Telemedicine for Insulin Treated Gestational Diabetes Mellitus (TeleGDM)

An Exploratory Randomised Controlled Trial of the Effects of a Web-based GDM Support System on Health Service Utilisation, Maternal and Foetal Outcomes, Costs and User Experiences

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69717

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Declaration

This is to certify that:

1. The thesis comprises my original work towards the PhD except where indicated in the preface.

2. Due acknowledgement has been made in the text to all other material used.

3. The thesis is less than 100,000 words in length, exclusive of tables, maps, bibliographies and appendices.

Tshepo M. Rasekaba

March 2017
Acknowledgements

The PhD was a journey which as the candidate I cannot claim I traversed alone. A number of people and resources had a role directly or indirectly in making this journey evolve from a dream to a reality that has culminated into the work contained in this thesis. That is, to say the work was never a one man show and therefore I would to duly recognise the role played by several key persons and organisations in making this PhD come to life.

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Thank you everyone.

Finishing the PhD is only the completion of a step in a journey that continues...
Conflict of interest declaration

1. The web-based personal health record, Online Health Portfolio (OHP) (www.onlinehealthportfolio.com) which was used in this study was provided by a third party vendor for a fee. My PhD supervisors and I as well as members of my advisory panel have no commercial interest in OHP.

2. In the early stages of the study, I used glucometers that were provided by Abbott Diabetes Care, Australia. My PhD supervisors and I as well as members of my advisory panel have no commercial interest in Abbott Diabetes Care, Australia.
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<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ABS</td>
<td>Australian Bureau of Statistics</td>
</tr>
<tr>
<td>ADIPS</td>
<td>Australasian Diabetes in Pregnancy Society</td>
</tr>
<tr>
<td>AC</td>
<td>Abdominal Circumference</td>
</tr>
<tr>
<td>ADS</td>
<td>Australasian Diabetes Society</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>BGL</td>
<td>Blood Glucose Level</td>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>BPD</td>
<td>Bi-Parietal Diameter</td>
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<tr>
<td>CALD</td>
<td>Cultural and Linguistic Diversity</td>
</tr>
<tr>
<td>CDE-RN</td>
<td>Credentialed Diabetes Educator-Registered Nurse</td>
</tr>
<tr>
<td>CGM</td>
<td>Continuous Glucose Monitoring</td>
</tr>
<tr>
<td>CINAHL</td>
<td>Cumulative Index to Nursing and Allied Health Literature</td>
</tr>
<tr>
<td>CONSORT</td>
<td>Consolidated Standards of Reporting Trials</td>
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<tr>
<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
</tr>
<tr>
<td>CSQ</td>
<td>Client Satisfaction Questionnaire</td>
</tr>
<tr>
<td>DES</td>
<td>Diabetes Empowerment Scale</td>
</tr>
<tr>
<td>DSE</td>
<td>Diabetes Self-Efficacy</td>
</tr>
<tr>
<td>EFT</td>
<td>Equivalent Full Time</td>
</tr>
<tr>
<td>EMBASE</td>
<td>Excerpta Medica dataBASE</td>
</tr>
<tr>
<td>FL</td>
<td>Femur Length</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>GDM</td>
<td>Gestational Diabetes Mellitus</td>
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<tr>
<td>GSMA</td>
<td>Groupe Spéciale Mobile Association</td>
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<tr>
<td>HC</td>
<td>Head circumference</td>
</tr>
<tr>
<td>IADPSG</td>
<td>International Association of the Diabetes and Pregnancy Study Groups</td>
</tr>
<tr>
<td>ICT</td>
<td>Information Communication Technology</td>
</tr>
<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
</tr>
<tr>
<td>IDF</td>
<td>International Diabetes Federation</td>
</tr>
<tr>
<td>LGA</td>
<td>Local Government Area</td>
</tr>
<tr>
<td>LUSCS</td>
<td>Lower Uterine Segment Caesarean Section</td>
</tr>
<tr>
<td>MAGE</td>
<td>Mean Amplitude of Glycaemic Excursions</td>
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<tr>
<td>MRC</td>
<td>Medical Research Council</td>
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<tr>
<td>NH</td>
<td>Northern Health</td>
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<tr>
<td>NICU</td>
<td>Neonatal Intensive Care Unit</td>
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<tr>
<td>NVD</td>
<td>Normal Vaginal Delivery</td>
</tr>
<tr>
<td>OGTI</td>
<td>Oral Glucose Tolerance Test</td>
</tr>
<tr>
<td>OHA</td>
<td>Oral Hypoglycaemic Agent(s)</td>
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<tr>
<td>OHP</td>
<td>Online Health Portfolio</td>
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<tr>
<td>PRISMA</td>
<td>Preferred Reporting Items for Systematic Reviews and Meta-Analyses</td>
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<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>SCN</td>
<td>Special Care Nursery</td>
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<tr>
<td>SLA</td>
<td>Statistical Local Area</td>
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<tr>
<td>SEIFA</td>
<td>Socio-Economic Indexes for Areas</td>
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</table>
SMBG  Self-Monitoring Blood Glucose
SMS  Short Message Service
TNH  The Northern Hospital
USB  Universal Serial Bus
WHO  World Health Organisation
During the course of the PhD work I produced 2 papers which have been published in peer review journals. A third paper focussing on outcomes was in manuscript stage at the time of finalising this thesis. These papers were co-authored with my PhD supervisors; Associate Professors John Furler, Kwang Lim, Irene Blackberry and a member of my PhD advisory panel, Associate Professor Kathleen Gray. Mr Mark Tacey, a biostatistician was involved in authorship of the first paper. Copies of these papers are included in this thesis. One paper on a systematic review of the literature is provided as part of the chapter which outlines the systematic literature. The second paper was a protocol paper and it is appended at the end of the methods chapter.

Indicated below are the citations and an overview of what each author contributed to the papers.

**Paper 1**


Tshepo M Rasekaba conceived the topic for the systematic review, developed the review protocol, undertook literature search, was the primary literature reviewer, extracted the data, led the manuscript authorship and oversaw all journal submission and correspondence. John Furler, Irene Blackberry provided secondary review and data extraction. John, Irene, and Kwang Lim provided feedback on the protocol and contributed to the manuscript authorship. Kathleen Gray provided feedback and contributed to the manuscript authorship. Mark Tacey provided statistical oversight for the data analysis and provided feedback. All authors proofread and approved the final manuscript.

**Paper 2**


This peer reviewed paper was based on my PhD study protocol. The rationale for publishing my PhD project protocol was that the study was novel and innovative. First, at the time of conception and implementation early in 2013, my study was the first we were aware of in which telemedicine was specifically used in the management of gestational diabetes mellitus (GDM) in Australia. Second, previous studies that investigated telemedicine or telehealth in diabetes did so in the broader context of diabetes in pregnancy which included other types of diabetes besides GDM. Lastly, the study protocol came at a time that the technology ecosystem had changed from what existed during the latter studies. The information and communication technologies landscape had improved from dial-up modems, reliance on desktop computers and fixed line telephones for telehealth interventions at that time, to faster, more ubiquitous and mobile technologies such as broadband internet, smartphones, and tablet devices.

As the PhD candidate, I (Tshepo Rasekaba) conceived the project, wrote the protocol with substantive feedback and input from my supervisors (Kwang Lim, John Furler and Irene Blackberry). I led and coordinated the translation of the protocol into a manuscript for publication and my supervisors provided substantive feedback and input to authorship. Kathleen Gray later provided health informatics expert oversight to the protocol and provided substantive feedback and input to the manuscript authorship. All authors proofread and approved the final manuscript.

Conference presentations

In addition to the above publications, I presented at the following three international conferences during the course of my PhD:


**ABSTRACT**

Gestational diabetes mellitus (GDM) is a condition characterised by elevated blood glucose that occurs in pregnancy and affects 11-15% of pregnant women. Tightly maintaining blood glucose levels (BGL) within target in GDM is associated with better maternal and foetal outcomes. In contrast poorly controlled hyperglycaemia is associated with adverse outcomes such as higher rates of caesarean delivery, macrosomia, foetal shoulder dystocia and admission of the new-born to a special care nursery or neonatal intensive care unit.

At least 50% of women with GDM need insulin to maintain glycaemic levels within target. In the early stages of insulin commencement, women with GDM often require intensive monitoring, frequent advice and support for insulin titration. This can be difficult to manage in pregnant women who are often faced with other competing demands, including work and caring for a young family, which contribute to the challenges of managing GDM. Further, the need for intensive support, together with inconsistent attendance for appointments, contribute to difficulties with managing GDM through the out-patient setting. Telemedicine has previously been shown to enhance patient self-monitoring and enabling provision of accurate and timely data transmission and sharing between patients and clinicians. Use of telemedicine potentially enabled efficient communication with timely response by clinicians in addressing urgent situations where BGLs are outside the desired target range. As a result, telemedicine may provide an innovative approach to streamline GDM management given the intensity of support and demand for insulin-treated GDM services and burden to GDM patients to attend appointments for ongoing monitoring and support.

My PhD study involved a complex intervention and as a result drew from elements of the three theoretical frameworks. First the Medical Research Council (MRC) Framework which guides the development and evaluation of complex interventions which draws attention to the steps to follow, i.e. intervention piloting and then proceeding to the exploratory phase which was the mainstay for my study. The second was the Normalisation Process Theory (NPT) which emphasises translating and embedding complex interventions in practice, noting the TeleGDM study was
implemented in real practice. The third framework was the Telehealth Evaluation Framework which provides a guide to the elements to consider in order to standardise the evaluation of telehealth interventions.

My PhD project aimed to explore the impact of telemedicine on the management of insulin-treated GDM at Northern Health (NH). The project which is described in detail in this thesis consisted of:

i) A background literature review including a systematic literature review and meta-analysis of telemedicine for GDM management;

ii) Piloting the protocol at one of the campuses of NH. The pilot was aimed at gaining insights into the flow of the recruitment process and getting feedback on the chosen telemedicine system, before proceeding to an exploratory randomised controlled trial (RCT) stage;

iii) An exploratory RCT comparing an adjunct telemedicine intervention to usual care in the management of insulin-treated GDM. The study primarily looked at impact on service utilisation, i.e. outpatient GDM clinic appointments. Other outcomes included a range of maternal and foetal/new-born clinical outcomes, patient and clinician satisfaction and service provider costs; and

iv) A mixed methods outcome and process evaluation of the exploratory RCT.

Ninety-four patients and five CDE-RNs participated in my study. The findings showed that telemedicine support in the management of GDM produced health service and clinical outcomes similar to usual care. Adjunct telemedicine support had no significant impact on the number of face-to-face outpatient GDM clinic appointments, foetal biometrics, rates of caesarean deliveries, macrosomia, large for gestational age, admissions of new-borns to the special care nursery, birth-weight or costs. The intervention had the advantage of significantly reducing the time for patients to achieve optimum glycaemic control, an important outcome in GDM management. Importantly, while not superior to usual care in terms of health service use, telemedicine did not compromise the quality and safety of care in terms of foetal and maternal outcomes.

Uptake of the intervention, as reflected by the volume of GDM self-monitoring data entered into the telemedicine system by patients, showed that patients using this
approach shared less data with clinicians, when compared to the usual care method of handwritten data. There was greater usage of the telemedicine system to share data in first four weeks of the intervention.

Statistically, there was no difference between the intervention and control on health service provider costs. However, limitations of scaling up the intervention notwithstanding, there was potentially for a significant cost saving from a health service perspective.

Themes from patient interviews showed that telemedicine as a concept, may be acceptable among patients, facilitated proactive self-management, and enabled personalised feedback. Some patients suggested telemedicine could potentially reduce face-to-face clinic attendances, thus, saving them travel time or allow them to balance work and ongoing GDM care. These views were possibly from a self-selected group of patients who engaged more with using the telemedicine system element of the intervention. Patients who engaged less with using the system were reluctant to participate in interviews.

As clinicians involved in performing the clinical aspects of the study, Credentialed Diabetes Education-Registered Nurses (CDE-RNs) had mixed responses regarding telemedicine. For instance, some expressed views that telemedicine may be a supplement usual care, rather than an alternative substitute. They also cited the telemedicine system’s technical design, and lack of integration with existing ehealth systems as the negatives of telemedicine, as these factors resulted in increased work to use the system, adversely impacting on workflow and productivity.

In conclusion, while my study was exploratory, telemedicine support for GDM showed no impact on service utilisation and provider costs. Telemedicine produced similar maternal and foetal clinical outcomes as usual care, suggesting no added risk to clinical quality of care, but with the possibility of a shorter time to insulin dose stabilisation. Further research in telemedicine using, user-friendly technological platforms that are fit for purpose, and including robust health economic evaluation in GDM is still needed.
PREAMBLE

This thesis is the culmination of longstanding interest in health and medical research. From the first year after graduating with my bachelor's degree, filled with passion for evidence based clinical practice, to then forming a journal club in my workplace and running several research workshops, I pondered whether I was in fact cut out to do research. Eventually, my interest translated into action when my then boss handed me a document calling for research fellowship applications. I applied and was accepted into the Primary Health Care Research Evaluation and Development (PHCRED) program at the University of Melbourne and my PHCRED project in chronic disease management resulted in my first peer reviewed publication [1] and the first of several conference presentations.

Over the years since, I combined clinical work with research; mainly coordinating research projects of others, undertaking health services research and program evaluations as well as mentoring novice researchers. My interest in research into services for chronic disease management continued to increase and along the way I identified some service gaps and a whole range of other topics of personal interest to me, particularly in diabetes. Eventually I completed a Master of Public Health degree by research, again with a focus on chronic disease management.

A personal tragedy reinforced my special interest in diabetes when my father succumbed and subsequently passed on, following complications related to diabetes. On reflection I determined that his passing was premature and could have been avoidable had quality health services been available for him and many like him.

It was while I was working in a clinical research centre in 2012 that an opportunity arose to look into ways to address service gaps in type 2 diabetes care, particularly around service access and utilisation that would have flow-on benefits to patient clinical outcomes. My proposition was to look into service provision through telemedicine or telehealth. Thus, a PhD topic was born. However, after consulting widely on how to best pursue this academically, the most pragmatic way was to have the topic morph into a focus on gestational diabetes and so the PhD journey translating into this thesis began.

My thesis is organised into eight chapters. The first chapter sets the scene, defines and highlights the health service and clinical problem relating to gestational diabetes
mellitus (GDM) at the health service organisation where I conducted my research project. The second chapter is a general overview and scoping of the literature. I also introduce the theoretical frameworks that were important for the development my study, and its implementation and evaluation. These frameworks were the MRC framework, NPT and an Australian recommended telehealth evaluation framework.

In this chapter, I also provide part of the rationale for telemedicine as a solution to address the service utilisation burdens of GDM care. The chapter also covers the process I used for selecting the telemedicine system I used in my study. The rationale is augmented by the third chapter, in which I provide an in-depth literature review into telemedicine in GDM, through a systematic literature review and meta-analysis. This systematically appraises the evidence of how telemedicine as a proposed solution performs in GDM. The systematic review provides some answers to the status of the evidence. It also informed the questions and hypothesis for my study, which I outline in the methods chapter.

The fourth chapter is a description of the methodology and processes I used in my primary research, to implement and evaluate a telemedicine intervention for insulin-treated GDM. My research study was an exploratory randomised controlled trial (RCT) of telemedicine adjunct to usual care as an innovative approach to support GDM care and I used quantitative and qualitative process evaluation methods.

As a new study using a new, and previously untested protocol, I conducted a pilot before embarking on the exploratory RCT phase of my study. A description of the pilot relating to the critical issues and actions to address these issues ahead of progressing to the exploratory phase, is the focus of the fifth chapter. Immediately following this is the sixth chapter in which I present findings of my primary outcome as well as the secondary clinical outcomes. I also report and discuss the process evaluations findings in this chapter.

Then second last chapter is the discussion. Here, I revisit and discuss my main study findings, relating them to the underpinning theoretical frameworks, and comparing and contrasting the key findings with existing literature. The chapter also covers the strengths and limitations of my study and a brief reflection on my PhD journey.

Finally, my thesis comes to a close with a final short chapter eight. The chapter is a discussion and outline of the implications of my study findings to policy, practice and future research, before bringing my thesis to a conclusion.
Gestational diabetes mellitus (GDM) is glucose intolerance which develops or is first diagnosed during pregnancy [2-4]. The glucose intolerance and characteristic hyperglycaemic are linked to changes in glucose metabolism and decreased insulin sensitivity attributable to marked increases in oestrogen, progesterone, and secretions of placental lactogen and prolactin [5]. Poorly controlled hyperglycaemia in GDM is associated with serious perinatal and neonatal complications, including babies that are large for gestational age (LGA), greater chance for caesarean delivery, brachial plexus injury in the baby, preeclampsia, and gestational hypertension [6-8]. Further, nearly 50% of women with GDM develop type 2 diabetes within 8 years of delivery [9].

Earlier figures estimated the prevalence of GDM in Australia at 6-11% of pregnancies [4, 6] based on the then Australasian Diabetes in Pregnancy Society (ADIPS) diagnostic criteria. Following revision and adoption of the new diagnostic criteria by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) [4, 10], it is inferred the prevalence would be higher. A study published in 2013 [10] suggested an estimated prevalence of 11-15% based on the IADPSG diagnostic criteria. A diagnosis of GDM is made if any of the IADPSG criteria for plasma glucose level is met following a 75g Oral Glucose Tolerance Test (OGTT); fasting BGL ≥5.1 mmol/L, 1-hour after glucose load ≥10.0 mmol/L, or 2-hours after glucose load ≥8.5mmol/L [4, 10].

Several factors contribute to the pathophysiology and epidemiology of GDM. Older age, Asian, African/Middle Eastern or Polynesian ethnic background, a previous history of GDM, family history of diabetes, high body mass index or low socioeconomic status are some of the main risk factors for GDM. These factors increase the odds for developing GDM by up to six fold [2, 11]. The prevalence of GDM among women with at least one risk factor is up to six times greater than in low risk women [3], hence early screening, closer monitoring and intensive treatment of for these women is advisable [12-14].
The GDM clinic and pathology laboratory at Northern Health (NH)\(^1\) have adopted the IADPSG criteria. The implication of the recommendation to adopt IADPSG diagnostic guidelines is that more patients would be diagnosed with GDM, hence more women potentially requiring treatment. The American Diabetes Association’s Standards of Medical Care in Diabetes 2016 [4] indicate that the incidence of GDM could be 15-20% as a result of widening the diagnostic criteria and requiring only one positive result (versus two positive results previously) from the OGTT. The magnitude of the problems posed by GDM is reflected in this statement by the ADA [4], “...the anticipated increase in the incidence of GDM would have significant impact on the costs, medical infrastructure capacity, and potential for increased “medicalization” of pregnancies previously categorized as normal, but recommended these diagnostic criteria changes in the context of worrisome worldwide increases in obesity and diabetes rates with the intent of optimizing gestational outcomes for women and their offspring.”

Screening for GDM is routine practice in Australia and when the disease is identified it is managed under multidisciplinary care in hospital outpatient settings. Treatment objectives are to reduce hyperglycaemia and bring glucose levels to treatment targets of 3.5-5.5 mmol/L for fasting BGLs and less than 7.0mmol/L for post-prandial readings [7]. The ADA standards advise tighter control, with recommendations of fasting BGL ≤5.3 mmol/L and 2-hr postprandial BGL ≤6.7 mmol/L [4]. Treatment of GDM to control hyperglycaemia is a ‘step–up’ approach [4, 13]. First line therapy involves dietary modification and physical activity [4, 8, 10, 15] or addition of metformin, an oral hypoglycaemic agent (OHA) [8] if hyperglycaemia persists. However, metformin use in GDM remains controversial or is seldom used due to safety concerns in pregnancy [4, 16, 17]. Insulin is initiated if lifestyle measures and/or OHAs are inadequate in optimising BGLs, there is an indication of hyperglycaemia on at least two BGL readings over 1-2 weeks and there is evidence of macrosomia, i.e. foetal growth >90\(^{th}\) percentile on ultrasound foetal biometry [4, 15, 17]. Data from Australia

\(^{1}\) Northern Health (NH) is the health service organisation/entity incorporating three campuses: The Northern Hospital (TNH), Craigieburn Health Service (CHS) and Broadmeadows Health Service (BHS)
suggest that about 50% of women with GDM require insulin [18]. Women commenced on an insulin regimen require intensive follow-up for monitoring and regular adjustments of insulin dose [8, 18], further adding to the burden of GDM on limited services.

In summary, the increasing prevalence and incidence of GDM and the resource intensive approach to management on a background of limited outpatient services, puts pressure on health services and their capacity to provide quality health care. Under such increasing pressure, health services will struggle to meet the need and maintain the highest quality of care to optimise outcomes for mother and baby. This situation suggests that innovation is needed in delivery of services to get the best care to the right people at the right time. The focus of my PhD was primarily GDM-related health service utilisation which has implications for service capacity and explores impact on clinical outcomes and costs on a secondary level. In the following subsection, I provide a backdrop and context of the problem at the health service setting where my PhD project was conceived and implemented.

1.1 A brief description of the Australian healthcare system, the study setting and catchment population

1.1.1 The Australian Healthcare System

This section provides an outline and overview of the Australian healthcare system. It is a backdrop to the system in which the GDM services at the centre of my study occur. However, the primary focus and scope of this thesis is GDM services at a local level setting in the State of Victoria, one of several in Australia.

The world Health organisation defines health system as “(i) all the activities whose primary purpose is to promote, restore and/or maintain health; (ii) the people, institutions and resources, arranged together in accordance with established policies, to improve the health of the population they serve, while responding to people’s
legitimate expectations and protecting them against the cost of ill-health through a variety of activities whose primary intent is to improve health."[19]

In keeping with this definition, Australia endeavours to provide a health system that is universally accessible to all its citizens, permanent residents, and people on humanitarian visas or visiting citizens of countries that Australia has reciprocal healthcare arrangements with, e.g. United Kingdom, New Zealand, and Sweden etc. [20]. The system is funded by the Australian (commonwealth/federal) government through Medicare, which is the national health insurance scheme financed through taxation and is supplemented with a levy on individuals’ taxable income [21]. Australian territories and states, such as Victoria, then deliver and manage public health services which include public hospitals, and community based and primary health services [20]. If patients choose to access services privately, there is a voluntary private health insurance scheme to support this, whether a patients attends care in a public or private hospital [20, 21].

Medicare enables free or subsidised access to public hospitals, for treatment by a variety health professionals and pharmaceuticals for public patients. A fee scheme under Medicare, the Medicare Benefit Scheduled (MBS), covers 75% of fee for service for private patients in a public or private hospital. The MBS fees serve only as a recommended guide and practitioners who provide care under a fee for service may charge more, in which case the difference is payable by the patient. That notwithstanding, it can be argued that MBS fees are a close approximation of the cost of providing health care. Where patients are not covered by Medicare practitioners or health services bill them the full amount, determined by the practitioner or health service. This fee is usually around the MBS fee for a consultation and patients pay extra for pharmaceuticals and other consumables in private retail pharmacies. This payment arrangement underpins the rationale for the unit costing adopted for the evaluation of the health service provider costs for GDM (section 4.6.1).

In summary, under the Medicare arrangement patients have access to health services and the medical and allied health professionals the need for health care. Services include acute hospital care, outpatient care such as the GDM clinic which is
the focus of this thesis, and community and primary care services. Community and primary care services include general practice, and allied health services that are delivered as part of a general practitioner coordinated care. Also, services provided by nurse practitioners, who may include midwives, are also covered. Specifically for maternity services, women who have a non-GDM complicated pregnancy may be cared for through a shared care arrangement between primary care/general practice and hospital based obstetricians and midwives. Women with a pregnancy complicated by diabetes are cared for through hospital outpatient services by the obstetrics team (obstetrician and midwives), who directly look after pregnancy care, plus an endocrinology team comprising of the endocrinologists, diabetes educators and dietitians, who are the primary managers of the diabetes in pregnancy. Once more, care is either free or subsidised for public patients, whereas private patients personally and/or through private health insurance pay for the cost of care.

Then following sections are a description of care at the local setting where I conducted my study. The description includes the health service, the population and the local GDM services in the outpatient setting of Northern Health. Further descriptions are provided in the methods chapter section on usual care for GDM, as a contrast to the intervention implemented for this study.

1.1.2 Northern Health and catchment

Northern Health is the major health service organisation in the outer northern corridor of metropolitan Melbourne, in the state of Victoria, Australia. The organisation operates three campuses namely, The Northern Hospital, Broadmeadows Health Service and Craigieburn Health Service.

