constraints and enablers
    - 2.3.1. Mechanisms by which they act
  - 2.4. Integration of various types of care, including family planning, immunization and other services
  - 2.5. Expectations of outcomes for baby, mother, other family members
3. Potential for improvement
  - 3.1. Recent or potential changes in services or context
    - 3.1.1. Which changes are most significant, and why
  - 3.2. Feasibility and acceptability of more integrated services
  - 3.3. Specific attention to family planning and immunization Mechanisms by which changes have or could produce effect
  - 3.4. New outcomes expected from changes



**ANNEX 2: PARTICIPANT INFORMATION AND CONSENT FORM – Health Workers****Participant Information**

*This information sheet is provided to you by a researcher working for the Healthy Mothers Healthy Babies research program in East New Britain. Please read the study information below and tell the research team member what you understand this research to be doing. Please ask the researcher any questions about the study that you would like answered.*

**What this study is about**

This research study is called the **Health Services for Postnatal and Infancy Care study (HMHB Study 2a)**. It is part of the larger Healthy Mothers Healthy Babies research program based in East New Britain province. This HMHB Study 2a is researching the health care services being provided for mothers and babies from straight after childbirth (that is: from one hour after birth) until 12 months after birth. Other studies in the Healthy Mothers Healthy Babies program are looking at other aspects of pregnancy and childbirth.

**What this study examines**

This study will research

- What buildings, equipment, supplies, transport and staff are now in use to provide care following childbirth and throughout infancy, in health facilities and at outreach clinics in the community;
- What health workers and health managers know, think and do in relation to providing postnatal and infancy services;
- What health workers think about the way health services are organized and managed, including some questions about recent changes introduced by the government, and about other changes that have been proposed in other countries similar to PNG; and
- Some ideas for improving services, both immediately and after some time.

**Where and when the study is being conducted**

This research team will visit the five busiest health facilities providing postnatal care in ENB and a selected group of smaller clinics and outreach points that are served by these facilities. They will **interview** selected health staff, examine clinic **records**, and **observe** the clinic's operations and patient care. Later, the research team will compare what they find with what is expected by national and provincial policy and guidelines. This research is planned to take place in the middle of 2016, with the final report prepared by the end of 2016.

**Who is doing the research**

The study will be conducted by the Burnet Institute, the PNG Institute of Medical Research and the East New Britain Provincial Health Office. Additional advice is provided by the University of PNG, the National Department of Health (NDOH), the PNG office of the World Health Organization, the University of Melbourne and other Australian research institutions with experience in PNG. The study is funded from private donations provided to the Healthy Mothers Healthy Babies research program. Permission for the study is provided by the Medical Research Advisory Committee of the PNG National Department of Health. Other checks on the study procedures have been done by

independent committees of the PNG Institute of Medical Research and the Alfred Office of Ethics & Research Governance in Melbourne, Australia.

**What we are asking you to do**

You are invited to participate in this research by being interviewed, because we feel your experiences will be important to complete this research.

During the interview we will ask questions about

- your experiences and opinions related to providing care for mothers, babies and other family members,
- things that make it more difficult or easier to provide good quality care, and
- your ideas about changes in the way health services could be organised.

**We will keep your details private and confidential**

No study documents will record your name, apart from the consent form. Other documents will only record a Study Identification Number. Only authorized members of the research team will have access to study documents. We will make sure that any reports produced by this study will not identify you as an individual. The information you provide is not part of any assessment of your individual work, and your name is not provided to your manager.

If you agree to be interviewed, other people might be able to see that you have agreed to take part. But we will make sure that we do the interview some private where we can talk freely without being overheard.

**We will try to avoid causing you discomfort**

There is some risk that talking about these matters might make you embarrassed or uncomfortable. You are free to stop taking part in the interview at any time. If you are severely upset, the researcher will help you talk to an appropriate person.

If you have questions regarding study participants' rights, please contact:

- Secretary of the Ethics Review Committee, PNG Institute of Medical Research  
Phone: +675-531 4200, Fax: +675-532 1998, Email: [info@pngimr.org.pg](mailto:info@pngimr.org.pg),

OR

- The Alfred Office of Ethics & Research Governance.  
Attention: Ms Emily Bingle, Research Governance Officer  
Phone: +61 3 9076 3619, Email: [research@alfred.org.au](mailto:research@alfred.org.au)  
Note: Quote the following Alfred Health project number:

*If you agree to take part, please tell the research team member what you understand this research to be doing. Please ask the researcher any questions about the study that you would like answered.*

**Consent form for health managers and health care providers****Health Services for Postnatal and Infancy Care (HMHB Study 2a)**

|                                  |                                                                                                                                                               |
|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Principal Investigators:</i>  | Dr. Christopher Morgan, Burnet Institute<br>Mr Nicholas Larme, East New Britain Provincial Health Office<br>Ms Olga Saweri, PNG Institute of Medical Research |
| <i>Researcher administering:</i> |                                                                                                                                                               |

**Participant Declaration**

I have read and understand the Participant Information Sheet. I understand the aim of this study is to assess the provision of health care services for mothers, babies and other family members following childbirth. I understand that I will be interviewed regarding my experiences and opinions on these topics. I acknowledge that:

- risks of participating in this research have been explained to my satisfaction;
- taking part in this study is voluntary and I am aware that I can stop taking part in it at any time without explanation or prejudice;
- any information I give will be kept strictly confidential and my name will not be used to identify me in this study.

|                     |              |                  |
|---------------------|--------------|------------------|
|                     | <i>Name:</i> | <i>Signature</i> |
| <i>Participant:</i> |              |                  |

**Additional consent if officer-in-charge**

I am the senior health staff with responsibility for services on this day. In addition to the above consent, I also agree that the research team can examine clinic records and observe clinic operations.

|                     |              |                  |
|---------------------|--------------|------------------|
|                     | <i>Name:</i> | <i>Signature</i> |
| <i>Participant:</i> |              |                  |

**Witness and date**

|                 |  |  |
|-----------------|--|--|
| <i>Witness:</i> |  |  |
| <i>Date:</i>    |  |  |

**ANNEX 3: PARTICIPANT INFORMATION AND CONSENT FORMS – Focus Group Discussions**

*Presented in dual language format to accommodate clients who prefer to read in English. This version is provided for ethical review and will be re-formatted prior to use.*

**Tok Klia Pepa bilong bung toktok (Focus Group Discussion)**

|                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <u>Study Title: Health Services for Postnatal and Infancy Care study (HMHB Study 2a)</u>                                                                                                                                                                                                                                                          | <u>Wok Painimaut Het Tok: Helt sevises blong ol niubon bebi, na beibi klinik na ol femili (HMHB Study 2a)</u>                                                                                                                                                                                                                                           |
| <u>Principal Investigators</u><br>Dr. Christopher Morgan, Burnet Institute<br>Mr Nicholas Larme, East New Britain Provincial Health Office<br>Ms Olga Saweri, PNG Institute of Medical Research                                                                                                                                                   | <u>Wok Painimaut Tim (Het Lain):</u><br>Dr. Christopher Morgan, Burnet Institute<br>Mr Nicholas Larme, East New Britain Provincial Health Office<br>Ms Olga Saweri, PNG Institute of Medical Research                                                                                                                                                   |
| Please read this information sheet (or ask a friend to read it to you) before you decide to take part. Please ask if there is anything that is not clear.                                                                                                                                                                                         | Plis ridim ol tok klia pepa (o askim poroman long ridim long yu) pastaim yu tingting long wok bung. Plis askim sapos igat samting ino klia.                                                                                                                                                                                                             |
| <u>Why are we doing this research?</u><br><br>This HMHB Study 2a is researching the health care services being provided for mothers and babies from straight after childbirth until 12 months after birth. We want to understand what aspects are good, and what aspects not so good right now, and how services could be improved in the future. | <u>Bilong wanem na mipela wok painim aut?</u><br>Dispela HMHB studi 2a imekim wok painimaut long sait blong helt sevises na ol halivim, mama na bebi sa kisim long 12pla mun behain long em karim.<br>Mipela laik save long wanem ol sumting igutpela na wanem ol sumting inor gutpela long disla taim na hau long improvim ol sevises lon behain taim. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><u>What does this study involve?</u></p> <p>This study will use different types of interviews. We want to identify any problems women face in accessing healthcare. Group discussions will allow a group of women to tell stories about things they have seen and experienced. We will also do other interviews with health staff and observe how the clinic functions.</p>                                                                                                                                                                                                                                                                                                                          | <p><u>Dispela wok painim aut bai kisim wonem?</u></p> <p>Dispela wok painim aut bai kamapim kainkain askim. Mipela laik painim hevi ol meri I pilim long kisim helt sevis na sekup bilong femili. Bung toktok bai larim ol laen meri long tokim stori long ol samting ol ibin lukim na pilim. Toktok wantaim wanwan wantaim sampela ol meri bai larim ol meri long tokim stori bilong ol liklik mo. Mipela ba mekim ol sampela askim wantem ol helt wokman na ba mipla lukluk raun long hau klinik iwok.</p>                                                                                                                                                                                                                                                                                                                                                        |
| <p><u>What will happen to me if I agree to take part?</u></p> <p>If you agree to take part you will join a group of 6-8 women and will be asked to tell stories about problems you have seen or experienced accessing health services. We will also ask for ideas about how health services could be improved. Study staff will talk to you about the study and explain what taking part would mean for you. After you have had all your questions answered, you will be asked to sign or put your thumbprint on a <b>Consent Form</b>, to confirm that you agree to take part. If you cannot read then we recommend that you have a witness present for the discussion and to see your thumbprint.</p> | <p><u>Wanem samting bai kamap sapos mi wanbel long joinim?</u></p> <p>Sapos yu wanbel long join, yu bai stap insait long dispela grup wer ba igat 6-8pela meri na ba mipela askim yu long stori long ol hevi yu sa lukim na yu sa pilim long sait bilong kisim halivim long ol helt sevises. Mipela ba askim tu sapos yu gat sampela gutpela tingting long hau long improvim helt sevises</p> <p>Ol wok lain bilong wok painimaut bai toktok long yu long dispela wok painimaut na tok klia long stap bilong yu insait bai minim wanem long yu. Bihain long ol I bekim Olgeta askim bilong yu, ol bai askim yu long putim han mak o pinga mak long wanpela <b>Tok Orait Pepa</b>, long soim olsem yu wanbel long joinim. Sapos yu I nonap long rid orait Mipela laik olsem yu mas gat wanpela witnes I stap long taim bilong toktok na lukim han mak bilong yu.</p> |
| <p><u>Do I have to join the study?</u></p> <p>No. It is completely up to you to decide if you want to take part in the study or if you would rather not. <b><u>You will be free to withdraw at any time.</u></b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p><u>Inap long mi joinim dispela wok painimaut?</u></p> <p>Nogat. Em stap long yu yet long tingting sapos yu laik long joinim dispela wok painimaut o sapos yu no laikim. Sapos ol I kisim yu tasol yu tingting long ol bai inonap long askim <b><u>yu long laik bilong yu yet em yu ken lusim long wanem taim yu laikim.</u></b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <p><u>What are the benefits of being involved in the study?</u></p> <p>Your involvement in this study will provide valuable information for researchers, health staff and policy</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p><u>Wanem em ol gutpela bilong joinim dispela wok painimaut?</u></p> <p>Stap bilong yu insait long dispela wok painimaut bai givim planti gutpela samting long ol wok lain bilong wok painimaut, wok lain bilong helt na ol</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>makers about the types of problems women are experiencing in accessing health services. This work will help towards developing provincial and national policy on maternal health in PNG.</p>                                                                                                                                                                                                                                                                                                                                    | <p>lain bilong mekim kamap lo long ol dispela kain hevi ol meri na bilong wanem na ol ino save go long helt sentas. Dispela wok bai halivim long mekim kamap gut provincial na national polisi long gutpela helt long PNG.</p>                                                                                                                                                                                                                                                                                                                                                            |
| <p><b><u>Are there any risks involved in joining the study?</u></b></p> <p>There are no risks from taking part in the study. All the interviewers are trained staff with experience in asking questions and helping you to tell your important stories.</p> <p>If you feel distressed or uncomfortable, our staff will help you talk to someone about that.</p>                                                                                                                                                                    | <p><b><u>Igat sampela hevi long joinim dispela wok painimaut?</u></b></p> <p>Inogat wanpela hevi I stap long stap insait long dispela wok painimaut. Olgeta wok lain bilong askim em ol trein lain wantaim igat save long askim ol askim na halivim yu long stori long ol bikpela stori bilong yu.</p> <p>If yu no pilim gut tumas long toktok o bekim toktok, ol wok manmeri bilong mipela iken halpim long kisim narapela meri long yu toktok wantem</p>                                                                                                                                |
| <p><b><u>Will my details and the information I give you be kept secret?</u></b></p> <p>Yes. Your name and village will only be available to the study coordinator and the interviewer. These will be kept safely at our office. When you tell stories and ask questions we will not write your name down, just a study identification number unique to you or the group you are interviewed with.</p> <p>Neither your name or your village will not be identified in the write up of the results in any report or publication.</p> | <p><b><u>Bai ol dispela samting na ol toktok mi givim yu bai i stap hait?</u></b></p> <p>Yes. Neim bilong yu na ples bilong yu tasol bai I stap wantaim kodineita bilong wok painimaut na lain bilong askim. Dispela em bai ol I haitim long opis bilong mipela. Taim yu stori na askim ol askim bai mipela inonap long raitim igo daun, em wanpela wok painimaut namba tasol em I narapela kain tasol long yu o grup ol I askim yupela wantaim.</p> <p>Inonap neim bilong yu o ples bilong yu bai mekim kamap ples klia long taim bilong raitim ol risalts long wanpela ripot o buk.</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b><u>How will I find out about the results of this study?</u></b></p> <p>After the study has been completed the results will be analysed. This can take between 3-6 months. A plain language summary report in <i>tok pisin</i> and English will be produced and made available at the health facilities and to key stakeholders, including policy makers and health service providers. The results of the study will also be written up and submitted for review by a medical journal. Results may also be presented at scientific conferences.</p>                                                                                                                                                                                                                                                                                                                                                                                                         | <p><b><u>Hau na bai mi painimaut long risalt bilong dispela wok painimaut?</u></b></p> <p>Bihain long dispela wok painimaut em I pinis ol risalts bai ol I skelim gut. Dispela em inap long kisim namel long 3-6pela mun. Wampela klia tok pepa long <i>Tok Pisin</i> na English bai ol I kamapim na mekim I stap long helt sentas na long ol bikpela lain, wantaim ol lain bilong kamapim lo na lain bilong givim helt wok. Risalts bilong dispela wok painimaut bai tu ol I raitim na givim igo bilong lukim bilong wampela medikol buk. Ol risalts bai tu ol I soim long bung bilong ol saintist.</p>                                                                                                                                                                                                                                                                                                                                                                                       |
| <p><b><u>Who has approved this study?</u></b></p> <p>This study has been approved by the PNG IMR Institutional Review Board and the Medical Research Advisory Committee, PNG and Alfred Health in Melbourne.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p><b><u>Husait I tok orait long dispela wok painimaut?</u></b></p> <p>Dispela wok painimaut em ol PNG IMR Institutional Review Board na Medical Research Advisory Committee, PNG, na tu Alfred Health long Melbourne.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <p><b><u>Who can I speak to if I have a problem?</u></b></p> <p>If you would like any more information about this study please contact:</p> <ul style="list-style-type: none"> <li>• Dr Liz Peach, Burnet Institute Kokopo, 90/1 Takubar Industrial Centre, ENB.</li> <li>• 982 8610, 982 9781, 982 5059</li> <li>• Mobile: 7289 2558</li> </ul> <p>If you would like to speak to someone not directly involved you may contact:</p> <ul style="list-style-type: none"> <li>• Secretary of the Ethics Review Committee, PNG Institute of Medical Research Phone: +675-531 4200, Fax: +675-532 1998, Email: <a href="mailto:info@pngimr.org.pg">info@pngimr.org.pg</a>,</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• The Alfred Office of Ethics &amp; Research Governance. Attention: Ms Emily Bingle, Research Governance Officer Phone: +61 3 9076 3619, Email: <a href="mailto:research@alfred.org.au">research@alfred.org.au</a></li> </ul> | <p><b><u>Bai mi toktok long husait sapos mi gat hevi?</u></b></p> <p>Sapos yu laikim sampela moa toktok long dispela wok painimaut plis ringim:</p> <ul style="list-style-type: none"> <li>• Dr Liz Peach, Burnet Institute Kokopo, 90/1 Takubar Industrial Centre, ENB.</li> <li>• 982 8610, 982 9781, 982 5059</li> <li>• Mobile: 7289 2558</li> </ul> <p>Sapos yu laik toktok long wampela husait ino stap insait long dispela wok painimaut yu ken ringim:</p> <ul style="list-style-type: none"> <li>• Secretary of the Ethics Review Committee, PNG Institute of Medical Research Phone: +675-531 4200, Fax: +675-532 1998, Email: <a href="mailto:info@pngimr.org.pg">info@pngimr.org.pg</a>,</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• The Alfred Office of Ethics &amp; Research Governance. Attention: Ms Emily Bingle, Research Governance Officer Phone: +61 3 9076 3619, Email: <a href="mailto:research@alfred.org.au">research@alfred.org.au</a></li> </ul> |

## Informed Consent Form

## Tok Orait Pepa

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b><u>Study Title: Health Services for Postnatal and Infancy Care study (HMHB Study 2a)</u></b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b><u>Wok Painimaut Het Tok: : Helt sevises blong ol niubon bebi, na beibi klinik na ol femili (HMHB Study 2a)</u></b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b><u>Principal Investigators</u></b><br>Dr. Christopher Morgan, Burnet Institute<br>Mr Nicholas Larme, East New Britain Provincial Health Office<br>Ms Olga Saweri, PNG Institute of Medical Research                                                                                                                                                                                                                                                                                                                                                                                                                  | <b><u>Wok Painimaut Tim (Het Lain):</u></b><br>Dr. Christopher Morgan, Burnet Institute<br>Mr Nicholas Larme, East New Britain Provincial Health Office<br>Ms Olga Saweri, PNG Institute of Medical Research                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Name of researcher administering:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Please confirm that you agree to participate in the study by signing below. Thank you for your time.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Plis soim olsem yu wanbel long stap insait long dispela wok painimaut na putim han mak aninit. Tenk yu long taim bilong yu.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| I,<br>_____<br>(please write name here) have read the participant information sheet, or had the information sheet read to me, and I agree to take part in the study. I hereby confirm that:                                                                                                                                                                                                                                                                                                                                                                                                                             | Mi,<br>_____<br>(plis raitim neim long hia) bin ridim dispela tok klia pepa bilong joinim, o ol bin ridim tok klia pepa long mi, na mi wanbel long stap insait long dispela wok painimaut. Mi long hia soim olsem:                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 1. I have been given an opportunity to ask questions about the study and my participation in it.<br>2. The study procedures have been explained to me. I have been told that the answers I give will be recorded and the entered into a computer.<br>3. I understand that all information and experiences shared with the interviewer will be kept <u>strictly confidential</u> and will be stored securely.<br>4. I understand that my privacy will be maintained at all times and I will not be identifiable in any report about this study.<br>5. I understand that I am free to withdraw from the study at any time | 1. I I bin givim mi wanpela sans long askim ol askim long dispela wok painimaut na stap bilong mi insait.<br>2. ei bilong dispela wok painimaut em ol I bin tok klia long mi. ol I bin tokim mi olsem ol ansa mi givim em ol bai rekodim na putim I go insait long kompiuta<br>3. i save olsem olgeta toktok na ekspiriens mi serim wantaim ol lain bilong askim em bai I <u>stap hait</u> na bai ol I haitim gut.<br>4. i save olsem mi bai hait olgeta taim na bai ol ino nap long putim mi ples klia long wanpela ripot long dispela wok painimaut.<br>5. i save olsem mi fri long lusim dispela wok painimaut long wanem taim mi laikim. |



**Signature/Thumbprint of Participant****Han mak/Pinga mak bilong Lain Joinim**

|                                                       |       |              |       |
|-------------------------------------------------------|-------|--------------|-------|
| Signature or<br>thumb-print<br>Han mak o<br>pinga mak | ..... | Date<br>Deit | ..... |
|-------------------------------------------------------|-------|--------------|-------|

**Signature of witness (if volunteer is unable to read or write)****Han mak bilong witness (sapos manmeri ino nap long rid o rait))**

I, \_\_\_\_\_ (please write name) hereby confirm that the person named above has acquired a full understanding of the research study and has freely consented to participating in the study.

Mi, \_\_\_\_\_ (plis raitim neim long hia) long his tok stret olsem dispela manmeri neim bilong em I stap antap I kisim pinis olgeta save bilong dispela wok painimaut na I tok orait long stap insait long dispela wok painimaut.

|                      |       |              |       |
|----------------------|-------|--------------|-------|
| Signature<br>Han mak | ..... | Date<br>Deit | ..... |
|----------------------|-------|--------------|-------|

**Signature of interview study staff taking consent****Han mak bilong wok lain kisim dispela tok orait pepa**

I, \_\_\_\_\_ (please write name) hereby confirm that the person named above has acquired a full understanding of the research study and has freely consented to participating in the study.

Mi, \_\_\_\_\_ (plis raitim neim long hia) long his tok stret olsem dispela manmeri neim bilong em I stap antap I kisim pinis olgeta save bilong dispela wok painimaut na I tok orait long stap insait long dispela wok painimaut.

|                      |       |              |       |
|----------------------|-------|--------------|-------|
| Signature<br>Han mak | ..... | Date<br>Deit | ..... |
|----------------------|-------|--------------|-------|

### 10.1.6 Health Services Study – ethical approvals



Government of Papua New Guinea  
Medical Research Advisory Committee

National Department of Health

PO Box 807  
WAIGANI 131, NCD  
Papua New Guinea

Phone: + (675) 301 3685  
Fax: + (675) 323 9670  
Email: fhombhanje@dwu.ac.pg

DATE: 27/07/2016

Dr Christopher Morgan  
Burnet Institute  
Kokopo, ENB  
Papua New Guinea

Dear Dr Christopher Morgan,

**Subject: MRAC Decision on Proposal Reviewed**

The Medical Research Advisory Committee (MRAC) of Papua New Guinea has deliberated on your research proposal "Health Services for Postnatal and Infancy Care: Healthy Mothers Healthy Babies Study 2a".

MRAC is satisfied that you have addressed the issues it raised therefore the proposal has been given executive approval and assigned **MRAC No. 16.22**.

The MRAC would like to thank you for your submission and looks forward to the successful conducting of your study.

Investigators are reminded of approved research to be conducted according to the MRAC guidelines at all times and the importance of keeping relevant authorities including MRAC informed on the progress and outcomes of their study.

Best Wishes,

Professor Francis Hombhanje  
Chairman - MRAC



### ETHICS COMMITTEE CERTIFICATE OF APPROVAL

*This is to certify that*

**Project No:** 333/16

**Project Title:** Health Services for Postnatal and Infancy Care: Healthy Mothers Healthy Babies, Study 2a

**Principal Researcher:** Dr Christopher Morgan

**Protocol Version dated:** 1-Jun-2016

**Participant Information & Consent Form (Health Workers) Version dated:** 11-Mar-2016

**Participant Information & Consent Form (Focus Group Discussion-Clients) Version dated:** 1-Jun-2016

*was considered by the Ethics Committee on 28-Jul-2016, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on 8-Aug-2016*

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

**The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of**

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

**Additionally, the Principal Researcher is required to submit**

- A Progress Report on the anniversary of approval and on completion of the project (*forms to be provided*);

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).

#### **SPECIAL CONDITION**

Approval is subject to approval by the Papua New Guinea National Medical Research Advisory Committee. Confirmation of approval is to be provided once available. (Special condition satisfied 9-Aug-2016)

**SIGNED:**

**Professor John J. McNeil**  
Chair, Ethics Committee

*Please quote project number and title in all correspondence*

## 10.2 **Supplementary material for Chapter Five**

### 10.2.1 *Included studies, abstracts and data extraction table*

| Study code | Author (first) | Publication date | Full citation                                                                                                                                                                                                                                                                                                         | Study design category | Study design detail, including comparator group (<50 words)                                                                                                                                                                                                                                                                                                                      |
|------------|----------------|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| UDDI11     | Uddin          | 2011             | Uddin MJ, Saha NC, Islam Z, Khan IA, Shamsuzzaman, Quaiyum MA, et al. Improving low coverage of child immunization in rural hard-to-reach areas of Bangladesh: Findings from a project using multiple interventions. <i>Vaccine</i> . 2012;30(2):168-79.                                                              | CBA                   | Mixed methods CBA. Baseline and endline surveys, with four randomly selected sites from purposefully selected geographical areas, two from hills, two from low-lying. One site from each ecology received a screening checklist (for MOI) intervention, the other site received modified EPI schedules and community support groups. Surveys included quant, interviews and FGDs |
| GOOD13     | Goodson        | 2013             | Goodson JL, Finkbeiner T, Davis NL, Lyimo D, Rwebembera A, Swartzendruber AL, et al. Evaluation of using routine infant immunization visits to identify and follow-up HIV-exposed infants and their mothers in Tanzania. <i>Journal of acquired immune deficiency syndromes (1999)</i> . 2013;63(1):e9-e15.           | CBA                   | Before and after data collection in study sites, with comparison sites from same districts. Intervention trained staff to identify HIV-exposed infants, counselling, starting cotrim and referring if needed. Additional qualitative data collection. Qual also in Wallace 2014                                                                                                  |
| WALL14     | Wallace        | 2014             | Wallace A, Kimambo S, Dafrossa L, Rusibamayila N, Rwebembera A, Songoro J, et al. Qualitative assessment of the integration of HIV services with infant routine immunization visits in Tanzania. <i>Journal of Acquired Immune Deficiency Syndromes</i> . 2014;66(1):e8-e14.                                          | CBA                   | Interviews with 64 convenience sampled mothers in a CBA study of 8 facilities implementing integrated services. Also Goodson 2013                                                                                                                                                                                                                                                |
| DUBE12     | Dube           | 2012             | Dube Q, Dow A, Chirambo C, Lebov J, Tenthani L, Moore M, et al. Implementing early infant diagnosis of HIV infection at the primary care level: experiences and challenges in Malawi. <i>Bulletin of the World Health Organization</i> . 2012;90(9):699-704.                                                          | NC                    | All HIV+ mothers attending two facilities were offered EID at six weeks.                                                                                                                                                                                                                                                                                                         |
| TEJI11     | Tejiokem       | 2011             | Tejiokem MC, Faye A, Penda IC, Guemkam G, Ateba Ndongo F, Chewa G, et al. Feasibility of early infant diagnosis of HIV in resource-limited settings: the ANRS 12140-PEDIACAM study in Cameroon. <i>Plos One</i> . 2011;6(7):e21840-e.                                                                                 | NC                    | Prospective cohort, focused on EID and early HAART                                                                                                                                                                                                                                                                                                                               |
| MCCO12     | McCollum       | 2012             | McCollum ED, Johnson DC, Chasela CS, Siwande LD, Kazembe PN, Olson D, et al. Superior uptake and outcomes of early infant diagnosis of HIV services at an immunization clinic versus an "under-five" general pediatric clinic in Malawi. <i>Journal of Acquired Immune Deficiency Syndromes</i> . 2012;60(4):e107-e10 | CBA                   | Two clinics in different facilities, one immunization, the other clinical U5 clinic - well matched, but with PITC introduced to the immunization clinic. Prospective observational study of both cohorts. Note not CBA because only two sites                                                                                                                                    |
| ONGE12     | Ong'ech        | 2012             | Ong'ech JO, Hoffman HJ, Kose J, Audo M, Matu L, Savosnick P, et al. Provision of services and care for HIV-exposed infants: A comparison of maternal and child health clinic and HIV comprehensive care clinic models. <i>Journal of Acquired Immune Deficiency Syndromes</i> . 2012;61(1):83-9.                      | CBA                   | Observational prospective cohort study enrolled HIV-exposed infants (HEI) at 6–8 weeks of age in 2 purposively selected hospitals with similar characteristics but different models of service delivery. In the CCC model, HEI received immunization and growth monitoring in MCH but                                                                                            |

| Study code | Author (first)         | Publication date | Full citation                                                                                                                                                                                                                                                                                                                                                        | Study design category | Study design detail, including comparator group (<50 words)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------|------------------------|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                        |                  |                                                                                                                                                                                                                                                                                                                                                                      |                       | cotrimoxazole prophylaxis and infant HIV testing in the dedicated HIV CCC service. In the MCH model, all services were provided in the MCH clinic.                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| WANG15     | Wang                   | 2015             | Wang PC, Mwango A, Moberley S, Brockman BJ, Connor AL, Kalesha-Masumbu P, et al. A cluster randomised trial on the impact of integrating early infant HIV diagnosis with the expanded programme on immunization on immunization and HIV testing rates in rural health facilities in southern Zambia. PLoS ONE. 2015;10 (10) (no pagination)(e0141455).               | RCT                   | unblinded, location stratified, cluster randomised controlled trial, 60 facilities equally allocated to a control group, Simple Intervention group that received a sensitization meeting and the resupply of HIV testing commodities in the event of a stock-out, and a Comprehensive Intervention group that received the Simple Intervention as well as on-site operational support to facilitate the integration of HIV testing services with EPI.                                                                                                                                               |
| GOOD12     | Goodson                | 2012             | Goodson JL, Kulkarni MA, Vanden Eng JL, Wannemuehler KA, Cotte AH, Desrochers RE, et al. Improved equity in measles vaccination from integrating insecticide-treated bednets in a vaccination campaign, Madagascar. Tropical Medicine & International Health. 2012;17(4):430-7.                                                                                      | Observational         | cross-sectional survey (national) to compare measles vaccination coverage in districts with and without ITN integration - following a national measles campaign. stratified three-stage cluster sampling method was used to identify enumeration areas and households. Ten districts were chosen from each of three operational zones corresponding to 52 districts in the area without integrated ITN distribution, 33 districts in the area with integrated ITNs distributed by the Ministry of Health, and 26 districts in the area with integrated ITNs distributed by the Madagascar Red Cross |
| ARMS11     | Armstrong Schellenberg | 2011             | Joanna RM Armstrong Schellenberg, Werner Maokola, Kizito Shirima, Fatuma Manzi, Mwifadhi Mrisho, Adiel Mushi, Pedro Alonso, Hassan Mshinda, Marcel Tanner and David M Schellenberg. Cluster-randomized study of intermittent preventive treatment for malaria in infants (IPTi) in southern Tanzania: evaluation of impact on survival. Malaria Journal 2011;10:387. | RCT                   | Cluster RCT comparing survival rates with and without intermittent preventive treatment of malaria in infants (IPTi) in 243,000 households                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| BOJA11     | Bojang                 | 2011             | Bojang KA, Akor F, Conteh L, Webb E, Bittaye O, Conway DJ, et al. Two strategies for the delivery of IPTc in an area of seasonal malaria transmission in the Gambia: A randomised controlled trial. PLoS Medicine. 2011;8 (2)                                                                                                                                        | RCT                   | Cluster RCT with unit of randomisation being the catchment of RCH trekking teams. IPTc delivered by either RCH trekking team or by VHVs                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| DICK11     | Dicko                  | 2011             | Dicko A, Konare M, Traore D, Testa J, Salamon R, Doumbo O, et al. The implementation of malaria intermittent preventive treatment with sulphadoxine pyrimethamine in infants reduced all-cause mortality in the district of Kolokani, Mali: Results from a cluster randomized control. Malaria Journal. 2012;11 (no pagination)(73).                                 | RCT                   | Open cluster RCT: 22 health areas were randomized at a 1:1 ratio to either receive IPTi-SP or to serve as a control. Baseline and endline surveys using 30 cluster, population weighted sampling, with 35 (baseline) and 70 (endline) children aged 0-23 months per cluster. MICS derived questionnaire.                                                                                                                                                                                                                                                                                            |

| Study code | Author (first) | Publication date | Full citation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Study design category | Study design detail, including comparator group (<50 words)                                                                                                                                                                                                                                                                                                                                    |
|------------|----------------|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| WILL11     | Willey         | 2011             | Willey BA, Armstrong Schellenberg JR, Maokola W, Shirima K, Chemba M, Mshinda H, et al. Evaluating the effectiveness of IPTi on malaria using routine health information from sentinel health centres in southern Tanzania. <i>Malaria Journal</i> . 2011;10 (41).                                                                                                                                                                                                                              | RCT                   | Morbidity and health services study nested within larger RCT (ARMS11)                                                                                                                                                                                                                                                                                                                          |
| MONT13     | Monterrosa     | 2013             | Monterrosa EC, Frongillo EA, Gonzalez de Cossio T, Bonvecchio A, Villanueva MA, Thrasher JF, et al. Scripted messages delivered by nurses and radio changed beliefs, attitudes, intentions, and behaviors regarding infant and young child feeding in Mexico. <i>J Nutr</i> . 2013;143(6):915-22.                                                                                                                                                                                               | CBA                   | Sites in Morelos (intervention) and Puebla (control) matched on demographics and SES. Morelos received scripted messages from nurses at EPI and via radio. Measured pre and post intervention in both sites. Some significant differences between sites at baseline.                                                                                                                           |
| BOSE11     | Boselli        | 2011             | Giulia Boselli, Aya Yajima, Padmasiri Eswara Aratchige, Keith Ernest Feldon, Anonh Xeuatvongsab, Kongxay Phounphenghac, Khampiou Sihakhangd, Chanthavisouk Chitsavangb, Sylvanh Phengkeob, Albis Francesco Gabrielli, Claudio Politi, Antonio Montresora. Integration of deworming into an existing immunisation and vitamin A supplementation campaign is a highly effective approach to maximise health benefits with minimal cost in Lao PDR. <i>International Health</i> 3 (2011) 240– 245. | NC                    | Costs of the 2009 integrated Child Health Days (OPV, TT, vitamin A, deworming) were compared with the costs of the unintegrated 2007 national deworming campaign to generate evidence on the cost effectiveness of the integration of deworming into the Child Health Days. Questionnaires to health workers and women of child bearing age of 2009 campaign used to collect qualitative data. |
| HODG15     | Hodges         | 2015             | Hodges MH, Sesay FF, Kamara HI, Nyorkor ED, Bah M, Koroma AS, et al. Integrating Vitamin A Supplementation at 6 months into the Expanded Program of Immunization in Sierra Leone. <i>Maternal &amp; Child Health Journal</i> . 2015;19(9):1985-92.                                                                                                                                                                                                                                              | NRCT                  | 12 Peripheral health units assigned to provide caregivers with one of three packages - revised card (to include vitA), revised card + IYCF counselling ("mini" integration), or revised card + IYCF and FP counselling and provision ("full" integration). Data collected through monthly monitoring.                                                                                          |
| FRID12     | Friderichs     | 2012             | Friderichs N, Swanepoel D, Hall JW, 3rd. Efficacy of a community-based infant hearing screening program utilizing existing clinic personnel in Western Cape, South Africa. <i>International Journal of Pediatric Otorhinolaryngology</i> . 2012;76(4):552-9                                                                                                                                                                                                                                     | NC                    |                                                                                                                                                                                                                                                                                                                                                                                                |
| BAKA14     | Bakare         | 2014             | Bakare MO, Okoye JO, Obindo JT. Introducing depression and developmental screenings into the National Programme on Immunization (NPI) in southeast Nigeria: An experimental cross-sectional assessment. <i>General Hospital Psychiatry</i> . 2014;36(1):105-12.                                                                                                                                                                                                                                 | NC                    | Six week trial of post-partum depression screening during primary immunization at a hospital                                                                                                                                                                                                                                                                                                   |
| COOP15     | Cooper         | 2015             | Cooper CM, Fields R, Mazzeo CI, Taylor N, Pfitzer A, Momolu M, et al. Successful proof of concept of family planning and immunization integration in Liberia. <i>Global health, science and practice</i> . 2015;3(1):71-84.                                                                                                                                                                                                                                                                     | CBA                   | Proof of concept' pilot, comparison of HIS data before and after of a MCHIP supported project. Also included qual data from monitoring, and IDIs and FGDs at end-line                                                                                                                                                                                                                          |
| DULL16     | Dulli          | 2016             | Dulli LS, Eichleay M, Rademacher K, Sortijas S, Nsengiyumva T. Meeting Postpartum Women's Family Planning Needs Through Integrated Family Planning and Immunization Services: Results of                                                                                                                                                                                                                                                                                                        | RCT                   | separate sample, parallel, cluster-randomized controlled trial. Fourteen randomly selected primary health facilities were equally allocated to intervention (integrated family                                                                                                                                                                                                                 |

| Study code | Author (first) | Publication date | Full citation                                                                                                                                                                                                                                                                                                                                                                                                                                  | Study design category | Study design detail, including comparator group (<50 words)                                                                                                                                                                                                                                                                                                                                                   |
|------------|----------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                |                  | a Cluster-Randomized Controlled Trial in Rwanda. <i>Global Health Science &amp; Practice</i> . 2016;4(1):73-86.                                                                                                                                                                                                                                                                                                                                |                       | planning and immunization services at the same time and location) and control groups (standard immunization services only)                                                                                                                                                                                                                                                                                    |
| VANC14     | Vance          | 2014             | Vance G, Janowitz B, Chen M, Boyer B, Kasonde P, Asare G, et al. Integrating family planning messages into immunization services: a cluster-randomized trial in Ghana and Zambia. <i>Health Policy and Planning</i> . 2014;29(3):359-66.                                                                                                                                                                                                       | RCT                   | Cluster RCT in 10 public sector health facilities randomized to control or intervention groups. Quantitative and qualitative data from in-depth interviews. Midpoint process evaluation.                                                                                                                                                                                                                      |
| BRIE12     | Briere         | 2012             | Elizabeth C. Briere, Tove K. Ryman, Emily Cartwright, Elizabeth T. Russo, Kathleen A. Wannemuehler, Benjamin L. Nygren, Steve Kola, Ibrahim Sadumah, Cliff Ochieng, Margaret L. Watkins, and Robert Quick. Impact of Integration of Hygiene Kit Distribution With Routine Immunizations on Infant Vaccine Coverage and Water Treatment and Handwashing Practices of Kenyan Mothers. <i>The Journal of Infectious Diseases</i> 2012;205:S56–64. | CBA                   | Quasi-experimental only one intervention and one comparison - Cluster RCT comparing vaccination coverage and hygiene indicators following the distribution of a hygiene kit with the provision of hygiene counselling during routine immunisation visits in an intervention and a comparison district in Kenya over a one year period (baseline survey in Feb-Apr 2009 and follow up survey in Feb-Apr 2010). |
| RYMA12     | Ryman          | 2012             | Tove K. Ryman, Elizabeth C. Briere, Emily Cartwright, Karen Schlanger, Kathleen A. Wannemuehler, Elizabeth T. Russo, Steve Kola, Ibrahim Sadumah, Benjamin L. Nygren, Cliff Ochieng, Robert Quick, and Margaret L. Watkins. Integration of Routine Vaccination and Hygiene Interventions: A Comparison of 2 Strategies in Kenya. <i>The Journal of Infectious Diseases</i> 2012;205:S65–76.                                                    | CBA                   | Quasi experimental stratified cluster design - within the intervention arm of a two cluster "RCT" comparing the relative effectiveness of 2 distribution strategies. CHW or nurse distribution chose by coin toss, for the integration of vaccination and hygiene interventions (community health workers vs. nurses).                                                                                        |
| PATO11     | Patouillard    | 2011             | Patouillard E, Conteh L, Webster J, Kweku M, Chandramohan D, Greenwood B. Coverage, Adherence and Costs of Intermittent Preventive Treatment of Malaria in Children Employing Different Delivery Strategies in Jasikan, Ghana. <i>PLoS ONE</i> . 2011;6(11):1-9.                                                                                                                                                                               | RCT                   | Update of Kweku (in Wallace 2012) with additional cost and adherence data. IPTc by either VHWs (6 villages), OPDs (3) or EPI Outreach clinics (3).                                                                                                                                                                                                                                                            |

Note: RCT – randomised controlled trial, CBA – controlled before-after-study, NRCT – non-randomised trial, NC – non-controlled study.



| Study code | Location, country/s | Location, detail                                                             | Population addressed                                                                                                                                    | Intervention timing                                                                                                                                         | Immunization service delivery mode | Immunization service delivery contact point (facility, outreach, mobile, mixed) |
|------------|---------------------|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|---------------------------------------------------------------------------------|
| UDDI11     | Bangladesh          | Four 'hard-to-reach' rural sub-districts from hilly and low-lying areas      | Infants                                                                                                                                                 | Primary EPI schedule                                                                                                                                        | Routine                            | Facility                                                                        |
| GOOD13     | Tanzania            | Intervention in 4 urban/4 rural health centers                               | Infants, total of 7569                                                                                                                                  | First month immunization visit (4 weeks of age)                                                                                                             | Routine                            | Facility                                                                        |
| WALL14     | Tanzania            | Urban and rural clinics                                                      | Infants                                                                                                                                                 | First month immunization visit (4 weeks of age)                                                                                                             | Routine                            | Facility                                                                        |
| DUBE12     | Malawi              | Two facilities, one urban, one rural                                         | Infants of HIV+ mothers, age 6 weeks offered appointment following education during pregnancy and postnatal visits. Scheduled to match first EPI visit. | EID offered at six weeks. Cohort followed from birth.                                                                                                       | Routine                            | Facility                                                                        |
| TEJI11     | Cameroon            | Urban                                                                        | HIV-exposed Infants                                                                                                                                     | Test at six weeks, with followup tied to EPI visits                                                                                                         | Routine                            | Facility                                                                        |
| MCCO12     | Malawi              | Two urban outpatient clinics in Lilongwe                                     | HIV-exposed Infants                                                                                                                                     | Under fives                                                                                                                                                 | Routine                            | Facility                                                                        |
| ONGE12     | Kenya               | 2 purposively selected hospitals with similar characteristic                 | HIV-exposed Infants                                                                                                                                     | Infants 6 - 8 weeks of age                                                                                                                                  | Routine                            | Facility                                                                        |
| WANG15     | Zambia              | Rural health facilities, southern province                                   | Infants                                                                                                                                                 | Primary schedule                                                                                                                                            | Routine                            | Facility                                                                        |
| GOOD12     | Madagascar          | national, all districts                                                      | Infants                                                                                                                                                 | Measles campaign                                                                                                                                            | Campaign                           | Mixed (fixed and temporary campaign sites)                                      |
| ARMS11     | Tanzania            | Five-districts in southern Tanzania                                          | Children during routine immunization.                                                                                                                   | IPTi involves the delivery of sulphadoxine-pyrimethamine (SP) to children when they receive routine vaccinations at about two,three and nine months of age. | Routine                            | Facility                                                                        |
| BOJA11     | Gambia              | rural villages from the Upper River Region of The Gambia                     | Children aged 3 - 72 months                                                                                                                             | Monthly medicine during malaria season                                                                                                                      | Routine                            | Outreach                                                                        |
| DICK11     | Mali                | Rural district, Kolokani, of 208,000 population                              | Infants                                                                                                                                                 | Administration of 1/2 tab SP along with EPI vaccines                                                                                                        | Routine                            | Facility                                                                        |
| WILL11     | Tanzania            | 11 sentinel health facilities from among five-districts in southern Tanzania | Children during routine immunization.                                                                                                                   | As for ARMS11                                                                                                                                               | Routine                            | Facility                                                                        |

| Study code | Location, country/s | Location, detail                                                                                                                                                                                             | Population addressed                                                                                            | Intervention timing                                                                                                           | Immunization service delivery mode | Immunization service delivery contact point (facility, outreach, mobile, mixed)                                                                                                                                   |
|------------|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MONT13     | Mexico              | Rural communities                                                                                                                                                                                            | 6-24 month old children                                                                                         | Nurses either at home visits or clinic.                                                                                       | Routine                            | Facility and ? Home                                                                                                                                                                                               |
| BOSE11     | Lao PDR             | Data analysis at the national level                                                                                                                                                                          | 2007 campaign targeted 650,000 individuals and the 2009 campaign targeted 1,140,381 individuals.                | Annual Child Health Days.                                                                                                     | Campaign                           | Interventions provided on 1 day at each of the campaign sites located at central, provincial and district hospitals, at local health centres as well as at the outreach posts in the 17 provinces of the country. |
| HODG15     | Sierra Leone        | 12 clinics                                                                                                                                                                                                   | Infants                                                                                                         | Six month EPI visit                                                                                                           | Routine                            | Facility                                                                                                                                                                                                          |
| FRID12     | South Africa        | Cape metropolitan area<br>Urban PHC clinics chosen to represent 1 per sub-district, with the most 6 week EPI visits, 5 day services, close to a referral ectnr                                               | Infants                                                                                                         | 6, 10, 14 week EPI visits                                                                                                     | Routine                            | Facility                                                                                                                                                                                                          |
| BAKA14     | Nigeria             | University teaching hospitals                                                                                                                                                                                | Children during routine immunization.                                                                           | Two short depression screening questionnaires.                                                                                | Routine                            | Facility                                                                                                                                                                                                          |
| COOP15     | Liberia             | 10 purposefully selected HFs in 2 counties with relatively strong immunization performance                                                                                                                   | Post-partum mothers                                                                                             | New FP services colocated Mar - Nov 2012                                                                                      | Routine                            | Facility                                                                                                                                                                                                          |
| DULL16     | Rwanda              | 14 public primary health care facilities were randomly selected from a national sampling frame, from facilities with an average monthly client volume of at least 50 infant measles immunizations or greater | Mothers of infants attending immunization services (i.e., at 6, 10, and 14 weeks and at 9 months post-delivery) | Routine primary schedule up to measles.                                                                                       | Routine                            | Facility                                                                                                                                                                                                          |
| VANC14     | Ghana and Zambia    | Geographically separated facilities that offered both FP and immunization services. Randomised to control or intervention.                                                                                   | Women post-partum                                                                                               | Counselling at every immunization visit then offered FP referral at 9 months postpartum - to correspond with measles vaccine. | Routine                            | Facility                                                                                                                                                                                                          |
| BRIE12     | Kenya               | Homa Bay district was randomly selected as the intervention site and Suba district as the comparison                                                                                                         | Caregivers bringing a child <12 months to routine immunization visits                                           | Routine immunization visits for children under 1 year                                                                         | Routine                            | Routine immunization (EW: unclear whether hygiene kits were only distributed at facilities)                                                                                                                       |

| Study code | Location, country/s | Location, detail                                                                                                                                                                                         | Population addressed                                                  | Intervention timing                                   | Immunization service delivery mode | Immunization service delivery contact point (facility, outreach, mobile, mixed)                           |
|------------|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|-------------------------------------------------------|------------------------------------|-----------------------------------------------------------------------------------------------------------|
|            |                     | site (EW: not clear if Suba district was also selected randomly)                                                                                                                                         |                                                                       |                                                       |                                    | or during outreach. Margie Watkins is a co-author and confirmed this was only distributed at facilities). |
| RYMA12     | Kenya               | The intervention district (Homa Bay) was divided into 2 geographically clustered areas each containing 9 clinics. The distribution strategy to be used in each geographic area was determined at random. | Caregivers bringing a child <12 months to routine immunization visits | Routine immunization visits for children under 1 year | Routine                            | Routine immunization                                                                                      |
| PATO11     | Ghana               | 12 villages in Jasikan district, with relatively high and equitable baseline EPI coverage                                                                                                                | 3 - 59 month old children, and their caregivers                       | Routine immunization                                  | Routine.<br>Intensified routine.   | Outreach                                                                                                  |

| Study code | Immunisation service involved in integration (specific vaccines, other detail) | Additional program area being integrated | Disease priority, other than immunization | Additional program, detail of non-immunization service being integrated with immunisation                                                                                                                                                           | Nature of extra service being integrated, eg:                                                                                                            | Other integration change, if not service addition, eg planning, community engagement, supply chain, health information, other                                                                                                                                             |
|------------|--------------------------------------------------------------------------------|------------------------------------------|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| UDDI11     | Primary schedule                                                               | Child health                             | Sick child or other non-imm visit         | Screening checklist to identify children needing vaccination was introduced to health facilities for use on non-vaccination visits. Comparison arm to other sites that received modified EPI schedules plus community support groups.               | d.Immunization service by non-imm staff, if an EPI session was available ?? Should just be e. Immunization counselling by non-immunization staff         | Other support to EPI in the other sites not implementing checklist. These included altered outreach planning (two dates every second month, rather than one day every month) and community support groups to mobilise and promote careseeking and enable outreach visits. |
| GOOD13     | First month (4 weeks) visit for OPV1 and Penta1.                               | Disease Control                          | HIV                                       | HIV early infant diagnosis and treatment initiation                                                                                                                                                                                                 | a. Extra services: HIV diagnosis, initiation of cotrimoxazole, referral for full ART initiation. b. Extra counselling: on HIV testing.                   | Nil                                                                                                                                                                                                                                                                       |
| WALL14     | First month (4 weeks) visit for OPV1 and Penta1.                               | Disease Control                          | HIV                                       | HIV early infant diagnosis and treatment initiation                                                                                                                                                                                                 | a. Extra services: HIV diagnosis, initiation of cotrimoxazole, referral for full ART initiation. b. Extra counselling: on HIV testing.AS IN GOODSON 2013 | Nil                                                                                                                                                                                                                                                                       |
| DUBE12     | First 6 week visit                                                             | Disease Control                          | HIV                                       | Early infant diagnosis appointment offered to all HIV+ mothers.                                                                                                                                                                                     | c.Co-location, linked timing of EID to 6 weeks to avoid an extra visit.                                                                                  | Nil.                                                                                                                                                                                                                                                                      |
| TEJI11     | First 6 week visit                                                             | Disease Control                          | HIV                                       | HIV-exposed infant followup for testing and enrolment                                                                                                                                                                                               | c. Co-located service: HIV followup timed to accompany vaccination                                                                                       |                                                                                                                                                                                                                                                                           |
| MCCO12     | Any immunization visit                                                         | Disease Control                          | HIV                                       | Group counselling on HIV then private counselling and testing service offered. At the IC each caregiver met with the HIV counselor after the child received the vaccination and was weighed. At the U5C, clinicians and nurses would refer patients | c. Co-location - HIV counselling and escort using private room in an immunization clinic                                                                 |                                                                                                                                                                                                                                                                           |

| Study code | Immunisation service involved in integration (specific vaccines, other detail) | Additional program area being integrated | Disease priority, other than immunization | Additional program, detail of non-immunization service being integrated with immunisation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Nature of extra service being integrated, eg:                                                                                                                           | Other integration change, if not service addition, eg planning, community engagement, supply chain, health information, other |
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|            |                                                                                |                                          |                                           | for HIV testing based upon clinical suspicion while PITC staff recruited patients regardless of their presentation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                         |                                                                                                                               |
| ONGE12     | First 6 week visit                                                             | Disease Control                          | HIV                                       | collection of DBS for EID by polymerase chain reaction (PCR), provision of CTX prophylaxis, and HIV antibody testing, provided in the MCH. Note FP and other MCH services already integrated with immunization in MCH clinics.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | c. Co-located service - extra dedicated HIV nurse to supplement, who also did other MCH work.                                                                           | Peer counsellors in both models supported women, in control, would escort families to HIV clinic                              |
| WANG15     | All immunization visits - primary schedule - in first year                     | Disease Control                          | HIV                                       | <b>Simple Intervention group:</b> HIV testing commodities replenished directly (outside of govt supply) if a stock-out, and a sensitization meeting with facility staff was held by district health officials on integration of HIV testing and immunization. <b>Comprehensive Intervention group:</b> Both aspects of the Simple Intervention PLUS, on-site operational support to facilitate the integration of EID with EPI, which included guidance on how to optimize staffing and patient flow. Facility staff were instructed to administer dried blood spot (DBS) tests on all infants with known HIV-infected mothers and HIV antibody tests on all mothers with unknown or previously negative status who were either attending their infant's first immunization visit or had not been tested in the previous three months. All tests were offered in an opt-out manner. Facility staff were also instructed to provide group counselling to caregivers on the HIV testing service provided and general HIV testing education. These activities were supported by health volunteers conducted | a. Extra services by immunization staffb. Extra counselling by immunization staffc. Co-located service ? Group counselling and volunteers doing sensitisation meetings. | Support to HIV commodities for testing                                                                                        |

| Study code | Immunisation service involved in integration (specific vaccines, other detail)                                                                                                                                                                                                                                                                                                                          | Additional program area being integrated | Disease priority, other than immunization | Additional program, detail of non-immunization service being integrated with immunisation                                                                                                                                                                                                                                                                                                                                | Nature of extra service being integrated, eg:                                                                                                                       | Other integration change, if not service addition, eg planning, community engagement, supply chain, health information, other               |
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|            |                                                                                                                                                                                                                                                                                                                                                                                                         |                                          |                                           | sensitization meetings at communities in the facility catchment area and at the beginning of each under-five clinic to inform community members of changes to the under-five clinics.                                                                                                                                                                                                                                    |                                                                                                                                                                     |                                                                                                                                             |
| GOOD12     | Nationwide integrated campaign targeting 3.1 million children <5 years of age for measles vaccination (age 9–59 months), and for mebendazole (age 9–59 months) and vitamin A (age 6–59 months) administration. In the 59 malaria-endemic districts where ITN distribution had not previously been conducted (about half of total), long-lasting ITNs were also distributed to children aged 0–59 months | Disease Control                          | Malaria                                   | Distribution of free ITNs, Ministry of Health and the Malagasy Red Cross distributed more than 1.5 million ITNs together with measles vaccinations at fixed and temporary campaign sites, giving one ITN per child up to a maximum of two ITNs per household. Distributed in about half of the districts - ie those that had not received prior.<br>Note mebendazole and vit A already integrated in all campaign sites. | a. Possible some extra service by immunization staff, but not major.<br>c. Co-located service - distribution of ITN looks like was by Red Cross staff or MOH staff. |                                                                                                                                             |
| ARMS11     | DPT and measles vaccines                                                                                                                                                                                                                                                                                                                                                                                | Disease Control                          | Malaria                                   | Intermittent Preventive Treatment for malaria control in infants (IPTi)                                                                                                                                                                                                                                                                                                                                                  | a. Extra services were provided by immunization staff (nurses): IPTi.                                                                                               | Nil                                                                                                                                         |
| BOJA11     | RCH trekking teams (one arm of trial, other was VHWS)                                                                                                                                                                                                                                                                                                                                                   | Disease Control                          | Malaria                                   | 3 x monthly administration of IPTc - aimed primarily at over 1s, though included from 3 months                                                                                                                                                                                                                                                                                                                           | a. Extra services by members of the RCH trekking team (who also vaccinate, give vitamin A and do ANC). Additional four (adding to ~ 6) staff in each trekking team. | Support to malaria meds in supply chain.                                                                                                    |
| DICK11     | DTP 2, 3, measles, yellow fever                                                                                                                                                                                                                                                                                                                                                                         | Disease Control                          | Malaria                                   | Intermittent Preventive Treatment for malaria control in infants (IPTi)                                                                                                                                                                                                                                                                                                                                                  | a.Extra services by immunization staff giving IPTi                                                                                                                  | "in a context of a large pilot implementation of health services" "vaccination card, vaccines registration forms, monitoring and evaluation |

| Study code | Immunisation service involved in integration (specific vaccines, other detail)                                                                          | Additional program area being integrated | Disease priority, other than immunization | Additional program, detail of non-immunization service being integrated with immunisation                                                                                                                                                                                     | Nature of extra service being integrated, eg:                                                                                                                                                   | Other integration change, if not service addition, eg planning, community engagement, supply chain, health information, other                                                                                                                                                                                                  |
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|            |                                                                                                                                                         |                                          |                                           |                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                 | forms etc... were modified to allow the recording of the administration of the SP along with EPI vaccines and the health interventions. Forms for procurement and supply of SP were developed to be used along with those of other health interventions. Communities' leaders were sensitized and health staffs were trained." |
| WILL11     | DPT and measles vaccines                                                                                                                                | Disease Control                          | Malaria                                   | Intermittent Preventive Treatment for malaria control in infants (IPTi)                                                                                                                                                                                                       | EW: Not 100% clear from the article, but there was no mention of different health workers administering vaccines and IPTi.a. Extra services were provided by immunization staff (nurses): IPTi. | Nil                                                                                                                                                                                                                                                                                                                            |
| MONT13     | Any immunization visit                                                                                                                                  | Nutrition                                | IYCF                                      | Counselling tools with scripted messages and aids provided to nurses, who were already mandated to do nutrition education alongside immunization. Strong basis in ethnographic research and theoretical belief framework. Gave out magnet with key messages to put on fridge. | b. Extra counselling by EPI staff                                                                                                                                                               | Some social marketing theory, and supplementary radio messages.                                                                                                                                                                                                                                                                |
| BOSE11     | Child Health Days vaccinations (OPV for children under the age of 5, TT for women of child bearing age), plus vitamin A for children under the age of 5 | Nutrition                                | Vitamin A Defic Helminths                 | Provision of anthelmintic drugs to children and women of child bearing age, including pregnant women                                                                                                                                                                          | a. Extra services: MBZ tablets being added to Child Health Days (OPV, TT, vit A).                                                                                                               | Coordinated supply chain (MBZ tablets transported with vitamin A by MOH vehicles). Training: The integrated training on vaccination and administration of vitamin A and                                                                                                                                                        |

| Study code | Immunisation service involved in integration (specific vaccines, other detail) | Additional program area being integrated | Disease priority, other than immunization | Additional program, detail of non-immunization service being integrated with immunisation                                                                                                                                                     | Nature of extra service being integrated, eg:                                                                                            | Other integration change, if not service addition, eg planning, community engagement, supply chain, health information, other                                                                                                                                                                                                                                                                                                                                        |
|------------|--------------------------------------------------------------------------------|------------------------------------------|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                |                                          |                                           |                                                                                                                                                                                                                                               |                                                                                                                                          | anthelmintics was provided to health workers between 19 and 26 October 2009. The time dedicated to deworming was approximately 30 min during the 1-day seminar. Supervision, meetings and social mobilisation: The same supervision team was used to provide supervision/support activities. No additional meetings were necessary to discuss deworming and no additional social mobilisation was conducted. Therefore, no extra costs were reported in these areas. |
| HODG15     | Six month visit                                                                | Nutrition and Reproductive               | Vitamin A DeficFeeding                    | Vitamin A supplement, +/- IYCF counselling or IYCF counselling and FP counselling/service                                                                                                                                                     | c. Co-location, new six month visit for VAs, seen as part of EPI scheduled. and e. allows for catchup vaccination by non-EPI staff.      | Change to child health card to promote vitamin A service and include information on growth and FP. Extra support to ensure FP commodities available                                                                                                                                                                                                                                                                                                                  |
| FRID12     | Infants                                                                        | Other                                    | Hearing loss                              | a two-stage distortion product otoacoustic emissions (DPOAE) screening protocol at clinic level utilizing a DPOAE screener. A two-stage screening protocol was employed to reduce the burden of false positive referrals to tertiary hospital | a. Extra services by EPI staff - administering a hearing screening test                                                                  | Nil                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| BAKA14     | Routine Nigeria                                                                | Other                                    | Maternal depression                       | Depression screening                                                                                                                                                                                                                          | c. Co-location. Self-report questionnaire and interview by non-EPI staff. Weight, height and HC also measured more accurately than usual | Nil                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |



| Study code | Immunisation service involved in integration (specific vaccines, other detail)                                                                                                                              | Additional program area being integrated | Disease priority, other than immunization | Additional program, detail of non-immunization service being integrated with immunisation                                                                                                                                                                                                                                                                                                       | Nature of extra service being integrated, eg:                                                                                                                                                                                                                                                                                       | Other integration change, if not service addition, eg planning, community engagement, supply chain, health information, other                    |
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| COOP15     | Routine Liberia - mostly penta, also measles                                                                                                                                                                | Reproductive                             | Family Planning                           | FP counselling by immunization staff, with co-location of FP services                                                                                                                                                                                                                                                                                                                           | b. Extra one-on-one counselling by immunization staff using a FP job aid. <b>AND</b><br>c. Colocation of FP service                                                                                                                                                                                                                 | Nil.                                                                                                                                             |
| DULL16     | Mothers of infants attending immunization services (i.e., at 6, 10, and 14 weeks and at 9 months post-delivery)                                                                                             | Reproductive                             | Family Planning                           | Group education on PPFP<br>Brochure on PPFP<br>Screening by EPI staff on LAM criteria<br>Offer of FP referral on same day and site                                                                                                                                                                                                                                                              | b. Extra counselling by EPI staff - postpartum FP screening tool.<br>c. Co-location of linked FP service.                                                                                                                                                                                                                           | Altered timing of when FP was available.<br>Quality improvement checklist used by study team accompanying quarterly district health supervision. |
| VANC14     | Measles 9 month first dose                                                                                                                                                                                  | Reproductive                             | Family Planning                           | Vaccinators were trained to screen women for pregnancy risk, deliver a birth spacing message and refer mothers interested in preventing pregnancy to co-located FP services during their child's immunization visit. They were given a job-aid to guide them through this process that was made available in English and the local language. Pregnancy risk screening was based on LAM criteria | b. Extra counselling on FP by immunization staff with referral to co-located services.c. Co-location of linked FP service.                                                                                                                                                                                                          | FP providers also receiving training in a 'pregnancy checklist' to aid identification of when fertility returns.                                 |
| BRIE12     | Pentavalent vaccine (diphtheria, tetanus, pertussis, Haemophilus influenzae type b, and hepatitis B) and oral polio vaccine provided at 6, 10, and 14 weeks of age, and measles vaccine at 9 months of age. | Water, Sanitation and Hygiene            | Diarrhoea                                 | Provision of hygiene kits (WaterGuard sodium hypochlorite solution for household water treatment, soap, and pictorial educational materials) and one-on-one or group counseling sessions to mothers attending                                                                                                                                                                                   | a. Extra services were provided by immunization staff (nurses): distribution of hygiene kitb. Extra counselling by immunization staff: one-to-one or group counseling about water treatment and hand hygiene <b>OR</b> :c. Co-location: community workers distributed hygiene kit and provided one-to-one or group counseling about | Nil                                                                                                                                              |

| Study code | Immunisation service involved in integration (specific vaccines, other detail)                                                                                                                              | Additional program area being integrated | Disease priority, other than immunization | Additional program, detail of non-immunization service being integrated with immunisation                                                                                                                     | Nature of extra service being integrated, eg:                                                                                                                                                                                                                                                                                                                           | Other integration change, if not service addition, eg planning, community engagement, supply chain, health information, other |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                                                                                             |                                          |                                           |                                                                                                                                                                                                               | water treatment and hand hygiene<br><i>Note info is not included in this article, but is provided in Ryman et al 2012 which outlines the comparison made between two delivery strategies - one by nurses and one by community workers.</i>                                                                                                                              |                                                                                                                               |
| RYMA12     | Pentavalent vaccine (diphtheria, tetanus, pertussis, Haemophilus influenzae type b, and hepatitis B) and oral polio vaccine provided at 6, 10, and 14 weeks of age, and measles vaccine at 9 months of age. | Water, Sanitation and Hygiene            | Diarrhoea                                 | Provision of hygiene kits (WaterGuard sodium hypochlorite solution for household water treatment, soap, and pictorial educational materials) and one-on-one or group counseling sessions to mothers attending | a. Extra services were provided by immunization staff (nurses): distribution of hygiene kitb. Extra counselling by immunization staff: one-to-one or group counseling about water treatment and hand hygiene<br><b>OR:</b> c. Co-location: community workers distributed hygiene kit and provided one-to-one or group counseling about water treatment and hand hygiene | Nil                                                                                                                           |
| PATO11     | Routine Ghana                                                                                                                                                                                               | Disease Control                          | Malaria                                   | Dispensing of IPTc by EPI nurses during monthly outreach. Comparison with dispensing by nurses in paediatric OPDs and dispensing by VHWs at a central community point over three consecutive days.            | a. Extra services were provided by immunization staff (nurses): distribution of hygiene kitb. Extra counselling by immunization staff                                                                                                                                                                                                                                   | Nil                                                                                                                           |

Note: "Nature of extra service being integrated is coded as: a. Extra services by immunization staff, b. Extra counselling by immunization staff, c. Co-location, linked timing of services, d. Immunization service by non-immunization staff e. Immunization counselling by non-immunization staff

| Study code | Main outcomes measured, for immunization coverage (vaccines)                                                                                                                                                                               | Secondary outcome measures, immunisation service (eg vaccination provided, staffing, other)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Main outcome measured, for other service coverage | Other main outcome measure (if not coverage), specify                                                                                                                                                         |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| UDDI11     | Fully immunized increased in checklist sites from 52 to 81 (low) and 55 to 81 (hill), cf other supported sites where increased from 29 to 83 (low) and 69 to 89 (hill). Improvements seen for BCG, DTP and measles, mostly for latter two. | Status of missed opportunity identified and vaccinated shows that, of 1674 mothers in Sulla screened using the screening checklist, <b>184 (11%) were identified as missed opportunity for immunization</b> . Of the 184 children, 8 (4%) were vaccinated at the same clinics where they were identified, and the remaining 176 children were referred to the nearest EPI centres for vaccination. One hundred and sixtyone of the 176 referred children were followed up by concerned HAs and their supervisors, and 148 of them received vaccines at the referral clinics. In Kawkhali upazila, of 5968 mothers screened, 249 (4%) were identified as missed opportunity for vaccination. Of the 249 children, 22 (9%) were vaccinated at the same clinics where they were identified, and the remaining 227 children were referred to the nearest EPI centres for vaccination. Two hundred and twenty four of the 227 referred children were followed up by concerned HAs and their supervisors, and 127 of them received vaccines at the referral clinics. Interaction analysis and regression model suggests beneficial effect of the checklist, cf to other support in other arm of study |                                                   | Dropouts declined, as did 'left-outs' (unvaccinated)                                                                                                                                                          |
| GOOD13     | No coverage measure                                                                                                                                                                                                                        | OPV/Penta 1, OPV/Penta3, Measles in absolute doses provided measured in all sites. Small declines in doses given overall in study facilities, but worst in rural: declines of 33% Penta1, 35% OPV1, 23% Penta 3, 28% OPV/Penta3. Similar declines not seen in rural comparison sites.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | No coverage measure for other service.            | Uptake of HIV testing and initiation, in intervention sites only. Of the 7569 infants, 7423 (98%) had mothers with known status. 308 infants registered for followup care. No pre-intervention data reported. |
| WALL14     | Nil                                                                                                                                                                                                                                        | Nil                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Nil                                               | Qualitative - acceptability and feasibility of integrated HIV service.                                                                                                                                        |
| DUBE12     | Nil                                                                                                                                                                                                                                        | Nil                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Of 1214 HIV-exposed infants, 71.6%                | 14.5% of those who presented tested                                                                                                                                                                           |

| Study code | Main outcomes measured, for immunization coverage (vaccines)                               | Secondary outcome measures, immunisation service (eg vaccination provided, staffing, other) | Main outcome measured, for other service coverage                                                                                                                                                                                                | Other main outcome measure (if not coverage), specify                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                            |                                                                                             | presented for early diagnosis, Despite active tracing, only 87.3% (110/126) of the mothers of infants who initially tested positive were told their infants' test results. ART was initiated in 58% of the infants with confirmed HIV infection. | positive for HIV. Further testing of 103 of these 126 apparently HIV-positive infants confirmed infection in 88; the other 15 results were false positives. The initial polymerase chain reaction testing of dried blood spots had a positive predictive value (PPV) of 85.4%.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| TEJI11     | Nil                                                                                        | Extra vaccine (HiB) provided as incentive. No reported impact on EPI service                | Nil                                                                                                                                                                                                                                              | Completeness of followup of HIV-exposed infants. Concluded EID proved feasible, 1331 (83.9%) completed the EID process                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| MCCO12     | Nil                                                                                        |                                                                                             | Nil                                                                                                                                                                                                                                              | 7-times greater proportion of children accessed PITC at the immunization clinic (84.2% vs 11.4%, $p < 0.001$ ). More than three times more PCR recipients returned for their PCR result and were enrolled into the EID program                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| ONGE12     | Measles 9mo higher in MCH (69 vs 34%) and complete vaccination by 12 mo higher (61 vs 46%) |                                                                                             | No coverage measure for other service.                                                                                                                                                                                                           | Infants in MCH were 1.14, 1.42, 1.95, and 1.29 times more likely to attend 14-week, 6-, 9-, and 12-month postnatal visits, respectively, and 2.24 times (95% confidence interval: 1.57 to 3.18) more likely to attend all 4 visits.<br>In the MCH model, 96 infants (53.6%) attended all 4 study follow-up visits, whereas only 35 infants (19.0%) in the CCC model attended all 4 visits ( $P = 0.0001$ ) (Fig. 2). After controlling for caregiver's age, marital status, education level, employment status, counseling, maternal parity, staging, mother on CTX, mother on ARV, place of delivery, and infant gender, the adjusted probability of attending all 4 study follow-up visits for an infant in the MCH model was 2.24 times (95% CI: 1.57 to 3.18) greater than that for an infant in the CCC model. |

| Study code | Main outcomes measured, for immunization coverage (vaccines)                                                                                                                                                                            | Secondary outcome measures, immunisation service (eg vaccination provided, staffing, other)                                                                                                                                                                                                                                                                                                                  | Main outcome measured, for other service coverage                                                                                                                                                       | Other main outcome measure (if not coverage), specify                                                                                                                                                              |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                         |                                                                                                                                                                                                                    |
| WANG15     |                                                                                                                                                                                                                                         | average number of DPT1 doses was slightly higher during the intervention period across all study arms (6.7%, 3.2% and 7.7% more doses per month over baseline in control, Simple Intervention and Comprehensive Intervention facilities respectively). Difference between Simple and Control (control increased more) was still non-sig and even at lowest CI would less than a priori definition of 'harm'. | main study relied solely on administrative data, monthly data collection.                                                                                                                               | average number of infant DBS tests changed by -0.49, 0.43, and 1.19 tests per month over baseline in Control, Simple and Comprehensive Intervention facilities, respectively. Larger increase in maternal re-tests |
| GOOD12     | Vaccination campaign coverage was higher in ITN districts (70.8%) than non-ITN districts (59.1%) (RR = 1.3, 95% CI 1.1–1.6).                                                                                                            | Among children in the poorest wealth quintile, vaccination coverage was higher in ITN than in non-ITN districts (Q1; RR = 2.4, 95% CI 1.2–4.8) and equity for measles vaccination was greater in ITN districts (equity ratio = 1.0, 95% CI 0.8–1.3) than in non-ITN districts (equity ratio = 0.4, 95% CI 0.2–0.8).                                                                                          | reported in Kulkarni 2010 - in integration districts 76.8% of households possessed at least one LLIN from any source and 56.4% of households possessed a campaign net.                                  | Kulkarni: Post-campaign, the LLIN use target of $\geq 80\%$ by children less than five years of age and a high level of LLIN use (69%) by pregnant women were attained                                             |
| ARMS11     | Intervention and comparison divisions had the same coverage of DTP3 (86% vs 86%) and similar coverage of measles (78% vs 80%).                                                                                                          | Nil else quantitative.                                                                                                                                                                                                                                                                                                                                                                                       | Intervention and comparison divisions had different coverage of 3 documented doses of IPTi (48% vs 2%) and different coverage of 3 documented OR reported doses of IPTi (77% vs 6%).                    | Divisions implementing IPTi had a 14% (95% CI -12%, 49%) HIGHER mortality rate in two-11 month olds in comparison with non-implementing divisions (P = 0.31)                                                       |
| BOJA11     | Children >12 months fully vaccinated: 69% trekking team, 79% VHW                                                                                                                                                                        | Nil                                                                                                                                                                                                                                                                                                                                                                                                          | VHWs substantially higher coverage level of three courses of IPT than delivery by RCH trekking teams (74% versus 48%, a difference of 27% [95% CI 16%–38%]).                                            | Primary outcome: malaria incidence rates 2.8 vs 1.2 per 1,000 child months, RCH vs VHW, rate difference 1.6 [95% confidence interval (CI) 0.24 to 3.5                                                              |
| DICK11     | Coverage of vaccines increased significantly in both control and intervention zones compared to baseline. The proportion of children completely vaccinated increased significantly from 36.7% (95% CI 25.3%–48.0%) at baseline to 53.8% | No difference in BCG coverage (note BCG was not a IPTi associated vaccine.                                                                                                                                                                                                                                                                                                                                   | Proportion of children in the target age groups who received IPTi with each of the 3 vaccinations DTP2, DTP3 and Measles, were 89.2% (95% CI 85.9%–92.0%), 91.0% (95% CI 87.6%–93.7%) and 77.4% (95% CI |                                                                                                                                                                                                                    |

| Study code | Main outcomes measured, for immunization coverage (vaccines)                                                                     | Secondary outcome measures, immunisation service (eg vaccination provided, staffing, other)                                                                                                                                                                           | Main outcome measured, for other service coverage                                                                                                                                                                                                                    | Other main outcome measure (if not coverage), specify                                                                                                                                                                                                                                                                                                                                                               |
|------------|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            | (95% CI 43.4% - 64.1%) (P < 0.001) in the control zone and to 69.5% (95% CI 64.2% - 74.7%), (P < 0.001) in the intervention zone |                                                                                                                                                                                                                                                                       | 70.7%- 83.2%) respectively. The corresponding figures in non intervention zone were 2.3% (95% CI 0.9% -4.7%), 2.6% (95%CI 1.0% -5.6%) and 1.7% (95% CI 0.4% - 4.9%). Vit A and ITN use increased moderately and were similar in intervention and control at endline. |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| WILL11     | Similar or better in intervention vs comparison. DPT2 72% vs 66%, DPT3 60% vs 49% (p=.019), measles 50% vs 33% (p=.003)          | Comparison of timeliness of vaccination and IPTi - comparable across intervention and control                                                                                                                                                                         | iPT uptake 1+ was 72% and 3 dose was 22% in the six intervention facilities                                                                                                                                                                                          | Malaria incidence and anaemia.Trend to less malaria in intervention group, but not stat sig. Overall trend for less malaria and less anaemia complicated analysis.                                                                                                                                                                                                                                                  |
| MONT13     | Nil                                                                                                                              | Nil                                                                                                                                                                                                                                                                   | 31% reported receiving scripted messages at health centre.                                                                                                                                                                                                           | Women in the intervention communities reported feeding green vegetables and beef more often than women in the control communities, but the frequency of chicken or fish consumption did not significantly differ between the 2 groups. BF frequency higher.                                                                                                                                                         |
| BOSE11     | Coverage data on immunizations was not separately reported.                                                                      | Nil else quantitative.                                                                                                                                                                                                                                                | Similar coverage of 84% reported for the vertical (2007) and the integrated (2009) campaigns.                                                                                                                                                                        | The estimated cost of provision of MBZ through the national deworming campaign implemented in 2007 was US\$150 000. The cost of covering 1 140 381 individuals obtained by applying the multiplication factor of 1.75 was estimated at US\$262 558. The additional cost to integrate deworming into the immunisation campaign was estimated at US\$30 927, which is equivalent to US\$0.03 per dewormed individual. |
| HODG15     | No significant difference in the number of fullyvaccinated infants between groups (96%).                                         | No significant difference in the number of fullyvaccinated infants between groups (96%). Significantly more infants received 'catch-up' vaccinations (doses 2 or 3) of polio pentavalent and/or PCV in both the full and mini package versus the revised CH card only | <b>Vitamin A:</b> routine VAS coverage between 6 and 7 months of age was 69.4 % (95 % CI 68.9–70.3 %). Significantly higher routine VAS coverage was observed in the full: 74.5 % (95 % CI 73.7–75.3 %) and                                                          | <b>FP:</b> Overall 69.9 % of women counselled on FP at the 6 months contact point accepted FP commodities (181/259). <b>Growth:</b> At 6\9 months of age, the mean WAZ was significantly higher for both the full and mini versus the revised                                                                                                                                                                       |

| Study code | Main outcomes measured, for immunization coverage (vaccines) | Secondary outcome measures, immunisation service (eg vaccination provided, staffing, other) | Main outcome measured, for other service coverage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Other main outcome measure (if not coverage), specify                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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|            |                                                              |                                                                                             | <p>mini: 71.7 % (95 % CI 71.7–72.6 %) versus the 'revised CH only' group: 60.2 % (95 % CI 59.8–61.1 %) (<math>p = 0.002</math>, <math>p \leq 0.001</math> respectively). <b>IYCF</b>: Significantly higher rates of exclusive breast feeding (EBF) were recorded in the full versus revised CH card only group up to 4 months of age (<math>p \leq 0.0001</math>). <b>FP</b>: Counseling for FP was provided to 61.8 % (95 % CI 60.8–62.9 %) of caregivers in the full compared with 4.8 % (95 % CI 2.9–6.8 %) in the mini and 1.5 % (95 % CI 0.0–3.2 %) in the revised CH card only group (<math>p \leq 0.0001</math> for both). Commodities were provided to 44.5 % (95 % CI 43.2–45.9 %) of caregivers in the full compared with 2.4 % (95 % CI 0.8–5.4 %) in the mini: and 0.8 % (95 % CI 0.0–2.6 %) in and revised CH only group (<math>p \leq 0.0001</math> both).</p> | <p>CH only group (<math>p \leq 0.0001</math>). The overall prevalence of moderate underweight was 12.6 % (95 % CI 5.7–25.5 %) and severe underweight was 8.2 % (95 % CI 0.6–58.8 %). At 9–12 months of age, the mean WAZ was significantly higher for the full versus mini and full versus revised CH only groups (<math>p \leq 0.005</math>, <math>p \leq 0.0001</math> respectively) and a trend towards significance in the mini versus revised CH card only group (<math>p = 0.065</math>). The overall prevalence of moderate underweight was 4.8 % (95 % CI 1.0–19.8%) and severe underweight was 1.0 % (95 % CI 0.1–7.2 %). NOTE differences in exclusive and early breastfeeding at baseline confound these.</p> |
| FRID12     | Nil                                                          |                                                                                             | <p>Coverage rates, illustrated in Fig. 2, indicate the number of babies initially screened at the PHC clinic compared to the number of babies who attended their 6, 10 or 14-week immunization visit. As evident from Fig. 2, three of the clinics presented with coverage rates between 74.6 and 85.3% but the majority had much poorer coverage. Although 98.5% (<math>n = 1987</math>) of the total subjects in the sample group were successfully screened at stage one, the overall coverage rate across the 8 clinics was 32.4%.</p>                                                                                                                                                                                                                                                                                                                                   | <p>Referrals to tertiary screening services. Varied widely.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

| Study code | Main outcomes measured, for immunization coverage (vaccines)                                                                                             | Secondary outcome measures, immunisation service (eg vaccination provided, staffing, other)                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Main outcome measured, for other service coverage                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Other main outcome measure (if not coverage), specify                                                                                                                                                                                                                       |
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| BAKA14     | No coverage measure                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Nil                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Depression by MINI - 15.2% and by EPDS screening - 24.8%                                                                                                                                                                                                                    |
| COOP15     | No coverage measure                                                                                                                                      | <p><b>Doses administered</b> before and after showed, in Lofa, increase in number of Penta 1 (by 35%) and Penta 3 (by 21%) doses administered in intervention sites, vs decreases in Penta 1 (11%) and Penta 3 (6%) in non intervention sites. In Bong increase Penta 1 (9%) and Penta 3 (5%), but non pilot sites had larger increases in Bong.</p> <p><b>Dropout</b> rate from the Penta 1 to Penta 3 increased: Lofa 14% 2011 to 25% 2012, cf decrease elsewhere; Bong 6% 2011 to 9% 2012, while stayed unchanged elsewhere. NB 10% = a problem.</p> | FP coverage not measured                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>10 - 45% accepted referral, over 80% followed through, and 90% utilised a method</p> <p>Total number of new contraceptive users at the intervention facilities - 44% and 34% of all new contraceptive users at each county were EPI referrals</p>                        |
| DULL16     | Measles data only: "no downward trend in numbers immunized for measles in intervention over study period". Trends parallel to control - ie: not inferior |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Significant, but modest increase. "statistically significant and positive effect on modern method use among intervention group participants compared with control group participants (regression coefficient, 0.15; 90% confidence interval [CI], 0.04 to 0.26). In other words, we observed an 8% increase in the intervention group and a 7% decrease in the control, resulting in a 15 percentage point difference between the intervention and control groups when comparing baseline to follow-up results" |                                                                                                                                                                                                                                                                             |
| VANC14     | Nil                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Use of non-condom modern FP method trend to increase, <b>slightly</b> more in intervention group but no significant difference                                                                                                                                                                                                                                                                                                                                                                                  | Almost no women in Ghana or Zambia could name all three LAM criteria spontaneously at pre-test or at post-test. Very few women could name two criteria, although at least 50% of women in every study group could name at least one of the criteria spontaneously. Of women |



| Study code | Main outcomes measured, for immunization coverage (vaccines)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Secondary outcome measures, immunisation service (eg vaccination provided, staffing, other) | Main outcome measured, for other service coverage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Other main outcome measure (if not coverage), specify                                                                                                      |
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|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | naming one criterion, 'return of menses' was the most commonly identified; it was named by over 80% of these women. Other knowledge showed no improvement. |
| BRIE12     | <p>In Homa Bay, <b>implementation coverage (children aged 2–20 months)</b> increased significantly from baseline to follow-up among all children (61% vs 70%, P 5 .007) and among urban children (68% vs 84%, P , .0001); there was no change in implementation coverage among rural children. In Suba, implementation coverage increased significantly from baseline to follow-up among all children (47% vs 58%, P 5 .005) and among rural children (46% vs 57%, P 5 .01); the increase among urban children was not statistically significant. In Homa Bay, <b>up-to-date coverage (children aged 2–13 months)</b> also increased significantly from baseline to follow-up among all children (57% vs 66%, P 5 .04) and among urban children (69% vs 82%, P , .0001) (Table 3); there was no change among rural children. In Suba, up-to-date coverage increased significantly from baseline to follow-up among all children (37% vs 53%, P , .0001) and among rural children (36% vs 52%, P 5 .0003); the change among urban children was not statistically significant.</p> |                                                                                             | <p><b>Water treatment:</b> Awareness of WaterGuard exceeded 97% at baseline and followup in both districts. From baseline to follow-up, there was a statistically significant increase in the percentage of Homa Bay respondents who reported ever using WaterGuard (77% vs 95%, P , .0001), reported treating their current drinking water with WaterGuard (30% vs 44%, P , .0001), and had a WaterGuard bottle observed in the home (26% vs 62%, P , .0001). In contrast, the increases in Suba from baseline to follow-up of respondents who reported ever using WaterGuard (80% vs 85%) and treating their current drinking water with WaterGuard (37% vs 39%) were not statistically significant; however, there was a significant increase in observed WaterGuard in the home from baseline to follow-up (30% vs 44%, P , .001). The percentage of stored water samples with detectable residual chlorine did not increase in either district. In the subsample of households completing the expanded questionnaire, a significant increase was observed among Homa Bay respondents from baseline to follow-up in knowledge of</p> |                                                                                                                                                            |

| Study code | Main outcomes measured, for immunization coverage (vaccines)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Secondary outcome measures, immunisation service (eg vaccination provided, staffing, other) | Main outcome measured, for other service coverage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Other main outcome measure (if not coverage), specify |
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|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                             | correct use of WaterGuard (52% vs 72%, P , .0001); no improvement was noted among Suba respondents. Hygiene: The percentage of households with soap increased from baseline to follow-up in Homa Bay (89% vs 92%, P 5 .04) but not in Suba. The percentage of respondents demonstrating correct handwashing technique increased in Homa Bay (25% vs 51%, P , .0001), but the observed improvement in Suba was not statistically significant.                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                       |
| RYMA12     | From discussion section: With the exception of OPV3 decreases in rural nurse sites, coverage either did not change or increased. It is unclear why a drop in OPV3 was seen in rural nurse sites. Administration of Penta3, given at the same time as OPV3, did not similarly decrease. A possible contribution of OPV stockouts (only slightly higher in rural nurse clinics) is difficult to assess because prior stockout data were unavailable. Vaccine coverage improvements occurred only in urban nurse sites. The demographics of the urban households differed from rural households in that completion of primary school was higher and median distance to the health facility was shorter. Urban households had higher vaccine coverage than rural households, but urban households were only in nurse strategy sites, which although unavoidable in |                                                                                             | From discussion section: Hygiene outcomes did not differ by distribution strategy. From results section: The high percentage of child caregivers reporting ever having heard of WaterGuard or knowing where to buy it at baseline limited the ability to observe changes in these indicators. However, significant increases occurred for most other hygiene knowledge and practice indicators, particularly in rural sites; the magnitude of the increase was similar across distribution strategies. Caregivers who reported ever using WaterGuard increased significantly for rural sites (SWAP and nurse) but not for urban nurse sites where the baseline was already high (Figure 2). Additionally, households reporting WaterGuard use and households with a bottle of WaterGuard observed increased from baseline to follow-up in both SWAP and nurse |                                                       |

| Study code | Main outcomes measured, for immunization coverage (vaccines)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Secondary outcome measures, immunisation service (eg vaccination provided, staffing, other) | Main outcome measured, for other service coverage                                                                                                                                                                                                                                                                                               | Other main outcome measure (if not coverage), specify                                                                                                                                                                                                                                                                                                            |
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|            | implementation of this evaluation, confounded analyses of the comparison between CHW and nurse distribution. From results section: "Implementation coverage" and "up-to-date" coverage significantly increased in urban nurse sites, with no change in either nurse or CHW rural sites. First, second, and third dose coverage of Penta increased in urban and rural sites. In rural nurse sites, third-dose OPV (OPV3) coverage significantly decreased between baseline and follow-up. Dropout (children who received the first Penta dose [Penta1] but not the third Penta dose [Penta3]), among children 4–13 months of age (ie, eligible for all Penta doses during the intervention) decreased significantly from 21% at baseline to 9% at follow-up in urban nurse sites with a nonsignificant decrease from 29% to 24% in rural SWAP sites and to 26% in rural nurse sites. |                                                                                             | sites. Despite the increases in reported WaterGuard use, the percentage of homes where stored drinking water tested positive for free chlorine residual did not increase in either SWAP or nurse sites. Correct knowledge of WaterGuard use and ability to demonstrate proper handwashing increased significantly in both SWAP and nurse sites. |                                                                                                                                                                                                                                                                                                                                                                  |
| PATO11     | Reported in Kweku                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                             | Outcomes also reported in Kweku. VHWs achieve higher IPTc coverage and adherence at lower costs than facility-based nurses. Overall, impressive adherence rates were achieved with all three delivery strategies: 326/472 (69.1%) VHW, 171/248 (69.0%) OPD, 151/244 (61.9%) EPI, 322/492 (65.4%) combined OPD and EPI.                          | Cost measures: The economic cost per child receiving at least the first dose of all 4 courses was US\$4.58 when IPTc was delivered by VHWs, US\$4.93 by OPD nurses and US\$ 5.65 by EPI nurses. The unit economic cost of receiving all 3 doses of all 4 courses was US\$7.56 and US\$8.51 when IPTc was delivered by VHWs or facility-based nurses respectively |

| Study code | Secondary outcome measures, additional service   | Feasibility measures                                                                                                                                                                                                                           | Acceptability measures                                                                                                                                                                                                                               | Equity measures, differential coverage, marginalised groups                                              | Cost measures | Effects on organisation of immunisation services                                              |
|------------|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|---------------|-----------------------------------------------------------------------------------------------|
| UDDI11     |                                                  | Health care providers found screening checklist feasible (1 - 2 minutes) . Follow-up also said to be feasible.                                                                                                                                 | Field staff liked the checklist and found it acceptable.                                                                                                                                                                                             |                                                                                                          |               |                                                                                               |
| GOOD13     | Nil else quantitative.                           | Qualitative data with providers and clients suggested overall in favour of integrated service, mothers citing time saved. Long wait times at urban clinics reported by mothers.                                                                | Qualitative data with clients: mothers appreciated opportunity to learn HIV. Some mothers, especially rural, expressed fear of HIV stigma, perceiving inadequate privacy, and some reported this being a deterrent to vaccination for other mothers. | Urban rural distinction. Much larger dose-given decline in rural. Acceptability problems worse in rural. |               | Long wait times mentioned in urban clinics, unclear whether this was due to the intervention. |
| WALL14     | Nil else quantitative.                           | A number of attitudinal, infrastructure and patient flow barriers identified                                                                                                                                                                   | Mothers appreciated time saving and chance to learn HIV status. Providers valued extra service reach.                                                                                                                                                | Reached some families otherwise not accessible                                                           |               |                                                                                               |
| DUBE12     |                                                  | Unfortunately, since HIV exposure was not documented on the standard infant health passports and there was limited privacy in the clinics, it proved impossible to integrate the services for early infant diagnosis with vaccination clinics. | Privacy cited as main constraint on integration.                                                                                                                                                                                                     |                                                                                                          |               |                                                                                               |
| TEJI11     |                                                  | Strict linking to immunization clinics may have limited ability to complete followup.                                                                                                                                                          |                                                                                                                                                                                                                                                      |                                                                                                          |               |                                                                                               |
| MCCO12     | children that received PITC at the IC were found | Said more feasible for providers but again not                                                                                                                                                                                                 | Acceptability 'measured' by uptake of PCR testing after                                                                                                                                                                                              |                                                                                                          |               |                                                                                               |

| Study code | Secondary outcome measures, additional service                                                                                                                                                           | Feasibility measures | Acceptability measures                                                       | Equity measures, differential coverage, marginalised groups                                                                                                                                                                                                                                                                                                                                                       | Cost measures | Effects on organisation of immunisation services |
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|            | to be considerably younger (2.6 vs 17.0 months, $p<0.001$ ), with much higher percentages identified as HIV exposed (17.6% vs 5.3%, $p<0.001$ ) and eligible for PCR testing (7.9% vs 3.5%, $p<0.001$ ). | clear how.           | PITC - much higher in Imm clinic                                             |                                                                                                                                                                                                                                                                                                                                                                                                                   |               |                                                  |
| ONGE12     | Similar CTX and positivity proportions at 12 mo across groups                                                                                                                                            |                      | Caretakers found acceptable in both models. Other comments positive          |                                                                                                                                                                                                                                                                                                                                                                                                                   |               |                                                  |
| WANG15     | Over time, children were being tested earlier across all facilities, with the average age of a first DBS test dropping from four months to three months of age between January 2012 and January 2014.    |                      |                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                   |               |                                                  |
| GOOD12     |                                                                                                                                                                                                          |                      | Assumed that ITNs provided extra incentive for poor families to participate. | Among children from the poorest households, children in ITN districts were twice as likely to have received measles vaccination during the campaign compared with those in non ITN districts (wealth Q1:RR = 2.4, 95% CI 1.2–4.8; wealth Q2: RR = 1.8, 95% CI 1.4–2.4). No significant differences were found in the wealthiest three quintiles (wealth Q3: RR = 1.0, 95% CI 0.8–1.2; wealth Q4: RR = 0.9, 95% CI |               |                                                  |

| Study code | Secondary outcome measures, additional service                | Feasibility measures                                                                                                                                                                         | Acceptability measures                    | Equity measures, differential coverage, marginalised groups                                                                                                                                                                                                                                                                                                                                       | Cost measures                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Effects on organisation of immunisation services              |
|------------|---------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
|            |                                                               |                                                                                                                                                                                              |                                           | 0.7–1.2; wealth Q5: RR = 1.0, 95% CI 0.9–1.2). Improved equity for measles vaccination during the campaign was achieved in ITN districts (equity ratio = 1.0, 95% CI 0.8–1.3) compared to non ITN districts (equity ratio = 0.4, 95% CI 0.2–0.8).                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                               |
| ARMS11     | Nil else quantitative.                                        | Nil in the article.roughly one-third of children attending for EPI vaccines were not offered IPTi due to demand and supply side barriers, all of which had potential to be addressed [8,18]. |                                           |                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                               |
| BOJA11     | Costs - showed VHW were US\$1.63 per child vs RCH at US\$3.47 | RCH arm had high initial coverage but then dropped off, ? Why? Had to train 20 health professionals for trekking teams, vs 33 VHWs.                                                          | Overall acceptable. No specific measures. | For both delivery methods, coverage with the three treatments was similar in each socioeconomic group defined by wealth quintiles derived from household assets. In the VHW arm, coverage of three courses of IPT was 76% in the wealthiest quintile and 73% in the poorest quintile; in the RCH arm coverage of three courses was 40% in the wealthiest quintile and 48% in the poorest quintile | The highest percentage of the total costs associated with delivery by the RCH trekking teams was the the higher salary costs ... and the US\$28 monthly incentive required to pay trained health care professionals to deliver IPTc. This cost can be compared to US\$11 per month “incentive” given to the VHW for administering IPTc. The highest cost component of the VHW strategy was the delivery of non-IPTc drugs. Training costs were similar for both the RCH and the VHW delivery strategies. | Extra staff provided to cope with workload on trekking teams. |

| Study code | Secondary outcome measures, additional service                                                                             | Feasibility measures                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Acceptability measures                                                                                                                                                                                                             | Equity measures, differential coverage, marginalised groups | Cost measures                                                                                                                                                                                                                                       | Effects on organisation of immunisation services                                                                                                                                     |
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| DICK11     |                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | hypothesised high acceptability drove community uptake.                                                                                                                                                                            |                                                             |                                                                                                                                                                                                                                                     |                                                                                                                                                                                      |
| WILL11     | Nil else quantitative. Demonstrated value of routine HMIS in impact assessment, but with a strong need for quality checks. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                    |                                                             |                                                                                                                                                                                                                                                     |                                                                                                                                                                                      |
| MONT13     | Significant improvement in beliefs about green vegetables, beef, chicken, and fish, utility of breast milk after 6mo,      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                    |                                                             |                                                                                                                                                                                                                                                     |                                                                                                                                                                                      |
| BOSE11     | Nil else quantitative.                                                                                                     | The additional time spent for each child dewormed by a health worker was estimated at 1 min for pre-SAC and 30 s for WCBA. 20% of the staff reported difficulties in logistics, drug administration and the integrated training; however, all were able to treat all of the children and WCBA attending the CHD even if with some increased waiting time. In particular, logistical difficulties were reported only from one rural province. Four health workers (13%), all from the rural province of Khammouane, reported difficulty in transport of drugs and materials. The | The authors interviewed 109 WCBA in the four areas visited. WCBA reported satisfaction with the deworming campaign and appreciation of the simultaneous delivery of multiple interventions. None expressed complaints or concerns. | None mentioned.                                             | Demonstrates the higher cost effectiveness of integration of deworming into an existing immunisation and vitamin A supplementation campaign compared with the vertical implementation of an intervention exclusively delivering anthelmintic drugs. | Six health workers (20%) reported a complication in providing the multiple health products and this complication resulted in a longer waiting time for the people attending the CHD. |