Northern Health provides acute and ambulatory health care services to a catchment area that covers the Australian Bureau of Statistics (ABS) main statistical areas of Moreland-North, Tullamarine-Broadmeadows and Whittlesea-Wallan [22] (Figure 1). These three main areas have a combined population of 367 000 [22] and while they form the majority of the population served by NH, patients also come from rural towns and localities beyond the confines of the geographical boundaries shown in Figure 1.
The catchment population is one of the most socioeconomically disadvantaged areas of Greater Melbourne [22]. Figure 2 shows a spatial distribution map that illustrates the relative socio-economic advantage or disadvantage in parts of Victoria closest to Melbourne and the catchment of interest. This shows that areas in the NH catchment are ranked in the 1st to 3rd deciles, indicating a greater degree of socio-economic disadvantage. The figure also shows income levels in the area of interest relative to the Victorian state average. A slightly greater proportion of the catchment population are in the lower income bracket than the state-wide average.
Figure 1 Main geographical catchment of Northern Health (map produced in TableBuilder tool provided by the ABS)
Figure 2 SEIFA 2011 map showing a snapshot of levels of disadvantage in parts of Victoria and a chart of income levels (Source: ABS 2011)
The other stand out characteristic of the NH catchment is that the population has one of Victoria’s highest proportion of people from a culturally and linguistically diverse background (CALD). Languages spoken at home by residents of the area are shown in Figure 3. The predominant language in the Northern European languages category was English. Far more people in the NH catchment come from a cultural background other than English further highlighting the cultural diversity of the catchment.

![Language spoken at home](image)

**Figure 3 Percentage of person by language spoken at home (Source: ABS 2011)**

### 1.1.3 GDM service at Northern Health

Having described the catchment demographic make-up and highlighted the socio-economic disadvantage of the area served by NH, my next brief description brings focus on GDM at NH for further contextual background. To set the scene, NH had been experiencing an increasing number of births, with 2,694 births during the 2011/12 fiscal year and 3,031 in 2012/13 [23] and births are expected to continue to increase.
The area is growing and a significant proportion of the residents are within the childbearing age. This presents challenges where, housing and population growth outstrip service and infrastructure, such as public transport and health care.

Amongst the healthcare services provided by NH is the once weekly service at each of the three campuses. Pregnant women are referred from the obstetrics and gynaecology service for GDM screening and in line with guidelines, screening occurs at 24-32 weeks gestation or earlier if considered high risk [10, 15, 24]. I performed a short audit of the status of GDM at NH, using a dataset of 2500 pregnant women who gave birth at The Northern Hospital in 2012. Four hundred (16%) of the 2500 women had GDM and they attended NH GDM services for management of this condition. A little over half (232) of the 400 women with GDM went on to require insulin to control hyperglycaemia. The incidence of 58% for insulin-treated GDM, was slightly greater than the overall Australian data estimates of 50% [18]. This subgroup of women with GDM tends to be the greatest consumers of GDM healthcare resources, owing to the intensive follow-up and monitoring they require [8, 18].

Consistent with the cultural diversity of the catchment population highlighted above, the ethnic mix of the 2012 GDM cohort showed that 59% (236) of the patients with GDM were of Indian/Asian subcontinent, Arabic/Middle Eastern, Pacific Islander, Aboriginal, and African origins. These ethnic groups constitute a special interest group in the context of GDM because they are considered high risk for GDM [2].

The GDM health care team comprised Credentialed Diabetes Educator-Registered Nurses (CDE-RNs), dietitian and endocrinologist. The CDE-RNs also play a coordinating role in the clinic. Patient appointments are usually scheduled weekly or fortnightly, depending on glycaemic control and risk factors until delivery. Women with insulin-treated GDM, approximately 70% of the monthly throughput, attended scheduled weekly appointments for consultations with the CDE-RNs, endocrinologist and sometimes with the dietitian. During the course of the project that is at the centre of my thesis and PhD research, the GDM outpatient clinic at The Northern Hospital (TNH) operated once a week, with a throughput of approximately 40 patients per day. Clinic staff reported that the women often missed their clinic appointments due to the competing demands of family and life. This was further compounded by the added burden placed on the women by the increased intensity of GDM monitoring and follow-up frequency, following insulin initiation [18]. Women are expected to perform
four BGL tests a day, record these, together with keeping track of their diet, symptoms and insulin dose. The women are advised to call the CDE-RNs about any concerns. Otherwise the CDE-RNs initiate the call to follow up on progress when they do not hear from the women especially after a recent insulin dose adjustment. Communication between the women and the clinicians was often difficult due to repeatedly missed calls. Furthermore, the health service is located in the northern periphery of Melbourne and also serves a rural catchment. Because of this, limited public transport and longer travel times add to the multifaceted challenges of attending the clinic. Anecdotally, there were concerns these factors potentially impinged upon the quality of care and clinical outcomes. Although the fears and concerns were reasonable, no empirical evaluation had been undertaken to verify or refute them.

In summary, the increasing prevalence and incidence of GDM, the complexity of care required to manage GDM and the burden on the already limited existing health care resources, presented the challenge to come up with an alternative approach to providing care. Although evidence in GDM was limited, as a concept telemedicine was considered a potential innovative approach to support GDM care. Telemedicine as a concept in GDM care is described and discussed in the following background literature review section.
2 BACKGROUND LITERATURE REVIEW AND CONCEPTUALISATION OF A SOLUTION TO SUPPORT GDM CARE

2.1.1 Definition and taxonomy of telemedicine

Telemedicine is simply defined as “the use of telecommunications technology to provide medical information and service” [25]. Others [26], however have defined telemedicine as the use of information and communication technologies (ICT) to bridge the distance gap, in the pursuit of sharing health information and delivering health care, highlighting the ubiquity and capability of telemedicine to bridge geographical separation. The shared or exchanged information may pertain to diagnosis of disease, treatment, disease prevention, professional development activities for healthcare providers, health consumer/patient education or dissemination of healthcare research [26]. In terms of healthcare service delivery, telemedicine may involve health information sharing between healthcare providers and patients.

There are two other terms which are closely related to telemedicine, namely, telecare and telehealth, which are either qualified by the health professions involved or the extent of reach and purpose. For instance Telecare is defined as information sharing for the provision of nursing care and community support to patients [26]. In contrast, telehealth assumes a much broader definition of delivery of public health services which occurs at a distance, for the purpose of promoting wellness and independence; the consumers in this context are not necessarily people who are unwell [26]. The World Health Organisation (WHO) makes reference to a definition in which telemedicine is confined to service delivery by doctors while telehealth is much more inclusive of other healthcare professionals such as pharmacists and nurses [27]. In spite of this the WHO has adopted an interchangeable use of telemedicine and telehealth. This broader definition resonated with the goals of my study and telemedicine or telehealth is defined as;

“The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the
exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.” [27]

Finally, the other term in the taxonomy is telemonitoring. This refers to an approach whereby patients use sensors to monitor their own health condition or manually gather clinical data (e.g. blood pressure, blood glucose etc.) at home remotely and remotely share the data with their healthcare professional for evaluation and feedback on action to take [26-29]. There are other terminologies which describe the temporal aspect of information transmission; real-time for telemedicine systems that involve instantaneous information sharing [26, 28], or asynchronous telemedicine which involves modalities and systems that store information for transmission at a later time [26-28].

Information transmission between parties underpins telemedicine. Central to this are the modes and media of transmitting this information which over the years have included telephones, email [26, 27], short message service (SMS or mobile phone texting) [30], mobile phone/wireless device applications [31] as well as web-based platforms accessible via the internet [32]. Information exchange and sharing via telephone has the advantage of occurring in real-time. However, the disadvantages include potentially confining the parties to fixed locations, the cost of telephone calls and the decreasing reliance on landlines in favour of mobile phones. Mobile phones/wireless devices may also have the disadvantage of higher costs, however these technologies are pervasive and internet subscription costs related to these technologies are becoming more affordable [27]. Globally mobile phone usage subscriptions stood at 3.9 billion in 2012 [33]. In Australia, the Australian Bureau of Statistics reported that at the end of December 2012, 17.9 million people had a mobile phone handset which they used to access the internet [34]; 79% of households had internet access at home and 77% of households reported daily use of the internet [35]. With these levels of usage statistics, telemedicine that uses mobile phone and web-based platforms provides more attractive opportunities. The two platforms make use of existing subscriber services hence minimal, if any, additional costs will be incurred by the users/subscribers.
Regardless of the taxonomy, i.e. telemedicine, telecare or telehealth, the overarching feature and characteristic is information sharing using technology in order to deliver health care to support end users, who may be located at a distance from the health service provider. This occurs in an ecosystem defined as an interconnected, multi-level interaction between healthcare providers, healthcare consumers (i.e. patients), and the environment or context in which this interaction occurs [36]. The telemedicine, telecare or telehealth ecosystem involves three main players: i) the healthcare provider, ii) the consumer/patient and iii) an information sharing modality, e.g. telephone, mobile phone, and internet [26-28]. These constituent characteristic elements make telemedicine interventions complex. Complex interventions are defined as interventions characterised by “… several interacting components … [and] … the number of components and range of effects may vary widely … [or] … Some highly complex interventions … may comprise a set of individually complex interventions.” [37, 38]. As a complex intervention, my study involved technology, human factors (patients and clinicians) interacting in a healthcare environment.

In summary, the above and preceding definitions encompass four key elements of telemedicine, telecare or telehealth. These are i) clinical support, ii) bridging the distance/geographical separation, iii) use of a form of information and communication technology (e.g. telephone, text, videoconferencing, or the internet) and iv) linkage to improvement of health outcomes. For my thesis, I adopted the WHO definition and interchangeable use of telemedicine and telehealth. Details of telemedicine or telehealth, as a proposed health service approach to support the management of insulin-treated GDM with the view to mitigating health service utilisation are provided later in the methods chapter. In the next two subsections I provide a general narrative of the literature as preliminary evidence and consequent rationale, for the choice of telemedicine as an intervention approach in my thesis. A systematic survey of the literature for evidence of telemedicine in GDM follows in chapter 2.
2.1.2 Telemedicine/Telehealth in GDM and elsewhere

Telemedicine in GDM at NH was unchartered territory. New health service interventions selected to be piloted or implemented in practice need to have some evidence behind them. The evidence may be from previous research based on the population of interest and/or be based on translation of concepts informed by studies in different populations. I surveyed the literature for telemedicine as an intervention concept, in GDM and elsewhere, for some rationale as to whether telemedicine to support GDM management was a worthwhile pursuit. As the following narrative will show, there has been a lot work on telemedicine in other health conditions, while research specifically in GDM is limited. It is from these other conditions that much of the learning and evidence for translating telemedicine to GDM as an intervention concept in my approach emanates. Hence, the description here highlights: i) the limited number of studies in GDM, hence consideration and greater reliance on evidence from elsewhere and ii) distinctions between my study approach and these studies in GDM in terms of the interventions and the population.

Telemedicine has been implemented as a monitoring intervention in diabetes [28, 39-41] heart failure [28, 31, 41] and COPD[28]. Geisler and Wickramasinghe[40] trialled wireless technology in the form of a cellular telephones used by patients with type 2 diabetes, to relay BGL self-monitoring data to the hospital for ongoing monitoring, evaluation and action. Preliminary findings were that the system was feasible, easy to use and effective, with remotely monitored patients having fewer hospital visits [40]. Seto et al [31] performed an RCT to investigate telemonitoring in heart failure. They reported better quality of life, improvements in brain natriuretic peptide level (a marker for worsening heart failure) and heart failure self-care following a telemedicine intervention. The same study evaluated hospital utilisation, which did not improve when the telemonitoring intervention group was compared to the control group. In another telemonitoring study of a mixed group of patients with diabetes, heart failure and hypertension[41], there was an early detection of situations that necessitated medication change and review of health advice provided to patients. In their systematic review of telemonitoring in diabetes Jana and Pare [29] concluded that
In terms of demographic and other predictor factors for uptake and usage of telemedicine, Buysse et al [42] found that younger patients with type 1 or type 2 diabetes demonstrated high technological awareness and were high users of technology in managing diabetes. In the same study, treatment with insulin was predictive of greater uptake of telemonitoring. However, in their earlier study, Homko et al [32] found the level of usage of telemedicine was not significantly associated with factors such as age, number of children, education, total family income, computer ownership, or type of treatment for hyperglycaemia. In their subsequent study, however, they reported a significant association between higher income and the frequency of monitoring data transmission. These demographic and socio-economic factors had important relevance for the population considered in my PhD study. As pointed out earlier, first, the health service where my study was implemented serviced a population with high socio-economic disadvantage and, second, in spite of the mixed impact of age reported above, but by virtue of their younger age, the patient population of interest (women of child bearing age) for my study, would be expected to be more amenable to the idea of receiving telemedicine-supported care.

Studies of telemedicine in chronic disease management are not without criticism, often leading to justifiable questions about the utility of telemedicine itself. For the most part, the criticism emanates from methodological limitation of the trials, e.g. short intervention periods which may not allow sufficient time to demonstrate tangible benefits, the heterogeneous nature of the outcomes across trials, greater variability in the telehealth intervention modalities and only a small number of trials including economic evaluation [26, 28, 29, 43]. Variability across trials, makes pooling of data from different trials in order to compare and evaluate intervention effects, a challenging exercises.

In GDM, the impact or effect of telemedicine on outcomes appears to be mixed. In some studies, there are reports of better outcomes from telemedicine, whilst others have reported similar clinical outcomes when telemedicine interventions were compared to controls. Some of the reported benefits include modification of lifestyle behaviours related to illness, patient empowerment, decreased hospitalisation, reduced mortality, cost savings and the availability of data to clinicians facilitating...
their clinical decision making. Barriers to uptake and usage of telemedicine included slow data processing and transmission times associated with earlier generation information technology and hardware systems, increased work to engage with using the systems and higher costs.

In spite of the above, available literature appears to indicate that telemedicine in GDM is feasible and acceptable. There may be some benefits associated with telemedicine as an interventional approach, at least from a health service utilisation perspective and improvement of some clinical outcomes. For instance Perez-Ferre et al [44] reported an 82% reduction in unplanned face-to-face clinic visits among women with insulin-treated GDM, while Dalfra et al [45] reported 44% less visits by patients in the telemedicine group compared to controls. No significant differences were found in clinical outcomes (e.g. HbA1c, mode of baby delivery or size of the baby) of the intervention group compared to control [44]. A more recently published systematic literature review of diabetes in pregnancy [46] indicated that telemedicine significantly reduced HbA1c by 0.14% (95% CI: 0.25% to 0.04%) in a subgroup of patients with GDM, while there were no differences in other outcomes such as pre- and postprandial BGLs, pre-eclampsia, caesarean deliveries, new-born birth-weight and macrosomia. Homko et al [32] investigated telemedicine using a web-based system in women with GDM. While they found significant improvements in diabetes self-efficacy in favour of telemedicine, there were no differences in fasting or postprandial blood glucose and other pregnancy related outcomes. The authors also reported infrequent use of their web-based system, which they attributed to slow refurbished computers and slower dial-up internet service [32]. These issues somewhat improved with enhanced technology in their follow-up study [47].

There appeared to be high uptake and usage of telemedicine in the studies where it was used. One study [45] reported a high acceptance of telemedicine judged by the patients (85%) engaging in transmitting information, with 76% of the women sending their data weekly. Physicians were reportedly able to respond to the patients’ information the same day that it was received [45].

With the exception of studies by Homko et al [32, 47] the above narrated studies in GDM included a mix of type 1, type 2 diabetes in pregnancy in addition to gestational diabetes. Although in some [44], data were presented for the GDM subgroup, although the sample sizes were perhaps too small to perform more informative
subgroup analysis for the GDM group. There were also heterogeneity in the type of treatments for hyperglycaemia, i.e. participants included women with GDM managed with diet, oral hypoglycaemic agents, or insulin. In contrast to these studies, my study specifically aimed to target women with insulin-treated GDM. In chapter two I provide a more in-depth, systematic review and meta-analysis of the literature on telemedicine for GDM.

Whereas the studies I have discussed above investigated telemedicine in non-GDM diabetes and/or generally older populations and limitations notwithstanding for those in GDM, the general principles and findings make telemedicine translatable to GDM as a health service provision concept. It was on this basis that I conceived the Telemedicine for Insulin-treated Gestational Diabetes Mellitus (TeleGDM) study in which I aimed to explore the use of telemedicine in the management of insulin-treated GDM compared to usual care at the Northern Health. In the next section, I discuss the theoretical frameworks underpinning my TeleGDM study.

2.2 Theoretical frameworks underpinning the TeleGDM study

Research and propositions are informed by underlying fundamental assumptions, theories and concepts. According to Rice and Ezzy [48] a theoretical framework “…shapes the sorts of things that a research focusses on…” My study was informed by three important theoretical and conceptual frameworks: i) The MRC framework [37, 38], ii) NPT [49, 50] and iii) telehealth evaluation framework [51-53]. While I do not go into an in-depth critique of each of these frameworks, I present them briefly to highlight their relevance and importance as concepts for my study design, implementation and evaluation.

In this section, I provide an overview of the MRC framework, implementation espoused by the NPT and the telehealth evaluation framework. I relate these to my PhD study and thesis. The brief discussion provides a backdrop to the actions I undertook with the view to avoiding, or at the very least, minimising some of the implementation pitfalls that could lead to the failure of my study. Further, I framed my study outcomes
and some process, and qualitative evaluation descriptions to align with the dimension of the telehealth evaluation framework.

2.2.1 The MRC framework

Traditionally, RCTs in health have explored single interventions involving pharmaceutical agents, whereas healthcare involves other complex non-pharmaceutical interventions requiring evaluation as well [38]. In recognition of the different elements that make an intervention complex, the MRC framework outlines and recommends a phased process that distinguishes and clarifies the different questions that are being dealt with in each phase. The process may be a linear continuum or an iterative approach [38]. These phases are:

**Preclinical or theoretical phase:** This focuses on gathering existing evidence that might suggest the proposed intervention could work. The evidence may be either drawn from the specific context under consideration in the proposed study or may be drawn from other conceptually related areas. For example, in section 2.1.2 (page 23) I have provided an overview and discussion of telemedicine as a concept used in other health conditions. In a separate area of my thesis, chapter two, I looked at the evidence for telemedicine using a systematic review and meta-analysis of the literature in the context of GDM, the health condition that forms the subject of my thesis.

**Defining components of the intervention:** Here consideration is given to understanding the different components of a complex intervention and how they interact to influence the outcomes of interest.

**Defining trial and intervention design:** The exploratory phase, which is an early test of the intervention, is aimed at improving the performance of an intervention. Factors such as sample size calculations are usually not critical and one of the express purposes of this phase is to inform samples size and effect sizes for a future definitive trial (next phase). Based on my appraisal of evidence I identified that evidence for telemedicine in GDM was still limited and not compelling enough to warrant proceeding with a definitive RCT. As a result my study was exploratory in nature.
**Methodological issues for main trial:** The definitive trial phase which considers the key technical RCT design issues such as robust sample calculations, rigorous inclusion and exclusion criteria, randomisation leading to a more conclusive assessment of the effect of the intervention. Although exploratory, my study attempted to incorporate some of the key focuses of this phase.

**Promoting effective implementation:** This final phase aims to pave the way for translating and embedding the definitive trial findings in practice. It also involves long term surveillance once the complex intervention is embedded into practice. While my trial was not quite at this stage, I considered the elements of implementation in so far as embedding and carrying out my trial in a real world clinical setting, with the view to increasing the prospects of success for my trial or study.

### 2.2.2 Implementation and normalisation process theory

Telemedicine falls under the broader concept of ehealth where the latter refers to health systems that use information and communication technologies to increase access to healthcare, increase service quality and performance efficiency [54] in a cost effective way [55]. As demonstrated by the cross-section of telemedicine studies cited in the previous section there is an increasing use of telemedicine or telehealth, coupled with advocacy for the use of ehealth in order to increase health care access [56]. In spite of this advocacy and some of the evidence, there appears to be no corresponding increase in uptake of ehealth relative to research and trials of ehealth strategies. Attempts to translate and embed ehealth strategies in routine practice, reportedly often fail to demonstrate desirable benefits and outcomes [55]. The benefits of ehealth remain elusive, rendering ehealth more promise and potential than reality. This invariably becomes a vicious circle of limited evidence, on the one hand and failed translation, and sustainability of telemedicine on the other, feeding back into evidence limitations. Some of the failures or lack of successes of ehealth are traceable to implementation.

Mair et al [54] posits that one of the main reasons for low uptake and translation of ehealth (including telemedicine) into practice, relates to challenges around
implementation. New and innovative technologies in health involve complex processes of change at the levels of healthcare professionals, patients and the healthcare organisation. Clinicians may be critical and less inclined towards new technology if there are questions about its usefulness and acceptability, quality and reliability, or if the technology becomes a burden to staff or is perceived to undermine the values that are central to patient clinical care [56]; for instance, clinicians may consider face-to-face interaction with the patient, an important and valuable aspect of care, that telemedicine may potentially reduce.

Implementation is defined as a “deliberately initiated process, in which agents intend to bring into operation new or modified practices that are institutionally sanctioned, and are performed by themselves and other agents,” [57]. In this definition, agents refers to the stakeholders with vested interests in what is being implemented. For instance in the context of the TeleGDM study, these agents are patients, clinicians and the healthcare organisation, as well as the researcher. There are four key probing questions in NPT, which are centred on the work expected of the different actors in the process of normalising an intervention in practice:

i. What is the work involved (in the implementing telemedicine-supported GDM care in the context of my study)?

ii. Who does the work?

iii. How is the work supported?

iv. Is it worth doing the work?

The above four questions correspond to the four domains or constructs of the NPT, and these contracts are briefly described below.

Following on from implementation as defined above and drawing from other theories, May [57] proposed what he described as a “general theory of implementation” to guide understanding and assessment of complex interventions in practice, from conception to implementation. Implementation is underpinned by the recognition that it does not involve a finite execution of a single element. Rather implementation involves an interaction of multiple elements and processes each of which needs to be considered in the evolving process of implementing an intervention [57]. This
general integrative theory of implementation proposed by May highlights four key constructs derived from the Normalisation Process Theory (NPT): i) coherence, ii) cognitive participation, iii) collective action and iv) reflexive monitoring [49, 50, 54, 58, 59]. NPT itself clarifies how complex interventions like telemedicine could be embedded into practice and become routine care (normalised). The NPT domains are important elements of implementation, which, if ignored, could lead to unsuccessful implementation of ehealth [54], hence failure to normalise into routine care.

- **Coherence**: refers to the “sense making” work; that is, preliminary work undertaken to determine whether the users or stakeholders of a new ehealth system view it as something different to current practice. Users make sense of how the new intervention affects them and whether there is any value or benefit to be derived from the new intervention.

- **Cognitive participation**: activities carried out for the purpose of encouraging and engaging ehealth users to “buy-in” and embrace the ehealth initiative. A positive reception of ehealth initiatives by healthcare professionals can be an enabling factor for ehealth success. On the flipside negative perceptions and attitudes towards ehealth conspire against successful implementation.

- **Collective action**: activities carried out by stakeholders, i.e. individuals or groups in an organisation (managers and clinicians) or the organisation itself to embrace and enable ehealth by providing a conducive environment for ehealth to be operational. This involves supportive organisational factors in terms of polices, and resources; ease of use by both healthcare professionals and patients; confidence in ehealth and accountability of health, i.e. system security and error minimisation; and finally, assignment of responsibilities and provision of requisite training in readiness for implementation.

- **Reflexive monitoring**: continually appraising and evaluating whether ehealth is a worthwhile pursuit or not. That way gaps and areas of need may be identified for remedial action or modification of the intervention. This is even more pertinent in the face of the rapidly evolving landscape and ecosystem of technology.
In their systematic review, Mair et al [54] concluded that getting the views of ehealth implementers, i.e. senior managers and other staff tasked with implementing e-health strategies, is important. They also argue that aligning the ehealth strategy with the organisation’s goals, staff skills, and an ehealth approach that enhances and positively impacts patient-clinician interactions, are key significant contributors to successful implementation. Hibbert et al [56] argued that recognising the complex factors encountered by health professional in implementing new technologies could enable implementation and sustainability of telehealth. As such, specifically for the project and study central to my thesis, members of the GDM care team (clinicians) formed this critical group of health professionals, referred to as implementers or agents [49, 54, 57, 59] in the implementation and normalisation process theories. Therefore it was crucial to engage the implementers, right from the planning stage through to the implementation of telemedicine for GDM. During the formative stages of my PhD project, part of my preliminary work included initiating meetings with the GDM care team at NH to get the teams to “buy-in” as partners in the implementation process. In addition to this, I carried out an initial pilot to test the protocol, determine how introducing telemedicine support would fit into practice and identify any gaps in the process that might need to be addressed ahead of the exploratory RCT phase.