| Study code | Secondary outcome measures, additional service                                                                                                                                                                                                                                                                                                                                                    | Feasibility measures                                                                                                                                                                                                                                                                                                                     | Acceptability measures                                                                                                                                                                                                                                                                                                                             | Equity measures, differential coverage, marginalised groups | Cost measures | Effects on organisation of immunisation services |
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|            |                                                                                                                                                                                                                                                                                                                                                                                                   | integrated training on vaccination and administration of vitamin A and anthelmintics was provided to health workers between 19 and 26 October 2009. The time dedicated to deworming was approximately 30 min during the 1-day seminar. According to the EPI manager, this additional 30 min did not generate additional financial costs. |                                                                                                                                                                                                                                                                                                                                                    |                                                             |               |                                                  |
| HODG15     |                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                    |                                                             |               |                                                  |
| FRID12     |                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                    |                                                             |               |                                                  |
| BAKA14     | Some association of stunting with depression                                                                                                                                                                                                                                                                                                                                                      | Stated 'feasible', no measurement.                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                    |                                                             |               |                                                  |
| COOP15     | Contraceptive method mix among EPI referral acceptors: In Bong, nearly half of the same-day referred family planning acceptors committed to using LAM, while about one-quarter chose injectables and nearly one-quarter chose oral contraceptive pills). In Lofa, most same-day referral family planning acceptors (43%) chose injectables, while about one quarter chose LAM and another quarter | Managers and staff generally assessed as feasible. Long wait times to take up a referral was main disincentive.                                                                                                                                                                                                                          | IDI and FGD as well as measures of FP uptake of referral and method = good acceptability across clients and providers<br><br>reach was amplified beyond vaccinators' one-on-one communication with clients: many mothers reported sharing the information and take-home materials about family planning with friends, family members, and partners |                                                             |               |                                                  |



| Study code | Secondary outcome measures, additional service                                                                                                                                                                                                       | Feasibility measures                                                                                                                                                                                                                                                                                                                                                       | Acceptability measures                                                                                                                                                                                                                                                                     | Equity measures, differential coverage, marginalised groups                                                                                                                                                                                 | Cost measures                                                                                                                                                                                                                                                                                                                        | Effects on organisation of immunisation services                                                                                                                          |
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|            | chose pills. Less than 10% of women chose implants in either county                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                           |
| DULL16     |                                                                                                                                                                                                                                                      | Quarterly supervision visits. Measured perception of wait times.                                                                                                                                                                                                                                                                                                           | Used Health Belief Model. Asked acceptability questions.                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                             | Measured costs of intervention development, supervisions, training. Estimated US\$4.8 per woman.                                                                                                                                                                                                                                     |                                                                                                                                                                           |
| VANC14     | <i>referrals</i> in the Ghana site increased in the control group compared with the intervention group. In Zambia, increases of reported referrals were observed in the intervention group compared with the control; but differences were not large | Interviews found 11 of 15 vaccinators in both intervention groups in Ghana and Zambia reported using the job-aid with all of their clients, and 9 out of 15 in each country felt they increased referrals made to FP servicesIn Zambia, 13 of 15 vaccinators reported providing information to clients in group settings as opposed to individually - ? due to feasibility |                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                           |
| BRIE12     |                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                           |
| RYMA12     |                                                                                                                                                                                                                                                      | The combined distribution of hygiene products and education during vaccination visits was found to be feasible for both nurseand CHW-distribution strategies.                                                                                                                                                                                                              | Information from the interviews and focus groups indicated that the intervention was well accepted in both nurse and CHW sites by nurses, mothers, and CHWs, with no major criticisms of either distribution strategy. However, there was concern around the inequity of only offering the | Information from the interviews and focus groups indicated that mothers felt the intervention should be expanded to include anyone ,5 years of age coming into the clinic, particularly those with diarrheal illness and/or pregnant women. | Transportation allowances for CHW of 200 Kenyan shillings (KES; US \$2.60 per day) totaled 402,660 KES (US\$5223) over the year intervention, equating to an average cost of 240 KES (US \$3.12) per child reached (ie, up-to-date on vaccines; target population of 3048 in the 9 SWAP clinics 3 55% of children up-to-date in SWAP | Additional work associated with this intervention was reported to be minimal and readily incorporated into the normal routine, consuming only about 6% of a nurse's time. |

| Study code | Secondary outcome measures, additional service | Feasibility measures                                                                                                       | Acceptability measures                                                                                                                                                                                                                                                                                                                                                                                                                                               | Equity measures, differential coverage, marginalised groups    | Cost measures                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Effects on organisation of immunisation services |
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|            |                                                |                                                                                                                            | intervention to children being vaccinated. Despite reporting that the intervention increased their workload, nurses viewed it favorably. Many mothers reported that the program was effective at motivating women who otherwise might not vaccinate their children, as well as in encouraging mothers to vaccinate on schedule. However, some mothers cited barriers preventing women from being motivated by the program (e.g. they can buy Waterguard themselves). |                                                                | areas 5 1676 up-to-date children). In nurse clinics, nurses reported spending a median 15 hours permonth ( 6%) of their time providing the intervention.                                                                                                                                                                                                                                                                                                                      |                                                  |
| PATO11     |                                                | Costs including time estimates - deemed feasible for all. Attributed 20% of time by EPI staff to IPTc on monthly outreach. | All three routes deemed acceptable.                                                                                                                                                                                                                                                                                                                                                                                                                                  | Used remoteness - VHW delivery reached more remote communities | Ingredients costing of supply side, including time by VHW and nurses. The economic cost per child receiving at least the first dose of all 4 courses was US\$4.58 when IPTc was delivered by VHWs, US\$4.93 by OPD nurses and US\$ 5.65 by EPI nurses. The unit economic cost of receiving all 3 doses of all 4 courses was US\$7.56 and US\$8.51 when IPTc was delivered by VHWs or facility-based nurses respectively main financial cost drivers under the community-based |                                                  |

| Study code | Secondary outcome measures, additional service | Feasibility measures | Acceptability measures | Equity measures, differential coverage, marginalised groups | Cost measures                                                                                                                                                                                                                                                          | Effects on organisation of immunisation services |
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|            |                                                |                      |                        |                                                             | delivery strategy were resources for delivering drugs to the dispensing sites (28%) and for supervision (28%) (Table 3). In comparison, under the facility-based strategy, these resources represented 18% and 26% of the total financial cost respectively (Table 3). |                                                  |

| Study code | Effects on vaccines/supplies management, distribution and storage                                                         | Cadres involved                                                                                                                       | Knowledge and skills                                                                     | Time issues                                                                                                                                                                            | Quality of care                                                                                | Attitudes, values or motivations                                                                                                 |
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| UDDI11     |                                                                                                                           | PHC staff doing non-vaccination services                                                                                              | Screening checklist to boost ability to identify children needing vaccination            | Only took 1-2 minutes to implement                                                                                                                                                     |                                                                                                | Appreciated chance to identify children because knew many were missing out                                                       |
| GOOD13     | Stock-outs mentioned, but unclear whether due to intervention. Controlling for them did not change vaccine dose findings. | Nurses working in health centres.                                                                                                     | Able to be trained to followup HIV status, counsel, start prophylactic treatment, refer. | Wait times extended in urban. Noted high proportion (98%) of mothers had HIV status documented. Time needed would be greater if more mothers had not had ANC HIV testing done already. | No data on quality of care.                                                                    | Staff generally in favour of integrating services, because of ability to reach mothers who may not attend HIV-specific services. |
| WALL14     |                                                                                                                           | Nurses working in health centres.                                                                                                     | Able to be trained to followup HIV status, counsel, start prophylactic treatment, refer. |                                                                                                                                                                                        | Concerns exist that increased workload could lead to shortened counseling times at HIV testing | High value on finding infants needing treatment.                                                                                 |
| DUBE12     |                                                                                                                           | HIV staff                                                                                                                             | Nil reported.                                                                            | Nil reported.                                                                                                                                                                          | Nil reported.                                                                                  | Nil reported.                                                                                                                    |
| TEJI11     |                                                                                                                           | Colocated service only                                                                                                                |                                                                                          |                                                                                                                                                                                        |                                                                                                |                                                                                                                                  |
| MCCO12     |                                                                                                                           | IC nurses, dedicated HIV counsellors                                                                                                  |                                                                                          | ? More difficult integrating HIV into clinical care OPD? Higher volumes                                                                                                                |                                                                                                |                                                                                                                                  |
| ONGE12     |                                                                                                                           | Nurses in hospital MCH or HIV clinics                                                                                                 | Additional training and clinical support related to study setting.                       |                                                                                                                                                                                        |                                                                                                |                                                                                                                                  |
| WANG15     |                                                                                                                           | Nurse or midwife                                                                                                                      | Training on DBS                                                                          |                                                                                                                                                                                        |                                                                                                |                                                                                                                                  |
| GOOD12     |                                                                                                                           | Vaccinator and support staff                                                                                                          |                                                                                          |                                                                                                                                                                                        |                                                                                                |                                                                                                                                  |
| ARMS11     |                                                                                                                           | Article references "front line health workers" receiving training, but provides little information on the design of the intervention. | Trained front line health workers how to implement IPTi                                  |                                                                                                                                                                                        |                                                                                                |                                                                                                                                  |
| BOJA11     | Nil                                                                                                                       | Professional staff doing outreach in                                                                                                  | Trained front-line staff (and VHWs) to give IPTc                                         | Extra 4 staff to make teams of 10                                                                                                                                                      |                                                                                                |                                                                                                                                  |

| Study code | Effects on vaccines/supplies management, distribution and storage                                                                                                                                                                                                                                                                                | Cadres involved                                          | Knowledge and skills                                                                 | Time issues                                                                                                                                                                                                                                                                                                   | Quality of care             | Attitudes, values or motivations                                                                                                  |
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|            |                                                                                                                                                                                                                                                                                                                                                  | trekking teams                                           |                                                                                      |                                                                                                                                                                                                                                                                                                               |                             |                                                                                                                                   |
| DICK11     |                                                                                                                                                                                                                                                                                                                                                  | Health centre staff ?<br>Nurses. Definitely vaccinators. | Educated with dedicated training that covered IPTi and vaccines                      | Said to be under-utilised so had spare time capacity. time used for IPTi implementation is acceptable and was estimated to 12.4 minutes ranging from 1.6-28.9 minutes per nurse [30].                                                                                                                         |                             | staff adhesion and the enthusiasm toward this new intervention have resulted in the observed increase of EPI vaccination coverage |
| WILL11     |                                                                                                                                                                                                                                                                                                                                                  |                                                          |                                                                                      |                                                                                                                                                                                                                                                                                                               |                             |                                                                                                                                   |
| MONT13     |                                                                                                                                                                                                                                                                                                                                                  |                                                          | 4 day training on theory and communication skills                                    | Add "<10 minutes" to service. <i>But that's actually a lot in busy vaccination clinics. CF Vance aimed for 1 minute. DICK11 added 12 minutes. Wallace paper on time measures supports.</i>                                                                                                                    |                             |                                                                                                                                   |
| BOSE11     | No effect mentioned. (Vaccines were transported from the MoH's premises in Vientiane to provincial offices and subsequently to district offices and health centres with refrigerated containers in order not to spoil the vaccines. Vitamin A capsules and MBZ tablets were transported together by MoH vehicles. Owing to the limited volume of | Health workers involved in Child Health Days.            | Integrated training on vaccination and administration of vitamin A and anthelmintics | Reference made to some increased wait times reported by some health workers "20% of the staff reported difficulties in logistics, drug administration and the integrated training; however, all were able to treat all of the children and WCBA attending the CHD even if with some increased waiting time. " | No data on quality of care. |                                                                                                                                   |

| Study code | Effects on vaccines/supplies management, distribution and storage                                                    | Cadres involved                                                                                         | Knowledge and skills                                                                                                                                                                                                                                                      | Time issues                                                                                      | Quality of care                                                                                         | Attitudes, values or motivations                                                                                                                                                |
|------------|----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            | the MBZ, its transport did not require additional facilities (stored at central and peripheral level and vehicles)). |                                                                                                         |                                                                                                                                                                                                                                                                           |                                                                                                  |                                                                                                         |                                                                                                                                                                                 |
| HODG15     |                                                                                                                      |                                                                                                         | CHVs are frequently either young school leavers awaiting acceptance into a health-training institution or more senior community members with limited education.                                                                                                           |                                                                                                  |                                                                                                         |                                                                                                                                                                                 |
| FRID12     |                                                                                                                      | Clinic nurses, trained and mentored in IHS before the service commenced, served as screening personnel. | Nurses were trained by the program manager and colleague at their relevant clinics and received ongoing support and training from the program manager throughout the course of the screening program.                                                                     | utilizing already burdened clinic nursing staff as screeners may explain the poor coverage rates | importance of a program coordinator monitoring quality and providing on going support and training      |                                                                                                                                                                                 |
| BAKA14     |                                                                                                                      |                                                                                                         |                                                                                                                                                                                                                                                                           |                                                                                                  |                                                                                                         |                                                                                                                                                                                 |
| COOP15     |                                                                                                                      | Nurses                                                                                                  | OJT for new staff, and extra training on job-aid for vaccinators<br>Some FP staff dissuaded mothers from FP until six weeks post partum<br>Drop-out data underscores the need for vaccinators <b>and</b> family planning providers alike to inform mothers of the need to |                                                                                                  | Drop-out Penta1-3 attributed to one large facility in Lofa with HR constraints and supervisor turnover. | some vaccinators reported greater confidence in their roles and perceived that their value within the health system and community had increased as a result of the intervention |

| Study code | Effects on vaccines/supplies management, distribution and storage                                                                        | Cadres involved                                                                                                              | Knowledge and skills                                                                                                                                                                                                                                                                                  | Time issues                                                                                                      | Quality of care                                                                                                                                                                                                                                                                                                                                                                                   | Attitudes, values or motivations                                                                                                                                       |
|------------|------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                          |                                                                                                                              | return for their child's next vaccination                                                                                                                                                                                                                                                             |                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                        |
| DULL16     |                                                                                                                                          | EPI nurses                                                                                                                   | intervention group immunization and family planning providers attended a 3-day training on postpartum family planning and the use of a screening tool to assess pregnancy risk among postpartum women. Extra 3day training on LAM, pregnancy risk and PPFP. Single training session was insufficient. |                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                   | Used Health Belief Model to frame interaction                                                                                                                          |
| VANC14     |                                                                                                                                          | Nurses providing vaccination                                                                                                 | Half day training in LAM.                                                                                                                                                                                                                                                                             | Aimed for less than 30 seconds per messageDiscussion still implies problems of ? Feasibility or ? Other factors. | Early process assessment showed most were not doing counselling, so were re-trained. Although vaccinators reported using the job-aid and referring mothers to FP, it would appear that in Zambia, vaccinators generally delivered the messages in group settings and not individually. In Ghana, there is little evidence that the messages were consistently delivered to individuals or groups. | the intervention training and follow-up did not appear to change vaccinator behaviour as we intended, and subsequently the intervention was not implemented as planned |
| BRIE12     | Nil (monitoring of vaccine stock outs took place throughout the entire study period; no mention of monitoring of stocks of hygiene kits) | Not specified in Briere et al 2012, however info is available in Ryman et al 2012 (comparison of Nurse and Community Worker) | Knowledge to provide counseling about water treatment and hand hygiene                                                                                                                                                                                                                                |                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                        |

| Study code | Effects on vaccines/supplies management, distribution and storage                                             | Cadres involved                                                                                                                                                                                                    | Knowledge and skills | Time issues                                                                                                                                                              | Quality of care | Attitudes, values or motivations |
|------------|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------------------------|
| RYMA12     | Nil (stock outs of vaccines and hygiene kits were reported, with vaccine stockouts occurring more frequently) | Although both nurse and CHW strategies were viewed favorably, additional advantages of the CHW strategy were expressed, including the potential for CHWs to have a slower and less intimidating educational style. |                      | Additional work associated with this intervention was reported to be minimal and readily incorporated into the normal routine, consuming only about 6% of a nurse's time |                 |                                  |
| PATO11     |                                                                                                               | VHWs vs Nurses (in either OPD or doing monthly EPI outreach).                                                                                                                                                      |                      | Potential for fatigue - estimated 20% of nurses time on IPTc during monthly EPI outreach                                                                                 |                 |                                  |



| Study code | Clients' Knowledge                                                                                                                                                                                                            | Clients' Attitudes to service/s, acceptability, trust                                                                                                                                                                                                                                                                        | Care seeking and/or healthy behaviours                                           | Travel for care or referral                                                                                                                     | Marginalisation, inequity of access                                        | Health System Access overall and for marginalised                                                                    |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| UDDI11     |                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                              |                                                                                  |                                                                                                                                                 |                                                                            | Targeted hard-to-reach so focused on maximising every opportunity or innovative outreach oriented to difficult areas |
| GOOD13     | Mothers appreciated opportunity to learn more about HIV during integrated care. <i>Discussion:</i> Misconception that HIV test was needed to receive vaccination - may have been a major bias in study and/or actual barrier. | Positive attitude to receiving information on HIV. Positive trust in health workers maintaining confidentiality. Rural mothers reported HIV stigma risk due to inadequate privacy.                                                                                                                                           | Fear of HIV stigma may prevent some families attending for immunization service. | Nil                                                                                                                                             | Some rural disadvantage, possibly attitude/knowledge rather than distance. | Very high uptake of ANC HIV testing enabled the integration.                                                         |
| WALL14     | Fear of death from HIV drives reluctance.                                                                                                                                                                                     | Nearly all mothers across all sites expressed trust in their providers and described them as experienced, kind, and informative. Some report of fear of HIV stigma dissuading attendance at integrated services. Providers felt trust in vaccinations would transfer to HIV service. Disapproval of husbands another factor. |                                                                                  | Close to half of others, the majority from rural sites, mentioned benefits of cost and time savings because fewer facility visits were required |                                                                            |                                                                                                                      |
| DUBE12     | Nil reported.                                                                                                                                                                                                                 | Although all but one of the 50 women who declined to give consent for the infant testing said that they wanted to get permission                                                                                                                                                                                             | Nil reported.                                                                    | Extra visit just for EID rendered unnecessary                                                                                                   | Nil reported.                                                              | Nil reported.                                                                                                        |

| Study code | Clients' Knowledge | Clients' Attitudes to service/s, acceptability, trust                                                                                                                     | Care seeking and/or healthy behaviours                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Travel for care or referral                                                               | Marginalisation, inequity of access | Health System Access overall and for marginalised |
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|            |                    | from their spouses, none of these women ever returned for early infant diagnosis                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                           |                                     |                                                   |
| TEJI11     |                    |                                                                                                                                                                           | Of the parents of the 62 remaining infants, 45 gave various reasons to justify their failure to attend the follow up or to collect the HIV result. Over half (57.8%) reported moving and in 11.1%, the mothers were sick. Other reasons included refusal of HIV testing, fear of the HIV test results, forgetting about the follow up visit, the time required for the consultation, attending follow up in another health structure, and death of a parent. For 149 infants, no information could be obtained considered to be lost to follow up. |                                                                                           |                                     |                                                   |
| MCCO12     |                    | caregivers of PCR eligible infants found PITC at an IC more acceptable                                                                                                    | Possibly easier to do HIV testing at a routine service cf that providing illness care.                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                           |                                     |                                                   |
| ONGE12     |                    | Possibly having same service provider for EPI and for HIV may be less stigmatising. Positive attitude to both service options - driven by desire to see baby HIV-negative | One caretaker only expressed long waiting times                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Employment status affected followup possibly through difficulty in being absent from work |                                     |                                                   |

| Study code | Clients' Knowledge | Clients' Attitudes to service/s, acceptability, trust                                                 | Care seeking and/or healthy behaviours                                                                                                                                                                                                                                                                                                                                                                                         | Travel for care or referral         | Marginalisation, inequity of access                          | Health System Access overall and for marginalised |
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| WANG15     |                    | Generally positive attitudes towards testing.                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                     |                                                              |                                                   |
| GOOD12     |                    |                                                                                                       | From Kulkarni 2010: :A social mobilization campaign was conducted by the Ministry of Health and the Madagascar Red Cross one week before the campaign to sensitize the local population on the location and timing of the campaign. In addition, for one week post campaign the Madagascar Red Cross conducted hang-up activities in the communities to sensitize the local population on the proper way to hang and use nets. |                                     | Campaign raised equity of both vaccination and ITN ownership | Campaign model was pro-equity                     |
| ARMS11     |                    |                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                     |                                                              |                                                   |
| BOJA11     |                    |                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                | Not relevant - outreach in village. |                                                              |                                                   |
| DICK11     |                    | Hypothesised that concern about malaria drove care-seeking                                            | Families attracted to EPI by offer of IPTi was hypothesised                                                                                                                                                                                                                                                                                                                                                                    |                                     |                                                              |                                                   |
| WILL11     |                    |                                                                                                       | Nil reported.                                                                                                                                                                                                                                                                                                                                                                                                                  |                                     |                                                              |                                                   |
| MONT13     |                    |                                                                                                       | Significant change in specific beliefs and some feeding practice, but not in social norms                                                                                                                                                                                                                                                                                                                                      |                                     |                                                              |                                                   |
| BOSE11     |                    | Women of Child Bearing Age "reported satisfaction with the deworming campaign and appreciation of the |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                     |                                                              |                                                   |

| Study code | Clients' Knowledge                                                                                                                                                                                                                                                                                                                     | Clients' Attitudes to service/s, acceptability, trust                                                                                                                                            | Care seeking and/or healthy behaviours                                                                                                                                                                                                                                                                                                                                                                 | Travel for care or referral | Marginalisation, inequity of access | Health System Access overall and for marginalised |
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|            |                                                                                                                                                                                                                                                                                                                                        | simultaneous delivery of multiple interventions. None expressed complaints or concerns"                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                        |                             |                                     |                                                   |
| HODG15     |                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                        |                             |                                     |                                                   |
| FRID12     |                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                        |                             |                                     |                                                   |
| BAKA14     |                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                        |                             |                                     |                                                   |
| COOP15     | qualitative data also revealed that the integrated services improved knowledge and changed views about family planning among clients and providers alike. For example, several clients and family planning providers reported that before the intervention, they did not know that a woman with a young infant could use contraception | a lack of privacy at the EPI station prevented some women from accepting family planning referrals                                                                                               | When not taking up FP often wanted to discuss with partner first. None of the clients participating in the FGDs (neither referral acceptors nor non-acceptors) reported feeling discouraged to return to the facility for vaccinations. Rather, clients reported that they saw the value of vaccinating their child and would return regardless of their decision to accept a family planning referral |                             |                                     |                                                   |
| DULL16     | Non-use of FP mostly due to women waiting for return of menses                                                                                                                                                                                                                                                                         | perceived barriers to family planning use associated with lower family planning use.<br><br>98% happy to get FP information with immunization. 73% prefer to get FP on same day as immunization. | Used Health Belief Model to frame risk and information. Women with a higher perceived susceptibility to an unplanned pregnancy were more likely...to use a modern contraceptive method.<br><br>High level of service                                                                                                                                                                                   |                             |                                     |                                                   |

| Study code | Clients' Knowledge                                                                                                                                      | Clients' Attitudes to service/s, acceptability, trust                                                      | Care seeking and/or healthy behaviours                                                      | Travel for care or referral                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Marginalisation, inequity of access                                                                                                                                                                                          | Health System Access overall and for marginalised |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
|            |                                                                                                                                                         |                                                                                                            | satisfaction. More interactive and more question opportunity reported by intervention group |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                              |                                                   |
| VANC14     | Waiting for return of menses to assume fertility key knowledge gap. Other LAM knowledge targeted                                                        |                                                                                                            | Co-location thought to be essential, but ? Not enough                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                              |                                                   |
| BRIE12     | In addition, WaterGuard has been marketed in Kenya for 7 years, is widely available, and has high product awareness, which may have reduced its appeal. |                                                                                                            |                                                                                             | Increase in vaccination coverage reported in urban areas of Homa Bay (intervention site), whereas the provision of hygiene kits in rural areas appeared to have not incentivised increased vaccination coverage. Authors propose this may be due to higher transportation costs "Transportation to rural health facilities in Homa Bay cost \$0.50–\$2.50 while WaterGuard and soap cost only \$0.40, a value that may have been insufficient to motivate a trip to the clinic. | Benefit to immunization only seen in urban area                                                                                                                                                                              |                                                   |
| RYMA12     |                                                                                                                                                         | Mothers reported being motivated by incentive of hygiene kit, but this was offset if travel was difficult. |                                                                                             | Distance and/or cost for transport to get to the clinic were the most commonly cited barriers to vaccination. Incentives such as hygiene kits may not be of adequate value to overcome access barriers more common in rural areas; in urban settings, where clinic location is closer and more                                                                                                                                                                                  | Information from the interviews and focus groups indicated that mothers felt the intervention should be expanded to include anyone , 5 years of age coming into the clinic, particularly those with diarrheal illness and/or |                                                   |

| Study code | Clients' Knowledge | Clients' Attitudes to service/s, acceptability, trust | Care seeking and/or healthy behaviours | Travel for care or referral                                                                                                                                                | Marginalisation, inequity of access | Health System Access overall and for marginalised |
|------------|--------------------|-------------------------------------------------------|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|---------------------------------------------------|
|            |                    |                                                       |                                        | convenient, the incentive may be sufficient.                                                                                                                               | pregnant women.                     |                                                   |
| PATO11     |                    |                                                       |                                        | These differences reflected the more remote location of villages that received IPTc through VHWs compared to those where treatment was delivered through health facilities | Remoteness as above                 |                                                   |

| Study code | Finances, payments, procurement                                                                | Human resource allocation                                                                              | Clinical supervision                                                                    | Authority, delegations, accountability | Policy and leadership, norms and standards                                                            | Information systems                                                                       |
|------------|------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| UDDI11     | Nil                                                                                            | existing staff                                                                                         |                                                                                         |                                        | Enabled change to outreach policies in 'control' arm                                                  |                                                                                           |
| GOOD13     | Nil reported.                                                                                  | Existing staff required extra training.                                                                | Nil reported.                                                                           | Nil reported.                          | Nil reported.                                                                                         | Nil reported.                                                                             |
| WALL14     |                                                                                                |                                                                                                        |                                                                                         |                                        |                                                                                                       |                                                                                           |
| DUBE12     | Nil reported.                                                                                  | Nil reported.                                                                                          | Nil reported.                                                                           | Nil reported.                          | Nil reported.                                                                                         | HIV status not recorded on home-based record, so could not be integrated into routine EPI |
| TEJI11     |                                                                                                |                                                                                                        |                                                                                         |                                        |                                                                                                       |                                                                                           |
| MCCO12     |                                                                                                |                                                                                                        |                                                                                         |                                        |                                                                                                       |                                                                                           |
| ONGE12     |                                                                                                | Additional staff provided to boost both HIV and MCH services.                                          |                                                                                         |                                        |                                                                                                       |                                                                                           |
| WANG15     |                                                                                                | One lay counsellor per facility. Research team supported implementation - not measured to what effect. |                                                                                         |                                        | Current policy support for integration emphasised in sensitisation meetings in both intervention arms |                                                                                           |
| GOOD12     |                                                                                                |                                                                                                        |                                                                                         |                                        | National government commitment to integrated approaches.                                              |                                                                                           |
| ARMS11     |                                                                                                |                                                                                                        |                                                                                         |                                        |                                                                                                       |                                                                                           |
| BOJA11     | Extra incentives paid to both arms, but more than twice as much to professional staff cf VHWs. | Extra staff provided in professional teams - substantial amount - close to doubling teams size.        | Extra investment in staff supervision.                                                  |                                        |                                                                                                       |                                                                                           |
| DICK11     |                                                                                                |                                                                                                        | Intense supervision in intervention districts may have contributed to improved services |                                        |                                                                                                       |                                                                                           |
| WILL11     |                                                                                                |                                                                                                        |                                                                                         |                                        |                                                                                                       |                                                                                           |
| MONT13     |                                                                                                |                                                                                                        |                                                                                         |                                        |                                                                                                       |                                                                                           |
| BOSE11     | Reduced costs for the integrated campaign (Table 1 has costs per treated                       | Additional time spent by existing health workers to deliver deworming.                                 |                                                                                         |                                        |                                                                                                       |                                                                                           |

| Study code | Finances, payments, procurement                                                                                                                                                                                                                              | Human resource allocation                                                                                                                                                              | Clinical supervision                                                                                    | Authority, delegations, accountability | Policy and leadership, norms and standards                                                                                                                                   | Information systems                                                                                                                                                                                                                       |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            | individual falling from 0.23USD to 0.03USD when the campaign was integrated, although this cost only takes into account the additional cost of adding deworming and not reflecting a share of the other costs, with the exception of personnel and training) |                                                                                                                                                                                        |                                                                                                         |                                        |                                                                                                                                                                              |                                                                                                                                                                                                                                           |
| HODG15     |                                                                                                                                                                                                                                                              | turn-over of CHVs performing the IYCF counseling and demonstration was high,                                                                                                           |                                                                                                         |                                        |                                                                                                                                                                              |                                                                                                                                                                                                                                           |
| FRID12     |                                                                                                                                                                                                                                                              | utilizing already burdened clinic nursing staff as screeners may explain the poor coverage rates<br>Dedicated screening personnel may be necessary to ensure sufficient coverage rates |                                                                                                         |                                        |                                                                                                                                                                              | A test form including a brief medical case history, high-risk register, demographic information and screening outcome was completed for every visit to the clinic. A separate form was completed for every visit to the tertiary hospital |
| BAKA14     |                                                                                                                                                                                                                                                              |                                                                                                                                                                                        |                                                                                                         |                                        |                                                                                                                                                                              |                                                                                                                                                                                                                                           |
| COOP15     |                                                                                                                                                                                                                                                              | Important to have staff allocated to service on same day.                                                                                                                              | Frequent communication between EPI and FP staff<br><br>Monthly supervision was part of the intervention |                                        | Using the proof-of-concept experience, MCHIP has developed an implementation package outlining the process, training materials, tools, and key implementation considerations | IDI with service providers (vaccinators, in particular) suggested that the intervention may have contributed to greater staff appreciation for recordkeeping                                                                              |
| DULL16     |                                                                                                                                                                                                                                                              | Provider attrition through transfers was a problem.                                                                                                                                    |                                                                                                         |                                        | a strong policy environment aiming to improve maternal and child health, extensive engagement of the                                                                         |                                                                                                                                                                                                                                           |



| Study code | Finances, payments, procurement                 | Human resource allocation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Clinical supervision                                                                                                                              | Authority, delegations, accountability | Policy and leadership, norms and standards                                 | Information systems |
|------------|-------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|----------------------------------------------------------------------------|---------------------|
|            |                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                   |                                        | Ministry of Health in the planning and implementation of the intervention, |                     |
| VANC14     |                                                 | Providing individualized messages during child vaccinations may be too difficult in many developing country service delivery settings, which often do not allow for more than a few minutes of one-on one time between clients and vaccinators. Adding a staff member dedicated to FP would address this concern. If adding another provider is not realistic, it may be feasible to transfer other staff to the immunization service on days designated for child immunizations. Perhaps FP providers or community health workers could be assigned to work in immunization clinics to help generate demand for FP instead of vaccinators. However, inadequate staffing within many developing country health systems was one of the main reasons we did not increase or rearrange service delivery personnel | Regional health directors or their deputies participated in trainings and made field visits after implementation to encourage use of the jobaids. |                                        | Overall support for integrated service may have been lacking.              |                     |
| BRIE12     |                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                   |                                        |                                                                            |                     |
| RYMA12     |                                                 | Time required to deliver additional interventions should be carefully considered (see time issues under providers of care). Nurses appreciated having CHWs do the education.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                   |                                        |                                                                            |                     |
| PATO11     | No client payments and no client costs involved | No extra staff                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Supervision of VHWs needed, including to ensure correct dose by weight                                                                            |                                        |                                                                            |                     |

| Study code | Facilities, supplies and infrastructure                                                                                             | Patient flow processes                                                                  | Community engagement                                                                                                                   | Ideology                                                                                          | Contracts, legislation, regulations | Donors, aid, development policy                          | Corruption    | Security and political stability |
|------------|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-------------------------------------|----------------------------------------------------------|---------------|----------------------------------|
| UDDI11     |                                                                                                                                     |                                                                                         | Community support groups in 'control' arm but not in checklist arm                                                                     |                                                                                                   |                                     |                                                          |               |                                  |
| GOOD13     | Nil reported.                                                                                                                       | Wait times reported as a problem in urban clinics. Unclear if due to intervention.      | Major possible issue with mis-communication leading women to assume an HIV test was mandatory for vaccination at study health centers. | Possibility that service access may be conditional - in this case vaccination only with HIV test. | Nil reported.                       | Nil reported.                                            | Nil reported. | Nil Reported.                    |
| WALL14     | Facility layout believed to compromise confidentiality in rural facilities, eg identifying rooms by purpose.                        | Long queues, with mothers perceiving visit times longer due to integrated services.     | Mis-communication around mandatory nature of HIV testing                                                                               |                                                                                                   |                                     | Drive to scale-up PMTCT and EID - ?? May overshadow EPI. |               |                                  |
| DUBE12     | Space for privacy                                                                                                                   | Lack of privacy in vaccination clinics.                                                 | Nil reported.                                                                                                                          | Nil reported.                                                                                     | Nil reported.                       | Nil reported.                                            | Nil reported. | Nil reported.                    |
| TEJI11     |                                                                                                                                     |                                                                                         |                                                                                                                                        |                                                                                                   |                                     |                                                          |               |                                  |
| MCCO12     | More difficult to integrate universal testing into clinical OPD                                                                     | clinical OPD involved more and differing interactions - meaning less time for HIV test? |                                                                                                                                        | Link to recommendation for opt-out HIV testing                                                    |                                     |                                                          |               |                                  |
| ONGE12     | Study in hospital outpatients, not lower levels. Vaccine stockouts had significant impact.                                          |                                                                                         |                                                                                                                                        |                                                                                                   |                                     |                                                          |               |                                  |
| WANG15     | Stockouts noted in intervention but less than 3 days, due to inclusion of supplies in intervention. Stockouts in control facilities |                                                                                         |                                                                                                                                        | HIV testing all done as opt-out                                                                   |                                     |                                                          |               |                                  |

| Study code | Facilities, supplies and infrastructure                                                                                           | Patient flow processes                                                                                                                                                                          | Community engagement                                  | Ideology | Contracts, legislation, regulations | Donors, aid, development policy | Corruption | Security and political stability |
|------------|-----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|----------|-------------------------------------|---------------------------------|------------|----------------------------------|
|            | lasted over a month in some places. RE-supply was a key driver of impact                                                          |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| GOOD12     |                                                                                                                                   |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| ARMS11     |                                                                                                                                   |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| BOJA11     | Parallel system to ensure IPT supplies for both arms.                                                                             |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| DICK11     | Some support to supplies, but offered to both control and intervention.                                                           |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| WILL11     |                                                                                                                                   |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| MONT13     |                                                                                                                                   |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| BOSE11     |                                                                                                                                   |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| HODG15     |                                                                                                                                   |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| FRID12     | Screening was conducted in a nurse's office or designated room in the clinic where ambient noise levels were adequate for testing |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| BAKA14     |                                                                                                                                   |                                                                                                                                                                                                 |                                                       |          |                                     |                                 |            |                                  |
| COOP15     | Vaccine and FP commodity stock-outs interrupted. Hospitals had lower referral uptake than clinics.                                | Extended waiting times for family planning services needed correction. Privacy screens in immunization areas helped information focus and avoid stigma Proximity of services and clear pathways | Posters at immunization station to encourage referral |          |                                     |                                 |            |                                  |
| DULL16     |                                                                                                                                   | Flexibility allowed, for                                                                                                                                                                        |                                                       |          |                                     |                                 |            |                                  |

| Study code | Facilities, supplies and infrastructure                                                                                                                                                                                                                                                       | Patient flow processes | Community engagement | Ideology | Contracts, legislation, regulations | Donors, aid, development policy | Corruption | Security and political stability                                       |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|----------|-------------------------------------|---------------------------------|------------|------------------------------------------------------------------------|
|            |                                                                                                                                                                                                                                                                                               | variation by facility. |                      |          |                                     |                                 |            |                                                                        |
| VANC14     |                                                                                                                                                                                                                                                                                               |                        |                      |          |                                     |                                 |            | Nurses strike in Zambia interrupted implementation and data collection |
| BRIE12     | Monitoring data: Of 3 urban facilities monitored in Suba, 1 or 2 had infrastructure problems or stockouts in 8 of 11 months for which data were available. Of 2 urban facilities monitored in Homa Bay, 1 or both had infrastructure problems or stockouts in all of the 12 monitoring months |                        |                      |          |                                     |                                 |            |                                                                        |
| RYMA12     | Both nurses and mothers said that stockouts discourage women from returning to the clinic.                                                                                                                                                                                                    |                        |                      |          |                                     |                                 |            |                                                                        |
| PATO11     | Supplies for IPTc leveraged clinic systems                                                                                                                                                                                                                                                    |                        |                      |          |                                     |                                 |            |                                                                        |

### 10.2.2 Table of extracted data for outcome synthesis and forest plot display

| Study Author Code | Immunization platform | Country    | Publication year | Integration strategy                                                                                                    | Comparison group                                                                                                                                                                   | Vaccination assessment                                                                                                                           | Study type |
|-------------------|-----------------------|------------|------------------|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| UDDI11            | Routine               | Bangladesh | 2011             | Vaccination +/- vaccine advice by non-EPI staff using a screening tool (group B)                                        | Group A received modified schedule and community support groups                                                                                                                    | Coverage in two sites. FIC aOR adjusted for interaction                                                                                          | CBA        |
| GOOD13            | Routine               | Tanzania   | 2013             | Extra services +/- counselling by EPI staff                                                                             | Matched comparison sites                                                                                                                                                           | Average vaccine doses per month, % change over baseline                                                                                          | CBA        |
| MCCO12            | Routine               | Malawi     | 2012             | Co-located service + counselling by EPI staff.                                                                          | Immunization clinic vs U5 pediatric illness clinic                                                                                                                                 | Nil                                                                                                                                              | CBA        |
| ONGE12            | Routine               | Kenya      | 2012             | Co-located service in MCH clinic that provides vaccinations.                                                            | Services in a separate HIV specialty clinic. Clinics matched on service characteristics, including vaccination, at baseline.                                                       | Coverage increase                                                                                                                                | CBA        |
| WANG15            | Routine               | Zambia     | 2015             | Extra services +/- counselling by EPI staff + co-located service.                                                       | Two comparators: Control, and Simple (received one sensitisation meeting and additional supply support)                                                                            | No coverage. DPT doses monthly. 10,435 doses over implementation period - about 1,680 per month. ? Study size should reflect monthly assessment? | RCT        |
| GOOD12            | Campaign              | Madagascar | 2012             | Extra services by EPI staff + co-located service.                                                                       | Campaign vaccination teams not distributing ITNs                                                                                                                                   | Coverage increase. Equity increase.                                                                                                              | OBS        |
| ARMS11            | Routine               | Tanzania   | 2011             | Extra services +/- counselling by EPI staff                                                                             | Comparison group, no IPTi closely matched at for potential confounders including ITN ownership and usage. 3000+ children interviewed, but vaccination status reported on just 1731 | Coverage static                                                                                                                                  | RCT        |
| BOJA11            | Routine. ERA          | Gambia     | 2011             | Extra services by EPI staff + co-located service. EPI staff also had other family health duties, as RCH trekking teams. | Community based VHVs who had no role in vaccination.                                                                                                                               | Coverage slightly worse in integrated experience group                                                                                           | RCT        |

| <b>Study Author Code</b> | <b>Immunization platform</b> | <b>Country</b> | <b>Publication year</b> | <b>Integration strategy</b>                                                                                                                        | <b>Comparison group</b>                                                                                                                                                        | <b>Vaccination assessment</b>                                                                                                                                                                                                               | <b>Study type</b> |
|--------------------------|------------------------------|----------------|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| DICK11                   | Routine                      | Mali           | 2011                    | Extra services by EPI staff                                                                                                                        | No IPTi. Cluster randomised 22 sub-districts in one district.                                                                                                                  | Coverage increase.<br>NOTE: Baseline is for both control and intervention. Baseline figures in Table 1 do not add up. Totals not provided in Table, calculated from %. Note DTP3 in control sum comes to more than survey total (corrected) | RCT               |
| WILL11                   | Routine                      | Tanzania       | 2011                    | Extra services +/- counselling by EPI staff                                                                                                        | Comparison group, no IPTi<br>Health service data from same study as ARMS, 6 intervention, 5 control facilities. Well matched on malaria incidence and measles vaccine coverage | Uptake (because only measured tighter age group) static or increased                                                                                                                                                                        | RCT               |
| HODG15                   | Routine                      | Sierra Leone   | 2015                    | Co-located service.<br>"Full" - EPI+IYCF+FP                                                                                                        | Three arms - updated card only, mini IYCF+EPI, full IYCF+EPI+FP. Took card only as main comparator.                                                                            | Vaccine coverage                                                                                                                                                                                                                            | NRCT              |
| COOP15                   | Routine                      | Liberia        | 2015                    | Extra counselling by EPI staff, co-located service.                                                                                                | Pre-post in 10 facilities in 2 counties. Also compared with service data for non-pilot facilities in those counties.                                                           | Vaccine uptake based on administrative data. Some drop-out in pilot facilities.                                                                                                                                                             | CBA               |
| DULL16                   | Routine                      | Rwanda         | 2016                    | Extra counselling by EPI staff, co-located service.                                                                                                | No intervention. 14 facilities in total.                                                                                                                                       | Vaccination uptake static.                                                                                                                                                                                                                  | RCT               |
| BRIE12                   | Routine                      | Kenya          | 2012                    | Extra services +/- counselling by EPI staff <b>or</b> co-located service.<br><br>Sub-group analysis of the two approaches provided in Ryman below. | Comparison site with no intervention (Suba). Homa Bay intervention site - 18 facilities across two arms: one nurse-led, one CHV-led. Also differentiated by urban vs rural     | Coverage with either <b>vaccination implementation</b> (% children 2 - 20 mo receiving all vaccines due), or <b>uptodate vaccination</b> (% children 2-13mo receiving all age-appropriate vaccines)                                         | CBA               |
| RYMA12                   | Routine                      | Kenya          | 2012                    | Extra services +/- counselling by EPI staff or co-located service.                                                                                 | Nurse-led distribution vs CHV-led distribution.                                                                                                                                | Subset analysis of program above.                                                                                                                                                                                                           | CBA               |

| Study<br>Author<br>Code | Est'd<br>pop'n | Subgroups                                                                                         | Pre Integration |                        |            | Comparator      |                        |            | Post Integration |                        |            | Comparator main |                        |                |
|-------------------------|----------------|---------------------------------------------------------------------------------------------------|-----------------|------------------------|------------|-----------------|------------------------|------------|------------------|------------------------|------------|-----------------|------------------------|----------------|
|                         |                |                                                                                                   | Vaccin-<br>ated | Not<br>vaccin-<br>ated | Percentage | Vaccin-<br>ated | Not<br>vaccin-<br>ated | Percentage | Vaccin-<br>ated  | Not<br>vaccin-<br>ated | Percentage | Vaccin-<br>ated | Not<br>vaccin-<br>ated | Percentag<br>e |
| UDDI<br>11              | 2884           | Haor, FIC                                                                                         | 360             | 333                    | 51.95      | 177             | 434                    | 28.97      | 578              | 135                    | 81.07      | 588             | 121                    | 82.93          |
|                         |                | Hill, FIC                                                                                         | 359             | 293                    | 55.06      | 465             | 209                    | 68.99      | 567              | 133                    | 81.00      | 641             | 79                     | 89.03          |
|                         |                | Haor, DPT3                                                                                        | 506             | 187                    | 73.02      | 330             | 281                    | 54.01      | 656              | 57                     | 92.01      | 624             | 85                     | 88.01          |
|                         |                | Hill, DPT3                                                                                        | 528             | 124                    | 80.98      | 573             | 101                    | 85.01      | 616              | 84                     | 88.00      | 684             | 36                     | 95.00          |
|                         |                | Haor, measles                                                                                     | 450             | 243                    | 64.94      | 263             | 348                    | 43.04      | 592              | 121                    | 83.03      | 617             | 92                     | 87.02          |
|                         |                | Hill, measles                                                                                     | 456             | 196                    | 69.94      | 519             | 155                    | 77.00      | 574              | 126                    | 82.00      | 655             | 65                     | 90.97          |
| GOOD<br>13              | 7569           |                                                                                                   |                 |                        |            |                 |                        |            |                  |                        |            |                 |                        |                |
| MCCO<br>12              | 1757           |                                                                                                   |                 |                        |            |                 |                        |            |                  |                        |            |                 |                        |                |
| ONGE<br>12              | 363            | Measles at 9mo                                                                                    |                 |                        |            |                 |                        |            | 123              | 56                     | 68.72      | 63              | 121                    | 34.24          |
|                         |                | FIC at 12mo                                                                                       |                 |                        |            |                 |                        |            | 130              | 49                     | 72.63      | 103             | 81                     | 55.98          |
| WANG<br>15              | 10435          |                                                                                                   |                 |                        |            |                 |                        |            |                  |                        |            |                 |                        |                |
| GOOD<br>12              | 3158           | Weighted estimates of measles vaccination coverage for malarial areas, accounting for clustering. |                 |                        |            |                 |                        |            | 1629             | 604                    | 72.95      | 291             | 205                    | 58.67          |
| ARMS<br>11              | 1731           | DPT3 in 12-23mo                                                                                   |                 |                        |            |                 |                        |            | 661              | 108                    | 85.96      | 823             | 139                    | 85.55          |
|                         |                | Measles in 12-23mo                                                                                |                 |                        |            |                 |                        |            | 600              | 169                    | 78.02      | 766             | 196                    | 79.63          |
| BOJA11                  | 1096           | Fully vaccinated aged >= 12mo                                                                     |                 |                        |            |                 |                        |            | 289              | 130                    | 68.97      | 371             | 99                     | 78.94          |

| Study<br>Author<br>Code | Est'd<br>pop'n | Subgroups                                                                                                             | Pre Integration |                        |            | Comparator      |                        |            | Post Integration |                        |            | Comparator main |                        |                |
|-------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------|-----------------|------------------------|------------|-----------------|------------------------|------------|------------------|------------------------|------------|-----------------|------------------------|----------------|
|                         |                |                                                                                                                       | Vaccin-<br>ated | Not<br>vaccin-<br>ated | Percentage | Vaccin-<br>ated | Not<br>vaccin-<br>ated | Percentage | Vaccin-<br>ated  | Not<br>vaccin-<br>ated | Percentage | Vaccin-<br>ated | Not<br>vaccin-<br>ated | Percentag<br>e |
| DICK<br>11              | 1050           | FIC at 9-23mo                                                                                                         |                 |                        |            |                 |                        |            | 355              | 156                    | 69.47      | 279             | 240                    | 53.76          |
|                         |                | DTP3                                                                                                                  |                 |                        |            |                 |                        |            | 583              | 180                    | 76.41      | 432             | 286                    | 60.17          |
|                         |                | Measles in 12-<br>23mo                                                                                                |                 |                        |            |                 |                        |            | 440              | 88                     | 83.33      | 402             | 142                    | 73.90          |
| WILL<br>11              | 9880           | DTP3 in 3-11Mo                                                                                                        |                 |                        |            |                 |                        |            | 2889             | 1905                   | 60.26      | 2296            | 2366                   | 49.25          |
|                         |                | Measles in 9 -<br>11Mo                                                                                                |                 |                        |            |                 |                        |            | 1609             | 1599                   | 50.16      | 1009            | 2056                   | 32.92          |
| HODG<br>15              | 1196           | Integration<br>main = full<br>package.<br>Integration<br>alternate = mini<br>package.<br>Comparator =<br>change card. |                 |                        |            |                 |                        |            | 364              | 16                     | 95.79      | 367             | 30                     | 92.44          |
| COOP1<br>5              | 1490           |                                                                                                                       |                 |                        |            |                 |                        |            |                  |                        |            |                 |                        |                |
| DULL16                  | 1654           |                                                                                                                       |                 |                        |            |                 |                        |            |                  |                        |            |                 |                        |                |
| BRIE 12                 | 3394           | Urban + rural<br>vaccination<br>implementation                                                                        | 858             | 546                    | 61.11      | 546             | 629                    | 46.47      | 1681             | 738                    | 69.49      | 629             | 453                    | 58.13          |
|                         |                | Urban<br>vaccination<br>implementation                                                                                | 162             | 78                     | 67.50      | 70              | 52                     | 57.38      | 442              | 87                     | 83.55      | 130             | 79                     | 62.20          |
|                         |                | Rural<br>vaccination<br>implementation                                                                                | 676             | 488                    | 58.08      | 479             | 574                    | 45.49      | 1085             | 805                    | 57.41      | 501             | 372                    | 57.39          |
|                         |                | Urban+rural<br>uptodate<br>vaccination                                                                                | 531             | 394                    | 57.41      | 289             | 488                    | 37.19      | 1062             | 545                    | 66.09      | 382             | 341                    | 52.84          |