I held a number of formal and informal meetings with the GDM service clinicians (CDE-RNs, dietitian, the endocrinologists (registrars and consultants) and head of obstetrics). This was a step in engaging the staff and fostering a collaborative relationship and partnership that would enable successful implementation of telemedicine for GDM at TNH. Clinicians were an important part of the intervention, in that they were expected to engage with using the telemedicine system element of the intervention, Online Health Portfolio (OHP), described in section 4.6.2.1, page 75, to access, and review patient data as well provide feedback to patients regarding clinical care. The purpose of the meetings was to;

i. Network and engage the team,

ii. Consult the team to clarify the need, and the problem from their perspective and how telemedicine could potentially be useful in their work, and

iii. Gather important contextual information about the GDM service.
I also regularly attended the once monthly GDM team meetings in order to become a visible member of the team rather an outsider seeking to disrupt care processes. Furthermore, as part of the selection process for the telemedicine system (section 2.3, page 33), I organised a successful demonstration session of OHP. The outcome of this process was gaining the support of the clinicians and getting their input and feedback on the operational aspect of carrying out the study, in a way that kept disruption to the clinicians’ workflow minimal. The clinicians provided feedback on some refinements to OHP that enhanced system user-friendliness. Also, engaging in this process contributed to my overall understanding of some of the implementation issues, informed by NPT.

2.2.3 Telehealth evaluation framework

In addition to the MRC framework and the NPT, my research design methodology was informed by a telehealth evaluation framework. The framework was proposed by the Institute for a Broadband Enabled Society (IBES) (Appendix 4) [51-53], for consideration in and standardisation of the evaluation of telehealth interventions in Australia. I used the framework to partly inform the selection process for the telemedicine/telehealth system I used in my study (section 2.3, page 33). The framework sets out the four key dimensions to consider, when evaluating telehealth interventions. These dimensions are outlined below, with a brief explanation and how my study related to each one:

i) **Patient Control/Use/Accessibility** – the dimension prompts telehealth interventions to be responsive to patients’ needs and ensures accessibility and continuity of care. In the TeleGDM study this is demonstrated by the intent of the intervention (described later in the thesis) to remotely connect patients with clinicians using telemedicine-support and evaluation service utilisation as an outcome.

ii) **Clinician Quality of Care** – the focus here is that the evaluation explores clinical indicators as measures of effectiveness of the intervention. Although the TeleGDM is exploratory it nonetheless included evaluation of a range of maternal and foetal/neonate clinical outcomes.
iii) **Organisation sustainability** – this relates to economic evaluation of the intervention, i.e. questions on the cost of the intervention and whether there are cost savings to the healthcare provider through the intervention. The TeleGDM study included a cost minimisation analysis from a health care provider perspective.

iv. **Technology capability** – this relates to telehealth system integrity in so far as reliability and quality of data are concerned. Further, technology capability related to the technical design and performance aspect of the technological solution in a telehealth intervention.

I used the dimensions of the telehealth evaluation framework to categorise the quantitative outcomes (Table 2) of my study, as well as to describe and discuss the qualitative evaluation findings from participant interviews (section 6.7.3.2, page 167).

### 2.3 Selection of the telemedicine system

One of the key features of the intervention in my study was the use of technology that formed the telemedicine system for my study. The process I followed to select the system was underpinned by the telehealth evaluation framework described above. The process involved networking, and discussions with other people familiar with potential systems and platforms. This was in addition to my own online research and reviews of potential systems. Next, I used the telehealth evaluation framework (Appendix 4)[51-53] to inform my appraisal of candidate systems, ahead of ultimately settling for OHP. Three of the framework dimensions, were especially important in this exercise and are discussed below.

The first, of these was **patient control/use/accessibility**. In line with the aims of my study to address the issue of service utilisation, the system needed to facilitate patient contact with the service in order for patients to access health care that responded to their clinical needs, and in a timely manner, without patients’ reliance on in-person attendance all the time. Furthermore, the system needed to be user friendly so that patients would not be averse to using it, thus potentially denying them access to service, and thereby defeating the aim of the intervention in this study. Linking with
the technology capability, access may be influenced by the type of technology
devices that patients and clinicians have at their disposal. For instance a telemedicine
system, that is accessible via personal computers, smartphones, and other wireless
devices would have greater ubiquity than one restricted to access via a single type
of device. Thus, I preferred a telemedicine system that could be accessed via
different platforms and devices, to allow users a greater choice of how to access the
system and therefore the needed health support.

The second relevant dimension was organisation sustainability. Under this dimension
the principles espoused were that the system needed to be cheap without
compromising performance and quality. Besides this being a bigger picture factor
(cost effectiveness) for potential adoption and embedding of the system in routine
practice, cost for the system were covered under a limited budget for the TeleGDM
study. Hence, it was important that the system to be procured within budget. Other
criteria for consideration included training and access to technical support. Thus, the
location of the vendor was important, with a locally based one preferred over an
overseas based one.

Technology capability was the third dimension. The criteria under this dimension are
around the design of the system performance and quality. Consideration here
included accessibility via different platforms, i.e. personal computers (Windows® or
Mac®), smartphones of different kinds (Windows®, Apple’s iOS® or Android®) and
tablet devices. Other factors for consideration included data security, ability to set
alerts and messaging capability, with ability to route messages as SMS to the patient’s
smartphone for situations when urgent contact may be needed. Originally, I planned
to use a system that allowed automatic data upload as a way of reducing manual
data entry work and the risk of data errors. However, the plan was later discarded
because automatic data upload created data errors, confusion and extra work
contrary to expectations (see section 5.4, page 117 for details).

I identified five candidate systems during the selection process. The first two were
exclusively designed for use and access via personal computers only. The vendors
were based overseas, and the systems made use of cloud storage of data. This
manner of data storage presented jurisdictional challenges in a way that revealed
gaps between policy and advances in technology. At the time there were
uncertainties about data ownership, control and applicability of NH patient privacy
and confidentiality policies once the data were in the cloud. The first of the two systems was available for free. It was consumer product still in a beta stage, and the developer was a reputable multinational organisation. However, the system failed my glucometer compatibility test for automatic data uploads and the fact that it was a product still undergoing development and testing was problematic and risky for the study. The second system, was well established and had been previously used in practice and research. The disadvantages to selecting his system was its prohibitive initial set up costs and additional costs for modifications to add features I required (e.g. messaging and SMS capability), in order fulfil some of the access and continuity of care criteria. Nevertheless I strongly considered this system but after several months of negotiations and almost settling for this system, an agreement fell through at the last hurdle.

The third system was a GSM network compatible glucometer. The glucometer worked the usual way that ordinary glucometers functioned and stored test data in its memory. A piece of innovation in this technology was that when the glucometer got within mobile/cellular phone network connection zone, it automatically transmitted the user/subscriber BGL data in the memory to the proprietary company servers based in the US. The servers then routed the data to clinicians, with authorised access and a computer, with a compatible proprietary application installed, to view the patient data. The device was unavailable in Australia and the vendor was unwilling to accede to my request to send a test device for my evaluation unless I purchased it. Costs for this device were very prohibitive for the study; let alone for patients and the organisation and therefore potentially unsustainable in the long-term. The device required cellular network subscriptions, making it function like a smartphone on an overseas based network subscription, with roaming in Australia. Further, with control based overseas, there were potential technical support availability issues, and jurisdictional issues to contend with as well. As a therapeutic good or medical device, the glucometer required approval for use. In Australia, such approvals are granted by the Therapeutic Goods Administration (TGA), the statutory regulatory authority for medicines and therapeutic devices in Australia. The necessary approvals, even for use as research device, would have needed to be lodged with the TGA. All this would have meant getting entangled in a long costly process contributing to my PhD project overrun, and I had neither the resources nor the time to accommodate.
The fourth system was a smartphone application (app), available for purchase and installation. Use and access were via a smartphone only. Data sharing involved the patient creating a spreadsheet data report to be shared via email with whomever the user (patient) chose. While this was the cheapest, it was severely limited in its functional capabilities. It was only capable of a flat file BGL data input/output, and had no messaging or internal communication features. Once again, the vendor was located overseas. The nature of the smartphone app landscape is such that, one is never certain regarding technical support. The app relied on smartphone memory for data storage, which raised question marks about data security and scalability, i.e. potential data loss in the event the smartphone failed or storage reached capacity, noting I expected a large volume of BGL data throughout the study.

Going through above process took at least eight months. The time and effort invested pushed the start of TeleGDM project over time by at least six months. It took another few weeks before my supervisors and I became aware of OHP, and further 2-3 months before the final decision was made to choose OHP.

Online Health Portfolio was the fifth and final system I considered after the above four did not meet my requirements. The system was developed by a local, Melbourne-based company. Its key functional capabilities are outlined in the description of the intervention, described in the methods chapter (section 4.6.2.1, page 75). In brief, OHP met the multiplatform (smartphone, Mac® or Windows® personal computers or tablet devices) accessible. It was a web-based system, and user devices only served as input and output terminals rather storage. Data storage was on servers that were physically located in Melbourne. System use costs were affordable, with the cheapest annual patient subscription tier of $85 (discounted for the TeleGDM study). There was free subscription for clinician users. I perused whatever was publicly available on the system web-pages, and I set up a test account to trial OHP. The vendor was available to attend meetings to demonstrate the system, including demonstrations to the GDM care team at NH. Also, the vendor was open to acting on feedback to make some improvements at no additional costs. OHP had both automated BGL data upload and manual entry capabilities.

Before making contact with the vendor, my PhD supervisors and I found more information about OHP from an endocrinologist who used it in his private practice. The endocrinologist indicated that there was a reasonable level of uptake by his clientele,
mostly younger patients with type 2 or type 1 diabetes, and a limited number with GDM. He suggested the system was not as user-friendly in relation to overall organisation of data and that older patients struggled with using OHP, which he attributed to low computer literacy. Beside a small scale clinical use by only a handful of endocrinologists and some of their patients, OHP had never undergone a critical scholarly evaluation or been used in research, until the TeleGDM study. Further description and discussion of OHP, including some limitations that were not apparent during the selection process, are highlighted in the description and discussion of the protocol piloting (chapter 5). For instance, at the time the decision was made to select it, OHP lacked SMS capability, and the data output layout was deemed to be not user friendly by the CDE-RNs (see pilot description chapter; section 5.4, page 117).

In summary the above description and discussion demonstrate a telehealth evaluation framework guided approach to selecting the technology system or solution for my TeleGDM study. It highlights that no single system is ideal, but some have greater advantages than others. The selection process required a significant investment of time, inevitably contributing to project time overruns. Out of five potential systems, I selected OHP. It was a local product, hence greater assurance of technical support and the system’s cost was affordable.

2.4 Logic of the telemedicine intervention

Telemedicine-supported GDM care, was primarily designed to reduce the need for reliance on in-person outpatient clinic consultation appointments. The intervention was aimed at reducing the number of appointments (service utilisation) while maintaining, if not improving, clinical quality of care, as well as reducing costs associated with GDM service provision.

The premise of the intervention logic was that patients would continue to carry out self-management activities (condition monitoring and treatment) as prescribed, and use a telemedicine system to share self-monitoring data with their healthcare professionals (CDE-RNs). As a platform for sharing data, OHP provided a means for timelier data transmission to clinicians than the usual care process of relying on scheduled appointments, where patients to would bring critical clinical decision-
making data to their clinic appointments. The latter practice potentially created a time lag before inadequate glycaemic control was recognised. As long as patients used OHP to enter data and have the data available for clinicians to access, analyse and interpret, ongoing GDM care could be ensured, without the patient necessarily needing to be physically present; hence the potential for reduced number of face-to-face appointments.

Besides data sharing, the telemedicine system provided a means of communication between the patient and clinician. That way, information about individuated feedback, informed by the shared critical monitoring data, can be communicated to patients for translation into continuing self-care and management. That way, care need not be constrained or limited because of the geographic gulf between the patient and the clinical team.

Furthermore, continuity of care thus achieved could mean out of target BGLs are recognised and acted upon earlier, potentially expediting achievement of optimum glycaemic control. Thereby feeding into the cycle of less frequent appointments. The anticipated flow-on benefit was that, by recognising signs of sub-optimal glycaemic control early, adverse events, e.g. hyperglycaemia or hypoglycaemia, could be averted. As a consequence, adverse short-term impacts of GDM on the patient and foetus may be prevented. Other envisaged benefits at delivery included new-born birth-weight within the 90th percentile, decreased risk of SCN admission, and avoidance of C-section delivery.

The anticipated decrease in the frequency of GDM service appointments was expected to have corresponding cost savings to the healthcare organisation. The resources thus saved could be directed towards areas where care is most needed.

Finally, as workflow becomes more efficient as a result of data sharing and communication, facilitated by telemedicine support, greater clinician satisfaction would be realised due to reduced service demand pressures. Patients would also be expected to have potentially greater satisfaction due to assurance of continuity of care that does not necessarily have to rely on patients attending the GDM clinics in person.
In order for it to work, the above process relied on the supportive element of equipping the clinicians and patients with the necessary skills to use the technology; hence the patient and clinician training or induction described later in the thesis (section 4.6.3, page 78). Added to this is the availability of technical support to ensure optimum system operation. Seamless operation of OHP was important for the interaction between patients and clinicians in order to ensure continuity of clinical care.

As might be appreciated, the intervention elements (the technological system (OHP) and ancillary activities) and stakeholders (the clinicians, patients, researcher for technological support, coupled with implementation alongside usual care processes, made the intervention in my study a complex one. All the elements and factors interacted to influence the expected outcomes. Any one, or all of these have implications for the success (or lack) of the intervention in the TeleGDM study. One of the premises of NPT is that, healthcare interventions are a multifaceted interaction of various constituent elements of the work performed by individuals or organisations [57, 58, 60]. Such complex interventions are more reflective of real world practice and are more likely to be successful than single component interventions [61], underscoring the importance of each of the constituent elements of the intervention in my study. Underpinning such a multi-pronged intervention is behaviour and readiness to change on the part of healthcare providers and the recipients of healthcare [62]. Behaviour and readiness to change were not explicitly evaluated in this study, however implementing the TeleGDM study recognised that behaviour and readiness to change were integral to the success of this project. This phenomenon is discussed further in section 7.5, readiness to change (page 204).

2.5 Significance of this project and aims

The above sections provide a narrative of the health service problem that prompted the study described in this thesis. They provide preliminary rationale and justification of the chosen approach to address the identified problem informed by the MRC
framework and implementation and NPT. I conclude this chapter by recapping the broader statement of the aims and significance of my PhD study.

The higher incidence and prevalence of GDM, coupled with a significant proportion of the affected women requiring insulin to control hyperglycaemia and limited health care services, has increased the need for more innovative approaches to service provision. Telemedicine offers an opportunity to enhance service provision, however evidence in GDM is limited. Broadly the question that I aimed to answer in my study and thesis related to whether telemedicine was a viable approach to address the issue of the burden on service provision and whether by doing so, telemedicine had any effects or impact on clinical and other outcomes. My study aimed to explore the effects of telemedicine, primarily on the number of outpatient clinic appointments concerned with GDM care, as a measure of health service utilisation, which is an important indicator of health service performance.

The significance of this study was twofold. GDM is an increasing health problem and telemedicine in the context of GDM is a subject of interest from evidence based practice in relation to the state of the current body of evidence.

GDM is an increasing problem exerting increased burdens on existing limited services. It is both a health service and clinical problem that not only affects the mother but the unborn baby in the short term and longer term, thus feeding into wider public health concerns of diabetes or metabolic conditions. Hyperglycaemia and poorly controlled blood glucose in GDM is associated with serious perinatal and neonatal clinical complications (e.g., larger babies for gestational age, greater chance for caesarean delivery, baby brachial plexus injury, preeclampsia, gestational hypertension). The condition is also a risk factor for development of type 2 diabetes mellitus later in life [7, 63]. From an epidemiological perspective in the Australian context, GDM affects up to 15% of pregnancies [10]. With a reported 301,617 (an increasing) births registered in Australia in 2011[64], the 15% prevalence of GDM in the Australian population translates to up to 45, 200 women, half of whom will need insulin and intensive health monitoring. Not only does the condition affect mothers but their infants too, potentially doubling the number of directly affected lives annually. Babies born to mothers with GDM are predisposed to metabolic syndromes e.g. obesity, and glucose intolerance, later in life [7, 63].
As highlighted above, there are few studies of telemedicine in GDM. Many of these studies are limited in their design and sample, and effect size. Overall there is limited, if any, good evidence on the effectiveness of telemedicine in GDM. My study aims to make a contribution to the body of evidence for telemedicine in GDM. The next chapter is an in-depth review of the literature to apprise the evidence for telemedicine in GDM.
3 **SYSTEMATIC LITERATURE REVIEW**

3.1 **Overview**

In the background chapter, I looked at the literature from a general perspective to introduce the main concepts and ideas behind my study. My aim in this chapter was to appraise the status of evidence on the effect of telemedicine on GDM health care service utilisation, maternal, and foetal outcomes and other outcomes in GDM through a systematic literature review and meta-analysis. Systematic literature reviews and meta-analyses are established methods for evaluating existing knowledge and providing evidence for a defined intervention in a defined patient population. The approach brings together multiple individual studies into one whole that has a greater impact, where individual studies often suffer limitations of generalisability, validity or power [65, 66].

The protocol for the systematic literature review and meta-analysis is appended (Appendix 1). The protocol details the process and methods that were followed, the result of which is a copy of the published paper [67] appended in the next section 3.2. The findings further corroborate the paucity of good quality studies of telemedicine in GDM. Whilst telemedicine appears to reduce health service utilisation, i.e. outpatient GDM consultation appointments, clinical maternal and foetal outcomes from telemedicine were not significantly different from controls. None of the studies included an evaluation of costs. The conclusion from the review was that while the evidence is limited, telemedicine might be as good as usual care in relation to clinical outcomes. Without an indication on the cost status, the advantage of telemedicine lies in its potential to reduce service utilisation without compromising other important outcomes. Nonetheless, I determined there was sufficient background information, rationale and justification to proceed to the next step to trial and evaluate telemedicine at NH as a new and innovative approach to supporting GDM care at this setting. On the background of the limited evidence, implementing the telemedicine for testing as an alternative substitute intervention would be ethically problematic. As such, consideration was given to evaluating telemedicine as an add-on to usual care rather a substitute.
3.2 Published paper 1: Systematic literature review and meta-analysis
Review

Telemedicine interventions for gestational diabetes mellitus: A systematic review and meta-analysis

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A B S T R A C T
Objective: To evaluate the effect of telemedicine on GDM service and maternal, and foetal outcomes.
Methods: A systematic review and meta-analysis of randomised controlled trials (RCT) of telemedicine interventions for GDM was conducted. We searched English publications from 01/01/1990 to 31/08/2013, with further new publication tracking to June 2015 on MEDLINE, EMBASE, PUBMED, CINAHL, the Cochrane Central Register of Controlled Trials and the World Health Organization International Clinical Trials Registry electronic databases. Findings are presented as standardised mean difference (SMD) and odds ratios (OR) or narrative and quantitative description of findings where meta-analysis was not possible.
Results: Our search yielded 721 abstracts. Four met the inclusion criteria; two publications arose from the same study, resulting in three studies for review. All studies compared telemedicine to usual care. Telemedicine was associated with significantly fewer unscheduled GDM clinic visits, SMD. Quality of life, glycaemic control (HbA1c, pre and postprandial blood glucose level (BGL)), and caesarean section rate were similar between the telemedicine and usual care groups. None of the studies evaluated costs.
Conclusions: Telemedicine has the potential to streamline GDM service utilisation without compromising maternal and foetal outcomes. Its advantage may lie in the convenience of reducing face-to-face and unscheduled consultations. Studies are limited and more trials that include cost evaluation are required.

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1. Introduction

The prevalence of Gestational Diabetes Mellitus (GDM) is estimated between 2% and 16% of all pregnancies [1]. The diagnosis of GDM typically occurs in week 24–28 of pregnancy, when routine oral glucose tolerance test (OGTT) screening is performed [1,2]. Based on GDM management guidelines and recommendations, a ‘step-up’ approach is suggested to control hyperglycaemia [3,4]. First-line intervention involves dietary modification and physical activity [5–7] or an oral hypoglycaemic agent (OHA) [5]. In approximately half of cases, GDM is managed using insulin [2,5], which requires intensive monitoring and regular insulin adjustment [2]. The additional demand placed on pregnant women beyond regular prenatal care may lead to missed appointments and sub-optimal GDM management [4–6].

Suboptimal GDM control is associated with serious perinatal and neonatal complications including babies that are large for gestational age (LGA), greater chance of caesarean delivery, brachial plexus injury in the baby, preeclampsia, and gestational hypertension [4,5,8]. Nearly 50% of women with GDM develop type 2 diabetes within 8 years of delivery [9]. Furthermore, results of a systematic review and meta-analysis of associations between GDM and type 2 diabetes showed women with GDM had approx. 7.5-fold risk of developing type 2 diabetes compared to women with normoglycaemia during pregnancy [10].

Sustainable and innovative models of care that improve patient outcomes with minimal burden and disruptions on the patient are critical [11]. Fineberg argues that the key elements of sustainability are affordability for patients, healthcare service and government and acceptability by all stakeholders [12]. High cost and inefficient systems of care can be barriers to sustainability [12] of otherwise innovative health care provision. Hence cost benefits and/or savings are integral to sustainability of care.

Telemedicine refers to the use of information and communication technologies (ICT) to bridge the distance gap in the pursuit of sharing health information and delivering health care [13]. Interest in telemedicine is increasing as a potentially innovative and sustainable intervention approach to GDM management. Information sharing may occur between healthcare professionals or between healthcare professionals and patients. A distinction is often made between telemedicine (service delivery by doctors) and telehealth (service delivery by any healthcare professional) [14]. The World Health Organization (WHO) [14] has adopted an interchangeable use of telemedicine and telehealth. Another common term is telemonitoring in which patients remotely monitor their condition, relay data to their healthcare professionals for evaluation and feedback/action [13,15,16]. For the purpose of this review we adopted the broad definition of telemedicine/telehealth, including telemonitoring.

Systematic appraisals of telemedicine have been conducted for various diseases and population groups [15–19]. However, we have not identified any reviews that specifically or exclusively appraised the use of telemedicine in GDM. Jana and Pare [16] reviewed the use of telemedicine in type 1 and 2 diabetes and reported “...significant reduction in HbA1c and complications, good receptiveness by patients and patient empowerment and education.” Other systematic reviews of telemedicine or telemonitoring have reported mixed results. A review of telemedicine in chronic disease management generally reported similar outcomes between telemedicine and controls [15] while reviews of the use of telemedicine in asthma (where it may reduce exacerbations and hospitalisation [17]) and in smoking cessation (where higher quit rates were found in favour of mobile phone-based interventions [18]) have been positive.

Few studies of telemedicine include cost assessment. In 2002, only 9% of telemedicine studies reportedly included cost evaluations and the results were generally inconclusive [19]. Nevertheless net cost savings have been reported in favour of telemedicine, largely attributed to avoided travel-associated costs [20,21].

Despite the lack of systematic reviews of telemedicine in GDM, one quasi-controlled study that looked at telemedicine in managing diabetes in a mixed group of pregnant women with type 1 diabetes or GDM, showed acceptance levels of 85% and usage (weekly transmission of data) was 76% [22]. With mixed results in terms of effectiveness and costs, and yet rapid growth of telemedicine we conducted a systematic review of the literature and meta-analysis to examine the effect of telemedicine for GDM on glycaemic control, mother and infant...
perinatal outcomes, and GDM clinic utilisation, quality of life and costs.

2. Materials and methods

A systematic review and meta-analysis of randomised controlled trials (RCT) of telemedicine for GDM management was conducted. Telemedicine interventions included use of telephone, video-conferencing, mobile short message service (SMS), or web-based interfaces and other remote wireless relay systems.

2.1. Literature search

An electronic search of the literature was performed in English across multiple databases including MEDLINE, EMBASE, PUBMED, CINAHL, the Cochrane Central Register of Controlled Trials and the World Health Organization International Clinical Trials Registry Platform. The search used Medical Subject Headings (MeSH) and free text to cover the various synonyms of the search terms outlined in Appendix 1. Bibliographies and reference lists of included studies were scrutinised to identify any other relevant studies. Literature search and screening were conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2009) guidelines [23].

2.2. Inclusion criteria

The inclusion criteria were RCTs on telemedicine interventions in women with GDM that were published in English language. The telemedicine interventions included monitoring, consultation or providing feedback to patients in relation to GDM management. The literature search was limited to publications from 01/01/1990 to 31/08/2013 because publications on telemedicine in chronic disease management emerged in 1990 [15]. Also, an automated alert of the search history and criteria was set up to receive monthly updates on any new relevant publications since the end of the search period.

2.3. Exclusion criteria

Exclusion criteria were literature pertaining to other forms of diabetes, population groups other than GDM, or pooled results of GDM and diabetes population groups. Studies were also excluded if the aim was to assess reliability and validity of telemedicine modalities or to compare various telehealth or telemedicine modalities.