| Study<br>Author<br>Code | Est'd<br>pop'n | Subgroups                                  | Pre Integration |                        |            | Comparator      |                        |            | Post Integration |                        |            | Comparator main |                        |                |
|-------------------------|----------------|--------------------------------------------|-----------------|------------------------|------------|-----------------|------------------------|------------|------------------|------------------------|------------|-----------------|------------------------|----------------|
|                         |                |                                            | Vaccin-<br>ated | Not<br>vaccin-<br>ated | Percentage | Vaccin-<br>ated | Not<br>vaccin-<br>ated | Percentage | Vaccin-<br>ated  | Not<br>vaccin-<br>ated | Percentage | Vaccin-<br>ated | Not<br>vaccin-<br>ated | Percentag<br>e |
|                         |                | Urban <u>uptodate</u><br>vaccination       | 112             | 49                     | 69.57      | 43              | 41                     | 51.19      | 308              | 68                     | 81.91      | 79              | 59                     | 57.25          |
|                         |                | Rural <u>uptodate</u><br>vaccination       | 392             | 372                    | 51.31      | 248             | 445                    | 35.79      | 625              | 606                    | 50.77      | 305             | 280                    | 52.14          |
| RYMA1<br>2              | 2105           | Rural vaccine<br>implmntn,<br>nurse vs CHV | 676             | 488                    | 58.08      |                 |                        |            | 517              | 432                    | 54.48      | 566             | 375                    | 60.15          |
|                         |                | Rural vaccine<br>uptodate, nurse<br>vs CHV | 392             | 372                    | 51.31      |                 |                        |            | 294              | 314                    | 48.36      | 331             | 292                    | 53.13          |
|                         |                | Rural DPT3 4-<br>15mo, nurse vs<br>CHV     | 483             | 279                    | 63.39      |                 |                        |            | 446              | 181                    | 71.13      | 470             | 159                    | 74.72          |
|                         |                | Rural measles<br>10-20mo, nurse<br>vs CHV  | 413             | 214                    | 65.87      |                 |                        |            | 344              | 204                    | 62.77      | 342             | 155                    | 68.81          |
|                         |                |                                            |                 |                        |            |                 |                        |            | Nurse-led        |                        |            | CHV-led         |                        |                |
|                         |                |                                            |                 |                        |            |                 |                        |            |                  |                        |            |                 |                        |                |

| Study<br>Author<br>Code | Post alternate<br>Integration alternate |                   |            | Other<br>vaccine<br>analysis          | Other vaccine analysis type                                                                                                                           | Other vaccine analysis<br>result                                             | Cis for<br>measure<br>intervention                        | Vacc<br>outcome<br>Nil, N, MN, S,<br>MP, P | Linked<br>outcome<br>N, MN, MP, P | Linked intervention<br>assessment                                                                                                                                                                                                      |
|-------------------------|-----------------------------------------|-------------------|------------|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-----------------------------------------------------------|--------------------------------------------|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                         | Vaccinated                              | Not<br>vaccinated | Percentage |                                       |                                                                                                                                                       |                                                                              |                                                           |                                            |                                   |                                                                                                                                                                                                                                        |
| UDDI11                  |                                         |                   |            |                                       | OR adjusted for other<br>variables and for interaction<br>of site, baseline vs endline<br>(time)                                                      | 2.09 (1.73-2.53)                                                             | n/a                                                       | P                                          | Nil                               | Uptake measures with<br>mixed outcomes                                                                                                                                                                                                 |
| GOOD 13                 |                                         |                   |            | Mean<br>vaccine<br>doses per<br>month | % change over baseline,<br>urban INT = 4 fac x 24 mo<br>(pre) and 4 fac x 12 mo<br>(post)<br>COMP = 93 fac x 24 mo (pre)<br>and 93 fac x 24 mo (post) | Penta 1 pre,post change<br>INT +2% (490, 500)<br>COM +3% (3800, 3914)        | NB: raw<br>numbers<br>estimated<br>from chart in<br>Fig 2 | N                                          | MP                                | Study sites successfully<br>identified and registered<br>308 HIV-exposed infants<br>among 7569 infants.<br>However, nearly all mothers<br>arrived with<br>documented HIV status,<br>suggesting unusually high<br>prenatal HIV testing. |
|                         |                                         |                   |            |                                       | urban                                                                                                                                                 | Penta 3 pre, post change<br>INT +12% (420, 470)<br>COM +1% (3600, 3636)      |                                                           |                                            |                                   |                                                                                                                                                                                                                                        |
|                         |                                         |                   |            |                                       | urban                                                                                                                                                 | Measles pre, post<br>change<br>INT +11% (480, 533)<br>COMP +6% (3900, 4134 ) |                                                           |                                            |                                   |                                                                                                                                                                                                                                        |
|                         |                                         |                   |            |                                       | % change over baseline,<br>rural INT = 4 fac x 24 mo<br>(pre) and 4 fac x 12 mo<br>(post)COMP = 53 fac x 24<br>mo (pre) and 55 fac x 24 mo<br>(post)  | Penta 1 pre,post<br>changeINT -33% (170,<br>114)COM -6% (650, 511)           |                                                           |                                            |                                   |                                                                                                                                                                                                                                        |
|                         |                                         |                   |            |                                       | rural                                                                                                                                                 | Penta 3 pre, post change<br>INT -23% (170, 131)<br>COM -11% (610, 543)       |                                                           |                                            |                                   |                                                                                                                                                                                                                                        |
|                         |                                         |                   |            |                                       | rural                                                                                                                                                 | Measles pre, post<br>change<br>INT -28% (180, 130)<br>COMP -7% (675, 628)    |                                                           |                                            |                                   |                                                                                                                                                                                                                                        |

| Study Author Code | Post alternate<br>Integration alternate | Other vaccine analysis                     | Other vaccine analysis type              | Other vaccine analysis result                                                                                                                                                                                                                                                                       | Cis for measure intervention | Vacc outcome<br>Nil, N, MN, S, MP, P | Linked outcome<br>N, MN, MP, P | Linked intervention assessment                                                                                                                                                                                     |
|-------------------|-----------------------------------------|--------------------------------------------|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------------------------|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MCCO12            |                                         |                                            |                                          |                                                                                                                                                                                                                                                                                                     |                              | Nil                                  | P                              | Seven-fold higher proportion of PITC at immunization clinics. more than three times more PCR recipients returned for their PCR result and were enrolled into the EID program                                       |
| ONGE12            |                                         |                                            | RR unadjusted                            | 2.01                                                                                                                                                                                                                                                                                                | 1.61-2.51                    | P                                    | P                              | The average number of study follow-up visits for infants in the MCH model was 1.30 times (95% CI: 1.16 to 1.46) the number of                                                                                      |
|                   |                                         |                                            | RR unadjusted                            | 1.3                                                                                                                                                                                                                                                                                                 | 1.11-1.52                    |                                      |                                | study follow-up visits for infants in the CCC model after adjusting for employment status                                                                                                                          |
| WANG15            |                                         | Vaccine doses based on administrative data | Increase in average number of DPT1 doses | 6.7%, 3.2% and 7.7% more doses per month over baseline in control, Simple Intervention and Comprehensive Intervention facilities respectively. Difference between Simple and Control (control increased more) was still non-sig and even at lowest CI would less than a priori definition of 'harm' |                              | S                                    | P                              | average number of infant DBS tests changed by -0.49, 0.43, and 1.19 tests per month over baseline in Control, Simple and Comprehensive Intervention facilities, respectively. Larger increase in maternal re-tests |

| Study Author Code | Post alternate<br>Integration alternate | Other vaccine analysis | Other vaccine analysis type                                   | Other vaccine analysis result                                                                                                                                                                                                                | Cis for measure intervention | Vacc outcome<br>Nil, N, MN, S, MP, P | Linked outcome<br>N, MN, MP, P | Linked intervention assessment                                                                                                                                                               |
|-------------------|-----------------------------------------|------------------------|---------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------------------------|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| GOOD12            |                                         | Equity of coverage     | Coverage among children in poorest quintile.<br>Equity ratio. | Higher in ITN than in non-ITN districts (Q1; RR = 2.4, 95% CI 1.2–4.8)<br>Equity ratio for measles vaccination greater in ITN districts (equity ratio = 1.0, 95% CI 0.8–1.3) than in non-ITN districts (equity ratio = 0.4, 95% CI 0.2–0.8). |                              | P                                    | P                              | Coverage increase.<br>Reported in Kulkarni 2010 - in integration districts 76.8% of households possessed at least one LLIN from any source and 56.4% of households possessed a campaign net. |
| ARMS11            |                                         |                        |                                                               |                                                                                                                                                                                                                                              |                              | S                                    | P                              | Coverage increase. Intervention vs comparison divisions coverage of 3 documented doses of IPTi (48% vs 2%) and different coverage of 3 documented OR reported doses of IPTi (77% vs 6%).     |
|                   |                                         |                        |                                                               |                                                                                                                                                                                                                                              |                              |                                      |                                | Note mixed mortality outcomes.                                                                                                                                                               |
| BOJA11            |                                         |                        |                                                               |                                                                                                                                                                                                                                              |                              | MN                                   | MN                             | More children in the VHW arm received three treatment courses compared to the RCH arm (74% versus 48%, a risk difference of 27% [95% CI 16%–38%]).                                           |

| Study Author Code | Post alternate<br>Integration alternate |    |       | Other vaccine analysis | Other vaccine analysis type | Other vaccine analysis result | Cis for measure intervention | Vacc outcome<br>Nil, N, MN, S, MP, P | Linked outcome<br>N, MN, MP, P | Linked intervention assessment                                                                                                                                                                                                                                                                                                                                                  |
|-------------------|-----------------------------------------|----|-------|------------------------|-----------------------------|-------------------------------|------------------------------|--------------------------------------|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DICK11            |                                         |    |       |                        |                             |                               |                              | P                                    | P                              | proportion of children in the target age groups who received IPTi with each of the 3 vaccinations DTP2, DTP3 and Measles, were 89.2% (95% CI 85.9%-92.0%), 91.0% (95% CI 87.6% -93.7%) and 77.4% (95% CI 70.7%-83.2%) respectively. The corresponding figures in non intervention zone were 2.3% (95% CI 0.9% -4.7%), 2.6% (95% CI 1.0% -5.6%) and 1.7% (95% CI 0.4% - 4.9%).   |
| WILL11            |                                         |    |       |                        |                             |                               |                              | MP                                   | P                              | A total of 72% of children aged 2-11 months in intervention areas received at least one dose of IPTi, and 22% received all three doses..                                                                                                                                                                                                                                        |
| HODG15            | 365                                     | 13 | 96.56 |                        |                             |                               |                              | P                                    | P                              | Counseling for FP was provided to 61.8 % (95 % CI 60.8–62.9 %) of caregivers in the full compared with 4.8 % (95 % CI 2.9–6.8 %) in the mini and 1.5 % (95 % CI 0.0–3.2 %) in the revised CH card only group (p\0.0001 for both). Higher routine VAS coverage was observed in the full: 74.5 % (95 % CI 73.7–75.3 %) and mini: 71.7 % (95 % CI 71.7–72.6 %) versus the 'revised |

| Study<br>Author<br>Code | Post alternate<br>Integration alternate |  |  | Other<br>vaccine<br>analysis                   | Other vaccine analysis type                                                                 | Other vaccine analysis<br>result                                                                                                                                                                                                  | Cis for<br>measure<br>intervention | Vacc<br>outcome<br>Nil, N, MN, S,<br>MP, P | Linked<br>outcome<br>N, MN, MP, P | Linked intervention<br>assessment                                                                                                                                                                                                                                                                                                                      |
|-------------------------|-----------------------------------------|--|--|------------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------------------------------|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                         |                                         |  |  |                                                |                                                                                             |                                                                                                                                                                                                                                   |                                    |                                            |                                   | CH only' group: 60.2 % (95 % CI 59.8–61.1 %) (p =0.002, p\0.001 respectively). At 6\9 months of age, the mean WAZ was higher for both the full and mini versus the revised CH only group (p\0.0001).                                                                                                                                                   |
| COOP15                  |                                         |  |  | Vaccine doses given over 9 months pre and post | Penta 1 and Penta 3 doses Pilot period compared with same period previous year in each site | Lofa pilot:<br>35% more Penta 1<br>21% more Penta 3<br>Lofa control:<br>Penta 1 and Penta 3 administration decreased<br><br>Bong pilot:<br>little difference in Penta 1 and Penta 3 doses between pilot and non-pilot facilities. |                                    | MP                                         | P                                 | FP referral acceptance across the facilities varied from 10% to 45% per month, on average. Over 80% of referral acceptors completed the family planning visit that day, of whom over 90% accepted a contraceptive method that day. The total number of new contraceptive users at participating facilities increased by 73% in Bong and by 90% in Lofa |
| DULL16                  |                                         |  |  | Service data at all facilities.                | Measles vaccine, average doses per month.                                                   | no downward trend in the numbers of infants immunized for measles in the intervention facilities over the course of the study period                                                                                              |                                    | S                                          | P                                 | statistically significant, positive effect on modern contraceptive method use                                                                                                                                                                                                                                                                          |

| Study<br>Author<br>Code | Post alternate<br>Integration alternate | Other<br>vaccine<br>analysis | Other vaccine analysis type | Other vaccine analysis<br>result | Cis for<br>measure<br>intervention | Vacc<br>outcome<br>Nil, N, MN, S,<br>MP, P | Linked<br>outcome<br>N, MN, MP, P | Linked intervention<br>assessment                                                                                                              |
|-------------------------|-----------------------------------------|------------------------------|-----------------------------|----------------------------------|------------------------------------|--------------------------------------------|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| BRIE12                  |                                         |                              |                             |                                  |                                    | MP                                         | P                                 | significant increases in reported household water treatment (30% vs 44%, P , .0001) and correct handwashing technique (25% vs 51%, P , .0001). |
| RYMA12                  |                                         |                              |                             |                                  |                                    |                                            |                                   | Qualitative expansion of program above.                                                                                                        |

**10.2.3 Table of relevant but excluded studies**

| First Author                                  | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                                                   | Range of services integrated with immunization                                                                                                                                                   | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
|-----------------------------------------------|------|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------------------------|--------------------------------------------------------|
| Integration of immunisation into PHC settings |      |                                 |                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                  |                                      |                                      |                                                         |                                                        |
| Kosec                                         | 2015 | India                           | Kosec K, Avula R, Holtemeyer B, Tyagi P, Hausladen S, Menon P. Predictors of Essential Health and Nutrition Service Delivery in Bihar, India: Results From Household and Frontline Worker Surveys. <i>Global Health Science &amp; Practice</i> . 2015;3(2):255-73.         | Predictors of rates of distribution of immunization information and services were examined, alongside those for food supplements, pregnancy care information, and general nutrition information. | PHC                                  | PHC                                  |                                                         |                                                        |
| Mirza                                         | 2012 | Somalia                         | Mirza IR, Kamadjeu R, Assegid K, Mulugeta A. Somalia: Supporting the Child Survival Agenda When Routine Health Service is Broken. <i>Journal of Infectious Diseases</i> . 2012;205(suppl 1):S126-S33.                                                                      | Delivery of an 'integrated package of critical child survival interventions' (only vaccinations are listed; DPT)                                                                                 | PHC                                  | PHC                                  |                                                         |                                                        |
| Lhamsuren                                     | 2012 | Mongolia                        | Lhamsuren K, Choijiljav T, Budbazar E, Vanchinkhuu S, Blanc DC, Grundy J. Taking action on the social determinants of health: Improving health access for the urban poor in Mongolia. <i>International Journal for Equity in Health</i> . 2012;11 (1) (no pagination)(15). | Delivery of integrated package of key health and social services                                                                                                                                 | PHC                                  | PHC                                  |                                                         |                                                        |



| First Author | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                   | Range of services integrated with immunization                                                                                                                           | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
|--------------|------|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------------------------|--------------------------------------------------------|
| Berk         | 2012 | Kenya                           | Berk J, Adhvaryu A. The impact of a novel franchise clinic network on access to medicines and vaccinations in Kenya: A cross-sectional study. <i>BMJ Open</i> . 2012;2 (4) (e000589).                                                      | Polio, DPT, BCG and measles vaccines were accompanied by 'any medical treatment', fever, malaria, and those treatments specifically stocked by health franchise clinics. | PHC                                  | PHC                                  |                                                         |                                                        |
| Marin        | 2011 | Argentina                       | Marin GH, Silberman M, Uriarte A, Sarijulis M, Ozaeta B, Henen J. Healthcare model based on personalised attention: impact on maternal mortality and health system quality. <i>Quality in Primary Care</i> . 2011;19(5):311-6.             | Implementation of a personalised care/name responsible healthcare worker model for antenatal services, replacing an historical model.                                    | PHC                                  | PHC                                  |                                                         |                                                        |
| Cristia      | 2015 | Guatemala                       | Cristia J, Evans WN, Kim B. Improving the health coverage of the rural poor: does contracting-out mobile medical teams work? <i>Journal of Development Studies</i> . 2015;51(3):247-61.                                                    | Contracting-out mobile medical teams to improve health care coverage                                                                                                     | PHC                                  | PHC                                  |                                                         |                                                        |
| Fort         | 2011 | Guatemala                       | Fort MP, Grembowski DE, Verdugo JC, Morales LC, Arriaga CA, Mercer MA, et al. Implementation and progress of an inclusive primary health care model in Guatemala: Coverage, quality, and utilization. <i>Revista Panamericana de Salud</i> | Maternal and child health care                                                                                                                                           | PHC                                  | PHC                                  |                                                         |                                                        |

| First Author                                  | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                                                                      | Range of services integrated with immunization                                                                                                                                                                                                                              | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
|-----------------------------------------------|------|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------------------------|--------------------------------------------------------|
|                                               |      |                                 | Publica/Pan American Journal of Public Health. 2011;30(3):217-24.                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                             |                                      |                                      |                                                         |                                                        |
| Saxena                                        | 2016 | India                           | Saxena V, Kumar P, Kumari R, Nath B, Pal R. Availability of Village Health and Nutrition Day services in Uttarakhand, India. Journal of Family Medicine & Primary Care. 2015;4(2):251-6.                                                                                                      | Primary health care services at Village Health and Nutrition Days (VHNDs); blood pressure measurement, adult weighing, immunisation, vitamin A supplementation, child growth monitoring, supplementary nutrition, and identification of households for toilet construction. | PHC                                  | PHC                                  |                                                         |                                                        |
| Integration of immunisation into IMCI or iCCM |      |                                 |                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                             |                                      |                                      |                                                         |                                                        |
| Amouzou                                       | 2016 | Ethiopia                        | Amouzou A, Hazel E, Shaw B, Miller NP, Tafesse M, Mekonnen Y, et al. Effects of the integrated Community Case Management of Childhood Illness Strategy on Child Mortality in Ethiopia: A Cluster Randomized Trial. The American Journal of Tropical Medicine and Hygiene. 2016;94(3):596-604. | iCCM included identification of children needing catchup vaccination                                                                                                                                                                                                        | IMCI                                 | IMCI                                 |                                                         |                                                        |
| Teferi                                        | 2014 | Ethiopia                        | Teferi E, Alemu H, Bulto T, Ali I, Teno D. A descriptive study of the changes in coverage of preventive and promotive interventions before and after the introduction of integrated community case management (ICCM) in Ethiopia. Ethiopian Medical Journal. 2014;52 Suppl 3:151-5.           | iCCM included preventative and promotive interventions for maternal and child health.                                                                                                                                                                                       | IMCI                                 | IMCI                                 |                                                         |                                                        |

| First Author                         | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                                                     | Range of services integrated with immunization                                                                                                                                                                       | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
|--------------------------------------|------|---------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------------------------|--------------------------------------------------------|
| Basaleem                             | 2011 | Yemen                           | Basaleem HO, Amin RM. Integrated management of childhood illness in Lahej, Yemen: a qualitative analysis from the perspective of health providers. Eastern Mediterranean Health Journal. 2011;17(2):101-8.                                                                   | Integrated Management of Childhood Illnesses (IMCI)                                                                                                                                                                  | IMCI                                 | IMCI                                 |                                                         |                                                        |
| Shewade                              | 2013 | India                           | Shewade HD, Aggarwal AK, Bharti B. Integrated Management of Neonatal and Childhood Illness (IMNCI): skill assessment of health and Integrated Child Development Scheme (ICDS) workers to classify sick under-five children. Indian Journal of Pediatrics. 2013;80(6):448-54. | Study assessed skills of Integrated Management of Neonatal and Childhood Illness (IMNCI) trained workers, by comparing the agreement of their evaluations with physicians, in classifying sick under-five-year-olds. | IMCI                                 | IMCI                                 |                                                         |                                                        |
| Integration of immunisation at birth |      |                                 |                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                      |                                      |                                      |                                                         |                                                        |
| Wiesen                               | 2016 | Papua New Guinea                | Wiesen E, Lagani W, Sui G, Arava J, Reza S, Diorditsa S, et al. Assessment of the hepatitis B birth dose vaccination program, Papua New Guinea, 2014. Vaccine. 2016;34(3):367-72.                                                                                            | Knowledge, practice, vaccine management and data recording/reporting at Hepatitis B birth dose (BD) providers                                                                                                        | Birth-dose                           | Birth-dose                           |                                                         |                                                        |

| First Author                                       | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                               | Range of services integrated with immunization                                                                                                                                                                                                            | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
|----------------------------------------------------|------|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------------------------|--------------------------------------------------------|
| Taneja                                             | 2015 | India                           | Taneja G, Kiran V, Jain M, Sagar KS, Tripathi B, Favin M, et al. Institutionalizing early vaccination of newborns delivered at government health facilities: Experiences from India. International Journal of Medical Research and Review. 2015;3(05). | To increase newborn immunization coverage, interventions included on-the-job staff orientation posted in delivery rooms, sound supply chain mechanism to ensure vaccine availability, and strengthened documentation in vaccine administration registers. | Birth-dose                           | Birth-dose                           |                                                         |                                                        |
| Hutin                                              | 2013 | China                           | Hutin Y, Hennessey K, Cairns L, Zhang Y, Li H, Zhao L, et al. Improving hepatitis B vaccine timely birth dose coverage: Lessons from five demonstration projects in China, 2005-2009. Vaccine. 2013;31(S9):J49-J55.                                    | To increase Hepatitis B Vaccine Birth Dose (TBD), interventions included hospital coverage, population information/education/communication (IEC), and micro-planning for home delivery.                                                                   | Birth-dose                           | Birth-dose                           |                                                         |                                                        |
| Integration of HIV interventions with immunisation |      |                                 |                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                           |                                      |                                      |                                                         |                                                        |
| Binagwaho                                          | 2013 | Rwanda                          | Binagwaho A, Mugwaneza P, Irakoze AA, Nsanzimana S, Agbonyitor M, Nutt CT, et al. Scaling up early infant diagnosis of HIV in Rwanda, 2008-2010. Journal of Public Health Policy. 2013;34(1):2-16.                                                     | Early Infant Diagnosis (EID) of HIV, sample collection & results return                                                                                                                                                                                   | HIV                                  | HIV                                  |                                                         |                                                        |
| Bland                                              | 2013 | South Africa                    | Bland RM, Ndirangu J, Newell ML. Maximising opportunities for increased antiretroviral                                                                                                                                                                 | Testing for HIV in infants/ children infected, commencement of Antiretroviral Treatment (ART),                                                                                                                                                            | HIV                                  | HIV                                  |                                                         |                                                        |

| First Author | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                                                           | Range of services integrated with immunization                                                                                                                                                                                                  | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
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|              |      |                                 | treatment in children in an existing HIV programme in rural South Africa. BMJ (Online). 2013;346 (7899) (no pagination)(f550).                                                                                                                                                     |                                                                                                                                                                                                                                                 |                                      |                                      |                                                         |                                                        |
| Sinunu       | 2014 | Malawi                          | Sinunu MA, Schouten EJ, Wadonda-Kabondo N, Kajawo E, Eliya M, Moyo K, et al. Evaluating the impact of prevention of mother-to-child transmission of HIV in Malawi through immunization clinic-based surveillance. PloS one. 2014;9(6):e100741-e.                                   | Study assessed Malawi national PMCT program with cross-sectional survey. Program integrated early infant diagnosis, counselling and treatment initiation with immunization clinics. Study assessed 53 clinics in four districts.                | HIV                                  | HIV                                  |                                                         |                                                        |
| Woldesenbet  | 2015 | South Africa                    | Woldesenbet S, Jackson D, Lombard C, Dinh T-H, Puren A, Sherman G, et al. Missed Opportunities along the Prevention of Mother-to-Child Transmission Services Cascade in South Africa: Uptake, Determinants, and Attributable Risk (the SAPMTCTE). PloS One. 2015;10(7):e0132425-e. | 4-8 week old infants receiving first immunisations were assessed for uptake of antenatal and perinatal PMTCT services (maternal HIV testing, CD4 count test/result, and receiving maternal and infant antiretroviral treatment)                 | HIV                                  | HIV                                  |                                                         |                                                        |
| Wiegert      | 2014 | Zimbabwe                        | Wiegert K, Dinh T-H, Mushavi A, Mugurungi O, Kilmarx PH. Integration of prevention of mother-to-child transmission of HIV (PMTCT) postpartum services with other HIV care and treatment services within the maternal and child health                                              | In MCH clinics, staff were trained to conduct dried blood spot collection, counselling and initiation of treatment to prevent and manage mother-to-child transmission of HIV. This study was cross-sectional survey to assess national program. | HIV                                  | HIV                                  |                                                         |                                                        |

| First Author                          | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                                                            | Range of services integrated with immunization                                                                                                                                     | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
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|                                       |      |                                 | setting in Zimbabwe, 2012. PLoS one. 2014;9(6):e98236-e.                                                                                                                                                                                                                            |                                                                                                                                                                                    |                                      |                                      |                                                         |                                                        |
| Matsubayashi                          | 2011 | Uganda                          | Matsubayashi T, Manabe YC, Etonu A, Kyegombe N, Muganzi A, Coutinho A, et al. The effects of an HIV project on HIV and non-HIV services at local government clinics in urban Kampala. BMC International Health and Human Rights. 2011;11 (SUPPL. 1) (no pagination)(S9).            | HIV/AIDS services delivered within government-run general health clinics                                                                                                           | HIV                                  | HIV                                  |                                                         |                                                        |
| Integration of ITNs with immunisation |      |                                 |                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                    |                                      |                                      |                                                         |                                                        |
| Hartman                               | 2012 | South Sudan                     | Hartman F, Rumunu J, Guma V, Polich E, Lee A. Increasing access to malaria prevention in South Sudan by integrating net distribution and intermittent preventive treatment with antenatal care and immunizations. American Journal of Tropical Medicine and Hygiene. 2012;1):410-1. | Anti-malarial insecticide-treated net (ITN) household campaign included community sensitization, training, registration of households, actual hanging, supervision and monitoring. | ITN                                  | ITN                                  |                                                         |                                                        |

| First Author   | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                                                                                                                                                | Range of services integrated with immunization                                                                                                                                                                                                                        | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
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| Njau           | 2013 | Regional Africa                 | Njau JD, Stephenson R, Menon M, Kachur SP, McFarland DA. Exploring the impact of targeted distribution of free bed nets on households bed net ownership, socio-economic disparities and childhood malaria infection rates: Analysis of national malaria survey data from three sub-Saharan Africa countries. <i>Malaria Journal</i> . 2013;12 (1) (no pagination)(245). | Targeted free bed net distribution                                                                                                                                                                                                                                    | ITN                                  | ITN                                  |                                                         |                                                        |
| Zegers de Beyl | 2016 | Regional Africa                 | Zegers de Beyl C, Koenker H, Acosta A, Onyefunafoa EO, Adegbe E, McCartney-Melstad A, et al. Multi-country comparison of delivery strategies for mass campaigns to achieve universal coverage with insecticide-treated nets: what works best? <i>Malaria Journal</i> . 2016;15(1):58.                                                                                   | Allocation of ITNs was carried out with integration-based or stand-alone approaches, and by house-to-house or fixed point allocation. Data from Ghana, Nigeria, Senegal, South Sudan and Uganda. Some settings combined ITN distribution with immunization campaigns. | ITN                                  | ITN                                  |                                                         |                                                        |
| O'Meara        | 2011 | Kenya                           | O'Meara W, Smith N, Ekal E, Cole D, Ndege S. Spatial distribution of bednet coverage under routine distribution through the public health sector in a rural district in Kenya. <i>PloS One</i> . 2011;6 (10) (no pagination)(e25949).                                                                                                                                   | Distribution of Insecticide-Treated Nets (ITNs) to pregnant women/infants at immunisation (and antenatal) clinics.                                                                                                                                                    | ITN                                  | ITN                                  |                                                         |                                                        |

| First Author                                                                                          | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                                  | Range of services integrated with immunization                                                                                                             | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
|-------------------------------------------------------------------------------------------------------|------|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------------------------|--------------------------------------------------------|
| Theiss-Nyland                                                                                         | 2016 | Regional Africa                 | Theiss-Nyland K, Lynch M, Lines J. Assessing the availability of LLINs for continuous distribution through routine antenatal care and the Expanded Programme on Immunizations in sub-Saharan Africa. <i>Malaria Journal</i> . 2016;15(1):255.             | Continuous distribution of LLINs in 33 of 48 malaria-endemic African countries, through antenatal care (ANC) and Expanded Programme on Immunization (EPI). | ITN                                  | ITN                                  |                                                         |                                                        |
| Integration of Vitamin A, plus/minus antihelminthics, plus/minus WASH interventions with immunisation |      |                                 |                                                                                                                                                                                                                                                           |                                                                                                                                                            |                                      |                                      |                                                         |                                                        |
| Sesay                                                                                                 | 2014 | Sierra Leone                    | Sesay FF, Hodges MH, Kamara HI, Turay M, Wolfe A, Samba TT, et al. High coverage of vitamin a supplementation and measles vaccination during an integrated maternal and child health week in Sierra Leone. <i>International Health</i> . 2014;7(1):26-31. | Measles vaccination and Vitamin A Supplements (VAS) were delivered together at Maternal and Child Health Week (MCHW)                                       | Vitamin A                            | Vitamin A                            |                                                         |                                                        |
| Rah                                                                                                   | 2014 | India                           | Rah JH, Houston R, Mohapatra BD, Kumar SS, Saiyed F, Bhattacharjee S. A review of the vitamin A supplementation program in India: reasons for success in the states of Bihar and Odisha. <i>Food and nutrition bulletin</i> . 2014;35(2):203-10.          | Infants below 1 year to receive their first vitamin A supplement (VAS); Measles immunisation at 9 months. Children aged 1-5 to receive VAS every 6 months. | Vitamin A                            | Vitamin A                            |                                                         |                                                        |



| First Author   | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                                  | Range of services integrated with immunization                                                                                                                                                                     | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
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| Babaniyi       | 2013 | Zambia                          | Babaniyi O, Siziya S, Mukonka V, Kalesha P, Mutambo H, Matapo B, et al. Child Nutrition and Health campaign in 2012 in Zambia: Coverage rates for measles, Oral Polio Vaccine, Vitamin A, and de-worming. Open Vaccine Journal. 2013;6(1):1-19.           | Measles (and OPV) vaccine delivery included Vitamin A delivery and de-worming                                                                                                                                      | Vitamin A<br>Helminths               | Vitamin A                            | Helminths                                               |                                                        |
| Vince          | 2014 | Papua New Guinea                | Vince JD, Datta SS, Toikilik S, Lagani W. Integrated package approach in delivering interventions during immunisation campaigns in a complex environment in Papua New Guinea: a case study. Vaccine. 2014;32(36):4614-9.                                  | Single antigen Supplementary Immunization Activities (SIAs), and a multiple intervention programme                                                                                                                 | Vitamin A<br>Helminths               | PHC                                  |                                                         |                                                        |
| Verguet        | 2013 | South Africa                    | Verguet S, Jassat W, Bertram MY, Tollman SM, Murray CJL, Jamison DT, et al. Impact of supplemental immunisation activity (SIA) campaigns on health systems: Findings from South Africa. Journal of Epidemiology and Community Health. 2013;67(11):947-52. | Supplementary immunization activity (SIA) campaigns provide children with an additional dose of measles vaccine and deliver other interventions, including vitamin A supplements, deworming medications, and OPVs. | Vitamin A<br>Helminths               | Vitamin A                            | Helminths                                               |                                                        |
| Vijayaraghavan | 2012 | Somalia                         | Vijayaraghavan M, Wallace A, Mirza IR, Kamadjeu R, Nandy R, Durr E, et al. Economic Evaluation of a Child Health Days Strategy to Deliver                                                                                                                 | 9 interventions delivered during 2 Child Health Days (CHDs), including DPT vaccine.                                                                                                                                | Vitamin A<br>Helminths<br>WASH       | PHC                                  |                                                         |                                                        |

| First Author                                        | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                   | Range of services integrated with immunization                                                                                                                                                                                                                              | Category of non-immunization service            | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
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|                                                     |      |                                 | Multiple Maternal and Child Health Interventions in Somalia. Journal of Infectious Diseases. 2012;205(Suppl 1):S134-S40.                                                                                                                   |                                                                                                                                                                                                                                                                             |                                                 |                                      |                                                         |                                                        |
| Palmer                                              | 2013 | Regional Africa                 | Palmer AC, Diaz T, Noordam AC, Dalmiya N. Evolution of the child health day strategy for the integrated delivery of child health and nutrition services. Food & Nutrition Bulletin. 2013;34(4):412-9.                                      | Co-delivery of services: immunization and vitamin A and WASH                                                                                                                                                                                                                | Vitamin A<br>Helminths<br>WASH                  | Vitamin A                            | Helminths                                               | WASH                                                   |
| Mihigo                                              | 2015 | Regional Africa                 | Mihigo R, Anya B, Okeibunor J, Ajibola S, Boakye-Agyemang C, Muzenda L, et al. African vaccination week as a vehicle for integrated health service delivery. BMC Health Services Research. 2015;15(1):1-7.                                 | Vaccinations (eg OPV) were accompanied by vitamin A supplementation, de-worming tablets, malnutrition screening, water, sanitation and hygiene kit distribution, vitamin/mineral supplementation.                                                                           | Vitamin A<br>Helminths<br>WASH                  | Vitamin A                            | Helminths                                               | WASH                                                   |
| Molina-Aguilera                                     | 2012 | Honduras                        | Molina-Aguilera IB, Mendoza-Rodriguez LO, Palma-Rios MA, Danovaro-Holliday MC. Integrating health promotion and disease prevention interventions with vaccination in Honduras. Journal of Infectious Diseases. 2012;205(SUPPL. 1):S77-S81. | Integrated with immunisation: Health promotion and disease prevention (vitamin A supplementation, folic acid delivery, early detection of retinoblastic, breastfeeding promotion); Disease control activities during public health emergencies (cholera and dengue control) | Vitamin A<br>Helminths<br>IYCF<br>Other disease | Vitamin A                            | IYCF                                                    | Inf other                                              |
| Integration of WASH interventions with immunisation |      |                                 |                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                             |                                                 |                                      |                                                         |                                                        |
| Coates                                              | 2013 | India                           | Coates EA, Waisbord S, Awale J, Solomon R, Dey R. Successful polio eradication in                                                                                                                                                          | To increase Polio vaccine coverage, additional services included creative behavior change activities and materials                                                                                                                                                          | WASH                                            | WASH                                 |                                                         |                                                        |

| First Author                                                | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                           | Range of services integrated with immunization                                                                                                                                                             | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
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|                                                             |      |                                 | Uttar Pradesh, India: the pivotal contribution of the Social Mobilization Network, an NGO/UNICEF collaboration. <i>Global Health Science &amp; Practice</i> . 2013;1(1):68-83.                                                                     | that promoted vaccination awareness and safety, household hygiene, sanitation, home diarrheal-disease control, and breastfeeding                                                                           |                                      |                                      |                                                         |                                                        |
| Qadri                                                       | 2015 | Bangladesh                      | Qadri F, Ali M, Chowdhury F, Khan AI, Saha A, Khan IA, et al. Feasibility and effectiveness of oral cholera vaccine in an urban endemic setting in Bangladesh: a cluster randomised open-label trial. <i>The Lancet</i> . 2015;386(10001):1362-71. | Oral killed whole-cell cholera vaccine was accompanied by behavioural interventions to encourage safe drinking water and hand washing.                                                                     | WASH                                 | WASH                                 |                                                         |                                                        |
| Khan                                                        | 2013 | Bangladesh                      | Khan IA, Saha A, Chowdhury F, Khan AI, Uddin MJ, Begum YA, et al. Coverage and cost of a large oral cholera vaccination program in a high-risk cholera endemic urban population in Dhaka, Bangladesh. <i>Vaccine</i> . 2013;31(51):6058-64.        | Oral cholera vaccine was delivered in three groups: vaccines, vaccine plus safe handwashing practice and safe water, no intervention. Interpersonal communication preceded vaccination to raise awareness. | WASH                                 | WASH                                 |                                                         |                                                        |
| Integration of IYCF and ECD interventions with immunisation |      |                                 |                                                                                                                                                                                                                                                    |                                                                                                                                                                                                            |                                      |                                      |                                                         |                                                        |
| Coghlan                                                     | 2014 | Lao PDR                         | Coghlan B, Toole MJ, Chanlivong N, Kounnavong S, Vongsaiya K, Renzaho A. The impact on child wasting of a capacity building project implemented by community                                                                                       | Health/nutrition project, including monitoring and promotion of practices and health indicators, was delivered to address acute malnutrition in children.                                                  | IYCF                                 | IYCF                                 |                                                         |                                                        |

| First Author                                       | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                                  | Range of services integrated with immunization                                                                                       | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
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|                                                    |      |                                 | and district health staff in rural Lao PDR. Asia Pacific Journal of Clinical Nutrition. 2014;23(1):105-11.                                                                                                                                                |                                                                                                                                      |                                      |                                      |                                                         |                                                        |
| Hamadani                                           | 2014 | Bangladesh                      | Hamadani JD, Nahar B, Huda SN, Tofail F. Integrating early child development programs into health and nutrition services in Bangladesh: Benefits and challenges. 2014(1308 1):192-203.                                                                    | Early Childhood Development (ECD) programs are integrated into health and nutrition services                                         | Early Childhood Development          | Inf other                            |                                                         |                                                        |
| Integration and other disease control or screening |      |                                 |                                                                                                                                                                                                                                                           |                                                                                                                                      |                                      |                                      |                                                         |                                                        |
| Mounier-Jack                                       | 2014 | Mali                            | Mounier-Jack S, Burchett HE, Griffiths UK, Konate M, Diarra KS. Meningococcal vaccine introduction in Mali through mass campaigns and its impact on the health system. Global health, science and practice. 2014;2(1):117-29.                             | Meningococcal A vaccine campaign carried out alongside routine vaccinations and antenatal care.                                      | Other infection                      | Inf other                            |                                                         |                                                        |
| Wei                                                | 2012 | Mali                            | Wei SC, Vanden Eng JL, Patterson AE, Doumbia S, Kleinbaum DG, Ryman TK, et al. Effect of the expanded program on immunization contact method of data collection on health behaviors in Mali. Journal of Infectious Diseases. 2012;205(SUPPL. 1):S103-S11. | During immunization visits, workers asked about 4 health behaviors related to bed net use, fever, respiratory disease, and diarrhea. | Other infection                      | Inf other                            |                                                         |                                                        |
| Joubert                                            | 2013 | South Africa                    | Joubert K, Casoojee A. Hearing-screening record-                                                                                                                                                                                                          | Hearing-screening and record-keeping by nurses during typical immunisation                                                           | Hearing                              | Hearing                              |                                                         |                                                        |

| First Author                           | Year | Setting<br>(country/ies<br>or region) | Citation                                                                                                                                                                                                                             | Range of services integrated with<br>immunization                                                         | Category of<br>non-<br>immunization<br>service | Category of<br>non-<br>immunization<br>service | Second<br>category of<br>non-<br>immunization<br>service (if<br>needed) | Third<br>category of<br>non-<br>immunization<br>service (if<br>needed) |
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|                                        |      |                                       | keeping practices at primary healthcare clinics in Gauteng. The South African journal of communication disorders. 2013;Die Suid-Afrikaanse tydskrif vir Kommunikasieafwykings. 60:27-30.                                             | sessions of children at Primary Healthcare Clinics.                                                       |                                                |                                                |                                                                         |                                                                        |
| Integration into 'non-health' settings |      |                                       |                                                                                                                                                                                                                                      |                                                                                                           |                                                |                                                |                                                                         |                                                                        |
| Kamadjeu                               | 2015 | Somalia                               | Kamadjeu R, Mulugeta A, Gupta D, Abshir Hirsi A, Belayneh A, Clark-Hattingh M, et al. Immunizing nomadic children and livestock-- Experience in North East Zone of Somalia. Human vaccines & Immunotherapeutics. 2015;11(11):2637-9. | Human vaccination was integrated into animal vaccination. Human vitamin A supplements were also included. | Non-health                                     | Non-health                                     |                                                                         |                                                                        |

| First Author  | Year | Setting (country/ies or region) | Citation                                                                                                                                                                                                                                                                                                                                                        | Range of services integrated with immunization                                                                                                                                                                                                            | Category of non-immunization service | Category of non-immunization service | Second category of non-immunization service (if needed) | Third category of non-immunization service (if needed) |
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| Patel         | 2012 | Zimbabwe                        | Patel D, Matyanga P, Nyamundaya T, Chimedza D, Webb K, Engelsmann B. Facilitating HIV testing, care and treatment for orphans and vulnerable children aged five years and younger through community-based early childhood development playcentres in rural Zimbabwe. <i>Journal of the International AIDS Society</i> . 2012;15 Suppl 2 (no pagination)(17404). | Early Childhood Development playcentres were established to provide health, nutritional and psychosocial support for OVC aged 5 years and younger exposed to or living with HIV, coupled with family support groups (FSGs) for their families/caregivers. | HIV<br>Non-health                    | Non-health                           | HIV                                                     |                                                        |
| Otieno-Masaba | 2013 | Kenya                           | Otieno-Masaba R, Bratt JH, Eichleay M, Solomon M, Munene M. Leveraging farmer field days to provide family planning and other health services in rural Kenya. <i>Journal of Biology, Agriculture and Healthcare</i> . 2013;3(9):24-30.                                                                                                                          | Female attendees (18-49 years old) at a dairy farmer cooperative event received Family Planning (FP) services, child immunizations, antenatal care, sexually transmitted infection screening and treatment, and HIV counseling and testing.               | HIV<br>FP<br>Non-health              | Non-health                           | FP                                                      | HIV                                                    |

| First Author                                  | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme                                                                                                                                                                                                                                                                                          | Evidence of benefit to other service                                                                                                                                                                                                                                                                                                                                                                                                                   | Other comment/s                                                                                                                                                                            |
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| Integration of immunisation into PHC settings |      |                          |              |                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                            |
| Kosec                                         | 2015 | Mix of settings          | Yes          | Monetary immunization incentives for Anganwadi Workers (AWWs) and above-median household head education were statistically significant positive predictors of household receipt of immunization services.                                                                                                                                      | AWWs receiving immunization incentives was associated with significantly higher odds of households receiving general nutrition information. Accredited Social Health Activists (ASHAs) receiving incentives for institutional delivery was marginally associated with higher odds of receiving pregnancy care information, and ASHAs who maintained records of pregnant women was significantly associated with households receiving such information. | Product-oriented incentives affect delivery of both product- and information-oriented services, although household factors are also important.                                             |
| Mirza                                         | 2012 | Outreach/mobile          | Yes          | Immunization services were reached in remote areas, and coverage disparity between the urban and rural areas was reduced from 17% (42% urban and 25% rural) to 10% (50% urban and 60% rural). In addition, infants were reached with a third dose of diphtheria-pertussis-tetanus vaccine, achieving 51% coverage during 2009 and 66% in 2010. | Not reported.                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                            |
| Lhamsuren                                     | 2012 | Mix of settings          | Yes          | Increased health access for the urban poor, as demonstrated by health staff having reached new clients with immunization.                                                                                                                                                                                                                      | Increased health access for the urban poor, as demonstrated by health staff having reached new clients family planning and ante-natal care services. Increased civil registrations which enable social service provision.                                                                                                                                                                                                                              | Need to measure and take action on the social determinants of health at the local area level in order to adequately reduce persistent inequities in health care access for the urban poor. |

| First Author | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme                                                                                                     | Evidence of benefit to other service                                                                                                                                                                                                                                                                                                      | Other comment/s                                                                                                                                                                                                                   |
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| Berk         | 2012 | Non-EPI outpatients      | Yes          | Children living within 30km of health clinic received 0.129 more DPT doses, 0.113 more Polio doses and 0.285 more total vaccinations.                     | Acutely ill children with proximity to clinic associated with 0.142 increased probability of receiving 'any medical treatment'; 0.117 for fever treatment; 0.064 for specific, locally-stocked treatments.                                                                                                                                | The franchise health clinic model could substantially increase access to essential vaccinations and treatments in low-income countries. Moreover, the model's benefits may accrue to lesser- and higher- income households alike. |
| Marin        | 2011 | Non-EPI outpatients      | Yes          | Significantly higher vaccination coverage in intervention (personalised care) group.                                                                      | For intervention (personalised care) group: five-fold increase in number of patients receiving antenatal services. Significantly increased rate of early detection of pregnancy and number of health consultations. Maternal gestation at delivery increased from 37.4% to 39.3% weeks and neonatal weight increased from 3048g to 3301g. |                                                                                                                                                                                                                                   |
| Cristia      | 2015 | Outreach/mobile          | Yes          | Article claims to document large impacts on immunisation rates for children                                                                               | Results indicate that mobile medical teams substantially increased coverage of health care services in Guatemala. Article claims to document large impacts on prenatal care provider choices.                                                                                                                                             | Contracted mobile medical teams could be effective in other developing countries. The programme increased substantially the role of physicians and nurses at the expense of traditional midwives.                                 |
| Fort         | 2011 | Outreach/mobile          | Yes          | Vaccination coverage for children in first 12-23 months reached 95.6% at implementation site 1 and 92.7% at site 2, compared with national average 71.2%. | Postnatal coverage at both implementation sites was 100%, compared to national average of 25.6%. Adherence to national treatment guidelines (ie quality of care) increased. Utilisation increased, with only 7.5% of families not using health services at site 1 and 11.2% at site 2.                                                    | The inclusive health care service delivery model will be extended to at least 3 additional sites.                                                                                                                                 |