2.4. Study selection

A search of the literature was performed by primary author (TR) according to the search strategy outlined above. Retrieved titles and/or abstracts were screened to eliminate duplicates and identify potentially relevant titles. Full text articles in the final list were obtained for eligibility screening and data extraction by three independent reviewers (TR, IF and IB). Included studies were assessed for quality and data extraction.

2.5. Outcomes

The primary outcomes of the review were GDM health service utilisation, glycaemic control and neonate birth-weight. Health service utilisation measures covered face-to-face and non-face-to-face, as well as scheduled or unscheduled consultations. Secondary outcomes were caesarean mode of delivery, gestational age at delivery, macrosomia, large for gestational age (LGA), neonatal intensive care admission or special care nursery admission, quality of life and costs.

2.6. Data analysis and synthesis

Summary data and descriptions of the studies are presented in the results section. Methodological quality of included studies was assessed using the Downs and Black [24] checklist. The checklist was developed as a tool to assess the quality of studies that use randomised or non-randomised designs. The tool is a 27-item checklist with five sub-scales: reporting, external validity, internal validity (bias), internal validity (confounding/selection bias) and power, which are aggregated to give a possible best score of 32. The checklist has no cut-offs for high or low quality, however the authors reported an overall mean (sd) of 14.06 (3.39) for RCTs. Hence for the purpose of this review we considered scores greater than the reported average as better than fair quality.

Next a meta-analysis of the studies was performed using RevMan version 5.3 [25] with plans to perform assessment of consistency using I² statistics [26] and where there was evidence of inconsistency (heterogeneity) or the number of studies too small, results would be presented only as descriptive statistics and narrative in lieu of pooled data meta-analysis. Effect size for continuous outcomes data are presented as standardised mean differences and odds ratios (OR) for dichotomous or proportion outcomes with forest plots. The level of statistical significance was set at \( p < 0.05 \).

3. Results

Our search yielded 721 articles. After screening for duplicates, relevant titles and abstracts, 14 full text publications were obtained for further screening. A further 10 publications were then excluded for the following reasons: comparison of two telemedicine interventions [27], presented pooled data for GDM and TZDM [28], outcomes were different from those we aimed to evaluate [29,30], editorial commentaries [31,32], methodology paper [33], different population group (pregnant women without GDM or postpartum women) [34,35] and non-RCT [36]. Thus 4 publications [37-40] met the inclusion criteria for review; 2 publications [39,40] were of the same study, resulting in 3 studies for review (PRISMA Fig. 1). Subsequent tracking and alerts to ensure capture of new relevant publications since the end of the search period produced no new relevant publications up to June 2015.

All the included studies compared telemedicine to usual care. The mean(SD) quality score was 18.3(2.1) (Table 1). The lowest scoring study was Homko et al. [38] with a score of 16 and the highest score was 20/32 for the Homko et al. [37]
study. All the studies scored particularly low on external validity and power subscales.

For the included studies, telemedicine involved self-monitoring by pregnant women, a data transmission medium and communication between healthcare providers and the women. In the first Homko et al. [38] study, telemedicine involved an interactive web-based disease management system which allowed participating women to send their self-monitoring blood glucose readings and other health data (foetal movements, insulin doses and episodes of hypoglycaemia) to their GDM healthcare professionals over the internet [38]. Internet access in this study used dial-up modems over refurbished computers provided by the investigators. The system allowed messaging and feedback between the women and healthcare professionals. There were also links to educational resource materials on GDM on the system webpage. The second Homko et al. study used the same system described above but with some enhancements to enable better access and interaction with the system such as an interactive voice response telephone system, asynchronous phone messaging and automated reminders for patients to send data [37]. In the third study by Pérez-Ferre et al., the telemedicine intervention involved providing women with a cellular phone installed with a BGL data recording application and glucometers with infra-red data transmission capability [39,40]. Glucose readings from the glucometers were automatically uploaded to the cellular phone via infra-red for onward transmission via short message service (SMS) to the women’s hospital based GDM healthcare professionals. In turn the healthcare professionals accessed the data through a web-based application over the internet. Feedback messages were typed on the messaging service on the web application and transmitted to the patient’s cellular phone as SMS.

The three studies covered a range of therapies for controlling hyperglycaemia, namely diet, OHA or insulin [37,38] and insulin with other therapies [39,40]. Only one study measured quality outcome in the form of diabetes self-efficacy [38] and none of the studies evaluated costs.

Outcomes are reported in Tables 1–3. Some notable general observations were that the studies reported glycaemic control
### Table 1 – Characteristics of the three included studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population/sample</th>
<th>Intervention/control</th>
<th>Study Quality Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Participants</td>
<td>Baseline, n</td>
<td>Follow-up, n</td>
</tr>
<tr>
<td>Homko et al. (2007)</td>
<td>University hospital prenatal clinics</td>
<td>GDM, 18-45y.o, ≤ 33 weeks gestation</td>
<td>T = 34</td>
<td>T = 25</td>
</tr>
<tr>
<td>Pérez-Ferre et al. (2010)</td>
<td>University hospital</td>
<td>GDM, &lt;28 weeks gestation</td>
<td>T = 50</td>
<td>T = 49</td>
</tr>
<tr>
<td>Homko et al. (2012)</td>
<td>University hospital prenatal clinics</td>
<td>GDM, 18-45y.o, ≤ 33 weeks gestation</td>
<td>T = 40</td>
<td>T = 36</td>
</tr>
</tbody>
</table>

T = Telemedicine group, C = Control.
as HbA1c and/or pre and post-prandial BGL. Also as noted in the outcomes tables, some results were reported as not significant without actual p-values. Significant differences between telemedicine and usual care groups were observed in health service utilisation among the insulin treated subgroup (Table 2) [39,40], and the sub-domains of diabetes self-efficacy (managing the psychosocial aspects of diabetes and assessing dissatisfaction and readiness to change) [38] (Table 4). There were no statistically significant differences in glycaemic control, birth-weight, macrosomia, caesarean deliveries, or special care nursery admissions (Tables 3 and 4). Similarly, pooled data meta-analysis results showed non-statistically significant differences in glycaemic control (Fig 2 and Fig 3) and caesarean delivery rates (Fig 4), all with small effect sizes. Large for gestational age (LGA) was not significantly different between the telemedicine and usual care, OR = 1.50 (95%CI: 0.70, 3.22). Since only three studies were included sensitivity analysis was not performed.

4. Discussion

Our systematic review of RCTs on telemedicine for GDM showed that good quality trials in this area were few in number. The sample sizes in the individual studies were small ranging from 57 to 97 after attrition, for a maximum pooled

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Birth-weight, mean(sd), g</th>
<th>Macrosomia</th>
<th>Delivery</th>
<th>SCN/NICU Admission</th>
<th>Diabetes self-efficacy, mean(sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homko et al. (2007)</td>
<td>T = 32</td>
<td>C = 25</td>
<td>T = 3374(634)</td>
<td>NS</td>
<td>T = 26%</td>
<td>T = 9%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C = 3151(452)</td>
<td>NS</td>
<td>C = 12%</td>
<td>C = 40%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>T = 28%</td>
<td>NS</td>
<td>T = 69%</td>
<td>C = 10%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C = 12%</td>
<td>NS</td>
<td>T = 69%</td>
<td>C = 40%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td>NS</td>
<td>T = 22%</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NS</td>
<td>Total DSE: T = 4.9(0.5), C = 4.0(0.5), p = 0.053</td>
<td>Subscale 1: T = 4.5(0.5), C = 4.0(0.6), p = 0.039</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NS</td>
<td>Subscale 2: T = 4.3(0.5), C = 3.9(0.5), p = 0.036</td>
<td>Subscale 3: T = 4.4(0.7), C = 4.1(0.6), p = 0.268</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NS</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Pérez-Ferre et al. (2010)</td>
<td>T = 49</td>
<td>C = 48</td>
<td>T = 3308(488)</td>
<td>NS</td>
<td>T = 61%</td>
<td>T = 34.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C = 3370(479)</td>
<td>NS</td>
<td>C = 8.3%</td>
<td>T = 20.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>T = 61%</td>
<td>NS</td>
<td>T = 40.8%</td>
<td>C = 10.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C = 8.3%</td>
<td>NS</td>
<td>T = 40.8%</td>
<td>C = 10.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P = 0.068</td>
<td>NS</td>
<td>T = 22%</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NS</td>
<td>Total DSE: T = 4.9(0.5), C = 4.0(0.5), p = 0.053</td>
<td>Subscale 1: T = 4.5(0.5), C = 4.0(0.6), p = 0.039</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NS</td>
<td>Subscale 2: T = 4.3(0.5), C = 3.9(0.5), p = 0.036</td>
<td>Subscale 3: T = 4.4(0.7), C = 4.1(0.6), p = 0.268</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NS</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Homko et al. (2012)</td>
<td>T = 36</td>
<td>C = 38</td>
<td>T = 3373(469)</td>
<td>N/A</td>
<td>T = 25%</td>
<td>T = 11%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C = 3249(469)</td>
<td>N/A</td>
<td>C = 18.4%</td>
<td>C = 18.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>T = 25%</td>
<td>N/A</td>
<td>T = 25%</td>
<td>C = 18.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C = 18.4%</td>
<td>N/A</td>
<td>T = 25%</td>
<td>C = 18.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P = 0.3</td>
<td>N/A</td>
<td>T = 0.3</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P = 0.4</td>
<td>N/A</td>
<td>T = 0.3</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NS</td>
<td>T = 0.3</td>
<td>N/A</td>
</tr>
</tbody>
</table>

T = Telemedicine group; C = Control; NVD = Normal Vaginal Delivery; DSE = Diabetes Self-Efficacy. Subscale 1 = DSE Managing the Psychosocial Aspects of Diabetes. Subscale 2 = Setting and Achieving Diabetes Goals. Subscale 3 = DSE Assessing Dissatisfaction and Readiness to Change.
sample of 154. Even with pooled data the sample was underpowered to detect any difference across clinical outcomes.

Our findings suggest that telemedicine reduced the need for face-to-face consultations and unplanned face-to-face consultations while achieving similar maternal and foetal outcomes. Complementing GDM care with telemedicine interventions has the capacity to streamline health services by targeting more urgent cases for face-to-face consultations without compromising mother and baby outcomes for those who receive care and support via telemedicine. The fact that only one study with 97 participants [39] contributed to the findings of the benefits of telemedicine means caution needs to be exercised on account of the risk of bias (also related to the failure to account for the three out of the original 100 participants who dropped out of this study).

Despite the limited number of included studies and the small sample sizes, we found that the benefit on GDM health service utilisation is more prominent when telemedicine is targeted at women with insulin-treated GDM [39]. This group of women often requires much more intensive monitoring and support in the early stages of insulin initiation and titration [2], which current usual care alone struggles to achieve. Targeting the insulin treated group is supported by the observation from a study of patients with type 1 and type 2 diabetes, where insulin therapy was found to be predictive of greater uptake of telemonitoring compared to non-insulin treatment [41]. Moreover, younger population with high levels of technological awareness and usage was shown to be more receptive to ICT interventions [41]. Expectant women have a similar demographic profile, suggesting telemedicine may be a good fit for the insulin-treated GDM population. Glycaemic control showed an improving trend in favour of telemedicine (Figs. 2 and 3) although the overall pooled results showed similarities between the telemedicine group and controls. A similar trend was observed in relation to rates of caesarean deliveries in one of the studies (Fig. 4). The studies included in our review are few, therefore any biases and design limitations inherent in these studies are likely flow on to the findings of our review.

With similar maternal and foetal outcomes between telemedicine interventions and usual care, the question remains as to whether telemedicine may offer a cost advantage over usual care. As highlighted by one of the studies included in our review, the superiority of telemedicine over usual care may lie in telemedicine’s potential to improve efficiency [37]. Although there is an initial cost outlay to set up telemedicine interventions, there is a net future cost saving. An Australian cancer service study reported a service level net.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Telemedicine</th>
<th>Usual Care</th>
<th>Std. Mean Difference</th>
<th>Std. Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean SD Total</td>
<td>Mean SD Total</td>
<td>Weight</td>
<td>IV, Random, 95% CI</td>
</tr>
<tr>
<td>Horno 2007</td>
<td>6.1 0.8 32</td>
<td>6.2 2.2 25</td>
<td>36.8%</td>
<td>-0.08 [0.56, 0.48]</td>
</tr>
<tr>
<td>Pérez 2010</td>
<td>5.3 0.4 48</td>
<td>5.4 0.4 48</td>
<td>63.2%</td>
<td>-0.25 [0.65, 0.15]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>81</td>
<td>73</td>
<td>100.0%</td>
<td>-0.18 [-0.50, 0.14]</td>
</tr>
<tr>
<td>Heterogeneity: TAU² = 0.00; CHI² = 0.30, df = 1 (P = 0.58); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 1.11 (P = 0.27)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig. 2 – Forest plot of glycaemic control (HbA1c).

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Telemedicine</th>
<th>Usual Care</th>
<th>Std. Mean Difference</th>
<th>Std. Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean SD Total</td>
<td>Mean SD Total</td>
<td>Weight</td>
<td>IV, Random, 95% CI</td>
</tr>
<tr>
<td>Horno 2007</td>
<td>106.6 13.2 32</td>
<td>104.5 13.6 25</td>
<td>43.2%</td>
<td>0.15 [-0.37, 0.66]</td>
</tr>
<tr>
<td>Horno 2012</td>
<td>107.4 12.9 38</td>
<td>109.7 16.5 38</td>
<td>56.8%</td>
<td>-0.15 [-0.81, 0.30]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>68</td>
<td>63</td>
<td>100.0%</td>
<td>-0.02 [-0.36, 0.32]</td>
</tr>
<tr>
<td>Heterogeneity: TAU² = 0.00; CHI² = 0.75, df = 1 (P = 0.39); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 0.12 (P = 0.91)</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig. 3 – Forest plot of mean (1-h and 2-h) post-prandial BGL.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Telemedicine</th>
<th>Usual Care</th>
<th>Odds Ratio</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events Total</td>
<td>Events Total</td>
<td>Weight</td>
<td>M-H, Random, 95% CI Year</td>
</tr>
<tr>
<td>Horno 2007</td>
<td>0 32</td>
<td>19 25</td>
<td>18.3%</td>
<td>0.02 [0.00, 0.41] 2007</td>
</tr>
<tr>
<td>Pérez 2010</td>
<td>17 48</td>
<td>12 48</td>
<td>41.2%</td>
<td>1.18 [0.69, 2.04] 2010</td>
</tr>
<tr>
<td>Horno 2012</td>
<td>13 36</td>
<td>19 38</td>
<td>40.9%</td>
<td>0.67 [0.32, 1.33] 2012</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>117</td>
<td>111</td>
<td>100.0%</td>
<td>0.48 [0.10, 2.35]</td>
</tr>
<tr>
<td>Total events</td>
<td>30</td>
<td>41</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: TAU² = 1.28; CHI² = 3.42, df = 2 (P = 0.039); I² = 79%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 0.90 (P = 0.37)</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Fig. 4 – Forest plot of caesarean deliveries.
cost saving of approximately $320,000 (Australian) over nearly four and half years when a tele-ontology model was compared to a usual care model service [20] while an estimated net cost saving of about $9 000–$11 000 per 200 consultations per year was also observed in Denmark in a telemedicine service for type 1 and type 2 diabetes [21]. A significant amount of savings from both studies largely related to avoided transportation costs after taking into consideration the annual costs of the telemedicine system.

Our review highlights the potential effect of telemedicine in the management of gestational diabetes and a number of limitations. We included only English publications in our review. However, we did not identify any non-English titles or abstracts that fitted our inclusion criteria. Even though we pooled data for some outcomes, the studies used different telemedicine approaches and hypoglycaemic treatments, i.e., oral medications, insulin or diet, which may have a bearing on the effect and size of outcomes. As such, we elected to use random effects modelling for our meta-analysis to counteract the latter variations. Outcome selection bias on our part may be a possibility arising from the fact that there are other outcomes and metrics often used in GDM, e.g., neonatal hypoglycaemia, shoulder dystocia, and Apgar score. Nevertheless, we selected a range of outcomes to cover a broader effect of telemedicine in GDM. Finally, the small number of studies meeting the inclusion criteria was such that sensitivity analysis to assess the extent of bias and inconsistencies in individual studies in a meta-analysis was not possible [26,42].

5. Conclusion

Telemedicine has the potential to reduce GDM service utilisation while producing similar maternal and foetal outcomes as usual care. Its advantage may lie in the ability to deliver support and monitoring remotely for the convenience of pregnant women and reducing face-to-face and unscheduled consultations. Studies are limited and more trials that include cost evaluation are required.

Conflict of interest statement

All the authors declare no conflict of interest.

Author contributions

TR conceived the review topic, drafted the protocol, performed literature search, review data extraction, data analysis and authored the manuscript.

JF performed literature review, data extraction and contributed to manuscript authorship and editing.

IB performed literature review and contributed to manuscript authorship and editing.

MT provided secondary data analysis, contributed to manuscript authorship.

KG provided technical oversight, contributed to manuscript authorship and editing.

KL performed secondary literature review, contributed to manuscript authorship and editing.

Acknowledgements

We would like to acknowledge Dr Patty Chondros for her biostatistical advice during the early phase of conception of the review. We would like to thank Prof Doris Young and Prof Danny Liew for their feedback on the selection of outcomes. TR is supported by Australian Postgraduate Association (APA) scholarship, PhD top-up scholarship from Institute for Broadband Enabled Society (now Melbourne Networked Society Institute), University of Melbourne and a small project grant from Northern Health, Victoria, Australia. JF is supported by NHMRC Career Development Fellowship.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at http://dx.doi.org/10.1016/j.diabres.2015.07.007.

References


In summary, there are few quality studies of telemedicine in the context of GDM. In spite of the methodological limitations of the few available studies, telemedicine for GDM appears to offer promise, and may reduce service utilisation. The studies generally showed clinical outcomes from telemedicine interventions, did not significantly differ from outcomes realised through usual care. None of these studies included a cost evaluation, which, in the absence of significant differences in clinical outcomes, may be an important element that informs practice and policy relating to telemedicine interventions for GDM.
4 Methods

4.1 Overview and design

In this chapter I will outline and discuss the study methods which I used to answer the research questions of the TeleGDM study. The chapter describes the study population and setting, study design, the intervention, data collection procedures and how I analysed the data. At the end of this chapter, I have appended a copy of the TeleGDM study protocol paper. This peer review journal paper, is an abridged version of the TeleGDM study proposal and protocol. The paper is included in this thesis for the reason that the protocol was about an innovative use of current technology in the context of GDM. Previous studies of telemedicine in GDM were based on technologies that had become obsolete and superseded by newer and cheaper ubiquitous technologies. At the time my study was conceived there were no other trials of telemedicine in GDM in Australia.

A number of methodologies exist to answer research questions, test hypotheses and provide empirical evidence. The methods are classified into two broad categories, quantitative and qualitative methodologies. Selection of which methodology to use to answer a clinical and/or health service research question, let alone any research, is dictated by the best methods fit for the question and purpose of the research.

Randomised controlled trials, which are primarily quantitative based, are the gold standard and the pinnacle of generating empirical evidence for practice [68, 69]. In spite of this, RCTs have the limitation of “...not tell[ing] the whole story...” [70], due to reliance on quantitative methods only. Qualitative methodologies can thus augment findings from RCTs. Approaches such as interviews provide more in-depth information about participants’ experiences and process-related issues [71], which would otherwise not be captured by quantitative methods, such as an RCT, alone. When used together, quantitative and qualitative methods complement each other in a design which harnesses the combined strength of both methods. This is increasingly becoming common, especially in health services research [72]. Health services
research by its nature is a multidisciplinary field which draws on expertise from both research paradigms to provide a greater understanding of the health services issues [72].

The MRC framework and the NPT both embrace process evaluation [37, 38, 49, 50, 59], undertaken as an integral component of implementation of complex interventions. Process evaluation is a means for shedding light into the factors that lead to the successes or failures of the intervention [37, 73]. It aids in explaining, “why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimised,” [37] for the local setting [73].

I designed a mixed methods study involving an exploratory randomised controlled trial (RCT), that encompassed process and outcome evaluation, in order to answer my research questions. The quantitative aspect of the study focussed on the primary outcome, health service utilisation, and clinical measures. I supplemented these with qualitative evaluation involving semi-structured interviews and survey questionnaires with Likert and free text response items. Furthermore, I included some process evaluation, which comprised of process measures focusing on the fidelity of engaging with the telemedicine system of choice, for data sharing (intervention) and the task of keeping self-monitoring data via a handwritten record (usual care/control).

Prior to undertaking the RCT, I piloted my protocol and intervention. My aim was to get insights into how the intervention work in a real clinical practice and health service setting. It was a test of how my study protocol would fit and work alongside the GDM clinic usual care processes, in order to identify areas that required refinement, ahead of the RCT. A detailed description of the pilot, is provided in the fourth chapter, which follows the methods.
4.2 Research questions, hypotheses and objectives

4.2.1 Research questions

The broader health service and clinical problem for my study, was whether a telemedicine-supported GDM management service would have better outcomes or not, compared to existing processes of care, in a real world clinical setting. The outcomes related to health system performance (outpatient GDM service utilisation) and clinical outcomes for the mother and baby. I also sought to investigate patient and clinician satisfaction levels, the potential for a cost advantage from using telemedicine and how telemedicine for GDM might be received by the patients and clinical staff in the GDM care team.

The systematic literature review and meta-analysis described in the previous chapter demonstrated a gap in knowledge relating to the evidence for telemedicine in GDM. The evidence was inconclusive, thus adding to the rationale and formulation of the health service and clinical research questions, I needed to answer though my own empirical research. These questions were:

1. What is the effect of an adjunct telemedicine used to support the management of GDM on:
   
   a. The number of scheduled face-to-face, unscheduled face-to-face (walk-in and telephone) consultations as indicators of outpatient GDM health service utilisation?
   
   b. A range of maternal and foetal clinical health outcomes? The selected measures for these outcomes are outlined in Table 2.

2. What is the impact of this adjunct telemedicine intervention on,

   a. Patients’ (pregnant women) perceived satisfaction with healthcare for GDM, diabetes self-efficacy and their experience with the concept of
telemedicine support and the telemedicine system that was used in the TeleGDM study?

b. Clinicians’ satisfaction and experiences with telemedicine as a concept and the specific telemedicine system selected for this study?

3. Can the health service provider save costs by providing a telemedicine-supported GDM care compared to current usual practice?

4.2.2 Hypotheses

The hypotheses for my study were that, compared to usual care, an adjunct telemedicine to support insulin-treated GDM management and care would result in:

i) Improvements in service system performance (utilisation) indicators; specifically the number of GDM-related outpatient clinic consultation appointments with endocrinology team (endocrinologist, CDE-RN and dietitian), with an estimated 30% reduction in face-to-face appointments,

ii) No difference or better maternal (glycaemic control, rates of caesarean delivery) and foetal (rates for macrosomia, large for gestational age, special care nursery admission) clinical outcomes, and

iii) A reduction in healthcare provider costs for the GDM outpatient service.

4.2.3 Objectives

In order to answer my research questions and address the health service and clinical problem, the objectives of my study and thesis were as follows:

1. To review relevant literature, including conducting a systematic literature review and meta-analysis, to appraise current evidence, on the effects of telemedicine in GDM. The objective was achieved as detailed in the first two chapters of this thesis,
2. Following on the above and drawing on implementation theory in the context of ehealth and the telehealth evaluation framework, to implement and evaluate a telemedicine intervention adjunct to usual care through an exploratory randomised controlled trial (the TeleGDM study) in a real world setting, by looking at a range of health service, maternal and foetal/new-born outcomes and costs,

3. To undertake a process evaluation using semi-structured interviews of both patient and clinician (CDE-RNs) experiences of using telemedicine, in order to augment the exploratory RCT. The CDE-RNs’ interviews supplemented their questionnaire-based assessment of satisfaction and quality of the telemedicine system.

4.3 Setting and population

4.3.1 Setting

Northern Health is the health service organisation that provides health care in the northern corridor of metropolitan Melbourne. The health service and its catchment are described in the background chapter (section 1.1.2 page 13). Northern Health provides healthcare across three campuses. These campuses are The Northern Hospital (TNH), which is a mid-size tertiary hospital that offers acute and a range of ambulatory (outpatient) care services. The second campus is Broadmeadows Health Service (BHS), located some 15km from TNH. BHS offers post-acute care and ambulatory care services. The third campus, located approximately 15km from NH is Craigieburn Health Service (CHS), which offers ambulatory care services. The ambulatory care services at all three campuses include an outpatient GDM clinic or service.