| First Author                                  | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme                                                       | Evidence of benefit to other service                                                                                                                                                                                                                                                                                                                                        | Other comment/s                                                                                                                                                                                                                             |
|-----------------------------------------------|------|--------------------------|--------------|-------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Saxena                                        | 2016 | Outreach/mobile          | Yes          | Of 24 VHNDs studied, immunisation was provided at 22 sites.                                                 | Of the 24 VHNDs observed, blood pressure measurement was done at 11 (45.83%) and weight at 13 (54.17%) sites in ante-natal care services. 1/3 of clients rated their satisfaction with VHND services as 3 or 4 on a 1-5 scale.                                                                                                                                              | Availability of other services were poor: vitamin A (at 3 VHND sites only), growth monitoring of children (7 sites); supplementary nutrition (5 sites); identification of households for construction of toilet (8 sites).                  |
| Integration of immunisation into IMCI or iCCM |      |                          |              |                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                             |
| Amouzou                                       | 2016 | Mix of settings          | Not clear    | No coverage change in immunization in differences analysis                                                  | Other services was primary focus - showed good iCCM implementation and quality but few families used iCCM providers                                                                                                                                                                                                                                                         | Consistent with IMCI findings that showed minimal change in immunization coverage when IMCI implementation studied. Also shows low usage of CHWs by families with sick children (cf Hodgins review paper on this).                          |
| Teferi                                        | 2014 | Mix of settings          | Yes          | Immunization coverage increased. Some increase in immunization occurred even when levels were already high. | Coverage increased for 10 of 15 coverage indicators, mainly for maternal, <b>immunization</b> , and nutrition services. In some cases, dramatic increases, i.e., for >4 antenatal care visits, antenatal iron and folate, and exclusive breastfeeding. Three indicators remained high and unchanged (bednet ownership, children sleeping under bednets, and any lactation). | Two indicators decreased (tetanus toxoid and households with >2 bednets). Scale-up of iCCM was consistent with increased coverage of most preventative and promotive interventions, which may contribute to the life-saving effect of iCCM. |
| Basaleem                                      | 2011 | Non-EPI outpatients      | Not clear    | Not reported                                                                                                | Not reported                                                                                                                                                                                                                                                                                                                                                                | Interviewees appreciated the clinical aspects of IMCI, but highlighted challenges in implementation. The gaps identified would endanger the positive influence of IMCI unless action is undertaken at different levels.                     |
| Shewade                                       | 2013 | Non-EPI outpatients      | Not clear    | Immunization card was asked for in 20% observations                                                         | IMNCI trained workers performed well in all aspects of counseling, except follow up.                                                                                                                                                                                                                                                                                        | Morbidity-wise, physician/trained worker agreement was poor for possible serious bacterial infection, feeding problem, respiratory problem and anemia. Physician and trained worker completely                                              |

| First Author                         | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme                                                                               | Evidence of benefit to other service | Other comment/s                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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|                                      |      |                          |              |                                                                                                                                     |                                      | agreed in 45% child observations for final diagnoses. All symptoms were asked only in 15% cases. Skills were poor overall for young infants. For children between 2 mo to 5 y, danger signs, neck stiffness, edema, wasting and pallor were checked in <40% observations. Immunization card was asked for in 20% observations.                                                                                                                                                                                                                                                            |
| Integration of immunisation at birth |      |                          |              |                                                                                                                                     |                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Wiesen                               | 2016 | Inpatient care           | Yes          | Overall timely BD coverage was 31%; BD vaccination was taking place in 81% of sampled health facilities.                            | Not reported                         | Overall timely BD coverage was 31%; Lack of cold chain and vaccine were the major reasons for not providing the BD. Insufficiencies in supervision, vaccine management, community outreach, and data management were identified as obstacles to achieving high timely hepatitis B BD coverage. Good supervision, knowledge of hepatitis B and hepatitis B vaccination, antenatal care including information about the hepatitis B BD, provision of vaccine refrigerators in maternity wards, and outreach vaccination for home deliveries were associated with higher timely BD coverage. |
| Taneja                               | 2015 | Inpatient care           | Yes          | Progressive increase of BCG and OPV zero dose, as well as Hepatitis B birth dose, introduced during the course of the intervention. | Not reported                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Hutin                                | 2013 | Mix of settings          | Yes          | Among institutional births, TBD coverage increased by 2% to 13% to reach post implementation coverage ranging from 98% to 100%.     | Not reported                         | Demonstration projects based on combined interventions increased TBD coverage. Use of standardized indicators for such projects would facilitate evaluation and identify intervention                                                                                                                                                                                                                                                                                                                                                                                                     |

| First Author                                       | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme                                                                                                                                                                             | Evidence of benefit to other service                                                                                                                                                                      | Other comment/s                                                                                                                                                                                        |
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|                                                    |      |                          |              | Among home births, TBD coverage increased by 7% to 56% to reach post implementation coverage ranging from 29% to 88%. Overall, TBD coverage increased by 4% to 36% to reach post implementation coverage ranging from 82% to 88%. |                                                                                                                                                                                                           | components that are most effective.                                                                                                                                                                    |
| Integration of HIV interventions with immunisation |      |                          |              |                                                                                                                                                                                                                                   |                                                                                                                                                                                                           |                                                                                                                                                                                                        |
| Binagwaho                                          | 2013 | Immunization Clinic      | Not clear    | Not reported                                                                                                                                                                                                                      | EID rates increased from approximately 28 to 72.4% (90.3% within prevention of mother to baby transmission program); sample turnaround time decreased from 144 to 20 days                                 | Rwanda rapidly scaled up and improved its EID program, but challenges persist for linking infected infants to care.                                                                                    |
| Bland                                              | 2013 | Immunization Clinic      | Not clear    | Not reported                                                                                                                                                                                                                      | The number of children (1 year to $\leq 15$ years) starting ART each year increased from 43 to 254; the number of infants increased from 2 to 59. Increased CD4 counts in children at start of treatment. | It is possible to improve the identification of HIV infected children and ensure a prompt start on ART where needed with relatively simple measures and limited implications for staffing and budgets. |

| First Author | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme | Evidence of benefit to other service                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Other comment/s                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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| Sinunu       | 2014 | Immunization Clinic      | Not clear    | Not reported.                                         | Survey data indicates 64.8% of HIV-infected mothers and 46.9% of HIV-exposed infants received some form of antiretroviral prophylaxis. 179 mothers identified as HIV-infected reported their HIV status to be negative on the study survey, further suggesting that provision of testing at immunization clinics has the benefit of identifying previously unknown HIV-infected women. It appears that the Malawian PMTCT program is preventing the majority of vertical transmission up to 2–3 months postpartum. | Challenges to full implementation of PMTCT remain, especially later in infancy. Also shows potential to monitor outcomes via immunization clinic data collection.                                                                                                                                                                                                                                                                                      |
| Woldesenbet  | 2015 | Immunization Clinic      | Not clear    | Not reported                                          | 80.4% of mothers tested positive for HIV received some form of maternal and infant antiretroviral treatment.                                                                                                                                                                                                                                                                                                                                                                                                       | Note: PMTCT services not necessarily given at time of vaccination; study was undertaken at time of vaccination about retrospective PMTCT uptake                                                                                                                                                                                                                                                                                                        |
| Wiegert      | 2014 | Non-EPI outpatients      | Not clear    | Not reported                                          | Approximately, 99% of responding facilities reported providing dried blood spot (DBS) collection and a basic HIV-exposed infant service package including early infant diagnosis of HIV (EID), extended nevirapine prophylaxis, and use of cotrimoxazole. DBS collection was integrated with immunisations at 83% of facilities.                                                                                                                                                                                   | CD4 testing with point-of-care machines was available at 37% of facilities, and anti retroviral treatment (ART) for both mothers and children was provided at 27% of facilities. More than 80% of facilities reported that DBS test results take >4 weeks to return; The long turnaround time of infant DBS test results and the lack of integrated ART programs in the MCH setting could reduce effectiveness of the national PMTCT and ART programs. |

| First Author                          | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme | Evidence of benefit to other service                                                                                                                                                                                                                                                                                                                                                                    | Other comment/s                                                                                                                                                                                                                                                                                                                               |
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| Matsubayashi                          | 2011 | Non-EPI outpatients      | Yes          | "Noticeable increase in pediatric immunisation."      | HIV/AIDS health services: Number of HIV lab tests and number of pregnant women diagnosed with HIV tests increased significantly. Non HIV/AIDS health services: TB lab tests and diagnoses increased significantly. Noticeable increase in pediatric malaria lab tests, malaria diagnoses, skin disease diagnoses. Patients' overall impressions were positive for both HIV and non HIV services (>90%). | In addition to providing HIV/AIDS services in a setting in which other primary health care is being delivered, there are positive effects not only on HIV/AIDS services, but also on many other essential services. There was no evidence that the HIV program had any deleterious effects on health services offered at the clinics studied. |
| Integration of ITNs with immunisation |      |                          |              |                                                       |                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                               |
| Hartman                               | 2012 | Campaign                 | Not clear    | Not reported.                                         | The household campaign was undertaken in 9 of 10 regions in Ghana. By end of April 2011, 9,683,160 ITNs had been handed in the homes of 19,366,320 in the country.                                                                                                                                                                                                                                      | Ghana is likely to achieve universal coverage of ITNs by July 2012.                                                                                                                                                                                                                                                                           |
| Njau                                  | 2013 | Campaign                 | Not clear    | Not reported.                                         | Both poorer and wealthier Angolan households almost achieved parity in bed net ownership. The poorest household in Angola had a 6.1% net use advantage over children in wealthier households.                                                                                                                                                                                                           | Poorest households were less likely to own a net by 21.4% in Tanzania, and 2.8% in Uganda; Wealthier households had a higher margin of using nets than poorest people in both Tanzania and Uganda by 11.4% and 3.9% respectively.                                                                                                             |
| Zegers de Beyl                        | 2016 | Campaign                 | Not clear    | Not reported.                                         | All of the campaigns, irrespective of strategy, successfully increased ownership of at least one ITN. Registration was equitable in most campaigns.                                                                                                                                                                                                                                                     | Maximizing registration completeness and using a universal coverage allocation strategy are likely to improve campaign outcomes. Campaigns that used a universal coverage allocation strategy were more effective in increasing the proportion of households with enough ITNs than campaigns that used a fixed number of ITNs                 |
| O'Meara                               | 2011 | Immunization Clinic      | Not clear    | Not reported                                          | No positive effects                                                                                                                                                                                                                                                                                                                                                                                     | Only 21% of households own any bednets (in Western Kenyan district examined), far lower than the national average, and                                                                                                                                                                                                                        |

| First Author  | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme                                                                    | Evidence of benefit to other service                                                                                 | Other comment/s                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------|------|--------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|               |      |                          |              |                                                                                                                          |                                                                                                                      | ownership is not significantly higher amongst pregnant women attending antenatal clinics. Coverage is spatially heterogeneous with less than 2% of the population residing in zones with adequate coverage to experience indirect effects of ITN protection.                                                                                                                                                                               |
| Theiss-Nyland | 2016 | Immunization Clinic      | Not clear    | Not reported                                                                                                             | 25 of 33 observed countries reported adopting policies of EPI-based distribution.                                    | LLIN distribution through ANC accounted for 9% of LLINs distributed, and LLINs distributed through EPI accounted for 4%. The LLIN availability ratios (distribution per visit) achieved were 55 % through ANC and 34 % through EPI. These continuous LLIN distribution channels appear to be under-utilized, especially EPI-based distribution.                                                                                            |
| Sesay         | 2014 | Campaign                 | Yes          | Overall measles coverage was 91.6% according to post-treatment survey, compared with 100% coverage reported during MCHW. | Overall VAS coverage was 91.6% according to post-treatment survey, compared with 100% coverage reported during MCHW. | Coverage was equitable; no significant differences by age group, sex, religion or occupation. Major reasons given for not receiving VAS and measles vaccination were not knowing about the MCHW or being out of the area. Mild adverse affects were reported at 29.1%, according to post-treatment survey, compared with 0.0% as reported during MCHW.                                                                                     |
| Rah           | 2014 | Immunization Clinic      | Not clear    | Not reported.                                                                                                            | The VAS program was most successful in two Indian states of Bihar and Odisha.                                        | The critical success factors for the VAS program in the two states include strong leadership and ownership by the state government; close coordination between the two departments that are involved in the VAS program; effective microplanning prior to each biannual round; flexible dosing mechanisms that enhance coverage in hard-to-reach areas; a stable procurement and distribution mechanism to ensure an adequate, timely, and |

| First Author   | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme                                                                                                                                                                                           | Evidence of benefit to other service                                                                                                                                                                                                            | Other comment/s                                                                                                                                                                                                                                                                                         |
|----------------|------|--------------------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                |      |                          |              |                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 | sustainable supply of VAS; intensive social mobilization and communication; and appropriate training and supervision of staff.                                                                                                                                                                          |
| Babaniyi       | 2013 | Campaign                 | Yes          | 96.1% children studied were vaccinated against measles; 83.1% received OPV                                                                                                                                                                      | 95.5% children received vitamin A; 93.4% were de-wormed                                                                                                                                                                                         | The 2012 measles campaign in Zambia was a great success but continued efforts are needed to adhere to the World Health Organization/United Nations Children's Fund (WHO/UNICEF) strategy to control measles.                                                                                            |
| Vince          | 2014 | Campaign                 | Yes          | The last SIA in Papua New Guinea showed relatively high coverage of all the interventions and demonstrated the operational feasibility of delivering multiple interventions in resource constrained settings. (intervention type not specified) | The last SIA in Papua New Guinea showed relatively high coverage of all the interventions and demonstrated the operational feasibility of delivering multiple interventions in resource constrained settings. (intervention type not specified) | The aims and results of this study are unclear/poorly outlined in its abstract.                                                                                                                                                                                                                         |
| Verguet        | 2013 | Campaign                 | Yes          | Measles vaccination alone averted 330 deaths.                                                                                                                                                                                                   | Vitamin A supplementation alone averted 820 deaths.                                                                                                                                                                                             | Cost-effectiveness (cost per death averted) of the SIA child health delivery platform varies substantially across South African provinces, and it is substantially more cost-effective when vitamin A supplementation is included in the interventions administered.                                    |
| Vijayaraghavan | 2012 | Campaign                 | Not clear    | For every \$1 million invested in the strategy, an estimated 615 children's lives, or 29 500 life years, were saved.                                                                                                                            | For every \$1 million invested in the strategy, an estimated 615 children's lives, or 29 500 life years, were saved.                                                                                                                            | If the pentavalent vaccine had been delivered during the CHDs instead of DPT vaccine, an additional 5000 children's lives could have been saved. The CHDs were cost-effective at \$34.00/life year saved. estimated average incremental cost per intervention for each targeted beneficiary was \$0.63. |

| First Author    | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme                                                                                                                                                                            | Evidence of benefit to other service                                                                                                                                                                                                                                                                                                                                                                                                      | Other comment/s                                                                                                                                                                                                                                                                                                                                                               |
|-----------------|------|--------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Palmer          | 2013 | Campaign                 | Not clear    | Not reported.                                                                                                                                                                                                                    | Whereas early Child Health Days (CHDs) were largely for codelivery of vitamin A, immunizations, and deworming, they have since evolved into diverse packages including services such as water purification tablets and screening for severe malnutrition. 'The scale-up of CHDs is helping countries to achieve high and equitable coverage of essential health and nutrition services.'<br>(Quality/perception of services Not reported) | Reliance on CHDs has been particularly marked in sub-Saharan Africa, where they are increasingly used to deliver five or more services per event.                                                                                                                                                                                                                             |
| Mihigo          | 2015 | Campaign                 | Yes          | More than 7,500,000 doses of different vaccine antigens were delivered in 17 African countries. 36,711,984 doses of oral polio vaccines (OPV) reached children in 10 countries.                                                  | Vitamin A administered to children under 5 years and women in post-partum in 13 countries with 31,500,000 tablets distributed. Over 21,190,000 deworming tablets were distributed to children <5 years and pregnant women in 9 countries. 6,377,222 children were screened for malnutrition in 3 countries while 3,814,680 water, sanitation and hygiene kits were distributed in 3 countries.                                            | Integration of other interventions with immunization during African Vaccination Week has shown potential for improving immunization coverage, as this dedicated period is used both for catch-up campaigns and periodic intensified routine immunization. A platform for integrated delivery of health interventions to people with limited access to regular health service. |
| Molina-Aguilera | 2012 | Campaign                 | Not clear    | Not reported                                                                                                                                                                                                                     | Not reported                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                               |
| Coates          | 2013 | Campaign                 | Yes          | While the SMNet worked in the highest-risk, poorly served communities, data suggest that (Polio) immunization coverage in Social Mobilisation Network (SMNet) communities was often higher than overall coverage in the district | Not reported                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                               |



| First Author | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme                                                                                                                                                                                      | Evidence of benefit to other service                                                                                                                                                                                                                                       | Other comment/s                                                                                                                                                                         |
|--------------|------|--------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Qadri        | 2015 | Immunization Clinic      | Yes          | Vaccine coverage was 65% in the vaccination only group and 66% in the vaccination and behavioural change group. Overall protective effectiveness was 37% in the vaccination group and 45% in the vaccination and behavioural change group. | Vaccination and <b>behavioural</b> change                                                                                                                                                                                                                                  | No vaccine-related serious adverse events.                                                                                                                                              |
| Khan         | 2013 | Outreach/mobile          | Yes          | Of the 172,754 target population, 141,839 (82%) and 123,666 (72%) received complete first and second doses of the vaccine, respectively. Two complete doses were received by 123,661 participants. Vaccine coverage in children was 81%.   | Not reported                                                                                                                                                                                                                                                               | Mass vaccination with oral cholera vaccine is feasible for reaching high risk endemic population through the existing national immunization delivery system employed by the government. |
| Coghlan      | 2014 | Outreach/mobile          | Yes          | Child immunisation coverage improved.                                                                                                                                                                                                      | Acute malnutrition was reduced from 12.4% to 6.1%. Unhealthy feeding practices declined: in 2008 40% of mothers fed newborns within first 2 hours of birth and 30.8% threw colostrum away; in 2011 these figures were 72% and 8% respectively. Maternal care was improved. | Improving the health environment and child feeding practices appears to have markedly reduced the level of wasting.                                                                     |
| Hamadani     | 2014 | Immunization Clinic      | Not clear    | Not reported.                                                                                                                                                                                                                              | There is sufficient evidence on feasibility of integrating ECD activities into nutrition and health programs.                                                                                                                                                              | Suggestions are made on measures to overcome the implementation problems and on suitable methods to establish high-quality ECD programs                                                 |

| First Author                                       | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme                                                                                                                                                                             | Evidence of benefit to other service                                                                     | Other comment/s                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------------------------------------------|------|--------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Integration and other disease control or screening |      |                          |              |                                                                                                                                                                                                                                   |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Mounier-Jack                                       | 2014 | Campaign                 | Not clear    | Problems with immunization were unrelated to the integration strategy. Rather they included the interruption of routine vaccination services while campaigns were operating, in the majority of health facilities surveyed (67%). | Benefits included strengthened communication and social mobilization, surveillance, and provider skills. | Antenatal care consultations were also reduced during the campaign period by 10% to 15%. Key informants argued that, with an average of 14 campaigns per year, mass campaigns would have a substantial cumulative negative effect on routine health services. Many also argued that the MenA campaign missed potential opportunities for health systems strengthening because integration with other health services was lacking. |
| Wei                                                | 2012 | Immunization Clinic      | Not clear    | Not reported                                                                                                                                                                                                                      | No positive effects                                                                                      | No evidence that EPI-CM (Expanded Program on Immunization Contact Method) increases healthy behaviors.                                                                                                                                                                                                                                                                                                                            |
| Joubert                                            | 2013 | Immunization Clinic      | Not clear    | Not reported.                                                                                                                                                                                                                     | Low rates of accuracy, but approximately half did some screening.                                        | Primary healthcare nurses who participated in this study do not adhere to the hearing-screening record-keeping practices as outlined by the national Department of Health. Poor record-keeping practices hinder the efficacy of hearing-screening programmes.                                                                                                                                                                     |
| Integration into 'non-health' settings             |      |                          |              |                                                                                                                                                                                                                                   |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Kamadjeu                                           | 2015 | Campaign                 | Yes          | 26,393 children received OPV (34% for their first time ever), 23,099 were vaccinated against measles.                                                                                                                             | 12,566 children received vitamin A supplements.                                                          | This program harnessed the high demand for veterinary services among pastoralist communities during the polio outbreak in Somalia, 2013-14. Integrated human and animal vaccination campaign was effective in reaching the unvaccinated children from these communities.                                                                                                                                                          |

| First Author  | Year | Service delivery setting | EPI benefit? | Evidence of benefit or harm to immunization programme | Evidence of benefit to other service                                                                                                                                                                                                                                                                                   | Other comment/s                                                                                                                                                                                                                                                                                                                                                                   |
|---------------|------|--------------------------|--------------|-------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Patel         | 2012 | Non-health care setting  | Not clear    | Not reported.                                         | 58.8% of the 697 children attending the centres were tested for HIV; 18% tested positive and were initiated on antibiotic prophylaxis. All those deemed eligible for antiretroviral therapy were commenced on treatment and adherence was monitored.                                                                   | This community-based playcentre model strengthens comprehensive care (improving emotional, cognitive and physical development) for OVC (Orphaned and Vulnerable Children) younger than 5 years and provides opportunities for caregivers to access testing, care and treatment for children exposed to, affected by and infected with HIV in a secure and supportive environment. |
| Otieno-Masaba | 2013 | Non-health care setting  | Not clear    | Not reported                                          | More than 80% of the 2,344 attendees received consultations. services provided most frequently during the field-days were non-reproductive health exams (66%), FP counseling (18%), and HIV counseling and testing (13%). One-quarter of current FP users acquired additional supplies of contraceptives at the event. | Of the women interviewed, 40% were affiliated with a dairy cooperative.                                                                                                                                                                                                                                                                                                           |

## 10.3 Supplementary material for Chapter Six

### 10.3.1 Questionnaire extract of integration questions, English and Tok Pisin

The extract below should be read in the context of the full questionnaire and data collection forms, which are outlined in Appendix 10.1.3. These were administered using electronic tablets with questions coded using Mobile Data Studio.

The overall structure varied at different time points but generally included:

- Consent, identification and site
- Demographics (including age, religion, marital status, education, employment, expenditure)
- Reproductive history
- Family planning
- Clinical pregnancy or postpartum history, mother and infant
- Verbal autopsy if death notified
- Risk behaviours
- Preventive care, ITN use, preventive treatments or supplements
- Feeding and vaccination history
- Preventive care received (detailed set of questions used to assess uptake of integrated care)
- Clinical symptom screen for mother and infant
- Planning of future care (type, site, location, expected provider)
- Family planning intentions
- Planning for health emergencies
- Knowledge of danger signs and other health risks
- Partner involvement and attitudes
- Satisfaction with care, and suggestions
- Barriers to access (family planning and others)
- Opinion on enablers of better access
- Integration questions
- Physical measurements, samples, health records review including vaccination record

#### Extract of English and Tok Pisin questions relevant to integrated services

Note: Tok Pisin version is authoritative version of question.

| <b>Section 6: Attitudes to health services</b>                                                                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Nau mi laik toktok wantaim yu long tingting na lukluk bilong yu long helt sevis bilong yumi. Yu ting wanem narapela kain helt sevis imas kamap behain long beibi emi wanpela mun inap long nau. Dispela ol askim mi laik harim tingting bilong yu yet long hau ol sevis iken kamap gutpela mo long halivim yu.</i> |
| Lastly, I would like to talk with you about your feelings about health care services, and what type of services you like for the period from one month after the baby was born until now. These questions are about your own ideas about how services would be more friendly or helpful for you.                      |

|                                                                                                                                                                                                                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Satisfaction</i>                                                                                                                                                                                                                   |
| <i>Yu wanbel tasol long halivim yu kisim long beibi sut klinik?</i>                                                                                                                                                                   |
| Were you satisfied with the care you received during routine baby clinic visits? (refers to routine prevention care like immunizations)                                                                                               |
| Partially' means mother was mostly happy, but some things could have been better.                                                                                                                                                     |
| 'No, not satisfied' means mother was mostly unhappy and many things could have been done better.                                                                                                                                      |
| 1;YES, FULLY                                                                                                                                                                                                                          |
| 2;YES, PARTIALLY                                                                                                                                                                                                                      |
| 0;NO, NOT SATISFIED                                                                                                                                                                                                                   |
| <i>Improvement suggestions</i>                                                                                                                                                                                                        |
| <i>Wanem ol sampela samting yu ting bai imas senis</i>                                                                                                                                                                                |
| For mothers who were partially satisfied, or not satisfied with ANC, please ask for any suggestions of what should have been improved.                                                                                                |
| <i>Open text</i>                                                                                                                                                                                                                      |
| <i>Why sites are chosen</i>                                                                                                                                                                                                           |
| Bilong wanem stret na u kam tasol long dispela hausik long beibi klinik, na u no go long beibi klinik long narapela hausik?                                                                                                           |
| Why did you choose your usual health facility for your routine baby clinic visits? Please choose the ONE MAIN reason. For example, why do you go there, rather than somewhere else?If mother has no suggestion, then leave all blank. |
| 2;HAS SUFFICIENT STAFF or EQUIPMENT                                                                                                                                                                                                   |
| 3;STAFF ARE WELL TRAINED                                                                                                                                                                                                              |
| 4;HAS GOOD MANAGEMENT                                                                                                                                                                                                                 |
| 5;STAFF ARE KIND & SYMPATHETIC                                                                                                                                                                                                        |
| 6;CARE WILL COST LESS                                                                                                                                                                                                                 |
| 9;MORE NEARBY FACILITY WAS SHUT                                                                                                                                                                                                       |
| 8;NO REAL CHOICE, THIS ONLY OPTION                                                                                                                                                                                                    |
| 1;CLOSE TO HOME                                                                                                                                                                                                                       |
| 0;OTHER [specify]                                                                                                                                                                                                                     |
| <i>Open text field, please probe for additional comments</i>                                                                                                                                                                          |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Partner involvement</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <i>Man bilong yu ikam wantaim yu long beibi klinik o nogat? Bilong wanem emi kam / Bilong wanem emi no kam? [choose one]</i>                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Does your partner go to routine baby clinic visits with you? Choose one option that best matches the mother's responses. May prompt her if needed. If husband does go, take care to distinguish whether he is present when the health worker does the assessment and check-up, or whether he just waited outside. If no answer, please ask the mother whether the husband would want to come or not.                                                                                                                                            |
| 1;YES and PRESENT DURING HW ASSESSMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2;YES but NOT PRESENT FOR HW CHECKUP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3;NO, COULD NOT COME but WOULD LIKE TO COME                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4;NO, HUSBAND UNWILLING                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 5;NO, MOTHER DOES NOT KNOW IF HE LIKES TO COME OR NOT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 0;OTHER [specify]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <i>Open text field, please probe for additional comments</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <i>Access barriers</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <i>Wanem sampela samting i mekim hat tumas long yu kisim gutpela halivim long beibi klinik? [choose any mentioned]</i>                                                                                                                                                                                                                                                                                                                                                                                                                          |
| What does the mother think are the main things that make it difficult to receive BABY CLINIC care (the vaccination clinic one month after birth)? Do not prompt her, but encourage the mother to give any reasons she can. "TIME AWAY FROM WORK AT HOME" includes women who are reluctant to leave household gardens. "OTHER OBSTRUCTIVE ATTITUDES FROM OTHER IMMEDIATE FAMILY" refers to obstruction from the husband/partner or a parent of the mother. If something like violence in the home is mentioned, please make a note using "OTHER" |
| 1;DISTANCE - HOME TO FACILITY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2;DIFFICULT TRANSPORT - ROADS/VEHICLES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 3;TIME AWAY FROM WORK AT HOME                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 4;TIME AWAY FROM WORK for EMPLOYER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 5;COST OF TRANSPORT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 6;COST OF HEALTH CARE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 7;INSUFFICIENT EQUIPMENT/MED SUPPLIES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 8;INSUFFICIENT STAFF SKILLS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 9;STAFF NOT KIND or SYMPATHETIC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

|                                                                                                                                                                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10;HEALTH CARE NOT NEEDED FOR MNH                                                                                                                                                     |
| 15;NO-ONE TO CARE FOR OTHER CHILDREN                                                                                                                                                  |
| 11;PARTNER FEELS HEALTH CARE NOT NEEDED                                                                                                                                               |
| 13;OBSTRUCTIVE ATTITUDES FROM IMMEDIATE FAMILY                                                                                                                                        |
| 14;OBSTRUCTIVE ATTITUDE from OTHER COMMUNITY MEMBERS                                                                                                                                  |
| 0;OTHER [specify]                                                                                                                                                                     |
| 16;CANNOT THINK OF ANY BARRIERS                                                                                                                                                       |
| Preventive care expectations [APPLIED VARIOUSLY TO POSTNATAL OR WELL BABY CLINICS, DEPENDING ON TIME POINT]                                                                           |
| I would now like to ask you for some of your ideas about what health services or what check-ups should be available at [ADJUSTED FOR UPCOMING TIME POINT].                            |
| <i>Wanem ol dispela helt sevis o sek up yu ting o laik bai mas kamap BIHAIN LONG YU KARIM BEIBI, INAP LONG WANPELA MUN? [choose all mentioned]*</i>                                   |
| This asks the mothers opinion or ideas on what MOTHER and BABY health services or what checkups should be available after the baby is born. This relates to [ADJUSTED TO TIME POINT]. |
| 1;WEIGH BABY                                                                                                                                                                          |
| 2;CARE FOR WARMTH                                                                                                                                                                     |
| 3;CARE FOR HYGIENE                                                                                                                                                                    |
| 4;VACCINATION                                                                                                                                                                         |
| 5;CHECK CONGENITAL ABNORMALITY                                                                                                                                                        |
| 6;CHECK FOR INFECTION                                                                                                                                                                 |
| 7;CHECK FOR JAUNDICE                                                                                                                                                                  |
| 8;CHECK MOTHER HEALTH, GENERAL                                                                                                                                                        |
| 9;CHECK MOTHER FOR BLEEDING                                                                                                                                                           |
| 10;CHECK MOTHER FOR INFECTION                                                                                                                                                         |
| 11;ADVICE ON BREAST FEEDING                                                                                                                                                           |
| 12;ADVICE - MOTHER NUTRITION                                                                                                                                                          |
| 13;ADVICE FAMILY PLANNING                                                                                                                                                             |
| 14;ADVICE ON SEXUAL HEALTH                                                                                                                                                            |
| 0;OTHER [specify]                                                                                                                                                                     |
| <i>Open question on services (do not prompt or lead, categorise answer/s given and then seek additional suggestions)</i>                                                              |

| <i>Adding extra services to preventive care visits</i>                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Wanem ol NARAPELA helt sevis o sek ap yu ting na laik bai mas kamap wantaim beibi sut klinik? I no beibi sut tasol i narapela sevis                                                                                                                                                                                                                                                                                                                                                    |
| <p>This question wants to know if the mother thinks there are any EXTRA health services that should be offered at the same time as INFANT CARE - that is at baby clinics in [ADJUSTED TO TIME POINT]</p> <p>This is mainly concerning extra services to be added at the same time as immunization visits. One example could be check-ups for other family members. Choose all options she mentions, and encourage her to suggest, but do not prompt her with specific suggestions.</p> |
| 15;WEIGH THIS BABY                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 16;FEEDING ADVICE THIS BABY                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 17;ILLNESS CARE THIS BABY                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1;VACCINATION for OTHER CHILDREN                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 2;FEEDING ADVICE for OTHER CHILDREN                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 3;VACCINATIONS in general                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 4;VITAMIN A                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 5;OTHER VITAMIN/NUTRITION SUPPLEMENT for CHILD                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 6;BEDNETS FOR MOSQUITO PREVENT                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 7;ADVICE ON DISEASE PREVENTION                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 8;ILLNESS CARE for OTHER CHILDREN                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 9;NUTRITION ADVICE for MOTHER                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 10;FAMILY PLANNING ADVICE - MOTHER                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 11;SEXUAL HEALTH ADVICE - MOTHER                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 12;FAMILY PLANNING ADVICE - HUSBAND                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 13;SEXUAL HEALTH ADVICE - HUSBAND                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 14;ILLNESS CARE - MOTHER                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 0;OTHER [specify]                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <i>Open field for extra suggestions or additional detail</i>                                                                                                                                                                                                                                                                                                                                                                                                                           |



|                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Acceptability of extra services</i>                                                                                                                                                                                                                                                                                                               |
| Acceptability of adding services - GOOD aspects                                                                                                                                                                                                                                                                                                      |
| <i>Yu ting emi gutpela sapos ol narapela helt sevis olsem famili plening i kamap wantaim beibi klinik [beibi sut klinik]? Bilong wanem?</i>                                                                                                                                                                                                          |
| If an extra service like family planning or sexual health information was offered at the same time as infant care, what would the mother's FEELING about this be? Are there any GOOD things about this, any GOOD consequences she can think of? Choose all mentioned. Do not prompt                                                                  |
| 1;GOOD because REDUCES COST                                                                                                                                                                                                                                                                                                                          |
| 2;GOOD because REDUCES TIME SPENT                                                                                                                                                                                                                                                                                                                    |
| 3;GOOD because PATIENT MAY HAVE SEVERAL HEALTH NEEDS                                                                                                                                                                                                                                                                                                 |
| 4; GOOD CHANGE, NO REASON GIVEN                                                                                                                                                                                                                                                                                                                      |
| 0;OTHER COMMENT [specify]                                                                                                                                                                                                                                                                                                                            |
| <i>Open field for additional comments on good aspects</i>                                                                                                                                                                                                                                                                                            |
| Acceptability of adding services - BAD aspects                                                                                                                                                                                                                                                                                                       |
| <i>Yu ting em i NO gutpela long famili plening i kamap wantaim beibi klinik [beibi sut klinik]? Bilong wanem?</i>                                                                                                                                                                                                                                    |
| If an extra service like family planning or sexual health information was offered at the same time as infant care, what would the mother's FEELING about this be? Are there BAD things about this change? Are there any bad consequences you can think of? Is there a reason she thinks it would be good or bad? Choose all mentioned. Do not prompt |
| 4;BAD because NOT NEEDED                                                                                                                                                                                                                                                                                                                             |
| 5;BAD because EMBARRASSING TO MIX THESE SERVICES                                                                                                                                                                                                                                                                                                     |
| 6;BAD because EXTRA LOAD ON STAFF                                                                                                                                                                                                                                                                                                                    |
| 0;OTHER COMMENT [specify]                                                                                                                                                                                                                                                                                                                            |
| <i>Open field for additional comments on bad aspects</i>                                                                                                                                                                                                                                                                                             |
| Other reason:                                                                                                                                                                                                                                                                                                                                        |
| Please ask the mother for any other comments about adding services.                                                                                                                                                                                                                                                                                  |
| <i>Open field for additional comments on integration</i>                                                                                                                                                                                                                                                                                             |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Other service delivery suggestions</i>                                                                                                                                                                                                                                                                                                                                                                                                        |
| <i>Wanem ol narapela helt sevis yu ting i mas kamap?</i>                                                                                                                                                                                                                                                                                                                                                                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <i>General suggestions for improvement</i>                                                                                                                                                                                                                                                                                                                                                                                                       |
| <i>Long lukluk na tingting bilong yu, wanem sampela samting i nid long senis we bai mekim helt sevis i isi na gutpela moa long beibi klinik?</i>                                                                                                                                                                                                                                                                                                 |
| In the mother's opinion, what are the most important things that need to change to help her get better raccess to ROUTINE care for the baby in the first 2 years of life? Please ask her to suggest up to three things just from her own ideas. Do not prompt, but encourage the mother to give up to 3 reasons if she can. Listen to the mother's opinions and then select one, two or three of the options that best match what she is saying. |
| 1;MORE STAFF available                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2;Health Facility CLOSER TO mother's home                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3;MORE CONVENIENT CARE TIMES                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4;Health Facility with BETTER ROOMS (eg privacy, space)                                                                                                                                                                                                                                                                                                                                                                                          |
| 5;STAFF YOUNGER or BETTER TRAINED                                                                                                                                                                                                                                                                                                                                                                                                                |
| 6;MORE AFFORDABLE CARE                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 7;MORE SUPPORT FROM COMMUNITY LEADERSHIP                                                                                                                                                                                                                                                                                                                                                                                                         |
| 8;BETTER HEALTH EDUCATION on WHAT CARE IS AVAILABLE                                                                                                                                                                                                                                                                                                                                                                                              |
| 9;BETTER COMMUNICATION TO REMIND WHEN CARE IS NEEDED                                                                                                                                                                                                                                                                                                                                                                                             |
| 10;IMPROVED TRANSPORT type, availability, cost                                                                                                                                                                                                                                                                                                                                                                                                   |
| 0;OTHER [specify]                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 99;CANNOT THINK OF AN IMPROVEMENT                                                                                                                                                                                                                                                                                                                                                                                                                |
| <i>Open field for other suggestions or comments. Please add detail here on mother's suggestions.</i>                                                                                                                                                                                                                                                                                                                                             |

## 10.4 Supplementary material for Chapter Seven

### 10.4.1 *Tables of results from Health Services Assessment*

#### **Health Services in Infancy – outcomes report and tables of qualitative data**

*Interim data as supplied to Provincial Health Office, 31st August 2017*

#### **1 Protocol summary, investigators and data sources**

##### **1.1 Study overview and approvals**

The **Health Services for Postnatal and Infancy Care study** (HMHB Study 2a) is part of the Healthy Mothers Healthy Babies (HMHB) research program based in East New Britain (ENB). The study investigates services for the mother and baby during the postnatal and infancy periods, that is: from one day after birth (or discharge from inpatient childbirth care) until 12 months after birth. The focus is on immunization and other preventive care, as well as other services that could be provided alongside immunization. A later HMHB study will provide a complementary examination of inpatient care during pregnancy and childbirth (HMHB Study 2b). This study's objectives were to:

- measure current infrastructure, equipment and supplies for preventive care in infancy,
- assess what health workers know, think and do in relation to providing postnatal and infancy services;
- assess health workers' preferences for changes to the way health services are organized – these changes will include the government Special Integrated Routine EPI Program (SIREP) in 2015/16; and
- identify opportunities for health system strengthening and improved quality of care.

This study consulted with health managers and national provincial, and district levels, and surveyed the five busiest health facilities providing maternal care in ENB (also partners in HMHB Study 1) and a selected group of smaller clinics and outreach points that are served by these facilities.

The study has been approved by the PNG IMR Institutional Review Board (IRB: 1603), the PNG Medical Research Advisory Committee (MRAC: 16.22), the East New Britain Provincial Government (PEC: 12/2016), and The Alfred Hospital Ethics Committee, Melbourne (333/16).

## 1.2 Investigators

Principal investigators:

- Christopher Morgan<sup>1</sup>
- Nicholas Larme<sup>2</sup>
- Olga Saweri<sup>3</sup>

Lead co-investigator:

- Elizabeth Peach<sup>1</sup>

Field research team:

- Pele Melepie<sup>1</sup>
- Lucy Au<sup>1</sup>
- Thalia Wat<sup>1</sup>

Co-investigators:

- James Beeson<sup>1</sup>
- Barbara McPake<sup>4</sup>
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- Robert Power<sup>1</sup>

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## 1.3 Data collection tools and data sources

Data collection took place in two phases: consultations with senior stakeholders in September/October 2016, and survey of health facilities, staff and clients from November 2016 to January 2017.

**Health manager and senior stakeholder** assessments comprised a *semi-structured interview* administered to:

- Four national program managers, government, WHO and UNICEF
- Four senior clinicians working at national level
- Eight program managers or coordinators at provincial or district levels
- Three clinicians working at provincial level.

**Health facility** assessments examined infrastructure, operations and staff views at Nonga General Hospital, St Mary's Hospital Vunapope, Kerevat Rural Hospital, Rabaul Town Clinic, Butuwin Urban Clinic, Napapar Health Centre, and Paparatava Health Centre. All but one of these facilities provide dedicated preventive health services (mainly oriented to childhood immunization) for families in the first 12 months after childbirth. The exception, Nonga General Hospital, provides a general children's outpatient service at which curative and preventive services are available.

Study assessments utilised a mix of data collection tools to enable cross-checking and comprised:

- **Audit** of infrastructure and equipment using checklists on electronic tablets administered by the field research team at 12 clinic points: 9 static, 3 mobile;
- **Observation** by the field research team of general clinic processes at 12 clinic points (as above), including observation of 15 individual patients using checklists;
- **Semi-structured interview** by the field research team using open questions and probes to encourage expansion, with 18 primary providers of primary providers of preventive family health or general child health services at 8 facilities, comprising 6 community health workers (CHW), 6 general nursing officers, 5 specialist nurses and 1 health extension officer (HEO);
- **Structured interview** using questionnaires on electronic tablets administered by the research team to 17 primary providers of preventive family health or general child health services at 8 facilities;
- **Focus group discussions** with 67 family members (66 female) immediately after receipt of services at 10 of the clinic points assessed above; and
- **Reflection and journaling** by the field research team added to structured data collected above.

**Table 1: Summary of study subjects and data collection tools**

| <i>Study subjects</i>                 | <i>Number</i> | <i>Details</i>                                       | <i>Tools</i>                                                                                                                                              |
|---------------------------------------|---------------|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Health managers and senior clinicians | 4             | National program managers                            | Semi-structured <b>interview</b> (qualitative)                                                                                                            |
|                                       | 4             | Senior clinicians, national level                    |                                                                                                                                                           |
|                                       | 8             | Managers, province or district                       |                                                                                                                                                           |
|                                       | 3             | Senior clinicians, province level                    |                                                                                                                                                           |
| Primary health care staff             | 1             | Health Extension Officer                             | Semi-structured <b>interview</b> (qualitative)<br>Structured <b>interview</b> (qualitative and quantitative, 17 staff)                                    |
|                                       | 5             | Specialised nursing officers                         |                                                                                                                                                           |
|                                       | 6             | Nursing officer                                      |                                                                                                                                                           |
|                                       | 6             | Community Health Worker                              |                                                                                                                                                           |
| Families                              | 67            | Caregivers of children attending services, 66 female | Focus group <b>discussion</b> (10 groups)                                                                                                                 |
| <i>Total</i>                          |               | <i>104</i>                                           |                                                                                                                                                           |
| Health service delivery points        | 1             | General paediatric outpatients                       | <b>Audit</b> of infrastructure and equipment<br><b>Observation</b> of general clinic procedures (12)<br><b>Observation</b> of patient flow processes (15) |
|                                       | 8             | Child/family health clinic, static                   |                                                                                                                                                           |
|                                       | 3             | Mobile child health clinic                           |                                                                                                                                                           |
| <i>Total</i>                          |               | <i>12</i>                                            |                                                                                                                                                           |

## 2 National, provincial and district views – coverage and plans

Government estimates of coverage with preventive care in the 2015 Sector Performance Annual Review shows no change or worsening in most estimates. The ENB rates for 2015 are similar to interim estimates from our HMHB Study 1 dataset. There is a stark contrast between maternal antenatal care uptake and preventive services for children, especially in the first year of life.

|                                    | ENB NHIS 2011<br>(SPAR 2016) | ENB NHIS 2015<br>(SPAR 2016) | HMHB 2015-17<br>Study 1* |
|------------------------------------|------------------------------|------------------------------|--------------------------|
| Pentavalent vaccine, third dose    | 79%                          | 64%                          | 58% (n=231)              |
| Measles vaccine 6 months           |                              |                              | 39% (n=161)              |
| Measles vaccine 9 months           | 60%                          | 32%                          |                          |
| Outreach clinics/1,000 U5 children | 46                           | 28                           |                          |
| Postnatal check post discharge     |                              |                              | 30% (n=477)              |
| Postnatal check in first 7 days    |                              |                              | 17% (n=477)              |
| Ante-natal care 1+ visit           | 92%                          | 89%                          |                          |
| Ante-natal care 4+ visits          |                              |                              | 75% (n=538)              |
| Childbirth in health facility      | 83%                          | 82%                          | 92% (n=519)              |

**\*Note:** interim data on incomplete sample, estimates for comparison purposes only

National policy and strategies aimed to improve preventive services after birth. Special Integrated Routine EPI Strengthening Program - **SIREP and SIREP Plus** are aiming to improve **immunization** from 2015:

- *“What makes SIREP different from the current routine EPI program is that it will be implemented on a quarterly basis rather than on a monthly basis and it will be integrated with additional maternal and child health (MCH) services. In addition, it is strengthened with intensified operational components necessary to ensure that the program is reaching every child and achieve high immunization coverage.*
- *SIREP Plus is the same as SIREP but will add delivery of supplemental vaccines and / or introduction of new vaccines within a given period of time of intensified activity. SIREP Plus ... will introduce MR and IPV vaccines in PNG”. SIREP Plus also includes Vitamin A and Albendazole alongside vaccination.*

Interviews with national and provincial managers during Phase 1 suggested that implementation through training, supply of new vaccines, and some funding support had commenced in ENB, but was not fully implemented. National stakeholders also expected that provincial, district and facility managers would have new micro-planning (including quarterly timing), new understanding of catchment populations to guide service planning, and that secondary training would have taken place within facilities. Provincial and district managers showed strong commitment to the concept as a path to renewal of service delivery, although not all had good awareness of the strategy. Those that did noted that repeated training and further funding was going to be needed.

National, provincial and district consultations did identify **likely barriers to, and enablers of immunization** service provision. These were reported more fully in the summary of Senior Stakeholder Consultations. In brief, important barriers were listed as: insufficient funding, failures

of supplies and equipment (including cold chain), difficulties in planning including outreach planning, gaps in staff knowledge and skills, and community attitudes or lack of knowledge. Enablers mentioned included strong local management, effective outreach, and non-government health services with greater control over staff.

**Integrated services** were seen as one aspect of SIREP Plus, as noted above, and integration across programs is also promoted in the Newborn Health Policy, the Ministerial Taskforce on Maternal Mortality and the current National Health Plan. Managers were consulted on the missed opportunities when immunization was not offered during sick child care, conflicting views as to whether integration of other services with immunization should be a priority, but strong support for the need for coordinated planning across MCH and EPI programs. When asked which services should be priorities, many managers cited family planning and nutrition services, some suggested tuberculosis, and some cited the SIREP Plus priorities of Vitamin A, and Albendazole.

As regards **postnatal care**, the 2014 Newborn Health Policy aims that “Every newborn baby should be followed up on day 1, 3 and 7, and 6 weeks after delivery”. This presumes either home visits or mothers attending health facilities for routine checks of their newborn. Interviewees at national and provincial levels could not provide any examples of routine home visits, nor of routine clinics targeting the postnatal period; many noting that there is no postnatal care established within current preventive care services. Some mentioned that the only service available at present is early postnatal care obtained while inpatient following childbirth in a health facility (which obviously excludes all childbirth in the community). Most managers consulted cited early discharge as a significant barrier. Interim data from the incomplete dataset from HMHB Study 1 shows that 42% of 470 women reported being discharged one day or less after childbirth (6.6% in less than 24 hours). In relation to this, neither the Newborn Health Policy nor the recommendations from the Ministerial Taskforce on Maternal Mortality specify a minimum duration of stay after childbirth. **Health of women** after childbirth was volunteered far less often than health of the newborn in discussions of postnatal care; and most managers acknowledged routine preventive care for women at this point in the life course was not commonly provided. PNG does have “well woman clinics” established at some provincial hospitals, however these seem oriented to reproductive health outside the post-partum period.

This summary has been collated from national level reports, interim HMHB Study 1 data, and from this study’s Phase 1 consultations with national, provincial and district managers (reported more fully in the Senior Stakeholder Consultation report). Evidence from the facility level, through Phase 2 data collection in this study, is reported below, in relation to current practice, implementation of SIREP, immunization barriers and enablers, integrated services, and postnatal care.

### 3 Current practice in ENB

#### 3.1 Clinic-level service planning

In health worker structured interviews, most (14 of 17) could describe a **recent change in the planning and organization** of immunization services, based on both quantitative and qualitative data: half related the changes to new vaccine introduction and half cited changes related to new service delivery changes (usually increased frequency), for example:

*“Biggest change is both static and mobile clinic used to provide immunization once a week and now vaccines are given daily”*

Almost all staff reported recent in-service training activity, attributing this to the SIREP program, discussed in the section below. Most staff report internal health facility meetings to discuss operations, and supervision visits within the past three months from either district or province levels.