The GDM clinics operated, once weekly, for approximately half a day, on non-public holiday weekdays, at each of the three campuses of NH. The TNH clinic operated on Monday with a GDM clinical care team of a consultant endocrinologist, two
endocrinology registrars, two Credentialed Diabetes Education-Registered Nurses (CDE-RNs) and one dietitian. The CHS clinic operated on Wednesdays and the clinical care team included a CDE-RN, Diabetes Nurse Practitioner/CDE-RNs, and a dietitian. When needed, patients travelled to the TNH to access an endocrinologist. At BHS the clinic ran on Tuesdays with one CDE-RN, the same diabetes nurse practitioner/CDE-RN who also worked at CHS, a dietitian and a consultant endocrinologist who joined the BHS team about 15 months after the start of the TeleGDM study. Although these half day clinics were designated GDM services, clinicians also saw a small number of patients with other types of diabetes in pregnancy and non-pregnancy diabetes. The caseload for the endocrinologists also included patients with other endocrine disorders. Outside designated appointment times and when needed, patients could access clinicians, especially CDE-RNs, on other weekdays or by phone regarding GDM-related queries. These unplanned consultations occurred during normal business hours. For after-hours emergencies, patients could present to the emergency department at TNH.

As an illustration of the throughput of the GDM services at NH, there were 2 694 live births in the fiscal year 2011/12 and 3 031 the following fiscal year 2012/13 [23]. The numbers are projected to continue to increase as the catchment population increases. Based on the 2012 calendar year, historical data showed that 400 (16%) of the 2500 pregnant women who gave birth at The Northern Hospital, had GDM during their pregnancy.

A typical clinic day at TNH campus had a throughput in excess of 40 patients, attending for appointments with the multidisciplinary GDM care team, as well as for obstetric reviews. This meant patients spent a considerable amount of time in the clinic, with some waiting time between being seen by the different members of the care team. Throughput at each of the other two campuses was around half of that of TNH. Therefore patients at these campuses tended to have less waiting in between appointments compared to TNH.

In addition to providing individualised clinical care, the CDE-RNs coordinated the GDM clinic activities, i.e. they were the primary contact for GDM-related issues and directed care, or liaised with other members of the team as needed. They also provided group based education sessions for those newly diagnosed with GDM. More
detail about GDM usual care processes is provided in the description of the intervention in section 4.6.1 (page 70).

4.3.2 Study population

The TeleGDM study participants were drawn from two population groups: one comprising of patients with insulin-treated GDM and the second made up of clinicians. Both of these groups were drawn from the setting described above.

The first point of contact with NH for pregnant women is the obstetrics and gynaecology service. It is through this service that screening for GDM is initiated. This typically occurs when the women are at 24-32 weeks gestation. Earlier screening is considered if a woman is deemed at high risk, e.g. previous history of GDM or the woman belongs to any of the high risk ethnic groups that are predominantly non-Caucasian [10, 15, 24].

A little over half (58% or 232) of the 400 women from the 2012 cohort with GDM at NH (cf. description of the setting above) required insulin to control hyperglycaemia. Also the demographic makeup of 59% (236) of the patients with GDM was of Indian/Asian subcontinent, Arabic/Middle Eastern, Pacific Islander, Aboriginal, or African origins. These ethnic groups constitute a special interest group in the context of GDM because they are considered high risk for developing GDM in pregnancy [2]. This short narrative gives a snapshot of the patient population that patient participant sample was recruited from.

The clinicians group included only the CDE-RNs, five in total (four CDE-RNs and a diabetes nurse practitioner/CDE-RN). One of the experiences of the protocol and intervention pilot was that CDE-RNs were the best placed members of the GDM care clinical team to better engage in the intervention than the other members of the clinical team; the CDE-RNs acted as proxy care coordinators. Hence the inclusion of only CDE-RNs in the clinicians’ participant group. As such reference to clinicians in the TeleGDM study exclusively refers to CDE-RNs unless departure from this is clearly indicated.
For purposes of clarity and distinction between the two participants groups in the TeleGDM study, the patients participant group would be referred to as patients or pregnant women occasionally, and clinician participants would referred to as clinicians or CDE-RNs.

### 4.4 Sample size calculation

Sample size calculations are an integral part of research. The calculation is a way of ensuring that the study has a sufficient number of participants, and is therefore, adequately powered to detect changes in the outcome of interest. An adequate sample size avoids false positives (benefit where there is none) and false negatives (no benefit when there is some) [74]. Decisions about sample size are a balance between having a robust enough sample to detect a difference in the primary outcome and the resources available to recruit a sufficient number of participants, to meet the aims of the study and to offset the negative factors that may affect the running of the study, i.e. non-compliance or attrition [75].

Rigorous sample size calculation is usually not crucial for exploratory studies, as these studies are usually intended to be the foundation for sample estimates for future, more definitive trials [37, 74]. I aimed to recruit all clinicians (n=5) from the group described in the study population section above, because of their small number. My projected sample size for patients was n=100. In particular, my patient sample size was primarily informed and driven by i) the limitation of smaller sample size of previous studies as noted in my systematic review, ii) the pragmatism on the basis of what was achievable within the constraints of a PhD timeline, and resources and iii) the clinic throughput; noting that 58% (n=232) of patients per annum in a previous cohort with GDM at NH required insulin. Even though the aim was for a patient sample of n=100, as would be noted in the description and discussion of the pilot in chapter five (section 5.1, page 112), the sample size was originally closer to the clinic throughput, but had to be revised when experience from the pilot indicated n>100 would be much more challenging to achieve.
Although a rigorous sample size calculation was not critical for my study because it (the study) was exploratory, I undertook this exercise to supplement the above pragmatic approach and to increase confidence in the power and validity of my exploratory study findings. My calculations were based on the primary outcome of my study (Table 2). These calculations were informed by findings from the studies [32, 44, 47, 76] that met the inclusion criteria for my systematic review (chapter 3) and another study [45], which, although excluded from the systematic review (because participants were a mix of women with GDM and those with type 1 diabetes), involved the study of telehealth in GDM. A summary of my calculations is presented in Table 1. The table shows the required sample sizes calculations for power=80% and power=90%. The extreme right column shows power projections for a sample size of n=188 determined by clinic throughput. Based on the calculated sample sizes my convenient and pragmatic patient sample of n=100, was such that even with an attrition of 30%, the proposed TeleGDM was sufficiently powered (power=80%, 2 sided \( p=0.05 \)) to detect differences in service utilisation (number of consultation appointments); effect sizes 1.58 (95% CI: 1.13, 2.04) for face-to-face appointments and 2.63 (95% CI: 2.08, 3.18) for unscheduled face-to-face appointments.
<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>Indicator</th>
<th>Reference study</th>
<th>Study outcomes#</th>
<th>Calc sample size (p=0.05)</th>
<th>Power calc. (if n=188)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service utilisation</td>
<td>Face-to-face appointments, mean(sd)</td>
<td>Perez-Ferre et al. [76]</td>
<td>T=4.25(0.93), C=6.22(1.48); n=97</td>
<td>14</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Unscheduled clinic visits, mean(sd)</td>
<td>Perez-Ferre et al. [76]</td>
<td>T=0.50(0.73), C=2.89(1.05); n=97</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Clinic visits, % difference</td>
<td>Dalfra et al. [45]</td>
<td>C 44% &gt; T; n=203</td>
<td>34</td>
<td>42</td>
</tr>
</tbody>
</table>

Sd=standard deviation; T=Telemedicine Group; C=Control Group; #n for analysed data
4.5 Recruitment and allocation of participants

The recruitment phase commenced on 30 August 2014 and continued through to 30 June 2016. The first patient was recruited on 8 September 2014 and the last patient reached study endpoint in the second week of November 2016. The process is summarised in Figure 4.

Figure 4 Design for the exploratory randomised controlled trial component of the TeleGDM study.
As the lead researcher, I carried out most of the recruitment for the study. Partway through the study, I was able to secure limited research assistance from two research nurses, whom I trained to perform recruitment and carry out baseline assessments when I was unavailable. I adopted a proactive approach in recruiting patients for my study, rather than passing information and/or displaying posters for potentially eligible patients and waiting for patients to make contact to express an interest in the study. Thus, I elected to actively seek out potentially eligible patients and directly approach them during outpatient GDM clinic days. I chose this strategy in order to increase the probability of uptake, while balancing this with ensuring that I observed the ethical obligations of informed and voluntary consent. A copy of the information and consent document is appended in Appendix 5.

4.5.1 Patient inclusion and recruitment procedures

The study inclusion criteria that applied to patients were:

- IADPSG criteria based clinical diagnosis of GDM confirmed by OGTT
- Gestational age up to 35 weeks
- Management of hyperglycaemia with insulin
- Internet access thorough any of these modalities: personal computer, smartphone or tablet
- Functional level of English determined by the ability to navigate the health care system without the need for an interpreter, or if an interpreter was required, availability of family members to assist the patient with study tasks, which were all in English

The exclusion criteria were:

- More than 35 weeks gestation
- Adequate control of hyperglycaemic through means other than insulin
• Pre-existing (pre-pregnancy) diabetes mellitus (T1DM or T2DM) or glucose intolerance.

• Currently taking corticosteroids or took corticosteroids in the previous three months.

• Require an interpreter to navigate the healthcare system and had no family members that could assist with facilitating completion of study tasks.

The recruitment process involved several elements to identify potentially eligible patients, screen and enrol those who consented. These elements were labour intensive but ultimately aimed to comprehensively identify and target as many potentially eligible patients as possible.

In discussing implementation in the background chapter I pointed out how I engaged with the GDM service and clinical team members, i.e. through the early introductory/briefing meetings and regular attendance of GDM team meetings. These actions also served the purpose of raising awareness of my study among the team members to facilitate recruitment. In addition, once recruitment commenced, I provided copies of the information flyer (Appendix 6) to all the members of the GDM clinical care team to pass on to patients during consultation when they advised them of the study.

I had remote and on-site access to NH’s secure electronic patient management system which included GDM patients’ schedule of outpatient appointments and the patients’ electronic medical records. A day before the clinic, I (or the RA) would access the appointment schedule, go through the GDM patients booking list and cross-check preliminary eligibility of insulin status and gestational age on their medical record; when the insulin and gestational age criteria were satisfied, collate a spreadsheet list of the potentially eligible patients. At the start of clinic the next day, I would liaise with the CDE-RNs to alert them to patients I would target for recruitment. I mainly liaised with the CDE-RNs more than other team members because nearly every booked patient would have an appointment with the CDE-RNs, whereas patients would only see other clinicians if needed. That is, a patient might be seen by the CDE-RN but not be seen by the dietitian or endocrinologist that day. Once clinic commenced, the clinicians would notify a flagged patient of the study, provide her
with an information flyer and direct her to me for detailed briefing, screening against the criteria and if the patient consented, recruitment proceeded to randomisation and enrolment. Details of the randomisation schedule are provided next subsection (4.5.2, page 68).

In addition to the above process for identification and referral of potentially eligible patients, other patients on the day’s list who might have not already been on insulin, but have insulin initiation on clinic day, would be referred too. However, on some occasions decisions were made to not recruit some patients in this latter category because they were distressed and overwhelmed by insulin initiation and therefore would be targeted for recruitment at a later time. Clinicians also referred patients who walked-in on the day without a pre-booked appointment, thus were not on the target list. Yet another small number of patients would occasionally be commenced on insulin outside designated clinic days and the clinicians would alert the recruiters about these, or they were identified in subsequent clinic lists.

Another important application in the ehealth system was the patient check-in application. As patients arrived for their appointments, they reported to reception staff who noted their arrival on the system. I had access to this system on my computer terminal, which I monitored between tasks. That way I had real-time access to patients’ arrival as well as as cancellations and failures to attend.

In order to keep disruptions to clinic workflow to the minimum during recruitment, I would generally see patients after their last appointment of the day. Patients typically had multiple appointments with different members of the GDM care team on the day, with waiting time between these appointments. I often made of use of the waiting time to see potentially eligible patients as well.

In the interest of patient privacy and confidentiality requirements of the health care organisation, eligible patient briefings and recruitment took place in a secure space/consulting room. While it might seem benign, the location of the room was also an important link in the recruitment process. A room that was in close proximity to the CDE-RNs consulting rooms was always available at both BHS and CHS. This facilitated access to the patients. At the TNH clinic, however, a room was not always assured and when available, was often away from the GDM clinic hub and the clinicians’
consulting rooms. Therefore TNH environment was sometimes not as enabling for recruitment as those of BHS and CHS.

The majority of patients were recruited using the process described above. There were, however, rare moments when a patient requested to be given time to think about participation, or could not stay to be seen for recruitment, particularly if attempts at recruitment followed the patient’s last clinical appointment for the day. In such cases I followed these up at the next appointment. As a last resort I would do phone follow-up. These last two strategies very rarely yielded results as the concerned patients rarely consented; underscoring the value of gaining consent from patients on the day, rather than relying on patients to make contact to express their interest in participating in the study.

Finally, as another strategy for recruitment, I collaborated with the Corporate Communications office at NH on a media release through the office of the chief executive officer. I provided a briefing of the study to a corporate communications advisor and we also arranged an interview between a consenting study patient and the local newspaper (Appendix 7). The strategy provided only a single lead and the patient who showed interest was ineligible in the end.

### 4.5.2 Patient randomisation

Assigning participants to the arms or groups of a study via a random allocation process helps to minimise bias and strengthens the validity of the study [77, 78]. Some of the key requirements of randomisation are that i) allocation is independent of the participants’ desires or preference of the study arm, ii) allocation cannot be predicted ahead of assignment and iii) allocations remain hidden until they are revealed for the purpose of assigning consenting participants to the study arm [77]. Participant assignment to the study arms typically follows a 1:1 ratio, although an uneven allocation ratio may be considered [79] depending on the requirement and purpose of the study.

For my study, a 1:1 stratified randomisation schedule was generated using STATA 11.0 (StataCorp LP), by a biostatistician who was independent of the TeleGDM study. Stratification was based on the risk of GDM, dichotomised into low or high risk. A
patients with no established risk of GDM was considered low risk and a patient with at
one risk factor was classified as having a high risk for GDM. The risk factors included a
previous history of GDM, or being of Indian/Asian subcontinent, Arabic/Middle Eastern
or Pacific Islander, Aboriginal, or African origin. As previously highlighted, NH historic
data showed that, among the NH patient population with GDM, 59% were in these
high risk ethnic groups (see sections 1.1.3, page 17 and 4.3.2, page 60). Hence, stratification followed a 3:2 ratio of high risk versus low risk.

Group allocation slips were generated using the randomisation schedule and were
sealed in opaque envelopes to ensure recruiter allocation concealment. The envelopes were numbered sequentially in two batches. In one batch (numbered 101-
200) were allocations for low risk patients and the other batch (numbered 201-300)
was for the high risk patients group. When a patient consented to participate, an
envelope was picked in sequence (depending on the patient’s risk status) and
opened to reveal the study arm (intervention or control) which that patient would be
allocated to.

4.5.3 Clinician recruitment

As has been pointed out in the description of the study population (section 4.3.2, page
60), there were five CDE-RNs who actively engaged in using the telemedicine system
for ongoing clinical care of patients in the intervention arm of the study. The same
CDE-RNs also provided routine clinical care to patients allocated to the usual care
arm of the study. I recruited all the CDE-RNs to participate and they formed the
clinician participant group of my study.

As members of the GDM care team, and due to their active involvement in delivering
patient clinical care for the study, the CDE-RNs were aware of the study and therefore
were not blinded. Their recruitment was in the form of a request to complete the
clinician assessment questionnaire indicated in the outcome summary table (Table 2)
and Appendix 13, and a request for an interview. All five agreed to both tasks and as
such their consent was implied.
4.6  Description of the intervention

The intervention for the study was telemedicine as an adjunct to usual care and it involved two main elements. The first of these was the telemedicine system, OHP, which patients used to share their GDM self-monitoring data with the clinicians. The second was the ancillary elements which supported implementation of the intervention, i.e. patient and clinician induction on how to use OHP. Together these elements formed the intervention package that was delivered as an adjunct to usual care. The telemedicine system was a commercially product sourced from a third party (Elevate Technologies Pty Ltd), that neither the research team nor the clinical team had any financial interests in. Details on OHP are provided in section 4.6.2.1 (page 75).

In this section, I start with a description of usual care GDM processes at NH. Usual care was the comparator treatment or approach for my study. The description is followed by that of the intervention; telemedicine support adjunct to GDM usual care. A summarised version of the intervention appears in the peer review journal paper of my research protocol [80]. A copy of the paper has been appended to the end of this methods chapter in section 4.9 (page 99).

4.6.1  GDM usual care (Control)

The primary service stream point of contact with NH for all pregnant women is the obstetrics and gynaecology service. It is through this service that screening for GDM is organised. Care becomes a collaboration with endocrinology for women who test positive on GDM screening, or have other types of diabetes, or other endocrine disorders in pregnancy.

As part of obstetric care at NH, and in line with set policy guidelines (Appendix 9), pregnant women are referred to the GDM clinic by the obstetrics and gynaecology service for routine screening of GDM. Screening for GDM follows a recommended standard protocol [4, 24] which involves undergoing a 75g oral glucose tolerance test (OGTT), after overnight fasting. Patients then present to the hospital pathology department for extraction of blood samples for fasting blood glucose level (BGL),
followed by ingestion of the glucose solution. Further blood samples are taken for measurements of BGL at 1-hour and 2-hour post-glucose ingestion of the glucose solution. The test is usually performed between 24 and 32 weeks of gestation. At risk women, i.e. those previously known to have had GDM during previous pregnancies, a family history of diabetes (type 1 or type 2), or belong to certain population groups (Asian, including Indian, Pakistani, Bangladeshi, Sri Lankan South Asians, Aboriginal, Pacific Islander, Maori, Middle Eastern, non-white African) may be screened earlier.

Patients who return a positive test on the OGTT are referred to the outpatient multidisciplinary endocrinology GDM care service, which is coordinated by the CDE-RNs, for ongoing GDM management. These services are the GDM clinics located at the three campuses of NH which are described in the study setting (section 4.3.1, page 58).

The first appointment in the GDM service is an intake appointment, after which, patients attend a multidisciplinary group education session on: diabetes care and ongoing management, including goals, expectations, and self-monitoring. The education session cover setting self-management goals, performing self-monitoring, diet, physical activity, and what to expect during the course of GDM care, i.e. optimal, or sub-optimal glycaemic control and indications of insulin initiation. Diabetes education on GDM management includes counselling patients to keep a daily record of pre-prandial (before breakfast) BGLs, three 2-hr post-prandial BGLs (post-breakfast, lunch and dinner), insulin dosing (for those on insulin) and writing comments about diet and symptoms. The goal of treatment is optimum glycaemic control based on self-monitoring blood glucose (SMBG) targets of fasting BGL<5.1mmol/L and 2-hr post-prandial BGLs<6.8mmol/L. Hypoglycaemic episodes (BGLs<4.0mmol/L) are also carefully monitored.

In order to monitor their BGLs, patients are provided with a free glucometer and logbook/diary to keep a handwritten record. Different brands of glucometers are available for prescription, but the most common, based on convenience, is the Abbott Freestyle Lite© (Abbott Diabetes Care Inc., Alameda CA) glucometer. The diary is also used to record symptoms, dietary and other comments that may assist in providing the context for a given BGL reading. Patients are expected to bring their diaries when attending the GDM clinic for review appointments.
Subsequent appointments in the GDM service for ongoing individualised care continued until the end of the pregnancy. These consultation appointments are with the different members of the GDM clinical care team and are aimed at reviewing, and monitoring progress, as well as reinforcing ongoing GDM management.

From here on, my description of usual care focusses on insulin-treated GDM.

Insulin initiation occurs when there is evidence of macrosomia. Otherwise insulin is initiated when a patient had two BGLs over target on two consecutive days. In such instances, scheduled face-to-face review appointments generally occur every 1-2 weeks (less frequently for non-insulin-treated GDM). There are provisions for patients to call the CDE-RNs if needed, or a walk-in (unscheduled appointment) during weekdays. This level of service utilisation, is corroborated by literature reports of intensive follow up and monitoring for insulin-treated GDM [8, 18], and potentially contributes to the high demand on service alluded to in the background chapter (section 1.1.3, page17).

The CDE-RNs are the first port of call for reviewing patient self-monitoring data, and making any necessary insulin titrations. For complex cases, insulin titrations are made in collaboration or consultation with the endocrinologists. The educators (CDE-RNs) also referred patients to the team’s dietitian when required. That is, as the primary contacts for patient in the GDM service, the CDE-RNs act as proxy coordinators directing care, or onward referral to other members of the team (dietitian or endocrinologist) for their input. Care then continues as a collaboration between all the members of the team and the patient, with liaison with the obstetrics team.

Clinical decisions are centred on the degree of glycaemic control informed by the BGL readings and other relevant self-monitoring information that patients keep a record of. Treatment adjustments, insulin titrations and/or counselling on dietary changes are made for persistent hyperglycaemia (two above target BGLs in a week or over two consecutive days) or hypoglycaemia. Insulin dose titration continues until BGLs stabilised; that is, until optimum glycaemic control is achieved and no further insulin dose adjustments are necessary. For the purpose of the TeleGDM study, I define the point at which no further insulin dose changes are necessary “insulin dose stabilisation” and therefore an alternative proxy marker of optimum glycaemic control.
Gestational diabetes mellitus service (consultation appointments) is free for eligible patients (Australian citizens, permanent residents and limited others on certain visa categories, e.g. humanitarian visas) under the Australian Medicare system. Medicare is the Australian government body charged with overseeing free and/or subsidised public health access. While patients are provided with glucometers by the GDM service, Medicare eligible patients have access to subsidised consumables, such as BGL test strips, and needles, for ongoing BGL self-monitoring. Patients who are not eligible for Medicare pay full price for GDM services and BGL self-monitoring consumables. Their consultation appointments in the GDM service is billed at $280 per appointment. This cost rate was important for GDM service cost attribution, details of which are provided in the cost data analysis (section 4.7.4.4, page 91).

During the course of GDM care, the team endeavours to maintain contact with the outside of hospital primary care by sending written progress updates to the patient’s general practitioner (GP) once a month, but this is often constrained the by the busy workload of the GDM service. Patient contact with the GDM service ends at the end of pregnancy. However, a small number of women have their 6-week post-partum OGTT and final follow-up review organised through the GDM service. From then on, ongoing surveillance for type 2 diabetes and any necessary care is an arrangement between the patient and her GP with no further input from the GDM care team.

Finally, usual care as described above was the control arm of the TeleGDM study. Thus, patients who were randomised to the control arm of the study, received care according to the usual care practices which are described above. It must be pointed out, though, that usual care evolved partway through the TeleGDM study, when the CDE-RNs at one campus began to intermittently request patients to share their BGL data as photos via smartphone messaging. This ended up becoming a parallel but independent small study in the GDM service at that campus.

Lastly, patients recruited to the TeleGDM study were asked to switch to using Freestyle Lite© (Abbott Diabetes Care Inc., Alameda CA) glucometers if they had been prescribed a different brand meter prior to being recruited into the study. First, the reason for this was to standardise BGL measurement devices for all study participants. Secondly, specifically relating to the intervention described below, this brand of meter was one of the few that were compatible with the telemedicine system (OHP) for automatic BGL data uploads via USB cable connection of the glucose meter to a
personal computer. However, as will be explained in the next chapter on piloting the intervention and protocol (section 5.4, page 117 and section 5.5 summary point 4, page 123), the plan to use the same type of glucometer was dispensed with due to issues with the quality of BGL data uploaded automatically via direct USB connection. Also after further consultation with my supervisors, we reached a conclusion that standardisation of BGL measurement was not critical for the study because the focus of the evaluation was not on the quality of measurement of BGLs. Furthermore, in a real world clinical setting such as the GDM clinics at NH, clinicians relied on data obtained using different glucometers, sometimes even by the same patient.

4.6.2 Intervention: Adjunct telemedicine using online health portfolio

The use of telemedicine as a service intervention, as described here, was a new and innovative approach to support the management of insulin-treated GDM at NH. Whereas the studies I presented in the background and systematic literature review, used telemedicine as an alternative substitute service for usual care, implementing the intervention in a similar manner presented an ethical issue that would have made ethical approval for the TeleGDM study difficult to obtain. As such, in order to avoid the ethical issue of denying patients current and established care at NH care, especially on the background of limited evidence for telemedicine in GDM, I had to implement the telemedicine approach as an adjunct to usual care. That is, the intervention involved telemedicine support, plus usual care as described above.

The key features of the intervention were

i) Usual care as described above.

ii) The use of a telemedicine system, OHP, for sharing self-monitoring GDM data and communication between patients and clinicians. A more detailed description of OHP follows in the section.

iii) Clinician and patient induction, as an ancillary support element, to facilitate engagement with using the telemedicine system.
4.6.2.1 Online Health Portfolio

Online Health Portfolio (OHP) (www.onlinehealthportfolio.com) [81], was chosen as the telemedicine solution or system for the TeleGDM study. It was selected from a total of four candidate systems, based on a decision guided by the telehealth evaluation framework [51-53]. The selection process is explained and discussed in the immediately following section.

OHP was a web accessible personal health record, with a secure username and password access, and it had a 256 bit data encryption security, with multiple redundant back-up servers. A patient’s record on OHP was controlled by the patient, allowing the patient to choose whom to share their data with, e.g. CDE-RNs, dietician, researcher or any other persons. The system could be accessed using a web browser on personal computer, smartphone, and tablet devices running different operating systems (Windows®, macOS®, iOS®, or Android®). The system provided capabilities and features to upload BGL data automatically or manually (all other data were manual entry only). There was an app, iHealth, which was a smartphone-based alternative to using a web-browser to access OHP via a smartphone. The personal computer version of iHealth facilitated automatic BGL data upload to OHP from a selection of glucose meters such as the Abbott meter referred to earlier (section 4.6.1, page 71), when connected to the computer via a USB cable.

Figure 5 is an illustration of the patient screens for manual entry of BGL readings and insulin dose. Users could send and receive message within the system. Clinicians also had access to an OHP feature that allowed them to send messages to a patient’s mobile phone as SMS. Alerts and reminders could be set on the system as required, to prompt patients to test and enter self-monitoring data. Another feature of OHP was the ability to plot graphs and charts of BGL data. Patients could graphically manipulate their own BGL data to observe trends and patterns for some personalised feedback.

Patients who were randomised to the intervention were expected to provide the same GDM self-monitoring data, and at the same frequency as under usual care, except, they provided or shared the data with the clinicians via OHP. Keeping the handwritten logbook record was a silent option in that, patients who were randomised
to use OHP, were neither encouraged nor discouraged from keeping handwritten records. The challenge regarding the logbook as observed during the pilot was that other clinicians besides the CDE-RNs did not engage with using OHP, and thus relied on the handwritten record.

After a pregnancy complicated by GDM, guidelines and best practice [4, 12, 82] recommend post-partum testing and ongoing surveillance, as preventive strategies against type 2 diabetes. This aspect of care is for the most part the domain of primary health care through general practice [82-84]. Thus, in order for GPs to take over care post-partum, engaging with them during the pregnancy is important. Originally in my study protocol (see Appendix 10), I considered patients’ GPs as participants in my study. However, following the pilot (section 5.5, page 123), a considered decision was made to leave out the GPs. The rationale being that, GPs played no active role in the usual management of GDM. They were only informed of their patient’s involvement with the GDM and obstetrics services at NH but they provided no direct clinical input. Also, in order to contain the scope of my, I revised my research questions to exclude GPs as participants. Nevertheless, I revisit the involvement of GPs in my concluding remarks, in the implications for future research (section 8.1.4, page 218) in order to highlight the important role that GPs could play.
Figure 5 OHP data entry screens; top panel-BGL entry and bottom panel-Insulin entry
4.6.3 User (patients and clinician) induction

Prior to commencement of the study, my supervisors and I attended an OHP demonstration which was delivered by the vendor. Once a decision was made to use OHP, the vendor performed another demonstration for the GDM clinical team at NH. I provided subsequent induction training for the clinicians when the first pilot patient was enrolled, and another refresher at enrolment of the first patient at each campus of NH.

I created clinicians’ (CDE-RNs) generic log on credentials and passwords ahead of induction to use OHP. The induction involved instruction and practice which included the basics of: logging on OHP using the pre-set credentials, navigating through the OHP webpages to view data, messaging, and setting up or turning off alerts. Advice to the clinicians was to log in and review data as would conveniently fit in with their workload, but a minimum of 1-2 days per week was advised. Other than that the study protocol did not provide any instruction regarding changing clinical decisions or appointment scheduling. These were the prerogative and express domain of the clinicians as they saw fit, based on data they reviewed to inform alteration to treatment or frequency of appointments.

The induction for patients was conducted face-to-face and one-on-one. It was conducted with each, patient that was randomised to the intervention. The induction was delivered by whoever performed the recruitment; i.e. mostly myself, or a trained RA. It involved hands-on instruction, and practice. This took place once a patient was randomised to the intervention. Instruction and practice were supplemented with a hand-out of written instructions (Patient hand-out, Appendix 8). In summary the patient induction included the following:

i. New patient sign up/registration of OHP

ii. Inviting clinicians/healthcare professionals including researcher (myself)

iii. Setting up alerts

iv. Data upload/entry

v. Messaging
Navigating through the system and setting graphical manipulation of data

Instructions on how to perform BGL testing, insulin administration, and handling and disposal of needles, as well as managing diet, were all part of the routine advice and education which was provided by the GDM clinical care team.

I was always available to address queries, or to troubleshoot minor technical difficulties, and act as the conduit to escalate technical issues I could not handle to the vendor. I performed these tasks from a study management perspective, as I had no resources to delegate this responsibility.

4.7 Quantitative measurements and outcomes

Although I describe quantitative data, and outcomes in this section, some quality measures are introduced, and included in the summary table of outcomes and measures (Table 2). Process evaluation, using qualitative and some quantitative methods, is the focus of section 4.8 (page 93). As Table 2 shows, I set my data and outcomes to align with the domains of the telehealth evaluation framework [51-53], in order to highlight the theoretical underpinnings of the evaluation.

4.7.1 Participant Characteristics

Participating patients’ demographic and characteristics data included patients’ chronological age, gravidity and parity, gestational age at GDM diagnosis, ethnic group, and previous history of GDM. Ethnicity and previous history of GDM were measures of GDM risk. Ethical approval undertakings precluded collection of detailed data on patients who did not consent to participate, however, basic characteristics (chronological age, gravidity and parity) for eligible but excluded patients were collected, in order to facilitate determination of selection bias, and generalisability of findings.
4.7.2 Outcomes

The TeleGDM study was primarily aimed at exploring the impact of TeleGDM on GDM service utilisation. Briefly, this outcome was informed by the recognition that GDM services were not coping with high demand for appointments. Therefore high service utilisation in the form of in-person clinic attendances was a priority problem at the health care organisation where this study was conceived.

The markers of service utilisation as an outcome were the number of outpatient GDM clinic consultations for endocrinology, diabetes education and dietetics. Utilisation was limited to the latter specialties because clinical intervention from these specialties had a direct influence on the trajectory of GDM management and glycaemic control. The consultations appointments included both planned or scheduled, and unplanned or unscheduled, appointments. In the context of the TeleGDM study, I defined planned consultation appointments as those booked by the clinicians in advance, which was typically done by the consulting clinician at the end of consultation. Unplanned appointments were those initiated by patients, whereby a patient presented to the GDM clinic without a prior booking (walk-in) or the patient was re-called to clinic or the consultation was provided over the phone. Obstetrics was an important part of antenatal care, but the obstetrics team (obstetricians and midwives) primarily focussed on the progress of the pregnancy and development of the foetus. As a result, members of the obstetrics team considered themselves to play a limited role in GDM clinical decisions (see section 5.3 on experiences from the pilot), hence had a negligible influence on GDM related appointments and were excluded from evaluation of service utilisation.

In addition to the primary outcome described above, the study explored a selection of secondary and process measures. These included maternal and foetal/new-born clinical outcomes, self-efficacy, satisfaction, and volume of usage of OHP, as well as service provider costs. The rationale for selecting these is described below.

The primary focus of this study is health service utilisation indicated by face-to-face clinic attendances, with scheduling decided by clinicians. The effect of the intervention on the primary outcome was premised on care shifting to telemedicine in lieu of face-to-face attendance. However such shifts and/or reductions in health
care utilisation may result in unplanned declines in the quality of care [85, 86]. In order to monitor and evaluate inadvertent decline in quality of care as a potential consequence of reduced attendances, a number of clinical outcomes (e.g. glycaemic control, foetal biometry, type of delivery, admissions to special care nursery etc.) were selected. These were selected to align with the outcomes that are clinically significant in the management GDM, are used widely in the literature in GDM and have been shown to correlate with and/or are markers of adverse pregnancy outcomes in GDM [14, 47, 87-89].

Use of quality measures in clinical research is increasingly becoming an important part of health service research best practice, especially where interventions have cost and funding implications [90] and such measures take into consideration the personal and social context of the patient [91]. Quality assessment instruments (DES-SF, CSQ-8, Modified Canada Health Infoway System and Use Assessment Survey), were selected for their ease of access and good face validity. Further information on the validity of the DES-SF and CSQ-8 and use in diabetes are described in the data and outcomes section of my protocol paper (section 4.9 of this chapter). Table 2 is summary presentation of the study outcomes, their indicators/makers, and measurement and assessment schedule.
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<sup>a</sup>LGA-Large for Gestational Age; <sup>b</sup>SCN-Special Care Nursery; <sup>c</sup>NVD-Normal Vaginal Delivery; <sup>d</sup>LUSC-Lower Uterine Segment Caesarean Section (C-section)
4.7.3 Data collection and management

This subsection of the methods chapter deals with data collection and management for the quantitative component of the TeleGDM study. The data collection time points are outlined in Table 2.

Data collection involved both primary and secondary methods and processes. In particular, secondary data collection methods are an acceptable method and source of data for empirical in research. It refers to data that whilst utilised in a given piece of research, were originally collected for a different purpose [92]. Study data were ultimately collated into a Microsoft® Access database which I had created for data entry, linkage and storage.

There are several motivations and reasons for using secondary data in research. These include the costs and time associated with conducting the research. Research by its nature is a costly exercise as a result of expenses associated with the human resources, questionnaire and software licences, data management and storage, research consumables, IT and computing infrastructure, among others. Where data are already available, such data may be used in lieu of collecting the same data, often at a cost, especially where there is limited funding for the study or research in question. Whilst there may be time and costs saving associated with using secondary data sources, there are downsides to this approach. The researcher often has no control over the manner in which data were collected, hence data quality and validity may be questionable or challenging to ascertain [92].

The TeleGDM study had limited funding, with only a small research grant just sufficient to pay for patient subscriptions to use the telemedicine system (OHP). The rest of the study related costs were met through in-kind support. As a result of the limited budget, I elected to source some secondary data from routine clinical care, and health service administrative data, to use in my study. Use of routine or secondary data is a recognised method of data collection that can be time, and cost efficient and datasets are reflective of real world practice [93, 94]. On the flipside, there are often questions and concerns around data completeness and accuracy of secondary data [94]. Using secondary data saved me some costs and time. It also lessened
reliance on collecting some of the TeleGDM study (primary) data directly from patients, therefore minimising putting undue burden on patients. For instance, rather than surveying patients about their appointment attendance history (primary data collection), more accurately recorded administrative data were available. Similarly, rather than ordering foetal biometry ultrasound scans for study purposes, which would have been costly, plus inconvenient and unnecessary for the patient, foetal morphology and biometry ultrasound reports from routine obstetric care were already available. The following provides an outline of my secondary data and sources.

i) Participants’ characteristics and baseline data: While data elements such as parity and gravidity, gestational age, and patient’s chronological age were collected primarily from patients at the time of recruitment and enrolment, some were obtained and/or verified from secondary data available in patients’ hospital-controlled electronic medical records. The principal source for GDM diagnostic data, GDM risk stratification, insulin dosing, was the patient medical record.

ii) Health service utilisation: The number of outpatients or phone based GDM clinic consultations for endocrinology, diabetes education, and dietetics, were obtained from a dataset provided by the Northern Heath data support unit. The dataset covered the period during which patients were enrolled in the study, and a short background period before enrolment.

iii) Insulin dose titrations: During planned and unplanned outpatient appointments, or telephone based consultations, clinicians (endocrinologist and/or CDE-RNs) made adjustments to patients’ insulin regimen, including changes to dosing, as may be clinically indicated. Patients kept a record of their daily insulin dose, on OHP or the handwritten logbook. I obtained insulin dose data from OHP extracts or the handwritten logbook. I verified the data and/or obtained missing data from the hospital electronic medical record.

iv) Foetal morphology/biometry: Patients underwent routine ultrasonography to determine foetal growth progress at the start of the second and third trimesters. Images were evaluated by the radiologists and reports were uploaded to the patients’ hospital-controlled electronic medical record. These reports were the source of data for foetal biometric data and determination of macrosomia.
v) **Birthing outcomes data:** Data relating to type of delivery (caesarean or normal vaginal delivery, gestational age delivery, new-born birth-weight, and new-born disposition (admission to special care nursery) were all sourced from the Birthing Outcomes Suite (BOS®, [http://www.mcats.com.au/](http://www.mcats.com.au/)), an obstetric data management system which NH used under licence. All data entries to BOS were performed by the obstetrics team (midwives and obstetricians). I created my own data extraction query to obtain study data from BOS®.

The rest of the data, were collected primarily from patients at baseline (enrolment) or other designated time-points (Table 2). These data included diabetes self-efficacy, and satisfaction with overall GDM care and BGL readings obtained from OHP (intervention) or handwritten logbook (control). These are all discussed below.

The central element of the intervention was the web-based telemedicine system (OHP), which, patients who were randomised to the intervention arm used to upload GDM self-monitoring data, such as SMBG, insulin dose, diet and symptoms. The parallel approach for the usual care group (control) was the handwritten logbook. Therefore the method for collecting SMBG and insulin dose data was weekly downloads, or extracts from OHP for those in the intervention group. Where no data were uploaded, I contacted the concerned patients via the OHP messaging system, or phone call to encourage data uploads. Contacting patients to encourage data entry was primarily a study data completeness strategy first and foremost. On a secondary level, it ensured data were available to clinicians for informed clinical decision making. Otherwise, the primary responsibility for encouraging data entry for clinical use rested with the CDE-RNs, who also attempted to contact patients to prompt them to enter data on to OHP. While my role in encouraging data entry was for research purposes, it potentially blurred the lines between core research activity and clinical/service intervention. This identified a potential emerging role as a result of the intersection of health and technology in the GDM clinical environment; this is discussed further in chapter eight (section 8.1.1, page 214).

SMBG data for patients in the control group were sourced from the patients’ handwritten logbook records. When patients presented for their outpatient appointments, and had their handwritten diaries with them, I obtained photocopies for later data transcription into my study database. Where possible, at the end of the
study, I contacted patients in the control arm of the study and asked them to forward copies of outstanding data via email or as photos via smartphone messaging.

The volume of SMBG data entered into OHP (Intervention) and handwritten data (control), were important process measures. That is, I used the data volume as a surrogate, quantitative measure of the fidelity of engaging with the intervention. The product of the four SMBG data points expected per patient, per day (section 4.6.1, page 71), and the patient’s length of follow-up gave the expected total number of SMBG data for that given follow-up time. The sum of the individual patient totals the provided the group total of expected SMBG data. This result was the denominator for calculating the percentage proportion of observed (actual) data entered in to OHP (intervention group) or handwritten (usual care group) for use in evaluating fidelity (section 6.6, page 146).

Costs were considered from a healthcare service provider perspective, i.e. costs incurred by NH in the course of providing GDM care. But, first, a brief note on public health funding in the Australian healthcare system; publicly funded and publicly operated health care services in Australia, whether primary, secondary or tertiary, are not for profit entities. Funding is provided by the government so that citizens and permanent residents, can enjoy free or subsidised health care in Australian public healthcare services. Medicare is the government scheme under which patients register to access free, or subsidised health care. Medicare also determines the minimum fee for service rates that health providers can claim for reimbursement for services rendered. As such, the assumption made for the TeleGDM study was that, not for profit healthcare provider organisations, such as NH, billed fee paying patients, rates similar to those set by Medicare, and that these were sufficient to cover service and operational costs.

As previously indicated (section 4.6.1, page 73), Medicare eligible patients paid no fee while Medicare ineligible patients paid a service fee at a rate of $280, per consultation, per clinician for GDM care. This rate remained unchanged throughout the TeleGDM study. Thus, the assumption was that, this rate reflected what the health service (hospital) considered the true operational and service provision costs for a face-to-face appointment, in the GDM service. Providing care over the phone, as would sometimes happen in the GDM service was not billed, therefore a fee was not applied for such consultations. Further justification for excluding costs related to
telephone consultations was that, Medicare had no rebate benefit schedule for telephone consultations, unless those included video conferencing [95], which in the case of the GDM service was not available.

There were costs associated with using OHP. However, during the time of the TeleGDM study the vendor allowed free use of OHP by healthcare professions. Thus, access to OHP by the CDE-RNs was free. Patients on the other hand had to pay a subscription fee of $85 per annum. The vendor provided a discounted rate of $60 per patient for those enrolled in the study, and this cost was incurred by the study for patients in the intervention arm. Other OHP usage costs related to equipment and data were considered negligible; accessing the web-portal consumed negligible amounts of data and used existing hardware and infrastructure. Therefore no cost was assigned.

I created a secure Microsoft® Access (MS Access) database to collate, manage and perform data linkage of primary and secondary datasets. Linkage utilised data patients’ unique record (UR) identifiers and study allocated participant ID. First pass data cleaning processes, i.e. elimination of duplicate records or any data fields in the raw secondary datasets not required for the study, were performed in my study database.

In the above sections, I described the types of data I collected for the TeleGDM study, the methods, i.e. primary or secondary, which I used to collect these data. I included the rationale for making use of primary or secondary data sources. In the next subsection of my methods chapter I will describe the methods that I used to perform my data analysis. The description confines itself to the quantitative data, while qualitative data will be dealt with in a separate section (section 4.8, page 93).

4.7.4 Data and statistical analyses

4.7.4.1 Overview and descriptive summary statistics

Once I had completed data cleaning and linkage I exported my final de-identified dataset to Stata IC13.1 (StataCorp LP) for variable coding, error checks, and general preparation for analysis. I adopted an intention to treat principle in my analysis. This
meant that all randomised patients were included in the analysis of my study’s primary outcome (health service utilisation) data, without any exclusion, which minimised the risk of selection and dropout bias [96].

Data variables were summarised using univariable descriptive statistics, and adjunct telemedicine support (intervention) was compared to usual care (control). Means and standard deviations were used for continuous, or scale data, while proportions and categorical data were reduced to percentages, with 95% confidence intervals. Ordinal or count data, e.g. the number of consultation appointments and gravidity, were summarised as medians and ranges, or interquartile ranges (IRQ).

Statistical hypothesis testing compared the intervention group to the control group, using univariable and multivariable procedures. Independent samples t-tests were used to compare group means, or the non-parametric equivalent Wilcoxon rank-sum (Mann-Whitney U) test if, data did not satisfy normal distribution on the Shapiro-Wilk test. For data summarised as percentages, the intervention was compared to control using the Chi-square test of association (intervention coded as 1=true or 0=false) or the Fisher’s exact test, when test cell counts were less than expected. Where groups were compared on medians, the equality of median test was used, and variable values equal to the median were allocated equally to below, or above, the group median.

Finally, multivariable statistical analyses were performed to test whether the intervention was a predictor for service utilisation, glycaemic control, and costs, while taking into account other potential explanatory variables; especially the duration of follow-up. Tests included Poisson regression and Cox proportional hazards analyses. Data analyses for specific outcomes are described in detail in the following subsections.

### 4.7.4.2 Outpatient GDM clinic service utilisation

Health service utilisation was the primary outcome of this study, and service pertained to outpatient GDM clinic consultation appointments relating to endocrinology, diabetes education or dietetics. In describing my study outcomes (section 4.7.2, page
80), I outlined that I used a combination of primary and secondary data sources, and 
service utilisation made use of secondary data.

Raw data outpatient appointments data for NH covering the period 1 July 2014 to 30th 
September 2016 were obtained from NH’s data support unit. This period covered the 
time participating patients were active, i.e. receiving care, in the GDM clinic prior to 
study entry (before enrolment), and the period from study entry to study exit (after 
enrolment). The dataset was imported into the study database for linkage with study 
participants, cleaning and organisation. 

Appointments data were organised into utilisation variables denoting total appointments, scheduled (pre-booked) and unscheduled (telephone and/or walk-in) appointments. In addition, appointments were delineated into attended (either face-to-face or telephone consultations), or unattended. Attended face-to-face appointments included both planned (scheduled) and unplanned (walk-ins). Being numerical count data, the number of appointments were summarised as medians with ranges, or IRQ, and the intervention was compared to control using the equality 
of median test. 

To test whether the intervention was a predictor, or had an impact on service 
utilisation, Poisson regression analysis was performed on i) the total number of appointments and ii) face-to-face appointments, while controlling for the length of follow-up. Patients entered the study at different gestational ages, hence had different lengths of follow-up, from study entry to study end point, thus potentially creating a dose-response phenomenon. As a consequence, length of follow-up, or active time in the study, was a confounder variable in the regression analysis.

4.7.4.3 Glycaemic control

Self-monitoring blood glucose data, and insulin dose data, were used as indicators of 
glycaemic control. Decision for Insulin initiation and subsequent titration in GDM is 
informed by the degree of control indicated distinctively by pre- and post-prandial 
BGLs [4, 12, 97]. That is, the type of prescribed insulin (basal and/or bolus) and dose, 
are targeted at the instances (pre- or post-prandial) where hyperglycaemia occurs.
Studies suggest that, post-prandial BGL monitoring, in particular, has been associated with better glycaemic control \[4, 97\], and hence is often the target for insulin does tiritations. Based on this SMBG data were reorganised to create separate variables: one pre-prandial and the three 2-hr post-prandial (breakfast, lunch and dinner) readings.

Data were then dichotomised into above or below treatment target (4.0-5.0mmol/L for pre-prandial BGL and 4.0-6.7mmol/L post-prandial readings) for statistical comparison, using the Chi-square test of association. Whilst treatment or GDM management objectives are to reduce instances of BGLs readings outside target, and bring readings to within target as much as possible, there is no established minimum proportion or percentage of readings that are within or outside target. The intervention group was then compared with the control group on the mean percentage of off-target BGLs. Because of multiple weekly comparisons, a Bonferroni correction \[98\] was applied to set the level of significance at alpha/n; where alpha=0.05, the standard cut-off for the p-value and n is the number of tests to be performed on the same data. For instance, if between groups pre-prandial off-target BGLs are compared weekly over five weeks, the p-value for statistical significance will be p<0.01, \((0.05/5=0.01)\). The Bonferroni correction avoids committing type I error (a false positive result).

In addition to SMBG data, I introduced insulin dose stabilisation, which I described in section 4.6.1 (page 70) as another marker of glycaemic control. In brief, insulin dose stabilisation was the point at which no further insulin titrations were necessary; hence, the assumption was that BGLs were within acceptable parameters. I compared my study groups on the time it took to reach this point, using the time to event analysis (Kaplan-Meier curves) to explore the time to insulin dose stabilisation. This was followed by Cox proportional hazard regression analysis, to test the contribution of the intervention to insulin dose stabilisation, with covariates from other variables (baseline insulin dose, chronological age, gestational age at GDM diagnosis, and at study entry as well as GDM risk), hypothesised to have an influence on glycaemic control.
4.7.4.4 Costs

Health economic evaluation aids in putting into greater perspective, the cost and effectiveness of different therapies, which assists decision making as to which intervention or service provides better value for money, relative to health outcomes. There are several methods for undertaking health economic evaluation, one of which is cost minimisation. This type of health economic evaluation is defined as “[an] evaluation method to use when the case for an intervention has been established and the programmes or procedures under consideration are expected to have the same, or similar, outcomes. In these circumstances, attention may focus on the cost side of the equation to identify the least costly option”[99].

Limitations notwithstanding, our systematic review showed that telemedicine was equally as effective as usual care across a range of clinical outcomes. In view of this similarity, and as hypothesised in the TeleGDM study (section 4.2.2, page 57), the focus in evaluating costs was on whether, from the health service provider perspective, telemedicine minimised utilisation costs, compared to usual care. That is, quality of care considered, does telemedicine support offer value for money?

One of the outcomes where telemedicine had significantly superior outcomes was in health service utilisation [76]. Specifically, telemedicine reduced the number of face-to-face consultations. Thus, I had hypothesised that a reduction in outpatient appointments in the GDM service would be associated with a corresponding cost saving for the healthcare service provider.

As previously described (section 4.7.3, page 86), a rate of $280 was applied to each outpatient appointment with the GDM care team (endocrinologist, CDE-RN and dietitian). Costs were summarised for the total number of appointments, attended appointments, and scheduled, or unscheduled appointments. Univariate statistical comparisons were performed, comparing the intervention and control, using the Wilcoxon rank-sum test. Similar to the outpatient clinic appointments, Poisson regression analysis was performed to test whether the intervention was a predictor for costs related to face-to-face, or scheduled appointment costs. Other predictor variables included in regression modelling were: length of follow-up during the TeleGDM study, patient age, gravidity, baseline gestation and GDM risk. Appointment
data were such that each patient had different types of appointments, i.e. walk-ins, scheduled and unscheduled, creating the possibility of utilisation data clusters. This one-to-many relationship between one patient and multiple appointment types, could result in small standard errors in utilisation data, creating a greater probability of a highly significant result; hence the likelihood of a type 1 error (false positive). Because of this, I performed Poison regression modelling, with a robust option, in order to minimise the chance of committing type 1 errors [100].