About half of front-line staff found it difficult to describe the **planning of static and mobile clinics**; those that did were evenly split on whether this was done on geographical or population basis. Eight of 18 staff felt able to estimate the proportion of their clinic’s catchment population reached by immunization services; estimates ranged from “about half” (2 staff), through “more than half” (5) to “nearly all” (1). Audit data showed mobile clinic planning, including vaccine quantity estimation, was based on staff estimates, including activity at previous clinics, rather than records of client names or numbers. Audit also found just one of ten immunization clinics displaying service activity: as a chart with percentage estimates of children reached.

All staff mentioned some means for **recording and tracking of children** needing vaccines, most citing the patient-held Child Health Record Book (the “Bebi Buk”), and five citing other recording systems, such as the child health register or use of other local records of births. Audit and observation data indicated that such tracking was less common than stated in interviews. Our audit found only one of 10 immunization clinics with geographical and population catchment information in use in planning, and one with an estimate of the population to be served, the others had minimal or no description of their catchment. Two clinics had child health registers with details of children needing vaccination, while eight clinics had no register in use. Both audit and observation indicated that none of the clinic sites had a listing of children who were overdue for vaccination, or a means to follow them up. Four clinics were observed to have Child Health Record Books available for purchase (at 3PNG kina each).

Audit and observation indicated that five of 10 immunization clinics had a clear **record of vaccinations** given in the previous month, although service tally sheets (used for the national health information system) and vaccine records were extremely difficult to reconcile. It was observed that current recording does not account well for new vaccines: inactivated polio vaccine (IPV) and pneumococcal conjugate vaccine (PCV), or rubella-containing measles vaccine (MR). Records for measles vaccine appeared less accurate than those for oral polio or pentavalent vaccine.

In terms of **service availability**, there was generally good agreement between health worker interviews and data obtained through audit and observation. Audit and observation demonstrates four of seven static clinics were available five days per week, the others between 1 and 3 days; two



mobile clinics were running monthly, one clinic defined as ‘mobile’ was running more than once per week. Most services ceased between midday and three pm. Health worker interviews indicated that one third of clinics overall were offering vaccination only on fixed days, while two thirds made it available every day. Two of 12 health facilities were reported as providing outreach that included overnight stays.

Records audit indicated relatively low proportion of **cancellation of planned** clinic services, with close agreement with interview data. Three clinics with quantitative records showed planned versus implemented service, over a year as 72/69, 21/19, and 40/21. Approximately half of those interviewed stated that clinics were cancelled once a month or less frequently. Most health workers during interview could not provide a rationale for why a clinic would be cancelled, even when probing questions were asked; a surprising finding given that staff opinions on a wide range of other topics were relatively easy to elicit. When reasons for cancellation were provided, adverse weather and transport resource shortage were cited more often than vaccine shortage; staff shortage was cited least often. Two government facilities reported slow disbursement of funds as limiting outreach, requiring cancellation of planned mobile clinics.

Seven of the ten focus group discussions with clients identified improved access through changes to service organization. The discussions suggested that mobile clinics are valued for convenience, especially in reducing transport costs. They also found that daily, ‘on-demand’ vaccination services are highly valued, for example:

*“Previous Immunization schedule was three times a week and now its daily, which is good because if I’m busy on Tuesday then can make it on Wednesday”* FGD Static EPI clinic

### 3.2 Clinic-level perceptions of the SIREP program

Many health workers, in structured interviews attributed changes in planning or organization to the SIREP program, although some seemed to conflate SIREP with broader immunization initiatives that pre-dated this, such as introduction of pentavalent vaccine.

Qualitative interview data indicates that most understand **SIREP objectives** around the introduction of new vaccines, and some reported the program’s intent to reform service planning, especially for mobile outreach services. Non-leading questions (prior to discussion of SIREP in the interview) show five of 18 staff focusing on geography as the main criteria for mobile clinic planning and three including consideration of population size; this provides only partial support for uptake of one aspect of SIREP principles that outreach visit larger population sites more frequently. Several staff mentioned the principle of visiting further, more “difficult” settings first and working back to base; an approach deriving from planning of mobile patrols in PNG from several decades ago. One staff member noted the change to quarterly mobile clinics that was proposed in SIREP workshops:

*“The SIREP program has changed the way mobile clinics are conducted. Before mobile clinics were done monthly and the numbers were not so good so after the change of the schedule to quarterly, we have a good number of babies seen on visits.”*

Most health workers were aware of **SIREP training** being conducted in the province and 11 of 18 staff reported some internal follow-up training within their facility; provided by staff who had

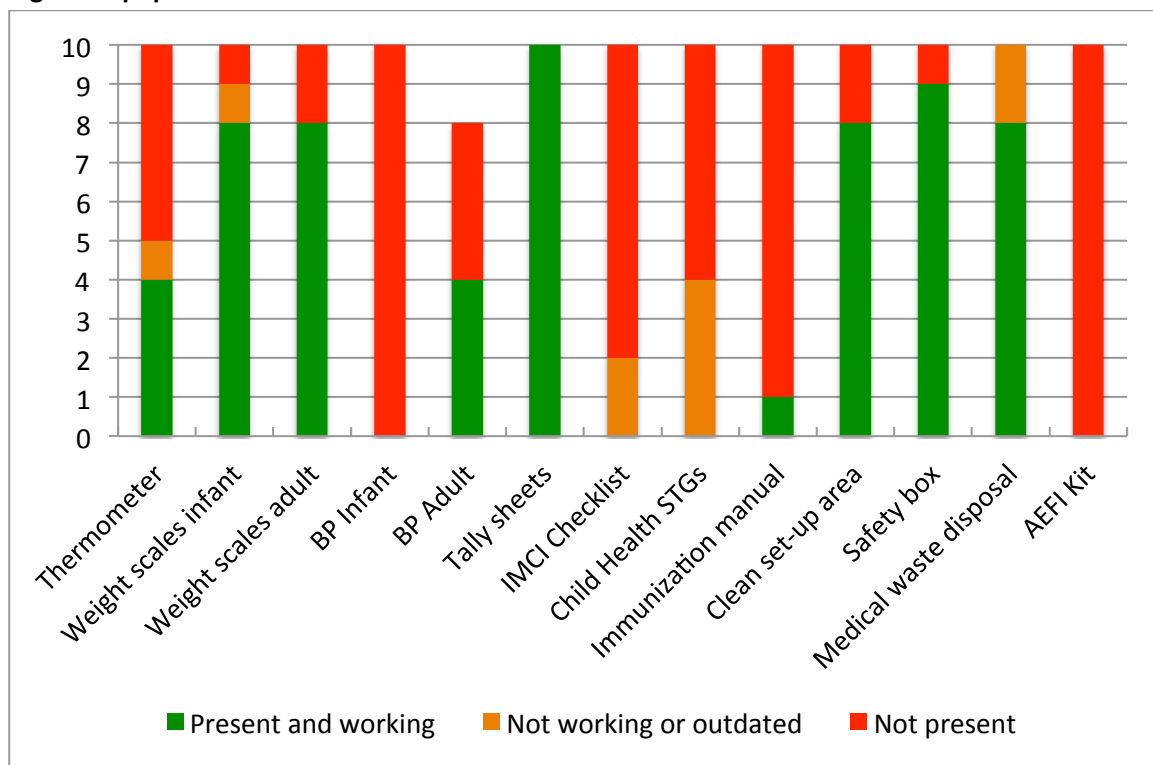
attended the SIREP workshops. When discussing what would be required to implement the SIREP approach to strengthened immunization, some staff mentioned the need to improve skills and knowledge, but this was only mentioned by staff who had had no engagement with SIREP training activities. Other comments on SIREP implementation noted that it may increase workloads and require additional staff, others suggested that it would require increased resources for outreach transport.

### 3.3 Immunization staffing infrastructure and equipment

Health worker structured interview reports of **clinic staff** largely concurred with audit measurements. A total of twenty vaccination staff were counted across 10 immunization clinics, comprising nurses (two nurses in one clinic, one in eight clinics, zero in one clinic) and CHWs (three in one clinic, one in seven clinics. During interview, health workers stated that clinic functions were usually shared across nurses and CHWs, often rotating between the two cadres. In five clinics with clearly allocated functions it was most common for the nursing officer to take weight, history, registration and screen for illness, while CHW usually administered the vaccines. Some clinics had additional support from clerks, but there were not reports of structured roles for trained health volunteers to help with organization, mobilization or education.

Audit and observation of **clinic infrastructure** at 11 locations found that nine clinics had road access while two mobile clinics were on walking trails. Six were housed in enclosed rooms as part of larger structures, four in open areas under a roof, and one in an open area that was unroofed. Waiting areas were commonly open areas with some shelter, sometimes in the same room as the treatment area. One third were judged as needing no repairs, one third needing minor repairs and one third needing major renovation. Four had a reticulated water supply, four had rain-water tanks, and three had no water source. Three waiting areas had toilets in good condition, six had toilets in poor condition and two had no toilets. Eight clinic sites had electrical power from a mains supply (three with a back-up generator), while three had no electric power and no solar- or gas-powered equipment. Two sites reported frequent power interruptions. For vaccine storage nine sites had appropriate, functioning cold chain equipment (two using vaccine carriers only) and two sites had domestic refrigerators. Use of temperature monitoring was extremely variable and no clinics had written temperature records.

Audit of **clinical equipment** at 10 immunization clinics (figure below) showed varying levels of functionality: reasonable for injection areas, safety boxes and weight scales, but no clinics had kits to manage acute severe adverse events following immunization (AEFI). While all clinics had tally sheets for recording national health information system data, levels of information resources were low: those few that had manuals or standard treatment guidelines available were out of date. Supplies of all relevant vaccines (including IPV and PCV) and injection equipment were noted in all clinics, although inconsistencies in activity reported (noted above) meant it was not possible to calculate whether quantities were appropriate to the populations served. All measles-containing vaccines observed were the newer measles-rubella combination. No supplies of the discontinued trivalent oral polio vaccine were observed.

**Figure: Equipment status observed at 10 EPI clinics**

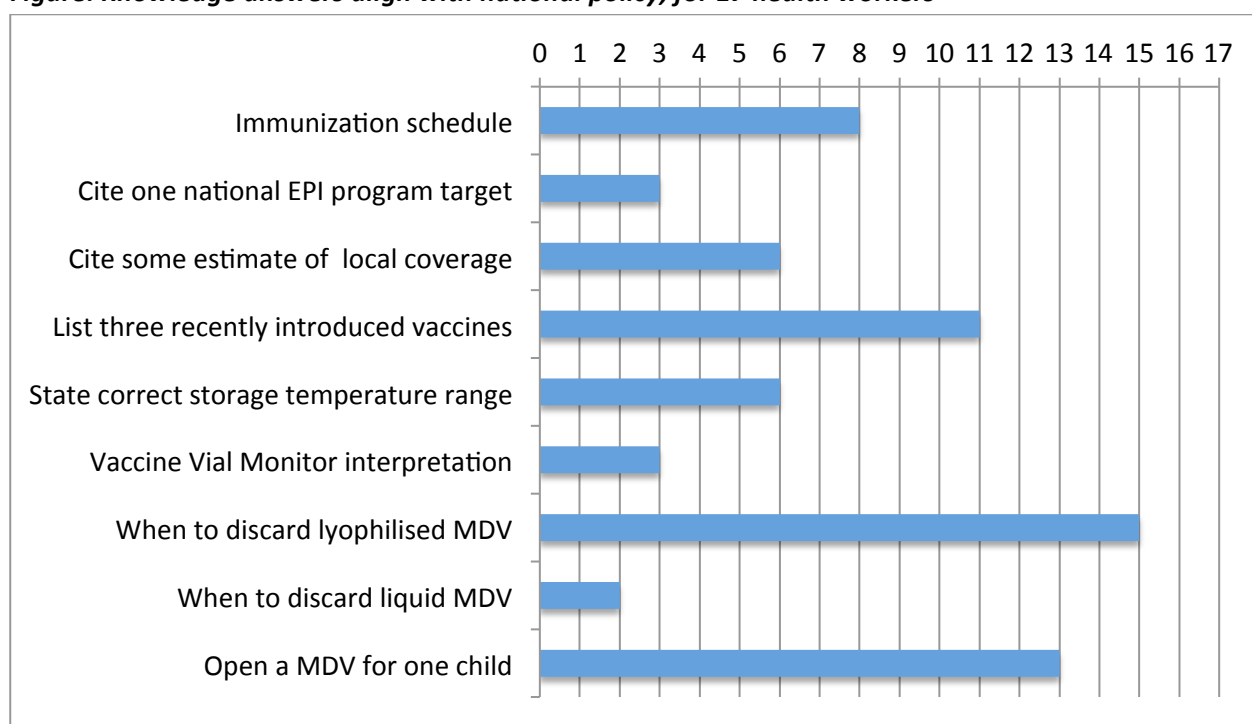
### 3.4 Health worker knowledge

Health worker knowledge (figure below) varied by topic; correct responses (in terms of national policy and WHO guidance) were very common in relation to new vaccines and handling of lyophilized multi-dose vial (MDV) handling (such as for measles), and common in relation to the vaccine schedule. However some knowledge gaps increase the risk of certain programmatic errors:

- Incorrect handling of liquid MDV (such as pentavalent vaccine or hepatitis B vaccine) risks unnecessary wastage, with many staff citing earlier than recommended discard times;
- Incorrect cold chain storage knowledge risks freezing damage to vaccines; and
- Incorrect interpretation of VVM risks heat damage to vaccines.

Front-line staff also found it difficult to clearly articulate immunization program objectives or planning principles, including:

- Birth-dose vaccination and vaccination in the second year of life were often omitted from descriptions of the vaccine schedule;
- Only a minority of staff could describe important factors in clinic-level service; and
- Few could cite national immunization program objectives, with disease elimination priorities especially infrequently mentioned.

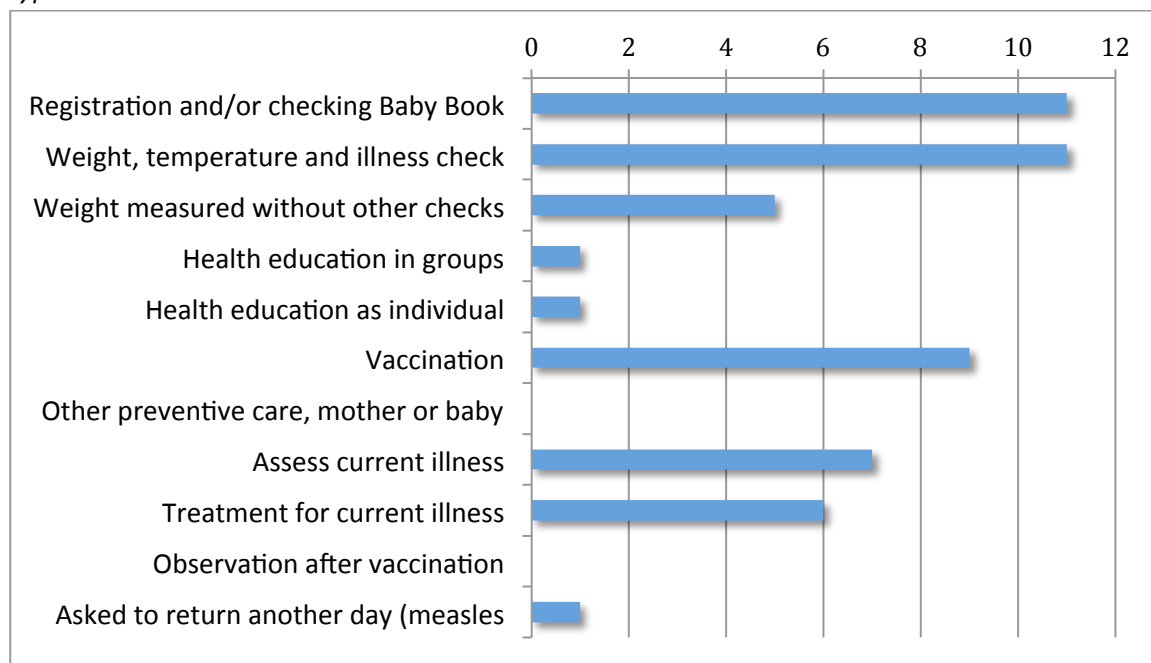
**Figure: Knowledge answers align with national policy, for 17 health workers**

### 3.5 Immunization and other service provision

Observations at 10 immunization clinics found them vaccinating a mean of 17 children per clinic (interquartile range 3 – 26, minimum = 1 and maximum = 62). Observation of **patient flow** shows that clients had between one and six (3 of 14) interactions, half had three or fewer interactions. The figure below shows the frequency of various staff-client interactions; illustrating that most clients received vaccination, registration, weight measurement and check for illness, but that educational interactions were more limited. No clients received preventive care for the mother, and no structured observation for AEFI after vaccination were seen.

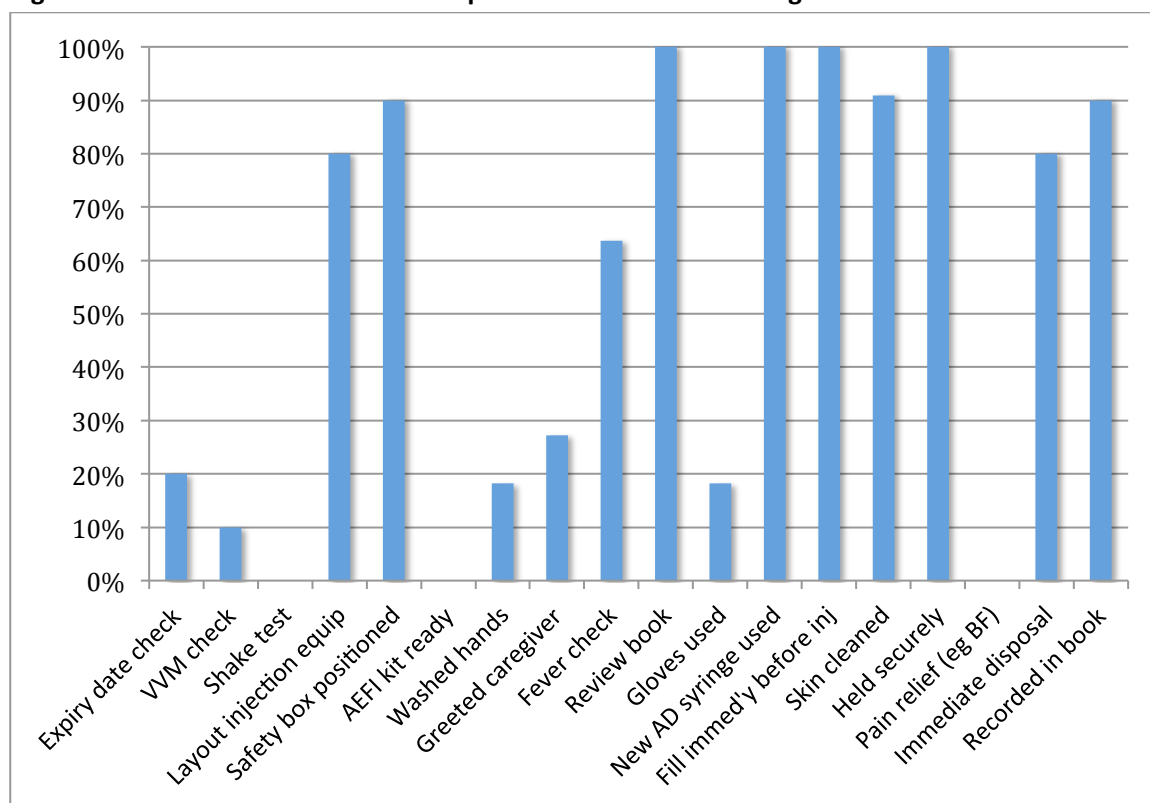
Although at interview most health workers cited they would open a **multi-dose vial** (MDV) for just one child, observation showed a family being asked to return on another day when measles vaccine would be opened, and a child being seen in a sick child clinic who was eligible for vaccination but asked to return at another time. Observation and audit data showed MDVs in use, but none were labeled with time and/or date to facilitate appropriate discard decisions.

**Figure: Staff-client Interactions Observed at 12 Child Health Clinics** *52 interactions across 15 typical clients*



Observation showed that, on checking Child Health Record Books, **vaccinations were missed** in 3/10 books reviewed, namely: hepatitis B birth-dose, BCG, IPV, PCV, and measles. It proved impossible to use audit data for a formal assessment of missed opportunity for vaccination based on records review, but audit and observation suggested that the newer vaccines, IPV and PCV were being administered at a similar rate to pentavalent. Missed opportunities seemed to occur more often for measles, BCG, and hepatitis B birth-dose vaccines, and administration of vitamin A was lower than expected for the population served. Reasons given for missed vaccinations included the vaccine being out of stock, baby born in the community, or the fact that clinic attendance was not for the purpose of vaccination. Other contributors were listed as low frequency of family health education or other forms of community engagement.

The figure below shows observed health worker practices during 11 vaccination sessions, compared against a structured checklist based on the WHO Immunization Session Quality Checklist (Immunization in Practice 2015, Module Five). Core elements of safe injection were done well, however preparatory checking of vaccines for heat or freeze damage were omitted, as was observation for AEFI after vaccination. Some client engagement activities were done less often.

**Figure: Observation of health worker practices before and during 11 vaccination sessions**

### 3.6 Patient experiences and community engagement during sessions

Observation of **waiting times** from the patient flow analysis (see above, Section 3.5) demonstrated that most clinics commenced between 8.30 and 9.00 am, however at some sites clients began arriving from 7am. Waiting times were significant (but less than observed waiting times for antenatal care as seen in HMHB Study 1). Time from arrival to last interaction ranged from 15 min to 3hours 30 min, from registration to last interaction from 10 min to 2hr 25 min; so much of time spent is in waiting for first interaction. The mean time from **arrival to first interaction** was 51 minutes, IQR 13 – 90; mean time from **arrival to final interaction** 92 min, IQR 20 - 131 min, longest was 3.5 hours; and the mean time from **first interaction to last interaction** was 43 min, IQR 5 - 60 min. One client waited 2 hours for a one minute interaction, during which she was told to come back another day when measles vaccine vial would be opened.

Although only two instances of **client education** were seen in the detailed patient flow analysis (above), in general clinic observation, group health education sessions were observed in three of 12 clinics. Topics included malaria and antenatal care, and sessions were delivered verbally. No instances were observed of education using pictorial materials, video, participatory exercises or take-home communication products. There was one observation of information provided to a client about the vaccine the child had received and the type of AEFI to expect at home. Audit data showed that five of 11 static clinics were displaying a National Department of Health immunization poster and one clinic had the “Immunization Rules” information on display.

Almost all **caregivers** attending were mothers of children needing vaccination, with some female grandparents. There were no male family members or caregivers observed across 12 clinics. In interviews with health workers, two reported having had fathers attending for an immunization service. Health workers attributed low levels of male involvement as due to embarrassment or the fact that immunization was not seen as men's business.

Client **fee payments** were directly observed at two facilities (government run) and reported at six facilities, often as an administrative charge of 20 toea per child needing vaccination. There were no fees tied to specific vaccines found. Additional administrative fees for attendance were reported at three facilities. In health worker interviews reports on the prevalence of fee payments for preventive services varied: five reported no fees, six reported both treatment and administration fees and three reported only administration fees as applying. One respondent reported the facility as seeking donations from clients. In client FGDs, fees were not reported as a barrier to access in response to an open question on this topic; noting that these were groups of clients who were already accessing services. *(Additional note: in interim incomplete analyses of HMHB Study 1 data, "health care costs" were cited as a barrier to routine preventive postnatal or infancy care by approximately 35% of mothers interviewed one and six months after childbirth).* Only one quarter of health workers in interview noted significant support to immunization clinics from local communities, often this support was in the form of donated food.

### 3.7 Integration of other health services during immunization sessions

Observation data suggested that **vaccination and illness care** took place together approximately half the time, with a number of observations where vaccination was omitted. In a general hospital where routine immunization was provided off-site, there were no instances observed where a child received vaccination as part of illness care. In some cases a child needing vaccination was referred to a different location and/or time for vaccination. Child illness treatment where needed was observed as available in all but one immunization clinics. Two sites were observed to be out of stock of common childhood illness medicines.

Other preventive care during immunization sessions was most common the checking of the infant's **weight**. This was infrequently followed by additional advice – in one instance an explanation of the weight-for-age chart was observed and two instances of feeding advice. There were no instances of height measurement observed. In patient interaction observations, **vitamin A** distribution was observed in 2 of 14 and **albendazole** in 1 of 14.

There was one instance observed where a mother was given hygiene and nutrition advice that applied to both her and her infant, but no other instances observed of maternal preventive or curative health care.

Interviews with health workers indicated, in responses to open questions, that the main constraint on provision of non-immunization preventive care was shortage of staff numbers. There were some mentions for insufficient staff time, but generally it was simply the absolute numbers of staff to operate clinics that was seen as the constraint.

In structured interviews with 17 health workers, when asked what additional services were actually provided, nine said they checked for childhood illness, seven mentioned the child's weight, six said

they counseled on hygiene, for mentioned family planning advice and one mentioned illness care for the mother. Of these, only checking of weight and childhood illness were noted in observational data collection, as discussed above. It is possible that checking for illness is conducted more as a screen for contra-indications to vaccination rather than a complementary service for the child; 13 of 17 health workers stated they would usually ask a sick child to return for vaccination at another time, and several related this to the desire to avoid opening a MDV.

### **3.8 Current practice in routine postnatal care**

Interviews with health workers confirmed the findings from consultations with managers in Phase 1: that there were no models of routine postnatal care functioning apart from pre-discharge checks following childbirth in a health facility. In structured health worker interviews, one third suggested that the first routine postnatal check is not required until the vaccination visit at one month of age. Interview data suggested that these inpatient pre-discharge checks are not always thorough and usually do not involve a structured checklist of routine preventive care. Interventions reported as forming part of these assessments, in the structured health worker interviews included birth-weight measurement, checking for congenital abnormalities, birth-dose vaccination, hygiene advice and family planning advice. In open questions on current practice, one respondent mentioned the use of post-partum iron supplementation to counteract the effect of blood loss. When asked about optimal timing of discharge after childbirth in a facility, two staff suggested 48 hours or more, six suggested 24 to 48 hours, and two suggested less than 24 hours. *(Additional note: in interim incomplete analyses of HMHB Study 1 data, 42% were discharged in in 1 day or less, 65% in two days or less, and 81% in three days or less).*

## **4 Barriers to improved service delivery**

Data on barriers to improved service delivery were derived from observations to a limited degree, with more data as health worker opinions expressed in interviews, and client discussion in response to open questions in FGDs.

### **4.1 Barriers to timely, effective vaccination**

Observational data suggests that clinics lack capacity to trace those children needing vaccination, both because there is insufficient understanding of catchment populations, minimal local records of births that are used in quantifying target populations, and insufficient application of population-based service planning. There is evidence that SIREP (discussed below) initiatives are starting to change service planning practices in some sites, but these are not yet fully taken up.

Observational data also suggests that cold chain equipment is in place in most clinics, with all powered equipment reliant on mains electricity, some with generator backup. There is no deployment of solar-powered equipment. As noted above, vaccine stock shortages were mentioned in interview but data limitations meant that observational data could not be used to match vaccine stocks to population. All vaccines in the routine schedule were observed to be in stock during observation at 10 clinics. Systems to check for proper vaccine handling to ensure potency, such as documentation of correct temperature maintenance, and/or checking of VVMs,



are not well established in any clinics observed. There was no structured approach to observation for serious AEFI observed.

Observational and audit data also showed limited advice provided to families on vaccinations provided, the overall immunization program, or expected AEFIs to monitor in the home. Observations also found limited community involvement in immunization sessions in the form of supporting volunteers, or practical support from local leaderships. Interview data from health workers also mentioned community engagement difficulties, stating a mix of issues comprising family ignorance of immunization benefits, other family duties distracting from attendance, some hesitancy in relating well to health staff, and family mobility.

Interview data from health workers suggested that staff shortages, especially in the face of increasing populations were seen as an over-riding constraint. However on detailed analysis it appears that staff shortage was mostly applied as a limit on providing additional services to vaccination, and that current staff numbers may be sufficient for current vaccination services. When forced in interview to choose one most important constraint on immunization coverage, staff shortage was less frequently mentioned than other barriers. As noted in the qualitative data analyses annexed below, other main constraints were more commonly cited as:

- Vaccine shortages;
- Cold chain infrastructure deficiencies;
- Insufficient transport resources for reaching remote populations;
- Adverse weather, both in obstructing travel to mobile clinics, and as a barrier due to lack of weather-proof clinic locations.

Less common barriers in health worker interview data included insufficient staff knowledge, and service planning that restricts immunization clinics to certain times and places. Only two health workers mentioned overall difficulties in funding flows (such as late disbursements) as constraining vaccination. Additional barriers mentioned less commonly included the lack of capacity for overnight patrols, and electricity interruptions. One staff member mentioned a community preference for nursing officers over community health workers.

When similar questions were asked in a frame of what would be required for a good quality service, similar responses were obtained but with the addition that a good service will have effective, supported outreach, and dedicated preventive care. Quality questions also highlighted the need for good vaccine management and some acknowledgement that this aspect needed strengthening. Client discussions in FGDs (catalogued in the annex below) largely agreed with the types of barriers suggested by observational and health worker interview data but dwelt more on issues of engagement and on the need for flexible service planning and provision, for example: *"We want regular mobile clinics at the village level... we want clinics to happen as scheduled"*. Other staff factors commonly raised in discussions related to hesitancy generated through feeling scolded, or through other staff attitudes. Also commonly raised were costs and difficulty in transport, particularly relating to the need to travel into urban centres for vaccination. Some client discussions raised the frustration of being turned away due to stock-outs of vaccines or if the infant is deemed too sick for vaccination. A few discussions raised other community-based issues such as distractions

of other duties, the need to dress children differently to attend for immunization, and the lack of support from male family members.

#### **4.2 Barriers relating to full implementation of SIREP**

In health worker interviews, SIREP was interpreted as relating to the introduction of new vaccines, quarterly intensification of routine immunization activities, and a shift to population-based service planning. As noted in the qualitative data overview annexed, health worker responses to open questions on what is required to support SIREP implementation cited (in order of frequency):

- more staff (to match populations);
- additional follow-up training;
- additional dedicated preventive care service points;
- transport resources;
- vaccine availability; and
- increased communication of what is involved in SIREP.

#### **4.3 Barriers to postnatal care**

The lack of reports of routine postnatal care outside of childbirth in a health facility meant that current constraints on postnatal care were difficult to derive from health worker interviews, although some barriers can be inferred from the responses consolidated in Section 3.8 above. Open questions to health workers on this topic (see Annex of qualitative data below) suggested that important limitations on provision of routine postnatal care largely relate to staff shortages, staff attitudes as to the importance of this intervention, distances and transport for community births, and one mention of institutional policies. Additional data on inpatient pre-discharge care will be gathered during the future HMHB Study 2b on childbirth and early neonatal care.

In this study, opinions on barriers to postnatal care were very difficult to elicit in client FGDs, due to their unfamiliarity with the concept as presented. However detailed questions on the topic are included in HMHB Study 1 interviews with mothers at delivery, and one month after childbirth; it is likely that future analysis of these data will be helpful in addressing this question.

## 5 Opportunities for improvement

In addition to the discussion in this section, the annexes at the end of this report also consolidate qualitative data from health worker, client and manager discussions that can provide a more detailed description of opinions regarding opportunities for improvement.

### 5.1 Targets, motivations, local changes and strengths

Health worker interview responses relating to significant changes in vaccination provided insight into what they most valued in providing immunization services, including:

- The desire to increase overall coverage and see more vaccines in use – sometimes attributing SIREP as part of this process;
- A contribution to visible reductions in disease, firstly pneumonia, but also mentioning measles and whooping cough;
- The desire to meet local and provincial health targets.

One example:

*“The change seen is the added vaccination which is PCV13. Since PCV was introduced there is now less number of babies admitted to our wads or seen at the outpatient with pneumonia... before this a lot of babies were seen with PNA.”*

When asked what strengths their local facility had, which could inform improved practice elsewhere, all but one health worker could describe good practices they felt should be shared.

These included:

- A commitment to mobile clinics to ensure reach and coverage;
- Community engagement using multiple channels, and employing more respectful care;
- Increased staff knowledge, especially relating to recent in-service training, including SIREP;
- Staff capacity, with some clinics citing the ability to now work in teams rather than as solo providers;
- Linking of immunization advice to immediate postnatal counseling in a facility that offered childbirth services;
- Use of local data and records for planning immunization;
- Newly established preventive care services; and
- More structured patient flow including use of triage systems

Although many of these were not always seen during observation or audit at clinic sites, these aspirations do offer a pathway for future improvement.

### 5.2 Opportunities through SIREP, with new vaccines and reform of service planning

In health worker interviews, the SIREP program was well recognized by many and seen as an important new approach with the potential to generate change. There were encouraging reports of frequent secondary training within facilities as a follow-up to SIREP in-service training. Several staff reported a desire for follow-up training, suggesting there is opportunity in further

intensification of SIREP inputs. Specific aspects of the SIREP approach that were seen as valuable for the future were noted as:

- New vaccines that can reduce disease;
- New planning that may improve access;
- The potential for efficiencies that could reduce service delivery costs; and
- The potential for integration of additional services.

### 5.3 Proposals for local service delivery and community engagement

A range of suggestions (seen more fully in the qualitative data in the annex) were raised for improving local service delivery. It was notable that an number of suggestions from health workers emphasised the need for improved community engagement in immunization and other preventive care services. These suggestions included:

- Establishment of additional dedicated preventive care service points
  - For example: *“Establish well baby clinic and mothers health check-up, so when they bring their children for check-up, they are checked as well”*
- More active community health education, including
  - Health talks prior to immunization sessions;
  - Promotion of supervised delivery as a route into sustained health system contacts;
- Deploying a broader array of community health promotion tools, including radio, participatory education and communication products
  - For example: *“Provide multiple ways of educational materials such as video, drama, cooking demonstration to family as preventive services. Multiple educations improve peoples’ knowledge on implementation of health talk at home.”*
- Male involvement, as fathers and community leaders in promoting more regular attendance at preventive care, possibly also including preventive services tailored to men’s health;

Other suggestions related to the effective resourcing and organization of services including:

- Ensuring sufficient staff numbers and capacity;
- Working on quality of peripheral services to reduce bypassing and the need to travel to urban centres or larger facilities for preventive care;
- Improving infrastructure;
- Improved outreach in ensuring adherence to schedules, and some suggestions to re-instate overnight patrols;
- Better vaccine management in terms of matching vaccine orders to populations (one suggestion) and stronger central supplies management (one suggestion); and
- Use of central coordination and planning channels.

#### 5.4 Integrated preventive services in the future

Health worker interview data also raised the prospect of more integrated services in the future as one means to improve preventive care reach, for example *“For effective mobile service, other immunization services combine with Family Planning for mother as well at the static clinic”*. When asked about priorities for future integrated services the most common services suggested to be added alongside vaccination were family planning and general family health education. Less common services mentioned were care for infectious disease, such as sexually transmitted infections or tuberculosis, and support to improved feeding and nutrition.

Several staff suggested drawing a stronger link between infancy services and antenatal services, especially in ensuring that the broad health education provided at some of the stronger antenatal services was equally employed in immunization and other preventive care clinics.

Clients’ suggestions in relation to future integration showed a slightly different emphasis to those of health workers. There was a strong preference, mentioned in a majority of FGDs, for inclusion of family planning, for example: *“we want family planning to be combined with immunization”*. Other high priorities were interventions to promote women’s health, including preventive checks on reproductive health and care for women’s illnesses in the post-partum period. Other priorities included care for sick children and advice on how to prevent childhood illness, and general health education for both mothers and fathers.

In discussing the reasons why more integrated services would be desirable, two key rationales were mentioned by both clients and health workers:

- Improving vaccination coverage by taking every opportunity to vaccinate, especially during sick child visits; and
- Reducing client costs (in time, money, and inconvenience).

The rationale that integrated services may be important because of co-morbidity, or co-existing health needs in mothers and their infants, was not raised by staff or clients. This under-recognized reality is a key area of study under HMHB Study 1.

#### 5.5 Future postnatal care

Health worker interview data provided some insights into what priorities they felt should be included into routine postnatal care, should this become feasible. These included:

- Advice and supplies for personal hygiene;
- Family planning advice;
- Maternal illness management;
- Nutritional advice (mostly oriented to the baby);
- And newborn vaccination.

Client opinions on postnatal care possibilities were difficult to elicit as noted above. There was less client emphasis on family planning at this point in the life course, and most mentions included general aspects of preventive care. Of interest were several requests to check maternal blood –

presumably in acknowledgement of the likelihood of anaemia following childbirth. Many mothers recognised that post-partum complications were common and said they would welcome better access to care for these. There were also mentions of the desire for respectful care during childbirth and for greater use of local languages.

Few health workers or clients were able to make suggestions for alternative mechanisms to provide routine preventive postnatal care. Those that were mentioned, by a few, were outreach visits to community centres, and home visits.

### ***Thematic Analysis from qualitative data sources follows***

## **6 Health Worker Open Questions**

### **Health Worker Respondents overview**

*All staff involved in managing or providing immunization and preventive care services, either as their primary function or secondary to their other role/s.*

| <i>Place</i>           | <i>HW Codes</i>        | <i>Number</i> | <i>Date</i>                  |
|------------------------|------------------------|---------------|------------------------------|
| Paparatava or Napapar  | 01, 02, 03, 04, 14, 15 | 6             | 9/11/16, 10/11/16, 1/12/16   |
| Vunapope               | 05, 06, 07, 08         | 4             | 11/11/16, 14/11/16           |
| Butuwin, Rabaul, Nonga | 09, 10, 11, 12, 13     | 5             | 15/11/16, 23/11/16, 28/11/16 |
| Kerevat or Warangoi    | 16, 17, 18             | 3             | 7/12/16, 12/12/16, 7/12/16   |

## **6.1 SIREP Implications and actions**

### **6.1.1 SIREP Implications**

*Note some responses may conflate SIREP with routine EPI or with other changes to EPI.*

| <i>Theme</i>                        | <i>Responses</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <i>HW Codes</i>                                                                                    |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| Planning changes may improve access | <ol style="list-style-type: none"> <li>1. It would change the normal immunization routine which is monthly and we don't get the immunization numbers expected. So the change has made it to go in time for babies immunization scheduled dates</li> <li>2. Cut down on cost for families to access vaccinations in town. Health workers will better monitor the number of children accessing immunization and plan accordingly</li> <li>3. Because of SIREP Program and we are conducting immunization daily instead of weekly as traditionally practiced.</li> </ol> | <ol style="list-style-type: none"> <li>1. 17</li> <li>2. 7</li> <li>3. 2</li> </ol>                |
| Potential to reduce disease         | <ol style="list-style-type: none"> <li>4. Less disease with immunization</li> <li>5. Improving health of babies in community</li> <li>6. Will reduce workload at the children's outpatient because immunization protects children from illness</li> <li>7. It will help stop measles out break</li> </ol>                                                                                                                                                                                                                                                             | <ol style="list-style-type: none"> <li>4. 12</li> <li>5. 11</li> <li>6. 8</li> <li>7. 3</li> </ol> |
| Introduces                          | <ol style="list-style-type: none"> <li>8. New vaccine knowledge</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <ol style="list-style-type: none"> <li>8. 18</li> </ol>                                            |

|                                          |                                                                                                                                                                                                                                                                 |                                            |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| new vaccines                             | 9. It would change the plan of schedule and we learn about new vaccines.<br>10. 1.1 Additional practice to immunization                                                                                                                                         | 9. 16<br>10. 4                             |
| Reduces health service costs             | 11. SIREP can be scheduled and therefore the Government will spend less<br>12. Will reduce workload at the children's outpatient because immunization protects children from illness                                                                            | 11. 7<br>12. 8                             |
| Potential for integration                | 13. SIREP Program will help to integrate the services within the clinic and during the outreach                                                                                                                                                                 | 13. 9                                      |
| Potential for less antibiotic resistance | 14. The SIREP Program will help to reduce the use of antibiotic on babies and therefore help to reduce the risk of drug resistance amongst babies                                                                                                               | 14. 7                                      |
| Adds to workload                         | 15. It is an additional work to me.<br>16. It needs more time and to program schedule especially for man power<br>17. It would affect the manpower<br>18. It's an added workload to me                                                                          | 15. 18<br>16. 14<br>17. 13<br>18. 10       |
| Not aware                                | 19. Was never part of the SIREP so cannot really tell<br>20. Was never part of the SIREP so cannot really tell<br>21. Was never part of the SIREP so cannot really tell<br>22. We only attend to well-baby and opportunistic<br>23. Was never part of the SIREP | 19. 12<br>20. 8<br>21. 5<br>22. 6<br>23. 1 |

### 6.1.2 What SIREP needs to be effective

| Theme                              | Responses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | HW Codes                                  |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| More staff (to match population)   | 1. We need more man power<br>2. Need to improve manpower so we can fully implement all services<br>3. Increase staff ceiling for this facility because population is increasing<br>4. Need to have more manpower<br>5. Need more man power                                                                                                                                                                                                                                                                                           | 1. 18<br>2. 16<br>3. 15<br>4. 13<br>5. 10 |
| Dedicated preventive care services | 6. Establish well baby clinic and mothers health check-up, so when they bring their children for check-up, they are checked as well <i>[general OPD]</i><br>7. Someone must be assigned full time to provide vaccination, Well baby clinic needs to be established<br>8. Have a separate wing in the facility that will be able to look at such programs and have Well baby clinic alone since currently both well babies and sick babies go to one area only to be checked and sent for treatment<br>9. Improve services on measles | 6. 13<br>7. 10<br>8. 9<br>9. 3            |

|                              |                                                                                                                                                                                                                            |                  |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| Transport resources          | 10. We need constant transport to effectively implement SIREP program.<br>11. This SIREP Program is worse in some areas that they cannot easily access some villages like in the bainings or Kerevat remote areas or Pomio | 10. 16<br>11. 9  |
| Vaccine availability         | 12. Availability of vaccines. At the moment there is no PCV/IPV and MRV<br>13. All Vaccines must be available at all times                                                                                                 | 12. 7<br>13. 8   |
| Communication efforts needed | 14. Awareness/toksaves has to be done and notices putout or given out to the ward members and LLG managers<br>15. Need to improve awareness on when and how to give                                                        | 14. 17<br>15. 11 |
| Community engagement         | 16. attendance of mothers bringing their children                                                                                                                                                                          | 16. 4            |

### 6.1.3 SIREP in-service done post training

| Theme                             | Responses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | HW Codes                                                                                      |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| In-service passed on to MCH staff | 1. Inservice has been done<br>2. All staffs under MCH have been in-serviced on SIREP and are now knowledgeable in all new vaccines<br>3. Yes, nursing officers who attended the training have trained us<br>4. Yes, staff who attended the training have trained us in the facility<br>5. Second In-charge of the facility who attended the training shared the skills with staff<br>6. Yes, SIC attended the training and imparted her skills to all the staff<br>7. Yes, I did train the staff at my facility<br>8. Three staffs were trained in the these facility who were then part of the SIREP Program so training was done by the 3 staffs to the other staffs and therefore they disseminated the information to other staffs<br>9. Yes, SIC conducted in-house training for all staff at ANC<br>10. Yes, SIC did in-house training to all the staff at the facility<br>11. Yes, I attended the training and did in-house training for all the staff | 1. 17<br>2. 18<br>3. 16<br>4. 15<br>5. 14<br>6. 11<br>7. 10<br>8. 9<br>9. 8<br>10. 4<br>11. 2 |
| Secondary training not reported   | 12. I did not attend the formal training but was involved in the actual implementation of SIREP program<br>13. Was never part of the SIREP so cannot really tell<br>14. Was never part of the SIREP so cannot really tell<br>15. Was never part of the SIREP so cannot really tell<br>16. We were not given any chance attend RIREP training that                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12. 13<br>13. 12<br>14. 8<br>15. 5<br>16. 6<br>17. 3                                          |



|                      |                                                                                                                                                                                                                                                         |                                          |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
|                      | <p>is why SIREP is done by MCH staff.</p> <p>17. There was no training done for us. Nurses were just appointed to be part of the SIREP program and the person who was train will do the immunization herself</p> <p>18. Was never part of the SIREP</p> | 18. 1                                    |
| More training needed | <p>19. But we need in-house training</p> <p>20. Need constant in-service on immunization and ensure everyone understands new changes in vaccines</p> <p>21. No proper training done but was just given information on the dosage and age group</p>      | <p>19. 14</p> <p>20. 11</p> <p>21. 7</p> |

## 6.2 Immunization service coverage and quality

### 6.2.1 Most important constraints

| Theme                            | Responses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | HW Codes                                                                                |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| Vaccine shortage                 | <p>1. Vaccine shortage and weather is a main problem faced in delivering the immunizations to babies.</p> <p>2. Shortage of vaccine supply at area medical store</p> <p>3. Main factor is supply of vaccine stock is not up to date to provide good immunisation</p> <p>4. Inconsistent supply of vaccines Vaccine supply is out of stock.</p> <p>5. Only the supply – some vaccines are not in stock at times</p> <p>6. Vaccine stocks (Limited/not enough)</p> <p>7. insufficient supply of vaccine from the provincial health</p>                                                                                                                                                                                                                                                                                                                                     | <p>1. 17</p> <p>2. 18</p> <p>3. 16</p> <p>4. 14</p> <p>5. 6</p> <p>6. 3</p> <p>7. 2</p> |
| Cold chain infrastructure        | <p>8. We do not have a vaccine fridge and less manpower <i>[general outpatient]</i></p> <p>9. No vaccine fridge so just using the cold box therefore cannot have all the vaccines needed to support the immunization coverage</p> <p>10. We do not have a vaccine fridge, we only use cold box to store vaccines at the facility</p> <p>11. Storage of Equipment especially vaccines-Storage facility for vaccines. All other areas are coming to get vaccines here at this facility because other facilities don't have a proper storage freezer for vaccines - it's worse in other facilities when it comes to cold chain</p> <p>12. Main problem is the facility is using domestic fridge to store vaccines and if main power supply goes out for several hours is not good we need a vaccine fridge.</p> <p>13. We need a new vaccine fridge instead of domestic</p> | <p>8. 13</p> <p>9. 12</p> <p>10. 11</p> <p>11. 5</p> <p>12. 4</p> <p>13. 2</p>          |
| Transport resources for reaching | <p>14. Transport, Ambulance is 13 years old and need proper maintenance</p> <p>15. Transport is not always available</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>14. 14</p> <p>15. 12</p> <p>16. 11</p>                                               |

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                     |
|--------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| remote populations                   | <p>16. Lack of vehicle to transport community mobile sites and at the moment we use one ambulance</p> <p>17. Physical environment such as scattered villages, mountains and hills is another barrier</p> <p>18. Physical environment – poor transport, scattered villages and lack of funds for transport</p> <p>19. No road access to many villages who are leaving right inside. Our transport cannot go right in and therefore coverage is not good. It's worse in the bainings and pomio</p>                                                                | <p>17. 10</p> <p>18. 6</p> <p>19. 1</p>                             |
| Staff shortages                      | <p>20. Shortage of staffs or lack of staffs</p> <p>21. Man power shortage</p> <p>22. Man power shortage</p> <p>23. Less number of staff and when plenty mothers attend clinic for immunization, sometimes we don't provide health education and proceed straight to vaccines</p> <p>24. Staff shortage so no one to help give immunization or do MCH</p>                                                                                                                                                                                                        | <p>20. 12</p> <p>21. 11</p> <p>22. 10</p> <p>23. 8</p> <p>24. 3</p> |
| Staff attitudes                      | <p>25. Staff shortage due to sickness, other social or cultural events that pops up</p> <p>26. Staff punctuality and timing is currently a problem. If staff turn up on time then they will be able to catch mothers on time</p> <p>27. Staff punctuality is a hindrance to coverage and quality. If staff turn up on time. The coverage will be high and they will be able to provide quality service</p> <p>28. Attitudes of staff who come to work with personal problems may not perform well or might inject wrong vaccine against what was prescribed</p> | <p>25. 15</p> <p>26. 9</p> <p>27. 7</p> <p>28. 2</p>                |
| General funding or infrastructure    | <p>29. Lack of funding from government and church structures</p> <p>30. Funding should be available at all times to carry out programs. Staffs will only attend to clinics/ special programs if there are funds available. These days are so different because people rely mainly on money [incentives] to carry out work which will also help boost their morale to support and give quality services.</p>                                                                                                                                                     | <p>29. 14</p> <p>30. 9</p>                                          |
| Difficulties in community engagement | <p>31. Difficulties in relationship between the community and the staff. Mothers are ignorant.</p> <p>32. Mother's Ignorance</p> <p>33. Mothers commitment during clinic days and therefore don't turn up at the clinic on the set dates</p> <p>34. Important factor is mobilisation of parents with their children from one location to another. When mothers are not in one location and a mobile clinic is held at that location then the child is missing her/his vaccine due for that month</p>                                                            | <p>31. 16</p> <p>32. 9</p> <p>33. 7</p> <p>34. 2</p>                |

|                       |                                                              |        |
|-----------------------|--------------------------------------------------------------|--------|
| Weather, floods, rain | 35. Weather. Continuous rain causes bad road conditions      | 35. 17 |
|                       | 36. Bad weather prevent mothers from coming for immunization | 36. 8  |