4.7.4.5 Other maternal and foetal/neonate outcomes

Percentages with 95% confidence intervals were computed for C-section (LUSC) deliveries, macrosomia, special care nursery (SCN) admission of the new-born, and large for gestational age. Statistical analysis involved tests of association (Chi-square or Fishers exact test) between these measures and the intervention. Gestational age at delivery, and new-born birth weight variables, were summarised as means and standard deviations. The study groups were compared using the Wilcoxon rank-sum test for gestational age at delivery, and the independent samples t-test for new-born birth weight.
4.8 Process evaluation and other secondary outcomes

This section is a description of the methods I used for process evaluation and the rest of the secondary outcomes qualitative evaluation component of the TeleGDM study. The section encompasses satisfaction, quality, and process assessment, using a combination of survey questionnaires and semi-structured interviews. The survey questionnaires included numerical Likert scale and free text responses. In addition, these data collection processes were supplemented with field observations. Notes and written diaries that are kept throughout the trial, allow for an analysis that provides a narrative account of practice [101]. The narrative adds to the context of process evaluation by highlighting local setting factors which influence the success, or failure, of an intervention [73, 101].

While an RCT maps quantitative outcomes, and the magnitude of effect and impact (or lack) of an intervention, it falls short on explaining the patient and clinician perceptions, experiences, process factors, enablers and barriers, that contribute to the observed quantifiable outcomes. Therefore, the objective was to undertake a process evaluation, using qualitative semi-structured interviews and survey instruments, or questionnaires, to supplement the quantitative component. The interviews explored both patient and clinicians’ experiences with the telemedicine element in supporting GDM care. The survey instruments were both descriptive and quantitative, capturing data for assessing quality measures of GDM self-efficacy, and satisfaction with overall GDM care, using Likert scale and free text responses. The clinician’s survey explored satisfaction with using telemedicine, as a concept to deliver care, and the experience of using OHP, as the telemedicine system element of the intervention. The latter survey questionnaire included quantitative and free-text responses.

4.8.1 Patient satisfaction and diabetes self-efficacy

Diabetes self-efficacy and client satisfaction were assessed with the diabetes empowerment scale short form (DES-SF), and client satisfaction questionnaire, (CSQ-
Assessments were performed at baseline at the time of recruitment, and at six weeks follow-up from study entry. Follow-up assessment targeted patients when they attended their outpatient clinic appointments. But in order to boost follow-up, data collection response rates, I also used an electronic mail out of questionnaires to patients, for completion and return via email. This was augmented by SMS and phone call reminders for questionnaire return. Follow-up phone calls for emailed questionnaires also presented the opportunity, when possible, to complete questionnaires while on the phone with the patient.

The CSQ-8 (Appendix 11), is an 8-item version of a suite of client satisfaction questionnaires developed to assess client satisfaction with health and human services [102]. Responses are on a Likert scale and the total scores range from 8 (lowest satisfaction) to 32 (highest satisfaction). The CSQ-8 is shorter and simpler, therefore was envisaged to be less onerous to complete. Its developers have reported strong reliability, and excellent face validity [102]. The questionnaire has been used in a study on type 2 diabetes [103], and was assessed for reliability and validity in another study evaluating women’s satisfaction with a childbirth related service [104]. Although the latter study [104] used two non-English language translated versions of the CSQ-8, the questionnaire showed high levels of reliability and validity, with Cronbach alpha values of 0.84 and 0.87 for the two languages it was tested in. I used the CSQ-8 questionnaire in my TeleGDM study to assess participating patients’ satisfaction with overall GDM care at baseline (study entry) and at six weeks follow-up, after exposure to telemedicine-supported GDM care. That is, I used the questionnaire to evaluate whether, relative usual care alone, the introduction of telemedicine-supported GDM care had any impact on patients’ experiences of satisfaction with overall GDM care. I used the same methods to increase response rates for the CSQ-8 as I did for the DES-SF.

The DES-SF (Appendix 12) [105] was developed from the 28 item, Likert scale response, DES questionnaire for measuring self-efficacy in people with insulin or non-insulin treated diabetes [106]. This original version of the questionnaire has three subscales; i) managing the psychosocial aspects of diabetes, ii) assessing dissatisfaction and readiness to change, and iii) setting and achieving goals. The longer version is the precursor to the shorter 8-item DES-SF version, which has high construct validity, and good reliability [32, 106], and still assesses psychosocial constructs of coping with and
managing diabetes. Drawing by inference from use of the longer version in GDM [32], the DES-SF had good face validity. Empirically, the DES-SF has high reliability (alpha=0.85), and the scores from the questionnaire have been found to correlate positively with improvements in HbA1c [105], a measure of glycaemic control from which efficacy could be inferred. Although the longer version of DES is more robust that it shorter version, its length potentially made it cumbersome for time poor women facing the demands and stresses associated with pregnancy. In recognition of this, I selected the DES-SF to assess diabetes (GDM) self-efficacy among my study patients. Scores of the DES-SF range from 8 (lowest self-efficacy) to 40 (highest self-efficacy). The DES-SF has no establised minimum clinically important difference.

Item responses were added to give a numerical total scores for each questionnaire. Group means were imputed for cases with missing data. The intervention was then compared with control using the Wilcoxon rank-sum test.

### 4.8.2 Clinicians (CDE-RNs) survey

Clinicians (CDE-RNs) were surveyed using a modified version of the Canada Health Infoway System and Use Assessment Survey (Appendix 13). The questionnaire was designed to survey administrators, clinical staff, and other staff engaged in using telehealth/ehealth systems in a healthcare setting. It explores ease of use, functionality, information quality, service quality, as well as public health efforts, of electronic systems and solutions for clinical decision support, and electronic health records [107]. The questionnaire has good face validity and was available for use at no cost. It has unrestricted use, allowing modifications to suit context. Therefore, I modified it to suit the TeleGDM study, by excluding questions or statements that made specific reference to the Canadian context.

In the TeleGDM study, OHP was the system of interest and focus of the clinician survey. For information presentation and clarity for the thesis, I summarised and grouped the survey outcomes into three key domains:

i) Overall satisfaction,

ii) System and information quality
iii) System usage and quality of (support) service

In my presentation of the survey findings, I summarised the Likert scale response items graphically. These are qualified and supplemented with descriptive summaries of the free text responses.

4.8.3 Semi-structured interviews

I conducted semi-structured interviews with clinicians and a select group of patients. The interviews were aimed at eliciting participants’ experiences around usability and acceptance of the telemedicine system (OHP) used in this study, and telemedicine as a concept in GDM care. The interviews were guided by schedules outlined in Appendix 14 and Appendix 15.

I developed the interview schedules by framing the questions around the telehealth evaluation framework dimensions of patient control, clinician quality of care, and technology capability/capacity [51]. One of my PhD supervisors provided feedback and suggestions to reframe and restructure the interview questions after reviewing the first interview.

4.8.3.1 Selection of interview subjects

Interview subjects were patients and clinicians (CDE-RNs) who engaged in using the telemedicine system during the intervention.

A criterion sampling approach was used to select a sample of patients for the interviews. One of the sampling methods for participants in qualitative research is criterion sampling whereby participants are selected against a carefully laid out set of criteria [108]. As such I aimed to select up to 15 patients who enrolled in the intervention arm of the TeleGDM study, and represented a spectrum of low to high users of the telemedicine system, as well as the cultural and linguistic diversity of the population. In relation to the CDE-RNs, because there was a small number of them, all five were considered for the interviews.
4.8.3.2 Interview data collection and analysis

The first half of the patient interviews were performed after reaching the 50% recruitment milestone and the second batch took place during the second 50% block. Patients were interviewed after study end point. All patient interviews were conducted one-on-one over the phone and recorded digitally using a free Windows® smartphone audio recording application for later transcription.

The interviews with clinicians were designed to be one-on-one and face-to-face. Because of timing and scheduling challenges on account of clinician’s busy workload and other reasons, the interview process had to be adaptable. One CDE-RN preferred to provide a written response to the interview schedule rather than conduct a sit down interview. One sit-down interview was conducted jointly with two CDE-RNs, and the remaining two were separate. These interviews were also digitally recorded for later transcription.

My analysis primarily followed a framework approach. Framework analysis sits under the broader suite of qualitative data analysis methods of thematic analysis, where common threads are identified from the data [109]. The framework analytical approach involves classifying concepts and themes from qualitative data into pre-existing categories [109, 110]. It is one of the methods of choice for analysing semi-structured interviews [109]. My study had its theoretical underpinnings in the telehealth evaluation framework, with its constituent domains [51-53], which are outlined in sections 2.2.3 (page 32). With this in mind, and the use of semi-structured interviews in the qualitative evaluation in my study, I performed a framework analysis of the interview transcripts. Despite this approach, I kept an open mind to identify and consider other themes, or concepts, which might not fit the categories of the telehealth evaluation framework.

I had originally planned to perform my interview data management and analysis with aid of NVivo 11 (QRS International). Instead I performed transcription in NVivo and carried out the analytical task on a word processor; there were 12 interview transcripts to consider and I found I was more efficient using the word processor rather than coding in NVivo. I read and re-read the transcripts for greater familiarity, and identification of codes and themes [111] that aligned with the domains of the
telehealth evaluation framework or identified new themes. Although I performed the coding and analysis, my principal supervisor and I listened to the first two clinician interviews and the first three patient interviews together. This provided the opportunity to discuss my preliminary themes, their interpretation and/or considerations for new ones, as well as to reconsider follow up questions in subsequent interviews. That is my supervisor provided advise and suggestions on enhancements to subsequent interviews and analysis. Due to resource and time constraints reflexivity with interview subjects was not followed after the transcripts were analysed.
4.9 Published paper 2: Study protocol
Protocol


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Abstract

Background: Women with insulin-treated gestational diabetes mellitus (GDM) require close monitoring and support to manage their diabetes. Recent changes to the diagnostic criteria have implications for service provision stemming from increased prevalence, suggesting an increased burden on health services in the future. Telemedicine may augment usual care and mitigate service burdens without compromising clinical outcomes but evidence in GDM is limited.

Objective: The Telemedicine for Gestational Diabetes Mellitus (TeleGDM) trial aims to explore the use of telemedicine in supporting care and management of women with GDM treated with insulin.

Methods: The TeleGDM is a mixed-methods study comprising an exploratory randomized controlled trial (RCT) and a qualitative evaluation using semistructured interviews. It involves women with insulin-treated GDM who are up to 35 weeks gestation. Participating patients (n=100) are recruited face-to-face in outpatient GDM clinics at an outer metropolitan tertiary hospital with a culturally diverse catchment and a regional tertiary hospital. The second group of participants (n=8) comprises Credentialled Diabetes Educator Registered Nurses involved in routine care of the women with GDM at the participating clinics. The RCT involves use of a Web-based patient-controlled personal health record for GDM data sharing between patients and clinicians compared to usual care. Outcomes include service utilization, maternal and fetal outcomes (eg, glycemic control, 2nd and 3rd trimester fetal size, type of delivery, baby birth weight), diabetes self-efficacy, satisfaction, and costs. Semistructured interviews will be used to examine user experiences and acceptability of telemedicine.

Results: The trial recruitment is currently underway. Results are expected by the end of 2016 in a follow-up paper.

Conclusions: Innovative use of technology in supporting usual care delivery in women with GDM may facilitate timely access to GDM monitoring data and mitigate care burdens without compromising maternal and fetal outcomes. The intervention may potentially reduce health service utilization.
KEYWORDS

gestational diabetes; telemedicine; Internet; electronic personal health record

Introduction

Recent changes to tighten the diagnostic criteria for gestational diabetes mellitus (GDM) [1] mean many more women will be diagnosed with this condition, placing increased demand on clinical services to provide diabetes care. Women with insulin-treated GDM, in particular, often require more intensive follow-up and support for titration of insulin and overall management of GDM [2,3].

The prevalence of GDM is estimated to be 6% to 15% of pregnancies [1,4] dependent on whether the diagnostic criteria set by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) or the Australasian Diabetics in Pregnancy Society (ADIPS) is used. The IADPSG’s revisions in recent years give higher prevalence estimates [1].

Good control of blood glucose level (BGL) in GDM is important to minimize the risk of pregnancy and birth complications associated with the condition. Such complications can include large for gestational age (LGA) babies, macrosomia, increased likelihood of cesarean delivery, preclampsia, and fetal shoulder dystocia [3-5]. First-line therapy to control hyperglycemia involves dietary modification and physical activity [1,3,6] or oral hypoglycemic agents (OHA) [3]. An insulin regimen is initiated if the OHA therapies are inadequate in optimizing BGL or there is evidence of increased risk of macrosomia [6]. Approximately 50% of women with GDM go on insulin regimen, which requires close monitoring and intensive follow-up for regular insulin titrations to control persisting hyperglycemia [2].

The increasing prevalence of GDM [7-10] and the intensive clinical care needed have implications for the capacity of health care services to provide timely care and the clinical outcomes of such care. There is a need to explore innovative ways to deliver care and support for women with GDM to ease the service burden while not compromising quality of care. This may also potentially deliver cost efficiencies and savings.

In our systematic review [11], telemedicine has emerged as a potentially effective intervention to address service utilization while producing maternal and fetal outcomes similar to or better than usual care.

Telemedicine is defined as “the use of telecommunications technology to provide medical information and service” [12]. Telemedicine (also known as telehealth) has been implemented as a monitoring intervention in diabetes, heart failure, and chronic obstructive pulmonary disease [9,10,13] with promising results. For instance, a small study that trialed the use of cellular phones to transmit self-monitoring blood glucose data in type 2 diabetes found the approach was feasible, easy to use, and resulted in patients having fewer hospital visits [8]. Recent studies exploring a smartphone application or text messaging in type 1 and/or 2 diabetes reported improvements in glycemic control in favor of the telehealth approaches [14,15], while self-efficacy and quality of life were unchanged [14]. A study of telemedicine in heart failure patients reported better quality of life and heart failure self-care while hospital utilization remained unchanged [13]. While there may be some cautious optimism about the benefits of telehealth-based interventions, usage by patients appears modest, approximately 34% to 39% [16]. It remains to be seen how all this translates to GDM, especially in a real-world clinical setting.

Specifically in GDM, telemedicine interventions compared to control/usual care may reduce service utilization such as face-to-face clinic visits (4.25 [standard deviation or SD 0.93] vs 6.22 [SD 1.48], respectively, P = 0.002) and unscheduled visits (0.50 [SD 0.73] vs 2.89 [SD 1.05], respectively, P < 0.001) [12], while achieving similar outcomes (with trends in favor of telemedicine) for glycemic control, birth weight, incidence of macrosomia [11,12,17,18] and diabetes self-efficacy [12,17,19]. The main limitations of studies of telemedicine in GDM that we identified in our systematic review of the literature [11] are that there are very few randomized controlled trials (RCT) and sample sizes tend to be small. None of the trials included in our review evaluated costs, perhaps due to the lack of an agreed standardized evaluation framework for telehealth interventions. We also identified other methodological limitations such as shorter interventions and the heterogeneous nature of the outcomes and telehealth interventions used [10,20-22]. Interventions were perhaps too short to have significant measurable impacts; outcome measures varied across studies, posing challenges to conducting effects through pooled data analysis, and the interventions varied considerably, ranging from telephone support and videoconferencing to text messaging [10,20-22], making comparison of studies and generalizability difficult.

Our innovative study, the Telemedicine for Gestational Diabetes Mellitus (TeleGDM) trial, uses a Web-based approach to augment the management of women with insulin-treated GDM. Our aim is to explore the effects of telemedicine on health system performances including patient utilization of outpatient clinical care, maternal and fetal clinical health outcomes, and patient and clinician satisfaction and acceptance with respect to the intervention technology. In addition, a cost comparison between the two arms of the trial will be performed to determine if there are any provider cost savings that might be associated with changes in outpatient clinic attendance.
We hypothesize that with timely access to patient GDM self-monitoring data, health service utilization would be decreased without compromising maternal and fetal outcomes with an associated provider cost saving, greater satisfaction with the telemedicine, and a positive user experience.

The project is registered with the Australian and New Zealand Clinical Trial Registry [ACTRN1261400934640], and ethics approval was granted by Northern Health Human Research Ethics Committee (HREC/P/11/14) and Bendigo Health Human Research Ethics Committee (HREC/15/BHCG/44).

Methods

Study Design

The TeleGDM trial is a mixed-methods study comprising an exploratory RCT and a qualitative evaluation using semi-structured interviews (Figure 1). RCTs are the gold standard for providing evidence for practice [23,24] but have a major limitation of “... not telling the whole story...” [25]. Qualitative methods such as interviews can provide more in-depth information about participant experiences [26] than would otherwise be captured by quantitative methods alone.

Population, Setting, and Inclusion Criteria

The first group of participants comprises pregnant women diagnosed with GDM who have commenced insulin therapy to control hyperglycemia. These women attended outpatient GDM clinics at two tertiary hospitals between August 30, 2014, and October 30, 2016, inclusive of follow-up. One hospital is in an outer metropolitan region with a catchment population of significant cultural and linguistic diversity. The other is regionally located and serves a population with a rural background. Combined, the two hospitals have approximately 5000 live singleton births annually, and approximately 800 of the pregnancies are affected by GDM.

Women with GDM (patient participant group) are eligible for inclusion if they have a clinical diagnosis of GDM based on the IADPSG criteria following an oral glucose tolerance test [1]. Other eligibility criteria include gestation up to 35 weeks and access to the Internet via a personal computer, smartphone, or tablet. Prepregnancy glucose intolerance, twin pregnancies, GDM not treated with insulin, and other types of diabetes are exclusion factors.

The second group of participants are Credentialed Diabetes Educator Registered Nurses (CDE-RNs) who provide GDM care at the two centers. The CDE-RNs are directly involved in the RCT component of the study and provide care to women with GDM in the course of their usual practice. The number of these clinicians across the two sites is 8; all are requested to complete the clinician assessments for the study.

Recruitment and Randomization

The women with GDM regularly attend outpatient GDM clinics at the hospitals. It is at these weekly clinics that prospective participants are recruited face-to-face. Clinicians identify potentially eligible patients, give them a study brochure and/or seek permission for referral to the lead researcher or study research assistants. Following referral, participants are
approached for face-to-face screening, detailed briefing, consent, randomization, and completion of baseline questionnaires. A 1:1 randomization schedule was generated in STATA 11.0 (StataCorp LP) by an independent statistician. The lead researcher and RAs have no involvement in routine care of the patients.

Some ethnic groups (Indian, Asian, Arab/Middle Eastern, Pacific Islander, Aboriginal, and African) are considered high risk for GDM [27]. Previous GDM and use of insulin in past pregnancies are also considered high risk factors for GDM. Therefore randomization was stratified according the level of risk (high or low). Stratification avoids group allocation imbalances on factors that have significant influence on prognosis, avoids type 1 error, and improves study power for small trials [28]. Group assignments are concealed in two sets of opaque envelopes; the first set is the randomization schedule for the low risk subgroup and the second for the high risk GDM subgroup. Following consent, the envelopes are consecutively opened for assignment by the recruiter. Clinicians are not blinded to group allocations because they need data from the intervention for clinical care.

**Usual Care (Control)**

Usual care refers to clinical GDM care processes currently in practice at the participating hospitals, and this will be the control group. In line with recommended best practice [29,30] diagnostic screening for GDM occurs at 24 to 28 weeks gestation for women with no known history of diabetes or earlier for those considered high risk for GDM. Following diagnosis through to end of pregnancy, ongoing care is provided via a multidisciplinary team of endocrinologists, dietitians, and CDE-RNs. The role of the team is in addition to obstetric care.

From an endocrinology perspective, care involves an initial group counseling and education with a CDE-RN and dietitian covering aspects of GDM self-management. The CDE-RNs provide the pregnant women with free BGL meters from an approved supplier. The meters are individual use and the women purchase their own consumables (ie, test strips and lancering devices). Treatment targets are ≤5.0 mmol/L for preprandial BGL and ≤6.7 mmol/L for 2-hour postprandial BGLs. Insulin is initiated or titrated if BGLs are above target over three successive days. Ongoing face-to-face appointments are scheduled with members of the team as needed until delivery. Appointments generally occur every one to two weeks as determined by the clinicians. Patients on insulin have more frequent reviews especially in the early stages of insulin initiation. Self-management involves keeping a daily paper diary record of GDM self-monitoring data (1 preprandial and 3 postprandial BGLs, insulin dosing, symptoms, and dietary information). The diaries are reviewed by the clinicians at each outpatient clinic. The women also have the option to call the CDE-RNs out of scheduled appointments if BGLs are outside target.

**Telemedicine (Intervention)**

The intervention is telemedicine as an adjunct to usual care. The main distinction to usual care is GDM self-monitoring data is shared via a telemedicine system in lieu of paper diaries. The intervention uses a Web-based portal, Online Health Portfolio (OHP) [31], for data sharing and communication between patients and clinicians and is premised upon (1) women with GDM undertaking regular GDM self-monitoring and entering data; (2) timely availability of data to clinicians via the Web-based OHP, hence timely response to the women's GDM care needs informed by the available data, and (3) upon carrying out advice and feedback the women will better manage GDM and require less frequent appointments. Currently there is no empirical evidence for OHP, and it was chosen for this study on pragmatic reasons and anecdotal accounts of independent endocrinologists who used it in their practice.

Online Health Portfolio is a secure Web-based patient-controlled personal health record that is accessed securely through an Internet browser on a personal computer, smartphone or tablet. It is a proprietary system developed and owned by a vendor who is independent of the study. It uses 256-bit data encryption and 5-minutes inactivity time logout. Besides data entry and preview, the users can have graphical visualization of summary data and trends filtered by pre- or postprandial meal type or time, set up automatic reminders on the internal calendar, and set trigger levels for BGL alerts. Reminders may be forwarded to the patient's smartphone as a short message service (SMS) text. There is an internal messaging feature within OHP to enable 2-way messaging of free text between clinicians and patients. Clinicians also have the option to send an SMS text to the patient's smartphone from OHP. Participating patients use their own Internet-connected devices while clinicians use their usual hospital-provided Internet-connected computers. Username and password access to OHP is independent of all other hospital applications and systems. While patients are at liberty to access OHP at any time, clinicians interact with OHP during the course of normal work hours (8:00 AM to 4:30 PM, Monday through Friday). Multimedia Appendix 1 and Multimedia Appendix 2 show some screenshots of the OHP.

The research team have no financial interest in the OHP. The lead researcher (TR) has had some input into modifications and refinements to the Web portal in order to enhance usability by the patients and clinicians. An example is the introduction of the diary view format in Figure 2. The vendor usually charges an annual subscription fee (AUD $85) to patients to use OHP while clinicians' subscriptions are free. For this study, patient subscriptions are covered in the study budget. OHP consumes negligible amounts Internet data, thus adding no perceptible costs to patients' home or mobile Internet service.

Upon enrollment, patient participants undergo individual semi-structured 30 to 45 minutes induction by the lead researcher or research assistants.

The induction is hands-on and covers the initial set-up with participants practicing all the tasks they are expected to perform independently from then on. Induction covers signing up, logging on, navigating through the OHP Web portal, data entry, messaging, and reviewing data trend/summary graphs. All data entry is practiced using the previous day's data. Performing BGL self-monitoring, administering insulin, and following dietary advice are part of routine diabetes education and counseling provided by a multidisciplinary endocrinology care
team as described under usual care. Participants are also instructed on how to share this health information with the GDM clinicians for the purpose of providing clinical care and with the project lead investigator for research data collection and data management purposes. When required and in order to improve study data collection, the lead researcher may set up automatic reminders on OHP to send reminders every second day to prompt the noncomplying patient to enter data. Activating or setting up automated reminders is not routine but it is targeted for those who fail to perform data entry according to expectations. This avoids inundating those who are compliant with unnecessary reminders.

Participants are asked to enter their GDM self-monitoring data onto OHP daily or every other day in order to minimize backlogs and associated data entry errors. Maintaining a paper diary is optional. Automated alerts about new data entries are sent to the clinicians via email prompting the clinicians to log in under their credentials to review the patient data. When required and depending on the reviewed data or patient queries, clinicians provide feedback to the patient via the messaging service about any necessary alterations to treatment (eg, insulin titrations, changes to diet). The CDE-RNs act as the gatekeepers to interact with the telemedicine system and to consult or liaise with other GDM service team members. Patients can also email or print reports for other interested parties who do not have direct access to the Web-based shared data.

Induction for clinicians involved in providing care was conducted by the lead researcher. It consisted of setting up log-on credentials, using and navigating through the OHP webpage, setting up alerts, reviewing patient data, and messaging. The induction included both demonstration and hands-on practice in group setting.