### 6.2.2 Constituents of a good quality service

|                               |                                                                                                                                                                                                                                                                                                          |        |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| Vaccine stock management      | 1. Must have good sufficient supply of stocks of vaccines every month and it must be ordered according to population and expiry dates meaning the vaccines has to be checked of their expiry dates before being sent out the health facilities so we don't have expired vaccines sitting in our fridges. | 1. 17  |
|                               | 2. All vaccines available. Maintain cold chain. Availability of vaccines                                                                                                                                                                                                                                 | 2. 18  |
|                               | 3. Maintain cold chain at all times                                                                                                                                                                                                                                                                      | 3. 16  |
|                               | 4. Maintain good cold chain Protect vaccine from sun light Keep at right temperature                                                                                                                                                                                                                     | 4. 15  |
|                               | 5. Vaccines available. If stocks are available then the service flow is constant                                                                                                                                                                                                                         | 5. 14  |
|                               | 6. Keep vaccine in cold chain at all times, ensure thermometers are at right temperature at all time, check VVM all the time                                                                                                                                                                             | 6. 11  |
|                               | 7. Keep potency of fridge by maintaining cold chain at all times                                                                                                                                                                                                                                         | 7. 4   |
|                               | 8. Enough stocks of vaccines                                                                                                                                                                                                                                                                             | 8. 3   |
|                               | 9. Maintain temperature of domestic fridge twice a day. Keep a proper record of stock in and out daily. Check VVM regularly                                                                                                                                                                              | 9. 2   |
| Staffing numbers and capacity | 10. Enough man power                                                                                                                                                                                                                                                                                     | 10. 18 |
|                               | 11. Enough staff must be available to implement in the immunization                                                                                                                                                                                                                                      | 11. 14 |
|                               | 12. Availability of staffs to provide immunization for all and to provide quality service                                                                                                                                                                                                                | 12. 12 |
|                               | 13. Staffs with knowledge on vaccines. Staff punctuality.                                                                                                                                                                                                                                                | 13. 7  |
|                               | 14. Enough staff to finish work on time, when we give more health it would prevent children from illnesses related to immunizable diseases                                                                                                                                                               | 14. 8  |
|                               | 15. Availability of staffs to provide immunization for all and to provide quality service                                                                                                                                                                                                                | 15. 5  |
|                               | 16. Nurse availability, enough supply all the time                                                                                                                                                                                                                                                       | 16. 6  |
| Staff skills and training     | 17. training staff on new vaccines so they give right vaccine per route and handle vaccines in a proper way                                                                                                                                                                                              | 17. 13 |
|                               | 18. Availability of staffs to provide immunization for all and to provide quality service                                                                                                                                                                                                                | 18. 12 |
|                               | 19. Staffs with knowledge on vaccines                                                                                                                                                                                                                                                                    | 19. 5  |
| Effective,                    | 20. vaccines and transport available                                                                                                                                                                                                                                                                     | 20. 14 |

|                                |                                                                                                                                                                                                                                                                                                                    |                           |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| supported outreach             | 21. Clinic patrols would make up a good quality service with separate ambulance for patrol alone. Currently the MCH is using one ambulance so at times it is called off for immunization<br>22. Good planned program with no cancelations of MCH<br>23. funds will help to purchase transport to transport vaccine | 21. 7<br>22. 4<br>23. 1   |
| Dedicated preventive care      | 24. Establish well baby clinic and mothers health check-up, so when they bring their children for check-up, they are checked as well <i>[general OPD]</i><br>25. Someone must be assigned full time to provide vaccination, Well baby clinic needs to be established                                               | 24. 13<br>25. 10          |
| Community aware and supportive | 26. Mothers must be aware of their next clinic dates<br>27. Good communication between the staff and the local community<br>28. Health awareness on review dates for vaccine                                                                                                                                       | 26. 16<br>27. 14<br>28. 6 |

### 6.2.3 Main limit on quality

*May consolidate this with 2.1 if answers did not distinguish adequately from 2.1*

|                                          |                                                                                                                                                                                                                                                                                                                                                                                       |                                                 |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Same as 2.3                              | 1. As above (10 respondents)                                                                                                                                                                                                                                                                                                                                                          | 1. 17, 18,<br>16, 14, 13,<br>12, 11, 9, 8,<br>6 |
| Insufficient outreach to community level | 2. It would be good to do overnight patrols. Too much relying on transport and funds making it difficult to cover the catchment population. We also need funds allocated to conduct overnight patrols                                                                                                                                                                                 | 2. 17                                           |
| Power outages                            | 3. Prolonged power outage<br>4. Power supply cut off, frequent power outages for so long can destroy the vaccine                                                                                                                                                                                                                                                                      | 3. 18<br>4. 15                                  |
| Community preferences on provider        | 5. Some educated clients do not want CHWs to attend to them. Currently, we have 5 Nursing Officers and 4 CHW people prefer NOs than CHWs                                                                                                                                                                                                                                              | 5. 11                                           |
| Service planning limits access           | 6. Number of day immunisation services is provided. Measles are given on Mondays and Thursdays only - this is worse in other catchment areas                                                                                                                                                                                                                                          | 6. 5                                            |
| Staff knowledge                          | 7. Knowledge – most staff are still confused with introduction of new vaccine on when to administer<br>8. Gaps in staff knowledge. We still have aging staffs who have limited knowledge and skills. Because many aging staffs still follow the old training and skills and takes time to adapt to new changes. Therefore the coverage is poor because of the gaps in staff knowledge | 7. 4<br>8. 1                                    |

### 6.3 Integration of other services with EPI

#### 6.3.1 Most important additional services

| <i>Theme</i>                        | <i>Responses</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <i>HW Codes</i>                                                                      |
|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Family planning                     | 1. Family Planning is number one on the list of integrating services<br>2. Family Planning, STI, TB screening and outpatient must be combined with immunization.<br>3. Family Planning<br>4. Family Planning to be combined with immunization<br>5. Family Planning<br>6. Family Planning because mother can be served as well as well as baby<br>7. Family Planning<br>8. Family Planning and health talk<br>9. Family Planning – both parents must bring their children to clinic so they can be educated at the same time<br>10. Family Planning because of lack of support from husband, when she brings her child for immunization, she may be served as well at the same time | 1. 17<br>2. 18<br>3. 16<br>4. 15<br>5. 12<br>6. 11<br>7. 10<br>8. 8<br>9. 4<br>10. 2 |
| General health education            | 11. Give health talks on different topics (ANCP – BI project very helpful). Health talk on the side effects of immunizations.<br>12. Health education<br>13. Including health talk<br>14. ANC, as inclusion of all relevant health education<br>15. Family Planning and health talk<br>16. Health education should be a must with immunization                                                                                                                                                                                                                                                                                                                                      | 11. 17<br>12. 16<br>13. 14<br>14. 9<br>15. 8<br>16. 6                                |
| STI                                 | 17. STI outpatient must be combined with immunization.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 17. 18                                                                               |
| TB                                  | 18. TB screening and outpatient must be combined with immunization.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 18. 18                                                                               |
| Nutrition general                   | 19. Nutrition                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 19. 16                                                                               |
| Breast feeding and infant nutrition | 20. Advice mother on breastfeeding and nutrition. Explain to mother on weight graph with immunization.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 20. 15                                                                               |
| Antenatal care                      | 21. Combine ANC with immunization<br>22. Antenatal<br>23. ANC to be integrated with all other services since the program has all the educational information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 21. 14<br>22. 12<br>23. 9                                                            |
| Involving fathers                   | 24. help both mothers and fathers to realize the importance of health care around mothers, babies and the family as a                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 24. 9<br>25. 4                                                                       |

|                              |                                                                                                                          |                  |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------|------------------|
|                              | whole<br>25. Family Planning – both parents must bring their children to clinic so they can be educated at the same time |                  |
| General illness management   | 26. and outpatient must be combined with immunization.<br>27. Outpatient                                                 | 26. 18<br>27. 12 |
| Every opportunity rationale  | 28. Because it's by chance that they came so we must treat problems as well, so it makes easier for them.                | 28. 18           |
| Client convenience rationale | 29. So it makes easier for them.<br>30. So she does not have to come back                                                | 29. 18<br>30. 11 |
| Co-located services          | 31. Callan services (Disability). Ante-natal should happen. VCCT should happen. Family planning should happen            | 31. 7            |

### 6.3.2 Constraints on integration

|                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                           |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Staff shortage, staff diverted to other care | 1. Staff shortage is the main problem<br>2. Staff shortage is the main problem we have<br>3. Manpower is the main factor that prevents additional services with immunization<br>4. Staff shortage is 1 main problem that is happening<br>5. Staff shortage because if one nurse is busy with immunization, then she does not have enough time to do FP<br>6. There is not enough staff to carry out responsibilities specifically in one section. One staff can be assigned to 2-3 sections making it difficult to provide many services all at once<br>7. Availability of staffs to conduct ANC and no proper facility in the community to conduct ANC<br>8. Manpower is the main factor, we need more staff<br>9. Because of lack of staff vaccinator is pulled out during immunization to help with COPD<br>10. Main factor is insufficient staff to provide immunization and Family Planning at the same time. | 1. 16<br>2. 15<br>3. 14<br>4. 12<br>5. 11<br>6. 9<br>7. 8<br>8. 6<br>9. 2 |
| Staff time an issue                          | 11. Staffs to have extra time with the families/ mothers/ babies to provide the proper help                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 10. 17                                                                    |
| Staff attitude, motivation                   | 12. Staffs attitude – When there is money funds available to conduct programs, and then they will be happy to provide a service. If not then they won't be able to provide it                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 11. 9                                                                     |
| Infrastructure                               | 13. Physical settings such as no privacy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12. 10                                                                    |
| Institutional policy                         | 14. Church run institution does not allow artificial family planning methods<br>15. Main factor barrier is Catholic run facilities have church                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 13. 7<br>14. 4                                                            |

|  |                                                                                        |  |
|--|----------------------------------------------------------------------------------------|--|
|  | policies that does not allow other FP methods to be practiced except ovulation method. |  |
|--|----------------------------------------------------------------------------------------|--|

#### 6.4 Planning and organization of mobile clinics and patrols

##### 6.4.1 Priorities in planning mobile clinics

| Theme                              | Responses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | HW Codes                                                         |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Geography, most remote first       | 1. Choose clinic site from further distance first and reverse backwards<br>2. Probably location/ population. Based on distance. Starts off with furthest location with high population area and then to the closest location with low population area<br>3. Based on distance. Starts off with furthest location and then to the closest location<br>4. Location will decide where to go for the mobile clinic. SIC is the one who decided where to go according to her own knowledge<br>5. Provide equal distribution of service by visiting every clinic site per month to ensure all babies due for vaccine are immunized and "I do not go by population" | 1. 10<br>2. 9<br>3. 7<br>4. 1<br>5. 2                            |
| Population size key factor         | 6. We follow MCH as rostered but currently we will go by population of babies under one year as instructed by provincial supervisors.<br>7. Probably location/ population. Based on distance. Starts off with furthest location with high population area and then to the closest location with low population area<br>8. Go by population and how often to conduct clinic depends on the number of children in one clinic site                                                                                                                                                                                                                              | 6. 14<br>7. 9<br>8. 4                                            |
| Transport resources to do outreach | 9. Availability of transport to do MCH clinics. It would be good to do overnight patrols. Too much relying on transport and funds making it difficult to cover the catchment population. We also need funds allocated to conduct overnight patrols                                                                                                                                                                                                                                                                                                                                                                                                           | 9. 17                                                            |
| Staff movement planning            | 10. Decided according to the number of clinics points and if one has 2 clinic points then we decide how to split the staffs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 10. 17                                                           |
| Follow what SIC or OIC says        | 11. Sister in-charge of MCH does the mobile schedule and we only follow<br>12. OIC does the schedule and we only follow<br>13. OIC does the planning<br>14. SIC is the one who decided where to go according to her own knowledge. SIC makes the decision on where to go to do the mobile clinic                                                                                                                                                                                                                                                                                                                                                             | 11. 18<br>12. 16<br>13. 15<br>14. 12<br>15. 11<br>16. 8<br>17. 5 |

|  |                                                                                                                                                                                         |  |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | 15. OIC does the schedule so I only carry out the orders<br>16. I only follow monthly schedule done by SIC<br>17. SIC is the one who decided where to go according to her own knowledge |  |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

#### 6.4.2 Determinants of cancellation

|                                |                                                                                                                                                                                                                                                                                                                                                           |                                                                 |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| Weather, including floods/rain | 1. Weather is the main reason for cancellation and SIC makes the decisions and if SIC not around then the OIC makes the call.<br>2. Bad weather and the OIC has to confirm before we cancel the program<br>3. Mainly weather since some locations don't have shelters that can be used during the clinic that the team cannot do MCH during a bad weather | 1. 17<br>2. 10<br>3. 7                                          |
| Lack of transportation         | 4. No transport also main reason<br>5. SIC cancel the mobile clinic depending on the situation e.g. no transport available<br>6. I make the decision to cancel mobile clinic due to no vaccines and ambulance in poor condition or other unexpected events that pops up                                                                                   | 4. 17<br>5. 18<br>6. 14                                         |
| Staff shortage                 | 7. If no staffs then clinics will be cancelled because only one staff is currently doing MCH and the OIC makes the decision on cancelling the MCH<br>8. When to stop mobile clinic depends on number of staff available and end of year's program                                                                                                         | 7. 9<br>8. 2                                                    |
| Vaccine shortage               | 9. I make the decision to cancel mobile clinic due to no vaccines and ambulance in poor condition or other unexpected events that pops up                                                                                                                                                                                                                 | 9. 14                                                           |
| Never cancel                   | 10. Never cancel any mobile clinic because communities are already informed                                                                                                                                                                                                                                                                               | 10. 4                                                           |
| Follow what SIC or OIC says    | 11. Again it's the OIC who cancel the mobile clinic<br>12. Again it's the OIC who cancel the plan<br>13. SIC makes the decision<br>14. SIC makes the decision the cancel the mobile clinic<br>15. I follow the SIC's instruction and can't say much on this<br>16. SIC makes the decision<br>17. SIC makes the decision on                                | 11. 16<br>12. 15<br>13. 12<br>14. 11<br>15. 8<br>16. 5<br>17. 1 |



## 6.5 Postnatal care

### 6.5.1 Most important PNC services

| Theme                                | Responses                                                                                                                                                                                                                                                                                                                                                                                           | HW Codes                                      |
|--------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Personal hygiene                     | 1. Educate on personal hygiene for mothers after delivery within first six weeks<br>2. Advice on personal hygiene, treat those who are sick and provide nutritional advice<br>3. Educate on personal hygiene for mothers<br>4. Personal hygiene for both mother and baby<br>5. Personal hygiene                                                                                                     | 1. 17<br>2. 16<br>3. 12<br>4. 10<br>5. 1      |
| Family planning                      | 6. Education on family planning – Different methods and ovulation within first six weeks<br>7. advice on family planning<br>8. Education on family planning – Different methods and ovulation<br>9. Family Planning. If there is family planning. Mothers will be able to care properly for herself and her baby and therefore prevent neo-natal sepsis and puerperal sepsis<br>10. Family Planning | 6. 17<br>7. 15<br>8. 12<br>9. 7<br>10. 1      |
| Routine maternal check               | 11. Before mothers discharge, they must have their peri, HB level and fundal height checked<br>12. observe mothers for any bleeding, lactation, bowl open or not and check for any abnormalities<br>13. Check mothers fundal height and assess if bleeding a lot or not for 24 -48 hours                                                                                                            | 11. 13<br>12. 8<br>13. 2                      |
| Preventive care mother               | 14. Always give iron supplements to mothers because of blood loss during delivery                                                                                                                                                                                                                                                                                                                   | 14. 4                                         |
| Maternal illness management          | 15. advice to come back if sick<br>16. Advice on personal hygiene, treat those who are sick and provide nutritional advice<br>17. check mother for bleeding<br>18. Postnatal care for both mother and baby, because mother may develop puerperal sepsis or postpartum haemorrhage or breast feeding problem<br>19. Treatment of infections                                                          | 15. 17<br>16. 16<br>17. 15<br>18. 14<br>19. 1 |
| Nutrition advice (? mostly for baby) | 20. Nutritional advise within six weeks<br>21. Advice on personal hygiene, treat those who are sick and provide nutritional advice<br>22. Nutritional advise Check weight graphs on baby's book to see if baby is growing<br>23. Breast feeding advice and monitoring<br>24. Baby must be breast feed as soon as possible                                                                           | 20. 17<br>21. 16<br>22. 12<br>23. 1<br>24. 2  |

|                            |                                                                                                                                                                                                                                                                                                                                          |                           |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Newborn illness management | 25. And the baby may develop neonatal infection or bleeding from cord or breast feeding problem.<br>26. Treatment of infections                                                                                                                                                                                                          | 25. 14<br>26. 1           |
| Newborn vaccination        | 27. Check baby if immunization is given before discharge<br>28. Immunization must be given straight after birth to prevent from infection                                                                                                                                                                                                | 27. 13<br>28. 2           |
| Newborn check congenital   | 29. Check baby for abnormalities                                                                                                                                                                                                                                                                                                         | 29. 15                    |
| General health education   | 30. Don't provide PNC but if does the main program that would be good to come in is Education and ANCP program is a preferred program. Because this program will cover almost everything a family should know about on woman's health and baby's health<br>31. Mothers should be well educated on importance on care of baby and herself | 30. 9<br>31. 6            |
| Outreach visits            | 32. Follow up – there should be follow ups for mother and baby for 6 weeks after delivery                                                                                                                                                                                                                                                | 32. 18                    |
| Early detection            | 33. That's where early detection of illness from mother and baby                                                                                                                                                                                                                                                                         | 33. 18                    |
| Assumed must be inpatient  | 34. Not relevant as we are outpatient<br>35. We have no inpatient it's only a day clinic<br>36. PNC is not included in our duties, its located to Postnatal ward                                                                                                                                                                         | 34. 12<br>35. 10<br>36. 8 |

### 6.5.2 Constraints on PNC

| Theme                        | Responses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | HW Codes                                                           |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Staff shortage and attitudes | 1. There should be enough staff and transport available to do follow ups.<br>2. Workload per staff is high therefore we do not have enough time for other vital services<br>3. staff shortage or when staffs are busy, they do not attend to PNC. For instance, if one nurse is busy with immunization then she does not have time to do peri-care or cord toilet or even give health education<br>4. Less man power<br>5. manpower is the main factor that limit us from providing PNC<br>6. Staffing is a problem and all settings are facing this problem<br>7. Lack of man power for staff to have enough time for one to provide one to one nursing care.<br>8. When nurses are busy during this shift may not attend to | 1. 18<br>2. 16<br>3. 15<br>4. 14<br>5. 13<br>6. 12<br>7. 4<br>8. 2 |

|                         |                                                                                                                                                                                        |                |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
|                         | mothers and her child                                                                                                                                                                  |                |
| Facility infrastructure | 9. Setting in the facility e.g. there is no proper bathing place for babies<br>10. No facility to provide PNC                                                                          | 9. 14<br>10. 9 |
| Staff attitudes         | 11. staffs punctuality. Staffs performance                                                                                                                                             | 11. 9          |
| Distance to attend HF   | 12. Distance of the health facility. Many of the populations live right inside [remote] and transport for them is a difficult thing so they have to walk to get to the health facility | 12. 17         |
| Transport for outreach  | 13. There should be enough staff and transport available to do follow ups.                                                                                                             | 13. 18         |
| Institutional policy    | 14. Catholic Church run facilities do not allow artificial methods of family planning. So cannot provide Family Planning methods to mothers who need it.                               | 14. 7          |
| Language                | 15. Health Education done in Tok Pisin is not well understood and should be done in local language (Kuanua)                                                                            | 15. 6          |

## 6.6 Significant changes in immunization

### 6.6.1 Significant changes (6.1, 6.2)

| Theme                       | Responses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | HW Codes                          |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Less disease                | 1. The change see is the added vaccination which is PCV13. Since PC was introduce now les number of babies admitted to our wads or seen at the outpatient with PNA. Before when PCV was not yet introduced, a lot of babies were seen with PNA.<br>2. No more measles cases seen due to Measles Rubella Vaccine<br>3. Plenty babies are not infected with measles because of Measles Rubella Vaccine<br>4. new vaccines have minimized the occurrence of diseases that are caused by pneumococcus | 1. 17<br>2. 11<br>3. 8<br>4. 4    |
| New vaccines                | 5. The change seen is the added vaccination which is PCV13.<br>6. more vaccines are available now a days compared to the past.<br>7. Only one change that was added onto the immunization program is the SIREP Program which introduced the 3 new vaccines MRV/PCV/IPV                                                                                                                                                                                                                            | 5. 17<br>6. 18<br>7. 9            |
| Improved supply of vaccines | 8. more vaccines are available now a days compared to the past.<br>9. Number of vaccines/immunizations is good and improves coverage                                                                                                                                                                                                                                                                                                                                                              | 8. 18<br>9. 16<br>10. 14<br>11. 2 |

|                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                          |
|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
|                                                        | <p>10. Because of SIREP program and we had enough vaccines and now the coverage is picking up. Previously there were not enough vaccines compared to the present</p> <p>11. Number of vaccines given per month has improved</p>                                                                                                                                                                                                                                                                                                                                                                                                                     |                                          |
| Changed service organization, including mobile clinics | <p>12. The SIREP program has change the way mobile clinics are conducted. Before mobile clinics were done monthly and the numbers were not so good so after the change of the schedule to quarterly, we have a good number of babies seen on visits.</p> <p>13. Increased coverage from SIREP</p> <p>14. Biggest change is both static and mobile clinic used to provide immunization once a week and now vaccines are given daily</p>                                                                                                                                                                                                              | <p>12. 17</p> <p>13. 18</p> <p>14. 2</p> |
| New preventive care                                    | <p>15. Don't have regular well baby clinic so started MCH which is done every day every month.</p> <p>16. a new intervention was started which is called MEDICAL WELLNESS CHECK. This clinic checks all staffs within the clinic every month for Cholesterol including other checks that should be done for individuals like BP/Urine/Bloods for cholesterol and weight height against the BMI. Other companies are also accessing the Wellness Checks</p> <p>17. Previously we do opportunists immunization but now because of well-baby clinic and immunization coverage is improving. Now we have nurse vaccinator where we had none before.</p> | <p>15. 12</p> <p>16. 9</p> <p>17. 6</p>  |
| No significant changes                                 | <p>18. No changes so far for well-baby clinic or immunization since started work 2 years ago.</p> <p>19. Cannot tell really but from the health secretary report that was given back to the MCH/well baby clinic the coverage currently is 50% only</p> <p>20. Haven't seen any changes.</p>                                                                                                                                                                                                                                                                                                                                                        | <p>18. 9</p> <p>19. 7</p> <p>20. 5</p>   |

#### 6.6.2 Reasons why it is seen as significant (6.3)

|                                          |                                                                                                                                                                                                     |                                        |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Coverage benefits from mobile clinics    | <p>1. More coverage from SIREP</p> <p>2. Number of vaccines/immunizations is good and improves coverage</p> <p>3. Mobile clinic is important because we are visiting mothers and babies at home</p> | <p>1. 18</p> <p>2. 16</p> <p>3. 12</p> |
| Outreach opportunity to track population | <p>4. Child health registration should be kept up to date when doing mobile clinic so to identify accurately on the coverage and provision of immunization</p>                                      | <p>4. 12</p>                           |
| Less                                     | <p>5. helped babies from all the villages and has improved the</p>                                                                                                                                  | <p>5. 15</p>                           |

|                    |                                                                                                                                                              |      |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| disease            | immunization coverage. As a result no more whooping cough cases seen in the facility<br>6. Not many babies are sick related to vaccines preventable diseases | 6. 8 |
| Provincial targets | 7. It is because we want to reach the provincial target                                                                                                      | 7. 2 |

### 6.6.3 Good practices from the past

May combine with strengths questions in Section 7

|                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                         |
|---------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Staff/client ratio was better in past | 1. Before numbers of staff employed were sufficient to implement, now the population is increasing and the rotation of staff per patient is high. Therefore, there is a need to recruit more staff to match the increasing population<br>2. Manpower in the past was ok but now the population is increasing compared to staff ceiling. Man power in the past years was good to provide all services but now, it is hard<br>3. Need more man power to effectively implement SIREP | 1. 18<br>2. 14<br>3. 11 |
| Transport resources used to be better | 4. Transport for mobile services was available                                                                                                                                                                                                                                                                                                                                                                                                                                    | 4. 16                   |
| Health talks prior to immunization    | 5. Provide health talks to all contact points to mothers before commencing immunization services                                                                                                                                                                                                                                                                                                                                                                                  | 5. 15                   |
| Infrastructure in past                | 6. if only we have a vaccine fridge in place as we used to do in the past before the second volcano eruption in 2008.                                                                                                                                                                                                                                                                                                                                                             | 6. 3                    |

## 6.7 Strengths and improvements

### 6.7.1 Strengths at present (7.1, 7.2)

| Theme                        | Responses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | HW Codes                       |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Commitment to mobile clinics | 1. Mix of static and mobile clinics in order to catch all babies<br>2. Every day mobile clinic is our strength. Some clinics don't do mobile clinic that's why the immunization coverage is low. Our mobile clinic is unique because we do mobile clinic everyday every month<br>3. Planned mobile clinics are never cancelled, e.g. if there is no ambulance available, we hire PMV bus<br>4. Transportation for MCH. When the ambulance is not available they hire private cars to transport them to their clinic sites. | 1. 17<br>2. 12<br>3. 4<br>4. 1 |

|                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                      |                                        |
|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Community engagement, multiple channels, respectful care | <p>5. Health awareness is very important and must be reinforced</p> <p>6. Engage with community counsellors to communicate with mothers from their wards to bring their babies for immunization and community engagement</p> <p>7. Community awareness including churches and LLGs on immunization to save. Create good communication with clients and feel comfortable instead of yelling and screaming at them</p> | <p>5. 18</p> <p>6. 15</p> <p>7. 11</p> |
| Increased staff knowledge                                | <p>8. All staffs under MCH have been in-serviced on SIREP and are now knowledgeable in all new vaccines</p> <p>9. In-house training, case review and staff participating in the meeting</p>                                                                                                                                                                                                                          | <p>8. 18</p> <p>9. 14</p>              |
| Staff capacity                                           | <p>10. We have specialist nurses e.g. 2 midwives and 2 HEOs who makes delivery and postnatal care easier. Also most deliveries are done at Kerevat because of midwives.</p> <p>11. Currently have enough staffs in the clinic with 1 NO and a NO midwife = 2 Nos and 5 CHWs. Therefore makes it easier for them to have 2 group doing clinics at different sites</p>                                                 | <p>10. 16</p> <p>11. 7</p>             |
| Advice on immunization at delivery                       | <p>12. babies delivered in the clinics so we can be able to map out a good immunization schedule for our clinic points.</p>                                                                                                                                                                                                                                                                                          | <p>12. 17</p>                          |
| Data and records for immunization planning               | <p>13. Supervised delivery to help to have record of all the babies delivered in the clinics</p> <p>14. Own method for recording children due for vaccination and tracking them from 1 mo to 12 mo. But though they know they have missing children due for vaccines and follow up, they don't do direct home visits</p>                                                                                             | <p>13. 17</p> <p>14. 7</p>             |
| Dedicated preventive service                             | <p>15. We have a well-baby clinic and a full time nurse which makes immunization easier for babies</p>                                                                                                                                                                                                                                                                                                               | <p>15. 6</p>                           |
| New infrastructure                                       | <p>16. We have a new facility unlike the past. The new place or settings is convenient to screen babies and vaccinate them within the same settings</p>                                                                                                                                                                                                                                                              | <p>16. 16</p>                          |
| Patient flow                                             | <p>17. Have triage system to identify very sick children quickly</p> <p>18. TRIAGE – helps me to identify children who are sick, and those who need immunization so other facilities could do the same</p>                                                                                                                                                                                                           | <p>17. 13</p> <p>18. 6</p>             |
| Cannot think of any strengths                            | <p>19. Cannot think of any strength</p>                                                                                                                                                                                                                                                                                                                                                                              | <p>19. 9</p>                           |

**6.7.2 Suggestions (7.3, 7.4)**

| <i>Theme</i>                                        | <i>Responses</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <i>HW Codes</i>                                                                                                                  |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Community health knowledge and engagement promotion | <ol style="list-style-type: none"> <li>1. Advice mothers on the importance of supervised delivery</li> <li>2. Health awareness is very important</li> <li>3. Both father and mother must be well educated on how to care for baby, importance of immunization, attend regular monthly clinic for health check. Regular health talks on Radio and through churches</li> <li>4. Give plenty health awareness on various topics on immunization, malaria, Diarrhoea, personal hygiene and TB. I must make it a priority to give health talk every day then others can adapt my way. At the village, my house must be a role model so others can follow.</li> <li>5. Educate mothers to bring their children all the time during mobile clinics. How we communicate with mothers and the importance of HE and ensure she understands then she will implement what she was told.</li> <li>6. Provide multiple ways of educational materials such as video, drama, cooking demonstration to family as preventive services. Multiple educations improve peoples' knowledge on implementation of health talk at home.</li> </ol> | <ol style="list-style-type: none"> <li>1. 16</li> <li>2. 18</li> <li>3. 13</li> <li>4. 11</li> <li>5. 8</li> <li>6. 2</li> </ol> |
| Involving men                                       | <ol style="list-style-type: none"> <li>7. Both father and mother must be well educated on how to care for baby, importance of immunization, attend regular monthly clinic for health check</li> <li>8. Encourage fathers to bring baby and mother to clinic. Set up a well-baby clinic and Men's Clinic</li> <li>9. Fathers must accompany mothers and baby to clinic. Sometimes baby miss immunization because mothers might be illiterate so fathers will assist mother for next visit date</li> <li>10. Support from both parents</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ol style="list-style-type: none"> <li>7. 13</li> <li>8. 10</li> <li>9. 6</li> <li>10. 2</li> </ol>                              |
| Staff numbers and capacity                          | <ol style="list-style-type: none"> <li>11. All facilities should have 3 midwives to help with ANC and Postnatal services.</li> <li>12. Increase the manpower because population is also increasing</li> <li>13. Have enough staffing in all section</li> <li>14. With good staffing currently if one staff is sick they can easily pull out a staff from the other group so they can still do clinics on that day</li> <li>15. Need more man power including student nurses</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <ol style="list-style-type: none"> <li>11. 16</li> <li>12. 10</li> <li>13. 9</li> <li>14. 7</li> <li>15. 4</li> </ol>            |
| Improve peripheral services to                      | <ol style="list-style-type: none"> <li>16. Other facilities must work efficiently so that their population under their catchment area must not by pass their facility to come to us for service. It makes us over</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <ol style="list-style-type: none"> <li>16. 18</li> <li>17. 5</li> <li>18. 6</li> </ol>                                           |

|                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                      |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| avoid bypassing                                | <p>worked.</p> <p>17. There has been mothers and babies from all other catchment areas are coming to our facility to access vaccines</p> <p>18. Also mothers should be encouraged to go to respective mobile sites instead of pouring into large facilities. Because our coverage rate is high and quickly run out of supply.</p>                                                                                                                                                                                                                                                                                                                             |                                                                      |
| Improve infrastructure                         | <p>19. Need a bigger fridge to store enough vaccines to cater for growing population</p> <p>20. Vaccine fridge at outpatients</p> <p>21. Domestic fridge should be replaced with vaccine fridge</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>19. 14</p> <p>20. 13</p> <p>21. 4</p>                             |
| Use central coordination and planning channels | <p>22. The OIC will express this issue during OIC meeting with the provincial leaders how this issue can be solved. It needs to be documented and presented during provincial OIC meetings</p> <p>23. Write a letter to District Health Manager and Provincial health leaders highlighting the facts and figures about the problems</p> <p>24. If OIC/SICs have strong leadership roles, they will be able to lead properly in everything in a clinic</p> <p>25. bring it up to the District and Provincial levels to ensure it takes place because men's illness is increasing and population as well.</p> <p>26. We want to reach the provincial target</p> | <p>22. 18</p> <p>23. 14</p> <p>24. 12</p> <p>25. 10</p> <p>26. 2</p> |
| Dedicated preventive care                      | <p>27. Establish well baby clinic and mothers health check-up, so when they bring their children for check-up, they are checked as well <i>[general OPD]</i></p> <p>28. Someone must be assigned full time to provide vaccination, Well baby clinic needs to be established. Set up a well-baby clinic and Men's Clinic</p> <p>29. Have a separate wing built specifically for Well Baby clinic since at the moment all babies well and sick go through the children's out patient</p> <p>30. Build separate wing for a well-baby clinic and mother and family to get all available service. This makes it easier for mums, babies and families</p>           | <p>27. 13</p> <p>28. 10</p> <p>29. 9</p> <p>30. 1</p>                |
| Integrated services                            | <p>31. For effective mobile service, other immunization services combine with Family Planning for mother as well at the static clinic</p> <p>32. Opportunistic vaccination. Albendazole deworms a child and he grows healthy so make it a rule for children to be given Albendazole at contact points</p> <p>33. If a midwife could take lead in follow up of mother and child might work with additional staff say 1 or 2</p>                                                                                                                                                                                                                                | <p>31. 10</p> <p>32. 8</p> <p>33. 4</p>                              |
| Regularity of                                  | 34. We want monthly mobile clinic to reschedule because it                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 34. 15                                                               |



|                                   |                                                                                                                                                                                                                                   |        |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| outreach                          | makes easier for mothers and babies.<br>35. Own system for tracking children from 1 – 12 mo, to trace late vaccines                                                                                                               | 35. 7  |
| Overnight and foot patrols        | 36. Should do foot patrols and overnight patrols to catch mothers and babies in the remote areas. Foot patrol and overnight patrols should happen to help cover the immunization to have an increase in the immunization coverage | 36. 17 |
| Vaccine stock management          | 37. Order vaccines according to population catchment                                                                                                                                                                              | 37. 17 |
| Better central vaccine management | 38. Area Medical Store needs to reschedule its supply to provide vaccines to facilities.                                                                                                                                          | 38. 14 |

## 7 Focus Group Discussions with Clients

### 7.1 Respondents overview

| <i>Place</i>        | <i>Code</i> | <i>Participants</i>    | <i>Number</i> | <i>Date</i> |
|---------------------|-------------|------------------------|---------------|-------------|
| Kerevat – Static    | KS          | Mothers                | 7             | 9/12/16     |
| Napapar – Static    | NS          | Mothers                | 8             | 30/11/16    |
| Rabaul – Mobile     | RM          | Mothers                | 6             | 22/11/16    |
| Warangoi – Static   | WS          | Mothers                | 8             | 12/12/16    |
| Rabaul – Static     | RS          | Mothers (7) Father (1) | 8             | 23/11/16    |
| Butuwin – Static    | BS          | Mothers                | 5             | 15/11/16    |
| Vunapope – Static   | VS          | Mixed                  | 5             | 11/11/16    |
| Paparatava – Mobile | PM          | Mothers                | 8             | 10/11/16    |
| Vunapope – Mobile   | VM          | Mothers                | 11            | 14/11/16    |
| Paparatava – Static | PS          | Mothers                | 1             | 9/11/16     |
| <i>Total</i>        |             |                        | <i>67</i>     |             |

### 7.2 Changes observed in immunization services

This was not an easy question to discuss and some answers were unclear.

| <i>Theme</i>    | <i>Responses</i>                                                                                                                                                                                                                                                                                                                                                                                                                                     | <i>Sites</i>                               |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Improved access | 24. Many mothers are bringing their children to mobile clinic because it makes easier for mothers; mobile clinic is depending on facility's schedule; mobile Services makes possible for many children to be immunized; well baby clinic at the village has provided accessibility to immunization services at the village and therefore has prevented a lot of babies from getting sick<br>25. Previous Immunization schedule was three times a day | 24. RM, VS, PM, VS<br>25. BS, PS<br>26. VS |

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                             |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|
|                                      | <p>and now its daily, which is good because if I'm busy on Tuesday then can make it on Wednesday; change in the number of days for immunization, before immunization happens only on Wednesdays</p> <p>26. There is a change in the way immunization is given this days</p>                                                                                                                                                                                              |                                                             |
| Staff factors                        | 27. Approach of staff is good and babies are assessed well                                                                                                                                                                                                                                                                                                                                                                                                               | 27. PM                                                      |
| No changes noted in immunization     | 28. No changes seen in the immunization, we do not see any changes; no changes seen in the immunization, we do not see any changes in the way nurses conduct mobile clinics and their attitude of giving immunizations; no changes seen in immunization;                                                                                                                                                                                                                 | 28. KS, NS, WS,                                             |
| Changes reported beyond immunization | <p>29. Fewer babies getting sick</p> <p>30. Implant is the only change we've seen that is a Family Planning Method</p> <p>31. Malaria program (CBD) has improved the health status of people and people are not spending any money to access the health facility because of testing and treatment availability at the village</p> <p>32. Cooking oil has been introduce to LBW babies to help mothers to help increase fat intake to help increase the baby's weight</p> | <p>29. VS, PS</p> <p>30. WS</p> <p>31. VS</p> <p>32. VS</p> |

### 7.3 Immunization service – access barriers and suggestions

| Theme            | Responses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Sites                                                                                               |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Service planning | <p>1. We want regular mobile clinics at the village / community; nurses do not follow schedule for mobile clinic; nurses don't turn up as schedule; we want health workers to conduct regular monthly mobile clinic at each mobile site; we want regular monthly clinic visits</p> <p>2. Only available one day – should be more; So we suggested immunization must be conducted twice in the facility instead of once a week</p> <p>3. awareness must be in advance so communities knows when the clinics will be held, no awareness to community that vaccines are out of stock</p> <p>4. Mothers waited for several hours at the facility to be served by health workers; waiting for 3-4 hours before my child is vaccinated</p> <p>5. suggest if Aid Post could be provided for immunization and other outpatients</p> <p>6. Community leaders could take lead in organizing mothers at community level</p> | <p>1.KS, NS, RM, RS, PM</p> <p>2.PS, NS</p> <p>3.KS, BS</p> <p>4.KS, NS</p> <p>5.RM</p> <p>6.PM</p> |
| Transport issues | <p>7. Not enough money for transport fare; no money to pay for transport fee; pay for bus fares; no money to pay for transport fee; bus fare – plenty kids some are left at home due to cost of transport fee</p> <p>8. No enough transport going to the community; no bus; some places difficult with transport; no transport/bus;</p> <p>9. When the weather is not so good then we cannot go the health centre and many mothers are leaving on the other side of the river or are right inside and when the weather is bad, we cannot go to the health centre</p>                                                                                                                                                                                                                                                                                                                                             | <p>7. KS, RM, WS, RS, VS, PM</p> <p>8. KS, RM, WS, RS, VS</p> <p>9. W S</p>                         |
| Staff factors    | <p>10. Nurses scolding clients for missed vaccines, attitude of staff is not good; attitude of staff is one of the main factor to well-baby clinic; staffs attitude towards mothers and babies has been a problem and therefore causes mothers from accessing the services easily at any time</p> <p>11. Staff must arrive on time for duty because they are paid fortnightly; nurses must arrive on time for duty</p> <p>12. Nurses strike, no staff</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>10. RS, BS, PM, VM</p> <p>11. KS, NS</p> <p>12. R M, WS</p>                                      |
| Supplies         | <p>13. Vaccine supplies run out and I spent money on bus fare and it's not good; My distance is far and when I come for vaccine found out that no supply so I am sent away; No stock of supply; Nil stock of vaccines. We walk from far and arrive at the clinic only to be told there are no vaccines available. So we go back and it takes us time to return to the clinic because we are living far away</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p>13. N S, RM, WS, VS, BS</p>                                                                      |

|                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                        |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Contra-indications | 14. Babies not vaccinated (turned away) when sick; when babies are sick, nurses do not give immunization. They are sent away and advice to come back the next day                                                                                                                                                                                                                                                                                             | 14. PS<br>, PM                                                         |
| Community factors  | 15. Customs/ other activities in the community during vaccine days; other commitments and therefore don't attend clinics for vaccinations<br>16. Pay for clothes to dress baby for health centre<br>17. At times, ignorance because of laziness<br>18. all depend again on the mother; no support from husband. They rely mainly on mothers to do all the visits or carry the baby to the clinic<br>19. Plenty kids and cannot take all of them to the clinic | 15. P<br>M, VM<br>16. W<br>S<br>17. V<br>M<br>18. V<br>M<br>19. V<br>M |

#### 7.4 Integration – preferences on what to add to immunization services

| Theme                   | Responses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Sites                            |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Family planning         | 1. We want family planning to be combined with immunization; integrate family planning with immunization; family planning should be integrated; family Planning to be combined with immunization; FP; FP; FP                                                                                                                                                                                                                                                                                | 1. KS, RM, WS, RS, VS, BS, VM,   |
| Women's health          | 2. Combine immunization with mothers general health check; combine obstetrics and gynaecology; general out patient should be done too to check blood and other illnesses; clinic must be held for both mum and children; we want mother's health to be assessed as well including nutrition and personal hygiene; good to have health care for mothers and babies together<br>3. Nutritional advice for mothers so they have more information and are to eat from the 3 balance meals a day | 2. NS, WS, VS, PM, VM,<br>3. VM  |
| Women's illness care    | 4. Combine TB, STI<br>5. mothers will be checked for other illnesses                                                                                                                                                                                                                                                                                                                                                                                                                        | 4. NS<br>5. PS                   |
| Child care              | 6. Know what to do when it comes to sickness<br>7. Breast feeding advice for mothers so they are able to be able to feed their babies better<br>8. Check baby's health and to check if the baby has other diseases                                                                                                                                                                                                                                                                          | 6. VM<br>7. VM<br>8. PS          |
| Other priorities        | 9. Education should be provided to both mothers and fathers so they are able to make better family decisions                                                                                                                                                                                                                                                                                                                                                                                | 9. VM                            |
| Reasons why integration | 10. Because of bus fare and lack of transport; because it will help save cost instead of coming back the next day or a different day; to minimise bus fare, as for the working                                                                                                                                                                                                                                                                                                              | 10. KS, WS, RS, BS, PM<br>11. WS |

|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                 |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| favoured | <p>mothers, I want to report to my manager with one medical certificate instead of two. "I can kill two birds with one stone, which is good"; because I don't want to come back the other day for FP; due to cost of transport fees especially for parents with many kids</p> <p>11. some mothers are shy to ask for other services like family planning so when they integrate, it will help such mothers</p> <p>12. because it makes easier for us mothers; because mothers health important</p> <p>13. Mothers and fathers will be educated so they are able to know what to do when it comes to sickness or immunization</p> | <p>12. NS, PM</p> <p>13. VM</p> |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|

### 7.5 Postnatal care – what to check, when and where

| Theme                            | Responses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Sites                                                                                                                                       |
|----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Preventive care                  | <p>1. General Health check for both mother and baby; check if baby is ok generally; proper neonatal care, check for abnormalities or injuries during birth; check new born babies and check general health for babies</p> <p>2. Family planning; FP services and counselling;</p> <p>3. Check for reproductive system of mother; reproductive system; mothers health and reproductive system</p> <p>4. Check our bloods so that we are aware of our blood level after birth</p> <p>5. Check if mother is breast feeding; breast feeding advice; mother if she is still breast feeding and baby is still breast feeding and check if mother is ok with the breast because sometimes mothers face problems with the breast</p> <p>6. Check baby if passing waste</p> <p>7. Nutritional advice for family; nutritional diet for both mothers and babies</p> <p>8. Personal hygiene</p> | <p>1. NS, WS, BS, VM</p> <p>2. RS, BS</p> <p>3. RM, BS, PM</p> <p>4. WS</p> <p>5. WS, VS, VM</p> <p>6. WS</p> <p>7. PM, VM</p> <p>8. PS</p> |
| Pre-discharge check              | <p>9. We want mothers to be thoroughly examined before discharge, examine the baby properly before discharge; health workers to check both mother and baby well before discharge; health workers to check babies properly before sent home, health workers to check mother health well before discharge;</p> <p>10. All babies must be vaccinated before discharge</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>9. KS, RM, RS,</p> <p>10. NS</p>                                                                                                         |
| Post-partum complications mother | <p>11. Many mums feel abdominal pains when not cleaned properly and some mothers still bleed; check mothers on personal hygiene and what to use when having menstrual period or when still bleeding</p> <p>12. Malaria; malaria and TB; malaria and AIDS</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>11. WS, VM</p> <p>12. VS, PM, PS</p>                                                                                                     |

|              |                                                                                                                                                                                                                                                                                                                                                              |                            |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Home visit   | 13. Want health workers to do follow ups to the village; nurse should check mum while at home; check up to occur at home                                                                                                                                                                                                                                     | 13. RM, WS, PM             |
| Other issues | 14. Nurses are too harsh on us during labour and we want them to understand us and treat us with respect.<br>15. Give pain killers to mothers<br>16. Health worker must use simple and local language on FP especially TL so mothers understand the consequences well before they can sign the consent. If they use Kuanua (local language) it would be good | 14. KS<br>15. NS<br>16. RS |

## 8 Senior stakeholders consultations

### 8.1 Introduction, sources, and usage of these findings

This summary of stakeholder views reports on interviews for Phase 1 of the Health Services for Postnatal and Infancy Care, Healthy Mothers Healthy Babies Study 2a (HMHB). The aim was to consult national, provincial and district stakeholders to develop theories regarding the determinants of coverage with routine, preventive health services during infancy in rural PNG.

These are based on open loosely-structured interviews with national, provincial and district stakeholders (annexed). Interviews covered immunization care, other preventive services at the time of well baby clinics, postnatal care, and the new government strategy for planning of immunization and other services: Special Integrated Routine EPI Program (SIREP). Probes encouraged stakeholders to reflect on determinants of coverage, contexts where coverage varied, and underlying mechanisms behind barriers or enablers of coverage. Interviews were carried out by two PIs (Chris Morgan and Nelly Saweri), one CI (Liz Peach), supported by the Burnet Institute Program Representative in Port Moresby (Thalia Wat). Liz Peach undertook all interviews carried out at provincial and district levels.

Stakeholders consulted include:

- Four national program managers, government, WHO and UNICEF
- Four senior clinicians working at national level
- Eight program managers or coordinators at provincial or district levels
- Three clinicians working at provincial level.

The sections below list barriers and enablers for immunization (and other well-baby clinic) services and postnatal care; list specific elements of the SIREP strategy that should be assessed in field evaluations; and list suggestions for improved integration of other services at immunization clinics. These views (which supplement document review) are used to refine the data collection tools to be used in interview, observation and audit of services during the field-work in phase 2. As discussed in the protocol, the approaches of realist evaluation inform both study phases; at this interim step an attempt was made to collate informants' theories on the *mechanisms* by which barriers or enablers operate, and any specific *contexts* that affect their operation. These theories will then be tested as part of formal data collection in Phase 2 of the study, with analysis aiming to identify configurations of context and mechanism that are linked to particular outcomes in terms of service provision in East New Britain province (ENB).

Responses regarding barriers and enablers of infancy preventive care were more numerous. In these lists, we have indicated at which level responses were mentioned: *national*, provincial or district (*P/D*), or *Both* (if a view was expressed at both levels).

### 8.2 Barriers to immunization and routine preventive care in infancy

This list notes at which level responses were mentioned: *national*, provincial or district (*P/D*), or *All* (if a view was expressed at both levels).

## Funding for operations, especially for outreach services (fuel, allowances, supplies):

- *All*: overall funding insufficient
- *All*: some funds not being accessed due to procedural issues or managers not knowing how to access available funds
- *P/D*: some funds late or not available
- *P/D*: mismatch between program priorities and funding allocations
- *P/D*: one voice noting fees for service a barrier in some areas

## Supplies and equipment

- *All*: failures of cold chain equipment at every level, in terms of absolute supply, breakdowns not replaced, and poor matching of equipment to situation
- *P/D*: vaccine stock-outs in national supply and at facility (not mentioned nationally)
- *P/D*: sharing between stores or facilities can overcome some supply problems

## Planning, organisation and management

- *All*: poor organisation of outreach, plans for service provision not implemented
- *All*: OIC management skills crucial, including creative problem-solving
- *All*: insufficient staff for workload
- *National*: need for population based planning, better catchment understanding (not mentioned at P/D)
- *National*: points to failures of supervision (not mentioned at P/D)
- *P/D*: planning, service delivery, commodities and supplies are all managed through different national systems, with different accountabilities, constraining efficiency
- *P/D*: some criticism of overly centralised planning (national or provincial) with desire for more decentralisation to district level

## Gaps in staff knowledge, attitudes, skills

- *All*: some knowledge gaps, *National*: gaps around new vaccines, population dynamics
- *All*: lack of incentives for rural service or outreach
- *All*: skills and technical support in measurement and monitoring lacking
- *All*: lack of staff motivation to provide required services, particularly without additional incentives.
- *All*: not client-oriented in attitudes to service provision, lack of focus on comforting infants during vaccination and educating parents on importance of immunization and immunization schedule.

## Community, demand-side barriers

- *All*: lack of awareness of schedule and services,
- *All*: some mention of complacency regarding vaccine-preventable diseases
- *All*: remoteness, travel costs
- *All*: some mistrust or rumours in specific, localised groups. *P/D*: conflates resistance to immunization with distrust of contraception
- *All*: lack of awareness of the importance of preventive as opposed to curative interventions.
- *National*: heterogenous communities with mixed clans, may be associated with some bias on part of service providers



- *P/D*: fees (formal/informal) for service mentioned by one respondent as a disincentive [noting national policy stipulates preventive primary care should be free]

### 8.3 Enablers of immunization and routine preventive care in infancy

Mention of enablers were fewer in number and from fewer respondents. When these were specifically probed for by the interviewer, they tended to be opinions on enablers that were prevalent in the past, or which were seen as potential supports for the future.

Specific enablers mentioned:

- *All*: creative, diligent OICs and other local managers. *P/D*: included mention of good communications, regular staff meetings, ability to air and address grievances
- *National*: new tools for population based planning and rapid convenience monitoring are hoped to enable better coverage
- *P/D*: some examples in parts of ENB of good coordinated planning between government and church health services mentioned
- *P/D*: coverage and services seen as better where an institution has greater control over staff deployment, as in church health services
- *P/D*: one mention of the potential to outsource service provision
- *National*: some mention of village health volunteers (VHVs) as potential for mobilisation of communities, and possibly support to some service provision
- *P/D*: a range of things said to work well in the past but are no longer active
  - Mobile health clinics mounted in a vehicle (non-government organisation)
  - Incentives to keep staff in rural areas
  - Village level active communication and reminders

### 8.4 Determinants of routine preventive postnatal care

These questions were introduced by asking the respondent to note that current national policy on postnatal care specifies a visit (either facility or home) with mother and baby three times in the first week of life; consistent with global WHO recommendations. No enablers of this were mentioned, nor were there any mentions of this actually happening, apart from mothers who remain in hospital for a period of time following a facility-based delivery.

Barriers to, and potential enablers of, routine preventive postnatal care did vary somewhat by level of informant and included:

- *All*: early discharge following facility-based delivery is a key constraint – driven by insufficient beds, and community attitudes
- *All*: awareness and attitudinal barriers among both families and health care providers, who see little value in routine post-natal care, with a sense of complacency that the health care work is completed when the baby is delivered
- *All*: post-natal care is not yet established within current structures of preventive care services, despite new policy
- *National*: need for inclusion of postnatal depression in PNC service package
- *All*: home visits could be useful but models to do this effectively or at scale have not been demonstrated in PNG

- *P/D*: there is a critical role for men, one respondent suggested that fathers may obstruct postnatal care seeking, another respondent felt that fathers and brothers are increasingly involved in antenatal care and could promote postnatal care
- *P/D*: there is a need to push preventive care out of hospitals, into rural or urban clinics, to enable access outside the inpatient post-partum period

### 8.5 Responses on specific issues: SIREP, integration, and clinician views

The **Special Integrated Routine EPI Strengthening Program (SIREP)** that was rolled out in 2015 and 2016 is a focus of this study and stakeholders were asked for opinions on the determinants of its success and how they might be measured. Responses include:

- *National*: a list of specific knowledge and practice elements to be assessed were provided, none of which were mentioned at *P/D* level, comprising:
  - Existence of population based micro-plan
  - New records of target populations, with multiple databases consulted
  - Plans for rapid convenience monitoring
  - Whether any secondary training has taken place within facilities
  - Whether any new approach to planning outreach, including division of sites into more frequent (monthly) or less (quarterly) visit schedules
- *P/D*: needs repeated input and more central technical support, still at an early stage (additionally, some stakeholders were not aware of the program or sure of what changes had been introduced with the program), *National* noted that current roll-out is around planning rather than implementation
- *National* noted SIREP has new funds attached but *P/D*: raised concerns that new approach to planning not backed up by funding
- *All*: strong sense that a new strategy for immunization, as seen in SIREP, is warranted due to fatigue with immunisation campaigns or “supplementary immunization activities” (SIA), blaming campaign mode for some poor staff attitudes, and wanting SIREP to be an intensification of routine immunization, not a new form of campaign.

**Integration** of other services with immunization is proposed by SIREP and a number of other national policy documents, so respondent views on the determinants of this were sought:

- *All*: strong sense that there are missed opportunities through immunization not being offered during clinical care of the sick infant or general outpatient care, with the exception of birth-dose vaccination as part of immediate newborn care, which was felt to be reasonably well integrated for deliveries that took place in facilities
- *National*: some sense that past SIA campaign models of immunization service provision worked to discourage integration, with one informant suggesting SIAs did allow integrated service delivery
- *All*: need for more coordinated planning between maternal and child health programs
- *All*: efficiency and supply side resource usage the major driver, still a failure to see co-morbidity or demand-side needs as reasons for integration

- *P/D*: Some stakeholders did not see integration as feasible or as a priority whilst others were strongly in favour of increasing effectiveness and efficiency of service delivery through integration.
- Priorities suggested for future integration of services with immunization included:
  - *All*: family planning, nutrition checks, feeding advice
  - *National*: vitamin A, albendazole (as per SIREP plan), tuberculosis
  - *P/D*: NCDs – especially by integrating clinical or diagnostic screening

**Clinician comments** generally echoed those of program managers, with some variation in viewpoint in that:

- Clinical respondents more often mentioned missed opportunities through failure of integration with clinical care, and
- Clinical respondents less often mentioned community-based options such as VHVs
- Clinicians at provincial level stated that outreach or supervision visits are limited mostly by lack of resources for transport, rather than lack of clinician time.

## 8.6 Mechanisms implied by consultations so far

In keeping with realist evaluation theory, the responses provided were scanned for respondents' views on the mechanisms by which determinants mentioned affected service coverage or provision. These were both *expressed* (in response to question probes on this) and *implied* (where this was clear within the response) mechanisms, and represent respondent theories on how barriers or enablers determine program outcomes; theories that can be explored further during the next phase of data collection. The various mechanisms extracted from analysis so far are listed below.

1. **Insufficient health system resources** limit staff, supplies, equipment available for service delivery, noting this is:
  - a. Seen as a pervasive mechanism although many other more locally remediable mechanisms were also implied (see other sub-sections below);
  - b. Funds and human resources less than global norms or national policies specify, these add to management stress, generate high workloads, cause staff demotivation, and practical difficulties of service delivery;
  - c. Fixed facilities are insufficient in number, not well distributed, and inadequately equipped; so the majority of the population can only be reached by outreach or community-based care. Vaccination requires outreach by skilled, equipped staff due to storage and administration characteristics of vaccines, and outreach requires resources and planning skills that are currently insufficient
2. **Inadequate cold chain equipment** is a specific resource limitation, including poor application of non-electric technologies (solar, gas), that creates a critical over-riding constraint on immunisation services because this limits the most peripheral point at which vaccines can be stored,
  - a. Also limiting outreach because current non-vehicle portable cold chain technology can only just support a single overnight trip, or single day trips

3. **Failures of procurement, distribution and allocation of existing resources** – commodities, equipment (including cold chain), funds – by national and/or provincial management mean non-implementation of planned activities, including:
  - a. National stock-outs of vaccines, and
  - b. National/provincial distribution errors restricting vaccine supplies available to stores and facilities
  - c. Vaccines or equipment already procured not distributed to where needed.
4. **Inadequate understanding of catchments and populations**, coupled with inexperience in basing micro-plans on this information, means:
  - a. Outreach is mis-directed and outreach resources inefficiently used; and
  - b. Poor collection, local analysis and use of data in the health information system limits understanding of clients, identification of gaps or delays
  - c. Lack of population data is also a contributor to forecasting mis-calculations that lead to national stockouts (although there are additional mechanisms driving stockouts including funding shortfalls, inefficient planning and occasional global shortages).
5. **Specific management gaps mentioned** that lead to inadequate service delivery:
  - a. Managers are not aware of the existence of resources (eg in district or provincial Services Improvement Programs), and/or how to access them, meaning outreach or other services not provided
  - b. Managers do not have the skills to be able to effectively plan and organise services and staff in line with existing programs and policies
  - c. Ineffective or unrealistic planning leads to mismatch between plans and implementation, creating uncertainty and distrust with staff and clients
  - d. Without active management of staff uncertainty or grievance clinical staff are demotivated in provision of vaccination
6. **Specific staff knowledge/attitude** issues:
  - a. Staff said to be unwilling to undertake outreach without additional monetary incentives such as those offered during special campaigns – underlying mechanism not cited, possibly poor pay and conditions or possibly demotivation from other system failures
  - b. Staff said to be unwilling to comply with, or unaware of, policies to open multi-dose vials for every opportunity vaccination mean children are not vaccinated at every opportunity, perhaps exacerbated by staff distrust of security of vaccine supplies
  - c. A mechanistic approach to vaccination restricting conceptualisation of the task to correct injection, means effective communication with the client is not prioritised and limited counselling on the nature of vaccination, next visit etc, fails to engage clients in the program

7. **Community** (dis)engagement and low levels of care seeking
  - a. Many responses proposed that low knowledge among families of both benefits (especially of post-natal care) and what is recommended (both postnatal care and immunization), leads to decreased care-seeking
  - b. Other factors interact with low knowledge to exacerbate decreased care-seeking:
    - i. Distrust or demotivation from experience of past service delivery failures (such as stockouts or mobile teams not arriving as planned)
    - ii. Other family priorities that supervene – especially for poorer families more dependent on subsistence farming
    - iii. Compounding cultural and geographical barriers that make care seeking additionally difficult
    - iv. Fees, formal or informal, direct or ancillary, acting as discouragement (even fear of fees) or actual barrier to poorer families, and those more distant who spend more on transport
  - c. Some specific anti-vaccination (or anti-contraception) rumours actively obstructed care-seeking, but not a pervasive mechanism and seen as highly localised in time and/or place
8. Compliance with policy is not enough: **creative problem solving** in addition to diligent local leadership is needed to overcome contextual difficulties, staff disaffection, overly complex procedures, and system failures; without this plans are not implemented, and services remain incomplete

### 8.7 **Context issues**

Realist evaluation theory requires that *mechanism* be linked to the specific *contexts* that affect the way they lead to particular *outcomes*, with outcomes in this case relating to coverage and quality of service delivery. These configurations that link context and mechanism will be described in the analysis of phase two of this study.

Stakeholders interviewed for phase one were also asked to consider specific contexts that would affect the way barriers or enablers determine coverage, and noted:

- Certain geographic locations with poorer access, especially those in hills (Bainings and Pomio) and those inaccessible except by water;
- Communities with mix of ethnic groups/clans – may be more likely to have pockets with lower uptake, and possibly where health care providers are less likely to offer services;
- Organisational restructures with district decentralisation, that may have benefits in tighter controls over staff and funding, but have also complicated funds distribution with lower awareness of where funds are and how to access them;
- Government and Church Health Services have different levels of control over staff deployment and micro-planning; but both are expected to provide primary health

care for free<sup>3</sup> and comply with national/provincial policies on service delivery (including SIREP and expectations for doing outreach;

- Some generic approaches or decisions taken at national level, eg move away from SIAs and campaigns, were felt to not always be appropriate in ENB.

## **8.8 Issues not addressed by stakeholders**

A number issues in and determinants of service delivery went unmentioned; these were issues we had expected to be relevant based on our prior experience and review of PNG and global literature. They had been included in initial protocol development and will be retained in phase 2. Issues we expected to canvas, but did not, include:

- Discussion of quality of services, although included in question guides proved difficult to answer, perhaps because of lack of a common understanding of quality frameworks as applied to preventive services;
- The difference in barriers and enablers between ANC (at high coverage) and EPI (at much lower coverage) was rarely mentioned, apart from fact that EPI is impossible without cold chain, and is also traditionally seen as reliant on outreach; in contrasting ANC with PNC some at provincial level mentioned that ANC coverage was much higher because there has been an emphasis on promoting its importance to healthcare workers over recent years at national and provincial levels, but that there is very little emphasis on or recognition of the importance of after delivery care
- Specific mention of a perception of unfriendly or scolding staff discouraging repeat attendance (something noted in qualitative research in PNG in the past);
- Enlistment of community engagement in practical support to service delivery, such as logistics for outreach, part from the mention of VHVs by some at national level;
- The presence of co-morbidity or multiple health needs in families as a key driver of the need for integrated services was not mentioned by any stakeholders – integration was seen only as relevant to more efficient use of health system resources and clients' time.

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<sup>3</sup> Historically church health services were permitted to charge fees, but legislation in 2014 required all primary health care to be free of charge; implementation of this was compromised in mid-2015 when severe govt budget cuts resulted in some facilities reinstating fee charges to remain viable.

#### **10.4.2    *Copy of publication arising from Chapter Seven***

RESEARCH ARTICLE

Open Access



# Strengthening routine immunization in Papua New Guinea: a cross-sectional provincial assessment of front-line services

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## Abstract

**Background:** Routine immunization programs face many challenges in settings such as Papua New Guinea with dispersed rural populations, rugged geography and limited resources for transport and health. Low routine coverage contributes to disease outbreaks such as measles and the polio that re-appeared in 2018. We report on an in-depth local assessment that aimed to document immunization service provision so as to review a new national strategy, and consider how routine immunization could be better strengthened.

**Methods:** In East New Britain Province, over 2016 and 17, we carried out a cross-sectional assessment of 12 rural health facilities, staff and clients. The study was timed to follow implementation of a new national strategy for strengthening routine immunization. We used interview, structured observation, and records review, informed by theory-based evaluation, a World Health Organization quality checklist, and other health services research tools.

**Results:** We documented strengths and weaknesses across six categories of program performance relevant to national immunization strategy and global standards. We found an immunization service with an operational level of staff, equipment and procedures in place; but one that could reach only half to two thirds of its target population. Stronger routine services require improvement in: understanding of population catchments, tracking the unvaccinated, reach and efficiency of outreach visits, staff knowledge of vaccination at birth and beyond the first year of life, handling of multi-dose vials, and engagement of community members. Many local suggestions to enhance national plans, included more reliable on-demand services, integration of other family health services and increased involvement of men.

**Conclusions:** The national strategy addresses most local gaps, but implementation and resourcing requires greater commitment. Long-term strengthening requires a major increase in centrally-allocated resources, however there are immediate locally feasible steps within current resources that could boost coverage and quality of routine immunization especially through better population-based local planning, and stronger community engagement. Our results also suggest areas where vaccination campaigns in PNG can contribute to routine immunization services.

**Keywords:** Papua New Guinea, Low- and middle-income country, Routine immunization, Campaign, Vaccination, Measles, Polio, Health service delivery

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## Background

Stronger routine immunization programs are critical to the ambitious Global Vaccine Action Plan (2011–2020), however immunization coverage is not increasing as planned in many difficult settings challenged by expanding childhood cohorts, population displacement by conflict or natural disasters, and limited resources to overcome geographical and infrastructural challenges [1, 2]. With the outbreak of polio in 2018, Papua New Guinea (PNG)'s immunization program faces the question familiar to fragile systems enduring a crisis, that is: how in the wake of a major, rapid emergency response to plan for long-term strengthening of a program that has shown no increase in coverage over the past 15 years. The World Health Organization (WHO) and United Nations Children's Fund (UNICEF) estimated PNG's 2017 coverage at 62% for both the third dose of diphtheria-tetanus-pertussis-containing vaccine (DTP3) and the first dose of measles-containing vaccine (MCV1), and at 60% for the third dose of oral polio vaccine [3], contrasting with Western Pacific Regional averages of 97% [4] for these antigens.

Measles, having been suppressed by regular supplementary immunization activities (SIAs) for 8 years, returned to PNG in a major outbreak in 2014, and polio, after a 20 year hiatus, returned in 2018 [5, 6]. In that year, PNG was one of five countries experiencing outbreaks of circulating vaccine-derived poliovirus disease [6, 7], the rare mutated form that results from persistent low coverage with the oral polio vaccine. This has required one of PNG's largest public health emergency responses, led by the national government with support from Global Polio Eradication Initiative and other development partners [8]. In the short-term, the response entailed repeated SIAs, with longer term plans for program reform, recognizing that it is sustained gaps in routine immunization services that are the primary cause of this form of polio [7].

This paper reports on a cross-sectional health services assessment investigating PNG government efforts to improve routine immunization prior to the polio outbreak. PNG had in 2015 introduced a new strategy to improve routine immunization and reduce reliance on SIAs, termed the Special Integrated Routine EPI Strengthening Program (SIREP) [9, 10]. This sought to improve program performance amidst the major challenges facing PNG's health services such as a stretched health workforce, financial constraints, and dispersed rural populations with minimal road access [11]. SIREP had four priorities: more efficient local planning based on locations of child populations, intensification of outreach services with realistic scheduling based on local resources, improved local information systems (including child health books), and staff training to support new vaccine introductions (most prominently Inactivated

Polio Vaccine (IPV) as well as pneumococcal and rubella vaccines). SIREP also aimed to integrate other primary health care with vaccination, starting with limited curative care, and addressing malnutrition through distribution of age-targeted vitamin A and anti-helminthic doses of albendazole [12]. SIREP attempted to merge the program intensification often seen in emergency campaigns [12] with internationally proven strategies for routine programming, such as those collated by WHO in "Reaching Every District (or Community)" [13] approaches and the Global Routine Immunization Strategies and Practices framework [14]. Our study aimed to investigate the relevance and effectiveness of SIREP in strengthening routine immunization through an assessment of front-line services. Such assessments are important to help guide the improvement of routine systems; an important longer-term complement to emergency responses such as those for polio.

## Methods

### Study concept and objectives

Our study focused on modifiable aspects of front-line services recognizing that, for coverage to increase, strategies to strengthen health system elements must ultimately enable changes in service delivery and uptake. Study objectives were to measure current infrastructure, equipment and supplies for preventive care in infancy; assess what health workers know, think and do in relation to providing postnatal and infancy services; assess health workers' responses to new strategies; and identify opportunities for health system strengthening and improved quality of care. We devised an evaluation framework that explicitly tested important elements of the SIREP strategy (noted in the Introduction), and that also referenced WHO standards for routine immunization programs [14, 15].

### Study setting and timing

Our study setting was East New Britain province (ENBP), part of a large island in PNG's north-east, whose population (approximately 393,000) [16] live in small towns and rural villages in highland and coastal topographies. Immunization is usually provided through urban clinics, small rural health centres, scheduled outreach to community sites, and hospital children's outpatients. ENBP performs relatively better than other PNG provinces on some indicators (such as skilled attendance at childbirth), but immunization is similar to national estimates with 60% of children receiving DTP3 and 48% MCV1 in 2016 [17]. Our research was nested within a long-term multi-partner research initiative in ENBP termed Healthy Mothers Healthy Babies (HMHB) that examines broader issues of women's and children's health.

We carried out a cross-sectional assessment of health facilities, staff and clients from November 2016 to January 2017, timed to follow the initial rounds of SIREP training and implementation. Sites surveyed comprised 12 clinics providing immunization services, nine in fixed facilities and three community outreach sites; purposefully chosen as they are all linked to the health institutions providing approximately 80% of maternal and child health care in ENBP [16]. Respondents for interview were chosen to provide a mix of seniority across front-line positions (Table 1).

#### Data collection tools and ethical considerations

Table 1 summarises the mix of interview, focus group discussion, structured observation and records audit. All tools reflected our evaluation framework by incorporating items testing core elements of the SIREP strategy, PNG's national immunization plans [11] and WHO standards for program monitoring [15], refined through consultation with national and provincial health managers. We also adapted WHO's 2015 Immunization Session Checklist [15] into a structured observation tool, devised a local tool to observe patient flow, and used concepts from realist evaluation to deepen interview questions with probes seeking respondents' views on context and mechanisms of change.

Data collection was carried out by trained local research officers using electronic tablets supplemented by paper-based note-taking. The research team included policy-makers and managers at national and provincial levels; however these investigators were excluded from front-line data collection or initial analyses, to avoid bias. Research officers were trained in quantitative and qualitative data collection, including techniques to minimise social acceptability bias, and to assess and counter perceived power imbalance between themselves and interview subjects. All free-text interview responses were recorded verbatim, focus group discussions were documented by a dedicated note taker, and both were digitally recorded for cross-checking. Interviews were conducted in English and

focus group discussions in Tok Pisin; both official languages of PNG.

#### Analysis

Quantitative measures from audit, structured observation and interview elements (such as for knowledge) were reported as proportions with no further statistical manipulation, respecting the purposeful sampling in our design. Thematic analysis of qualitative data was carried out by the first author (after translation of focus group discussion data), then validated by three other investigators (including two Tok Pisin speakers). After coding for themes predetermined in our conceptual framework and design, data were re-examined for emergent themes. In 2017, for critique and validation, a detailed data report was provided to all investigators and a summary provided to national and provincial stakeholders; this also allowed early dissemination of policy implications. Additional file 1 is available detailing tables of all themes derived from interview and focus group discussions, and data structure for the observational tool.

#### Results

Key findings from all data sources are summarised under six categories (Table 2) from our evaluation framework that combined priorities addressed by the national SIREP strategy [5, 11], WHO program advice [15] and the results of our thematic analysis. We present quantitative and qualitative findings in combination, to show the overall finding against each element of the evaluation framework, in particular the degree to which SIREP objectives were seen in practice. Findings were additionally categorised as either local strengths or areas needing improvement, with decisions on this allocation being made by the research team. A comprehensive table of findings and themes is available as Additional file 1, Tables 1 and 2.

#### Local service planning, infrastructure, supplies and staffing

Findings demonstrated that services were largely provided as planned from static clinics and some outreach

**Table 1** Data collection, respondents and tools

| Study subjects                      | Number | Details                                                         | Tools                                                                                                                                                                                                                                                                                                        |
|-------------------------------------|--------|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Primary health care staff           | 6      | Health Extension Officer or Specialised Nursing Officer         | Semi-structured interviews (mix of quantitative and qualitative fields)                                                                                                                                                                                                                                      |
|                                     | 6      | Nursing officers                                                |                                                                                                                                                                                                                                                                                                              |
|                                     | 6      | Community Health Worker (CHW)                                   |                                                                                                                                                                                                                                                                                                              |
| Family members                      | 67     | Caregivers of infants being vaccinated, 66 female 1 male        | Focus group discussion (10 groups)                                                                                                                                                                                                                                                                           |
| Health clinics and their operations | 9      | Child or family health clinic, static                           | Audit of infrastructure and equipment against PNG standards as described in national EPI plan [11].<br>Observation of general clinic procedures (12 sites)<br>Observation using WHO Immunization Session Checklist (11 sessions)<br>Observation of patient flow and staff-patient interactions (15 patients) |
|                                     | 3      | Mobile child health clinics (run by staff from the above sites) |                                                                                                                                                                                                                                                                                                              |

**Table 2** Key findings, categorised by study themes, encompassing SIREP and WHO program improvement priorities

|                                                                                                                   | <i>Strengths in local systems</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <i>Opportunities for improvement in local systems</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Local service planning and delivery<br><i>Data sources: interview and audit</i>                                   | <ul style="list-style-type: none"> <li>Recent innovations recognised by most (14/18) staff: new vaccines or planning, with one mention of new quarterly outreach increasing efficiency</li> <li>Recent in-service training in SIREP reported by many (11/18) staff</li> <li>Static services available 5 days per week</li> <li>All clinics tallied vaccinations to report into national health information system</li> <li>82% of clinics conducted as planned (annual total of 109 implemented of 133 planned)</li> </ul>                                                   | <ul style="list-style-type: none"> <li>Outreach was limited - minority (2/9) static facilities used outreach with overnight stays for remote areas</li> <li>Outreach planning process not able to be described by half the staff, less than a quarter planned on population basis, no clinics used population data to estimate outreach supply quantities</li> <li>Many clinics with few patients: mean 17/clinic, IQR 3–26, maximum = 62</li> <li>Estimation of coverage impossible for more than half (10/18) staff due to lack of catchment data, only one clinic displayed coverage</li> <li>No clinics with lists of children overdue for vaccination, one third of clinics used child registers</li> <li>Local reasons for clinic cancellation were adverse weather, lack of transport or slow disbursement of funds</li> </ul>        |
| Infrastructure and supplies<br><i>Data sources: interview, audit and observation</i>                              | <ul style="list-style-type: none"> <li>Most clinics had road access, with two outreach clinics on walking trails</li> <li>Water supply in nine (of 12) clinics and electricity in eight (of 9) static sites</li> <li>Functional injection equipment, safety boxes and weight scales in all clinics</li> <li>10 (of 12) clinics with appropriate, functioning cold chain equipment</li> <li>Supplies of all relevant vaccines (including IPV and PCV) and injection equipment present</li> <li>No expired or discontinued vaccines found</li> </ul>                           | <ul style="list-style-type: none"> <li>Eight (of 12) clinic sites needed renovation (by local standards), 9 (of 12) did not have usable toilets</li> <li>No clinics with kits for managing severe acute adverse events</li> <li>Cold storage monitoring inconsistent, no clinics with written temperature records</li> <li>Half the clinics had clear records of vaccine stock usage, not well reconciled with tallies of patients vaccinated, none able to match supply to population</li> <li>Recording forms did not clearly account for three new vaccines: IPV, PCV, MR</li> <li>Lack of important guidance documents: one (of 12) had an immunization manual, and four had child health standard treatment guidelines</li> </ul>                                                                                                       |
| Staff knowledge and staff practice during immunization sessions<br><i>Data sources: interview and observation</i> | <ul style="list-style-type: none"> <li>More than half of staff could correctly cite recently introduced vaccines (11/18) and handling of lyophilised multi-dose vials (15/18)</li> <li>Twenty staff (nurses and CHWs) across 12 clinics, vaccinating mean of 17 children per clinic falls below WHO maximums (30 per staff member [15]);</li> <li>Core interactions (weight, screening and vaccination) done for 14 of 15 observed patients</li> <li>Observation against WHO session checklist (Fig. 1) shows key elements of safe injection in over 80% sessions</li> </ul> | <ul style="list-style-type: none"> <li>Less than half of staff could correctly cite immunization schedule (8/18), one national program target (3/18), storage temperature (6/18), interpret vaccine vial monitor display (3/18), or handling of liquid multi-dose vials (2/18)</li> <li>Some important functions omitted in patient flow observations: educational interactions observed for just two of 15 patients, preventive care for mother and AEFI monitoring observed in none</li> <li>Waiting times in 15 patient flow observations were significant: mean 51 min arrival to final interaction (IQR 13–90, maximum 210)</li> <li>Observation against WHO session checklist sessions shows gaps in preparatory checking of vaccines, client communication and AEFI observation, and (for less than 20%) in safe injection</li> </ul> |
| Missed opportunities for vaccination<br><i>Data sources: interview, audit and observation</i>                     | <ul style="list-style-type: none"> <li>Most staff (13/18) stated they would open a multi-dose vial for just one patient</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                           | <ul style="list-style-type: none"> <li>Due vaccinations had been missed in 3 of 10 Child Health Record books</li> <li>Reasons for missing vaccination included vaccine out of stock, clinic visit not for purpose of vaccination, or (for birth doses) childbirth in community</li> <li>Two (of 15) observed patients asked to return another day for vaccination</li> <li>Thirteen (of 17 respondents) staff stated they would usually ask a sick child to return at</li> </ul>                                                                                                                                                                                                                                                                                                                                                             |

**Table 2** Key findings, categorised by study themes, encompassing SIREP and WHO program improvement priorities (*Continued*)

|                                                                                                                      | Strengths in local systems                                                                                                                                                                                                                                                                                                                                                                                                                       | Opportunities for improvement in local systems                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Integration of other services<br><i>Data source: interview and observation</i>                                       | <ul style="list-style-type: none"> <li>• All staff noted a policy of integrating other care and vaccination</li> <li>• Nine (of 18) staff cited at least one other care (usually childhood illness) regularly integrated</li> <li>• Child illness care available in nine (of 12) clinics</li> <li>• Child illness care accompanied vaccination in seven (of 15) observed patients</li> <li>• Weight measured in all observed patients</li> </ul> | <p>another time for vaccination</p> <ul style="list-style-type: none"> <li>• Four (of 18) staff mentioned maternal health service as integration option</li> <li>• Three clinics (of 12) lacked supplies, or service organization, to integrate childhood illness care with vaccination</li> <li>• No observation of catch-up vaccination with children presenting for illness</li> <li>• Three (of 15) patients observed to receive feeding counselling, two to receive vitamin A, 1 to receive albendazole</li> <li>• No observations of maternal preventive care or counselling</li> <li>• Staff reported insufficient numbers as main constraint on integrated care</li> </ul>                                                            |
| Community engagement and family viewpoints<br><i>Data sources: interview, observation and focus group discussion</i> | <ul style="list-style-type: none"> <li>• Three (of 12) clinics provided verbal group health education alongside vaccination sessions</li> <li>• Three (of 18) staff reported support (for example food) provided by local communities</li> <li>• No fees for vaccines reported or observed and families did not report fees as barrier to vaccination</li> </ul>                                                                                 | <ul style="list-style-type: none"> <li>• No reported use of community-based trained lay health workers to help with organization, mobilization or education.</li> <li>• Six (of 12) clinics charged small administrative fees</li> <li>• Many families (6/10 groups) cited travel time, and transport costs, as significant constraints on timely attendance for vaccination</li> <li>• Many families (6/10 groups) sought more mobile clinics, more "on-demand" vaccination, and more reliable clinic timing</li> <li>• Some families (4/10 groups) sought more respectful staff-client interactions</li> <li>• No male family members were observed in attendance, staff cited embarrassment as a constraint on male involvement</li> </ul> |

Notes: SIREP Special Integrated Routine EPI Strengthening Program, IPV Inactivated polio virus vaccine, PCV Pneumococcal vaccine, MR Measles-rubella combination vaccine, IQR Interquartile range

sites (Table 2). Several key aspects of SIREP were not yet implemented; there was limited intensification of outreach, no selective targeting of population concentrations, and minimal systems for tracking and finding under-vaccinated children. Infrastructure and supplies review showed a functional level of infrastructure, equipment and supplies across almost all operating clinics, as judged against standards in the national EPI plan. New vaccines were being deployed in keeping with the SIREP strategy and, reassuringly, no expired or discontinued vaccines (such as trivalent oral polio vaccine) were found. However there were important unmet needs for renovation, equipment renewal, improved temperature monitoring, and availability of guidance documents. A significant gap was the absence of equipment to manage severe adverse events following immunization (AEFI). Overall staffing was within WHO global standards for workload (30 vaccinees per staff member [15]) at current levels of operation, noting a number of clinics with relatively few patients (25% seeing three or fewer).

#### Staff knowledge and service delivery practices

Interviews (Table 2, with additional quantitative detail in the Additional file) showed some staff recognising SIREP objectives, many staff understanding the essentials of

safe and effective vaccination, and all staff reporting recent refresher training. Important knowledge gaps related to vaccines given at birth or in the second year of life, the links between vaccination and disease control, and proper handling of liquid multi-dose vials (with the risk that usable vials would be unnecessarily discarded). Structured observations tracking staff-patient interactions for 15 patients and applying the WHO Immunization Session Checklist to 11 immunization sessions (Fig. 1) demonstrated that while most staff provided a clean and effective vaccination injection, there were gaps in provision of education, counselling of families, AEFI readiness, and the checking of vaccines for heat or freezing damage. Several missed opportunities for vaccination were noted, as listed in Table 2.

Most staff at interview reported integration of other services with immunization (Table 2) as important, but observation found limited practice. Although national guidelines recommend integrated care for all infants [18], it was observed that: child illness care was provided alongside vaccination for approximately 50% of infants; while most infants were weighed, counseling on feeding or growth was uncommon; vitamin A and albendazole was distributed less often than scheduled; and no instances of integrating care for the mother were seen.

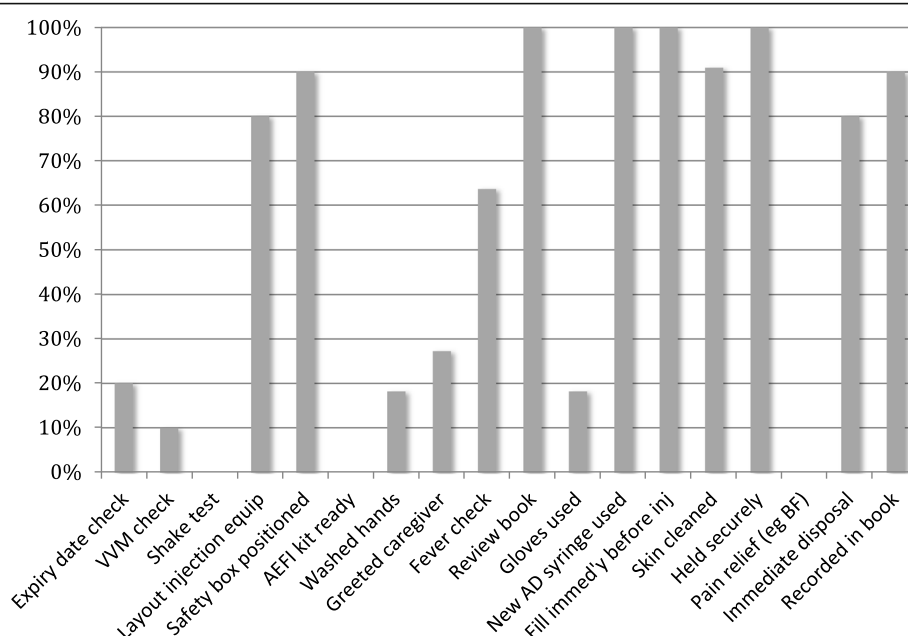


**Fig. 1** Health worker practices assessed against the WHO Immunization Session Checklist (percentage of provider-client interactions showing the practice). Note: Structured observation of 11 immunization sessions, using the 2015 WHO Immunization Session Checklist [15], which aims to avoid the most common programmatic errors reported by senior immunization managers in a WHO consultation. VVM = vaccine vial monitor, AD = Autodisable, BF = Breast-feeding

Staff reported lack of time and personnel as the most important constraints.

### Community engagement

As listed in Table 2, community engagement activities consisted of group education talks at 25% of clinics, but without use of pictorial, video, participatory, or take-home communication products. Local communities donated in-kind support to some clinics, but there was no structured engagement, nor use of trained community health volunteers. Small fees (generally between USD 0.3–1.0) for attendance, but not for specific vaccines, were seen in one third of clinics, but were not reported as a major barrier to access. Male parents or care-givers were rarely involved in immunization visits. Community members reported lack of support from family members as an occasional barrier to vaccination.

### Locally generated ideas for improvement

All participants (staff in interviews and community members in discussions), when prompted were able to describe local strengths or suggest improvements. Common ideas proposed by staff included more personnel, stronger support for transport needed to do outreach, better community engagement, more active community education, involvement of male parents or care-givers, and offering desirable extra services for both mother and baby. When asked to rank priorities, staff rated reliable vaccine supply and renewal of equipment and

infrastructure as more important than staff numbers or staff knowledge. Care-givers sought more frequent, reliable and ‘on-demand’ services, especially outreach, noting travel time and costs as a common barrier to uptake. Mothers, more often than staff, asked for the addition of family planning, promotion of reproductive health, and maternal illness care at immunization clinics.

### Discussion

Our findings depict an immunization service with an operational level of staff, equipment and procedures in place; but one that reaches just half to two thirds of its target population. The service strengths are similar to, or better than, many other sites in PNG [10], and the service deficiencies are similar to those identified for other low- or middle-income settings [1]. These findings point to a range of immediate opportunities to improve coverage and strengthen local service quality. We discuss these below and, in Table 3, synthesise them into ten recommended actions. By using an evaluation framework based on both PNG’s SIREP strategy and WHO standards, it is possible to relate recommendations to what was included in PNG’s SIREP strategy. Six of our ten proposed actions were already embedded in the SIREP strategy (and hence in national immunization plans), but insufficiently resourced or implemented in our study setting. Particular resource gaps lie in resourcing for outreach. Four actions proposed go beyond the current SIREP strategy.



**Table 3** Suggested local actions to improve routine immunization program coverage or quality, and potential contribution of emergency responses or campaigns, in rural Papua New Guinea

| <i>Local actions already proposed in the PNG government's SIREP strategy</i>                                                               | <i>Potential contribution of emergency responses or campaigns</i>                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Local planning based on populations rather than geography                                                                                  | Campaign coordinators help boost local routine planning capacity<br>Mapping child populations and data-sharing               |
| Intensified quarterly outreach focused on higher clinic numbers properly resourced and implemented                                         | Identify new outreach points, especially with population clusters<br>Clarify options and costs for transport                 |
| System for tracking unvaccinated children                                                                                                  | Mapping child populations and data-sharing                                                                                   |
| Integrated SIAs with additional vaccines, matching local priorities                                                                        | Involve district level in planning<br>Local flexibility in an expanded package of campaign services                          |
| Supportive supervision linked to refresher training including good communications and AEFIs                                                | Distribute resources to staff<br>Use campaign monitoring to collect staff priorities for capacity development                |
| Trained lay health workers (health volunteers) to track births and children, support outreach clinics and promote uptake at static clinics | Campaign organisation that promotes local involvement<br>Leverage campaign supports to enlist long-term interest and support |
| <i>Local actions that go beyond the PNG government's SIREP strategy</i>                                                                    | <i>Potential contribution of emergency responses or campaigns</i>                                                            |
| Standardise every opportunity for vaccination, by policy, training and accessibility of vaccine supplies                                   | Not easily addressed by emergency responses or campaigns                                                                     |
| Health communication products and programs to educate families on the complete vaccine schedule                                            | Distribute family-oriented communications materials promoting catch-up vaccination                                           |
| Test models of integrated services, responsive to community preferences                                                                    | Not easily addressed by emergency responses or campaigns                                                                     |
| Review of staff roles and functions to optimise allocations and workload                                                                   | Minimise incentives that discourage outreach as part of routine programs                                                     |

Note: SIA Supplementary Immunization Activity. AEFI Adverse Event Following Immunization

### Options for short-term improvements in existing services

Within current resources, improvements in coverage should be achievable with a fuller implementation of the changes to local service planning envisaged in the SIREP strategy. This recognises that many clinics see few clients (25% with 3 or less), and the fact that most planning is not yet tuned to where most children live. Other persisting gaps in knowledge and capacity that were prime targets of the SIREP strategy include improving catchment population data, increased frequency of service availability, a greater number of outreach points, and quarterly intensification of outreach. Change through improved local planning to reinvigorate outreach has proven successful in settings in Africa and Asia [13] that share similar burdens of disease and health system constraints to PNG. In past programmatic research in PNG, alongside the country's national coverage survey in 2004 [19] similar potential gains were identified. Reinforcement of SIREP training, already well recognised by front-line staff, appears a helpful starting point, but with a stronger commitment of resources to enable more outreach services. Such changes also meet many of the highest priorities expressed by family members in our study.

Our findings also indicate opportunities for increased community engagement and mobilisation; through increased group and individual counselling in the vaccination encounter and the creation and provision attractive, durable, "take-home" information products, aiming to

build community demand for a timely, complete schedule of vaccination. Outreach can benefit from stronger, formalised involvement of local leadership, possibly with the deployment of trained lay health workers; such community resources can also help register and track children needing vaccination. Improved session practices, including ensuring managerial and stock support to enable staff to open multi-dose vials even for one child; and the institution of AEFI equipment and periods of observation (which also allows time for education). This mix of enhanced community engagement plus improved local planning has driven routine immunization improvements in difficult settings in sub-Saharan Africa [20, 21], and vaccination support by trained lay health workers, termed "Village Health Volunteers" in PNG, has been proven in this country in the past [22].

### Interactions between campaigns and the routine program

PNG's 2018 polio outbreak has necessitated a major emergency response, with national and sub-national campaigns initially for polio vaccination alone and later with other antigens, particularly measles-rubella, similar to previous SIAs in that country [6, 23]. In Table 3, we have suggested where, based on our findings, emergency responses or campaigns could synergise with the proposed actions to strengthen routine immunization. In other settings, the "micro-planning" used in polio and measles campaigns can inform local service planning [13]. Such planning was flagged in PNG's SIREP strategy

but not fully implemented in our study site. Sharing of campaign coordination staff and systems to support local managers could help catalyse change by identifying new outreach sites, rebuilding local clinic registers and catchment descriptions, and setting benchmarks for sustainable, practical transport costs. Campaigns and emergency responses could also work for stronger community engagement, including communications with local leaders and trained health volunteers that advocate for long-term support to the continuing routine program. Other practical support could address the planning and information gaps noted in our study, by distributing Child Health Record Books, staff immunization manuals, and other key knowledge resources needed by the routine program.

There is global evidence, especially for measles/rubella SIAs, that they can boost routine programs [24]; but only if they accommodate the needs of routine immunization in the way they harmonise their planning, invest in suitably generic equipment, share staff and intelligence, use broadly supportive communications, and minimise unsustainable monetary incentives. PNG's past experience with SIAs suggest they had most success when they maximised district-level control of timing and operations, and of which package of services to integrate [25, 26].

### Longer-term issues

It is clear that changes limited to the front-line are insufficient and central reforms of management, a country-led technical advisory group, procurement and financing, and national re-equipping are also needed and have been repeatedly advised [10, 11, 27]; these were largely beyond the scope of our research. Our findings do illuminate the need for new thinking on the immunization workforce; in interviews staff consistently mentioned lack of personnel as an important constraint on extending outreach or integrating new services, in contrast to our observations that staffing was more than adequate for the clinics actually operating. Expanding services will eventually require an expanded cadre of vaccinators, but prior to that our findings suggest a need to expand immunization responsibilities among existing staff, in pursuit of greater efficiency. This could be coupled with the reestablishment of commitment to the national immunization program goals across all staff levels, as one contribution to a revitalisation of immunization professionalism.

One aspiration of the SIREP strategy, and of global immunization programs [28], is the greater integration of other services with vaccination; seen to a limited degree in our study by the distribution of vitamin A or albendazole. Our community discussion findings reflect a demand for integration that goes beyond this, prioritising relatively complex services such as maternal illness care, or family planning counselling and provision.

These require time and skill that seem difficult within current staffing and infrastructure limits that we have mapped, and would seem to need an integration strategy such as service co-location rather than simply adding tasks to current vaccinators. Testing models to address maternal as well as infant needs through routine contacts in the first year after childbirth, appears profitable and important. If integrated service provision prioritises care that families want, this may help build demand for and confidence in immunization services, as well as meeting their felt needs.

### Limitations and strengths

Our sample was restricted to functioning services and families who were willing and able to use those services so our study primarily relates to improving outcomes within existing services. Our data collection took place over the fourth and first quarters of the year, when wet weather events could bias perceptions of access. Despite careful training in unobtrusive observation and non-leading interviewing, there may be some observer effect and/or social acceptability bias affecting the validity of our findings. Single author coding of themes in qualitative analysis increases the risk of bias; our mitigation was to critically reflect on research perspective and carefully cross-check all inferences with local research staff, implementers and policy-makers. Study strengths include the assessment of a representative sample of functioning services, as well as the use of a broad mix of methods and attempt at more detailed interviewing than is the norm in previous service evaluations.

### Conclusions

Our assessment of front-line immunization services in rural PNG found opportunities to boost coverage and quality, even within current resources, especially through better population-based local planning, and stronger community engagement. Many, but not all, were contained in PNG's recent national strategy (SIREP) for routine program strengthening. Our results call for increased resourcing of and commitment to this approach, and also suggest areas where vaccination campaigns in PNG can contribute to routine immunization services.

### Supplementary information

**Supplementary information** accompanies this paper at <https://doi.org/10.1186/s12889-020-8172-4>.

**Additional file 1.** Additional quantitative knowledge data and thematic coding of qualitative data.

### Abbreviations

AEFI: Adverse events following immunization; DTP3: Diphtheria-tetanus-pertussis-containing vaccine third dose; ENBP: East New Britain Province; EPI: Expanded Programme on Immunization; HMHB: Healthy Mothers Healthy Babies research program; IPV: Inactivated polio vaccine;

MCV: Measles-containing vaccine; PNG: Independent State of Papua New Guinea; SIA: Supplementary immunization activity; SIREP: Special Integrated Routine EPI Program; UNICEF: United Nations Children's Fund; USD: United States dollar; WHO: World Health Organization

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# Authors' contributions

CJM conceived and designed the study, oversaw data collection, led analysis and interpretation, and led the preparation of the manuscript. JGB, MJLS and OPMS provided major contributions to study design. CJM, OPMS, EP, PM, and LA undertook data collection. OPMS, NL, EP, PM, LA, MJLS, MSR, LMV, BAMCP and JGB contributed to study design, analysis, interpretation, and the preparation of the manuscript. All authors reviewed and approved the final version of the manuscript.

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# Availability of data and materials

Summary tables of qualitative findings by thematic coding are provided available as supplementary material. Additional datasets used for the current study are available from the corresponding author on reasonable request.

# Ethics approval and consent to participate

All participants provided written informed consent, with measures taken to ensure confidentiality. The study was approved by the PNG Institute of Medical Research Institutional Review Board (IRB: 1603), the PNG Medical Research Advisory Committee (MRAC: 16.22), the East New Britain Provincial Government (PEC: 12/2016), and The Alfred Hospital Ethics Committee, Melbourne (333/16).

# Consent for publication

Not applicable.

# Competing interests

One author (MSR) provided technical advice to SIREP as part of employment with WHO. Other authors declare no competing interests.

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