Tasks expected of clinicians are to review patient data at their convenience, fitting in with their other routine clinical commitments through the day during weekdays. At the minimum, data are reviewed every 1 to 2 days during the week. Clinical decision making and advice in relation to ongoing management of GDM is at the discretion of the clinicians in accordance with existing clinical protocols without interference from the researchers. The same applies to scheduling of clinic appointments. Clinicians may also remind a patient when no data have been entered.

For research data collection, participant engagement, and/or troubleshooting purposes, the lead researcher periodically contacts participants via the OHP messaging feature or telephone and extracts all data from OHP to collate in a secure MS Access study database. The lead researcher is the primary contact for basic technical support queries, escalating any queries that cannot be resolved to the OHP vendor.

Sample Size

As an exploratory RCT, a stringent sample size calculation was deemed to be less critical for the TeleGDM trial. Therefore sample size has been set at 100 participants. This determination was largely pragmatic, based on resources, time constraints, the balance of probability for detecting a statistically significant difference in the primary outcome and a reasonable power for secondary outcomes. Estimates based on a finding of 44% fewer clinic visits among those receiving telemedicine versus controls [32] indicated a required sample size of 42 with a power of 0.9 for a similar outcome. Thus if the primary outcome in our study were to be less than the latter cited study, or there was 30% attrition, our set target sample offers good prospects for detecting a difference in the primary outcome.

Data and Outcomes

Data for research is collected by the lead researcher. This includes weekly extraction of data from OHP for those in the intervention arm in addition to questionnaire outlined below. For controls, photocopies of patients’ paper diaries are obtained when these patients attend their clinic appointments. In addition to these photocopies, where possible, BGL data are directly extracted from the BGL meter via USB cable connection. Finally, once patients have reached the study end point, they also asked to send outstanding self-monitoring data copies of their diaries via email or as photos via smartphone-based multimedia messaging service.

Demographic data together with diabetes self-efficacy and client satisfaction are collected at baseline with follow-up at least 6 weeks after enrollment in the trial. Self-efficacy and satisfaction are measured using the Diabetes Empowerment Scale—Short Form (DES-SF) [33] (Multimedia Appendix 3) and Client Satisfaction Questionnaire—8 Item (CSQ-8) [34,35] (Multimedia Appendix 4). The DES-SF is a shorter version of the original 28-item questionnaire for measuring self-efficacy in people with insulin- or noninsulin-treated diabetes [36]. The original questionnaire has three subscales: managing the psychosocial aspects of diabetes, assessing dissatisfaction and readiness to change, and setting and achieving goals. The longer version has high construct validity and good reliability [18,36]. The shorter version has 8 items, has high reliability (alpha of 0.85), and the scores were found to change positively with improvement in HbA1c [33]. To minimize the burden on participating women we selected the DES-SF to assess diabetes self-efficacy. The CSQ-8 has been used in diabetes research [37] and was assessed for reliability and validity in a childbirth service evaluation [38]. It is reported to have strong reliability, excellent face validity [34,35], good psychometric properties, high client and staff acceptability, and sensitivity to programs of varying quality [37]. The CSQ-8 is available under paid license while the DES-SF is free with appropriate attribution. Both the DES-SF and SCQ-8 questionnaires are self-completed face-to-face or administered over the phone at baseline and at least six weeks from enrollment. Further information on outcomes and data collection time points is provided in Table 1.
Table 1. Outcomes and indicators matched to the telehealth evaluation framework dimensions.

<table>
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<tr>
<th>Outcome</th>
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<td>Attendances and nonattendances from outpatient activity dataset; patient medical records</td>
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<td></td>
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<td></td>
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<tr>
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<td></td>
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<tr>
<td><strong>Secondary</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Clinical measures and satisfaction</td>
<td>Clinician quality of care</td>
<td>Glycemic control</td>
<td>BGL(^a), extraction from OHP(^b), glucometer downloads, patient paper diaries</td>
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<tr>
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<td>Routine billing administrative data for face-to-face/staff costs; OHP subscriptions</td>
<td>Study exit</td>
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<td>Tertiary</td>
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<td>Usage (patients and clinicians)</td>
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<td>OHP access, volume of data uploaded</td>
<td>Extraction from OHP logs</td>
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</tbody>
</table>

\(^a\)BGL: blood glucose level  
\(^b\)OHP: Online Health Portfolio  
\(^c\)DES-SF: Diabetes Empowerment Scale-Short Form  
\(^d\)LOA: large for gestational age  
\(^e\)SCN: special care nursery  
\(^f\)NVD: normal vaginal delivery  
\(^g\)LUSC: lower uterine segment cesarean section  
\(^h\)CSQ-8: Client Satisfaction Questionnaire-8 Item (CSQ-8)
The primary outcome of the quantitative exploratory RCT component of the study is service utilization. Maternal and fetal outcomes, satisfaction, and costs are secondary outcomes. In particular, one of the limitations of studies in our systematic review [11] was the lack of cost evaluation, however basic. Considering that studies appear to show virtually similar clinical outcomes between telemedicine and usual care/control [12,17-19], a form of cost comparison becomes important. There are several methods for undertaking health economic evaluation, one of which is cost minimization. This type of health economic evaluation is defined as ‘...evaluation method to use when the case for an intervention has been established and the programmes or procedures under consideration are expected to have the same, or similar, outcomes. In these circumstances, attention may focus on the cost side of the equation to identify the least costly option’ [39]. At the time of this protocol study, patients not covered by the Australian Medicare paid AUD $280 for each face-to-face consultation with a clinician for GDM care at the centers in this study. Because diabetes education, endocrinology, and dietetics are the key outpatient specialties involved directly in GDM management and therefore targeted for influence by the TeleGDM intervention, the AUD $280 cost rate will be assigned to these for service provided to patients between study entry and study exit. Study participant outpatient consultations data covering service access between commencement of recruitment and end of data collection for computation of provider costs will be sourced from the hospital data management unit. While clinicians provide service over the phone, which is a cost to the hospital, patients are not billed and hence this cost will not be included. Furthermore, implementing the intervention required existing equipment and infrastructure for the brief induction. Costs for these were considered negligible and therefore were not taken into consideration. Also Australian public hospitals by their nature are nonprofit making entities. Where fees are charged these are normally break-even and include overheads. Besides the AUD $85 per patient subscription there is no separate license fee for OHP.

Technology is central to the telemedicine support service for GDM and an important feature for evaluation. As such, technology capability will be assessed through the volume of data uploads by patients and qualitatively through sections 2 and 3 (system and information quality) of the Health Infoway System and Use Assessment Survey [40] (Multimedia Appendix 5).

Outcomes of interest are outlined in Table 1. These are aligned with the dimensions of the telehealth evaluation framework proposed by the Institute for a Broadband-Enabled Society [41-43].

**Qualitative Evaluation**

The aim of the qualitative evaluation is to supplement the RCT by exploring patient and clinician acceptance, adoption, and experiences of telemedicine to support care in the management of GDM. A semi-structured interview approach is used for both patient and clinician participants. The interview schedule is outlined in Multimedia Appendix 6. Subjects include those who are assigned to the intervention arm of the TeleGDM RCT and the CDE-RNs. A purposive sample of patients will be selected with the aim for up to 15 patients. Since there are only a few clinicians, all CDE-RNs who actively interact with OHP during the RCT will be included. Interviews are conducted by the lead researcher and the questions are open-ended, focusing on gathering interviewee experiences with telehealth-supported GDM management and the technology under use. Clinician interviews are face-to-face while patient interviews are carried out over the phone for the convenience of new mothers. All interviews are audiorecorded digitally for later verbatim transcription.

The interviews will be supplemented with field notes/observations. Notes or written diaries throughout the trial allow for an analysis that provides a narrative account of practice [44]. The narrative adds to the evaluation by highlighting factors in the local setting which may influence the success or failure of the intervention [44,45].

**Data Preparation and Analysis**

Quantitative data analysis will be performed using StataIC 13.1 (StataCorp LP) with an intention to treat analysis. Missing data for the primary outcome is expected to be minimal as all patient appointments and outcomes are recorded. For the DES and CSQ-8 losses to follow-up will employ last observation carried forward for missing values. Since case BGL data is serial and expected to be non-linear, case mean of nearby data points imputation will be used for missing data.

Summary univariate statistics will be used to describe the study populations and compare study groups at baseline. Categorical variables will be summarized as raw numbers and percentages and between groups comparisons will utilize chi-square statistics. Multivariate statistical analysis will be performed to compare the groups on primary and secondary outcomes. In addition, survival analysis will be performed to explore time to reach glycemic stability. Statistics will be reported with standard deviations or 95% confidence intervals as appropriate. Statistical significance will be indicated by $P<0.05$.

Patient and clinician interviews will undergo thematic analysis supported by NVivo 11 (QSR International). The interview transcripts will be analyzed separately for each participant group using an inductive approach to identify and/or infer themes and codes from the transcripts. Further themes will be classified according to the dimensions of telehealth evaluation framework [41].

**Results**

At the time of submission of this paper, recruitment and data collection were underway. Data analysis was pending and results expected at the end of 2016.

**Discussion**

**Summary**

Use of telemedicine to support care, specifically in the management of GDM, through a multiphase Web-based personal health record is an innovative use of current technologies. It is envisaged the study will show reductions in
health care utilization (eg, face-to-face clinic appointments) with an associated service provider cost saving. Other expected effects are GDM clinical outcomes similar to if not better than usual care. In addition, it is anticipated that both clinicians and patients will express greater satisfaction, usability, and positive views for telemedicine-supported GDM management.

The increasing prevalence of GDM and associated burdens [1-3] calls for innovative ways of service provision. The TeleGDM study explores a Web-based telemedicine approach to providing care and support to pregnant women with insulin-treated GDM. The intervention in the TeleGDM study relies on reliable and acceptable technology for efficient data sharing between patients and clinicians. Underpinning the intervention is the idea that telemedicine provides an engagement and interaction platform between the patient and clinician independent of face-to-face visits. The intervention incorporates some of the elements which are common for Web-based interventions (eg, self-management, communication, individualized feedback) [46].

Comparison With Previous Work
A few previous studies [12,17-19] have specifically explored telemedicine for GDM. These studies found better service utilization in terms of fewer face-to-face appointments and better diabetes psychological self-efficacy. There are some marked differences between the TeleGDM study and previous studies; TeleGDM uses technologies (broadband Internet and the ubiquitous mobile telephony Internet) which were not previously available. While in theory the approach in the TeleGDM study appears similar to those in the previous studies, the intervention has been implemented as adjunct to usual care for ethical reasons. That is, usual care is the current standard of care at the study sites, and therefore it would be unethical to deny patients what is current practice in lieu of a test intervention. However, the adjunct nature of the intervention means concurrent elements of usual care could become confounders.

Strengths and Limitations
The strength of the TeleGDM is the innovative use of current technologies in GDM, particularly in the Australian context. Second, the study uses a mixed-method approach to enhance the rigor of the evaluation and incorporates elements of a framework proposed for evaluating telehealth interventions in Australia [41]. The study includes cost evaluation, an important consideration which telehealth studies are often criticized for excluding [10]. Costs are only considered from a provider perspective and limited to billable consultations for pragmatic reasons, a potential methodological limitation. As such, a full economic evaluation that takes into account other costs could be a future consideration.

Internet security is one of the barriers to uptake of Web-based interventions [46]. Hence OHP uses 256-bit data encryption, individual username and password access, and an inactivity timeout. Despite these security measures, data breaches cannot be completely ruled out. Any interactions over the Web carry the risk that user privacy and confidentiality may be breached, however minimal. This may happen as a result of unauthorized access during the course of transmission, hacking into system servers, or users not exercising due diligence in securing their log-on information.

Conclusion
TeleGDM is an innovative use of technology to support care and management of insulin-treated GDM. It may mitigate burdens on the health care service and the women with GDM without compromising clinical outcomes. Results of this study are expected by the end of 2016.

Acknowledgments
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Conflicts of Interest
None declared.

Multimedia Appendix 1
Online Health Portfolio data entry screenshots.

[JPEG File, 105KB - resprot_v5i3e163_app1.jpg ]

Multimedia Appendix 2
Online Health Portfolio data view screenshots.

[JPEG File, 189KB - resprot_v5i3e163_app2.jpg ]

Multimedia Appendix 3
Diabetes Empowerment Scale--Short Form (DES-SF).
Multimedia Appendix 4
Client Satisfaction Questionnaire-8 Item (CSQ-8).

Multimedia Appendix 5
Canada Health Infoway System and Use Assessment Survey.

Multimedia Appendix 6
Clinician and patient interview schedule.

References
randomized controlled trial RENEWING HEALTH. JMIR Mhealth Uhealth 2014 Dec;2(4):e57 [FREE Full text] [doi: 10.2196/mhealth.3882] [Medline: 25499872]


http://www.researchprotocols.org/2016/3/e163/


Abbreviations

ADIPS: Australasian Diabetes in Pregnancy Society
CDE-RN: Credentialled Diabetes Education—Registered Nurse
CSQ-8: Client Satisfaction Questionnaire—8 Item (CSQ-8)
DES-SF: Diabetes Empowerment Scale—Short Form
GDM: gestational diabetes mellitus
IADPSG: International Association of Diabetes and Pregnancy Study Groups
LGA: large for gestational age
OHP: Online Health Portfolio
RCT: randomized controlled trial

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Piloting the protocol and intervention

Conducting a pilot is in keeping with research best practice, in line with the MRC framework for evaluating complex intervention [37, 38]. The MRC framework recommends conducting a pilot before proceeding to the exploratory phase, when conducting research which involves a complex intervention. In the previous methods chapter (section 4.1, page 55), I indicated that I piloted the intervention ahead of commencing the exploratory RCT. In this chapter I describe this pilot, linking this to the theoretical frameworks underpinning my study. I also discuss my observations, findings, and the changes I made subsequent to these findings, and the experience I gained from the pilot.

Piloting is useful for providing information around the feasibility of the protocol, and identifying aspects of the protocol that may require modifications prior to moving to the main trial [37, 38, 112, 113]. Drawing from NPT [49, 50, 58], piloting assists in optimising the intervention and design of a study [38, 58], in order to increase the prospects of success for the subsequent phases in the implementation cycle or continuum [58].

Performing the pilot in my study allowed assessment of how my study and intervention would fit alongside existing work flow processes, and whether, and what adjustments, I needed to make in preparation for progressing to the exploratory RCT phase. Piloting was an important step because the TeleGDM study involved a complex intervention of a newly developed and previously untested protocol. To recap, the intervention elements included the ancillary participant induction or training to equip the participants with the skills to use the telemedicine system as a part of their self-management of GDM and their interaction with GDM clinical services.

After receiving ethical approval, I conducted a 2-week pilot at The Northern Hospital, one of the campuses of NH with a GDM clinic. The aim was to pilot the protocol and intervention on two patients, and interview them about their experiences. I used purposive sampling to select two women to trial telemedicine supported GDM care. The selection strategy was mutually agreed with the CDE-RNs, and that they would
identify suitable women who needed intensive monitoring, and who frequently attended the GDM service because of persistent, difficult to control hyperglycaemia. Also, the patients for the pilot had to be open to using technology (the telemedicine system). The pilot was carried out with the objectives of:

1. Determining how the recruitment process would work.
2. Making an initial assessment of usability of the telemedicine system (Online Health Portfolio).
3. Identifying aspects of the intervention that might require modifications.
4. Observing the general dynamics, and clinic flow on a typical clinic day, when patients waited to be seen by the members of the clinical team.

The pilot patients underwent the induction, as outlined in the methods (section 4.6.3, page 78), and commenced using telemedicine-supported GDM care. Similarly, clinicians also underwent an induction. This was their second one because it had been several weeks since the first, without the opportunity to use the skills and consolidate the training in the intervening period.

A number of challenges, from recruitment, compliance with using the system, to the technical design of the telemedicine system, were identified and addressed during the pilot. These are detailed and discussed below. I conclude this chapter with the actions I took to mitigate the issues identified during the pilot.

5.1 Recruitment process

With the historical data showing a throughput of around 200 patients on insulin per annum, it was anticipated that it would not be difficult to identify two patients to participate in the pilot. But this was perhaps the first signal that the recruitment process might face challenges. Notwithstanding the restrictive purposive intent of selecting the pilot patients balanced against the inclusion/exclusion criteria, it took three weeks to recruit the first pilot patient and another week after that for the second. I identified the following critical issues which contributed to recruitment challenges:
i) Unusually fewer than expected patients on insulin over the three weeks of the pilot, the majority of whom declined participation, largely on the basis of lack of interest in engaging with technology, and a preference for usual care over the new and untried telemedicine-supported care.

ii) Although the NH catchment has a higher rate of patients with a CALD background (section 4.3.2, page 60), I had not anticipated that a significant proportion of those with insulin-treated GDM would require an interpreter to navigate the healthcare system and to hear about the study. This and other recruitment challenges, pre-empted a possible revision of the study sample size from close to n=200 to around n=100.

iii) The women were reluctant to change their glucometers to those that could interface with OHP, as required by the study protocol.

iv) Identifying space in a busy clinic environment, to brief women about the study, undertake baseline assessment, and perform the induction and training to use OHP, was challenging in the busy clinic environment at TNH. For patient privacy and confidentiality reasons as required by the NH policies, such interaction with patients needed to take place in a secure or private physical space. However, a vacant consulting room was only available once every fortnight. This meant space was only available on one of the three weeks earmarked for the pilot. The busy clinic schedules also meant that patients had to navigate from one clinician to the next during their time in the clinic. This presented challenges of finding space in the busy schedules for recruitment briefings.

5.2 Engagement and compliance with data upload/entry to OHP

One of the prompting questions to consider in the NPT is “are trial procedures sufficiently likely to normalise to make the trial feasible?” [58]. An important procedure in the TeleGDM study was for patients to upload and enter their GDM self-monitoring data for sharing with their clinicians who in turn used the data for clinical decisions making. The pilot afforded the opportunity to test uptake of the intervention and the
levels of compliance with data upload and entry to OHP procedures; a cognitive participation factor as described by the NPT framework [49, 54, 58].

Aligned with usual care self-monitoring processes, the protocol required patients to upload (via USB connection) four sets of SMBG data to OHP, plus (manual) entry of insulin dose, diet, and any other relevant comments. The pilot highlighted an engagement issue with performance of this procedure. After the first day of data upload/entry, none of the two patients uploaded any more data for a week, which indicated a low level of “cognitive participation” described in the NPT [58]. In response I sent reminder messages via OHP which also went to the participant’s mobile phones as SMS and set up automated reminders. One participant eventually resumed data upload after a week: more regularly for automatically uploaded BGL data, and sporadically for the manually entered insulin dose, diet, and relevant comments. This preliminary finding, appeared to suggest that automatic data upload might be more favoured that the tasks requiring manual data entry. Despite several reminders, there was no action or response from the second pilot participant.

While my efforts at encouraging data uploads were study data collection motivated, CDE-RNs required the data for clinical decision making. In demonstration of their commendable level of engagement (cognitive participation) and collective action [58], the CDE-RNs also attempted to encourage the pilot patients to upload data. It later emerged via the CDE-RNs, that the second patient, who was unable to upload data to OHP at all, indicated she had experienced technical difficulties, and was unable to use OHP. Instead she reverted to keeping a handwritten record of self-monitoring data. Murray et al [58] describe how the NPT can be used to optimise the trial. Drawing from the latter, It was crucial that I obtained details of the technical difficulties that hampered data upload, so that where possible, I could determine what remedial actions were required to enhance engagement, ahead of the RCT. However, I was unable to establish the nature or details of the technical difficulties, despite numerous attempts to contact the patient.

Although the pilot was planned to run for 2 weeks, I extended it for another week, after consulting with my PhD supervisors. Since the pilot patients had not uploaded data to OHP for the week after enrolment, it was felt that very little insight was gained from the
limited engagement with using OHP. More time was needed to get a clearer picture of patient and clinician interaction with OHP.

At the end of the three weeks of piloting, I attempted to contact the patients to conduct interviews to get their experiences. This was unsuccessful, however, due to difficulties with either making contact with the patients or finding mutually suitable time. In the end the interviews did not happen.

In spite of what did not work well, the pilot demonstrated the importance of taking advantage of the OHP messaging and reminder capability, to enhance patient engagement and data upload. It also highlighted the reality of expecting that not all patients will engage with participation to the same extent. That is, while steps and actions may be taken to maximise engagement and participation, there will always be areas where coherence, and cognitive participation remain low.

Lastly, although the focus here was patient engagement with data upload procedures, there was also an important observation that by encouraging patients to upload data, the CDE-RNs demonstrated their commitment to the intervention. The underlying motivation and incentive was commitment to providing clinical care. This, together with what I learnt as described above, and in the next sections, provided confidence that with some changes the trial could go ahead.

### 5.3 GDM care team use of OHP, roles and effects on workflow

At commencement of the pilot, I registered generic OHP accounts for members of the GDM care team (endocrinologists, CDE-RNs and dietitian), plus the obstetrician so they could access OHP as part of the intervention. I shared this information with the relevant members of the clinical team as part of the clinician induction, prior to and at commencement of the pilot. However, during the pilot, only the CDE-RNs engaged with using the telemedicine system (OHP) to review pilot participant patients’ data. The clinicians who did not access OHP beyond the induction phase advanced a number of important reasons which included the following:
i) Lack of integration of OHP into the existing electronic medical record which they used more frequently. OHP was a standalone system requiring separate logon from existing hospital-controlled health informatics applications, and systems that the clinicians used in the course of their work. They suggested that having another system to contend with added an extra burden of having to log on to yet another system/application on top of multiple other existing hospital applications and systems.

ii) Engaging with OHP was viewed as a relevant role for the CDE-RNs, because, for all intents and purposes, they were perceived by the rest of the team as the main gate-keepers and coordinators of care for patients in the GDM service. The basis for this was that, the CDE-RNs saw the patients with GDM, or other types of diabetes in pregnancy, more regularly, and referred on these patients, or consulted other members of the team, when needed. Although from observation, the CDE-RNs were happy to play this role, it raised implications for their role; clinical versus research. In essence, it became apparent that during the pilot (and hence beyond), the CDE-RNs took on an informal coordinating role, akin to a “health informatics nurse” role, which was indistinguishable between clinical and research activities.

iii) Although there was a collaborative relationship between obstetrics (obstetricians and midwives) and endocrinology in caring for patients with GDM, the obstetric team indicated that all GDM clinical management decisions were controlled and led by the endocrinology GDM care team. Hence they viewed engaging with OHP as not so relevant for their domain, although they reviewed patient handwritten diaries form time to time, which they preferred to do in lieu of OHP.

In relation to the frequency of accessing OHP, to review patient data during the pilot, the CDE-RNs reported looking up data daily for the first three days, then every other day, then sporadically and eventually, none at all by the third week. The concerted effort to engage with using OHP in the first few days, demonstrated a greater sense of both cognitive participation and collective action [50, 58] on the part of the CDE-RNs. Needless to say, the CDE-RNs expressed that repeated logging onto the system, when there were no new data, was a non-value adding, time consuming, activity in
the midst of competing duties; hence, this threatened organisational sustainability, as defined in the telehealth evaluation framework [51, 52]. The study’s disruption of workflow in this manner, risked undermining work efficient in an already busy clinical service environment, and therefore presented a threat to uptake of the telemedicine in the GDM service. As such, this highlighted the need for a well-functioning alert feature in OHP, so that CDE-RNs would only logon to OHP when needed. As a technical design feature, it aligned with the technological capability dimension of the telehealth evaluation framework [51, 52], to sustain workforce performance in an area of need (i.e. GDM service challenges that prompted this study). Having an alert feature was an opportunity to increase coherence [58], and harness the CDE-RNs’ level of enthusiasm and commitment described above.

5.4 System design and capabilities

Technology capability is one of the domains of the telehealth evaluation framework [51-53], outlined in the second chapter (section 2.2.3, page 32) of my thesis. System design, and the manner in which data are presented over the system, fit in the technology capability domain of the framework. In this subsection, I will describe and discus some design and layout issues which contributed to some negative disruptive aspects of technology. Poor technology capabilities could threaten sustainability of the technology in practice, quality of care, usage, and access [51-53].

One of the advantageous capabilities of OHP was direct data upload using the patient’s glucometer connected to a personal computer, with requisite iHealth application installed. This capability allowed a compatible glucometer to be connected to a personal computer via a USB cable, to automatically upload data stored in the meter to OHP. In principle, this minimised, if not eliminated, the human errors that might arise from manual data entry, thus potentially strengthening the reliability of data uploaded to OHP for clinical use. This was one of the strengths of OHP. But limitations of this capability were identified during the pilot, when there was a mismatch in BGL and meal times/types which is explained below.
In GDM management, it is critical to match given BGL data to a meal type (before or after breakfast, lunch, or dinner). Clinicians need to know whether a given reading relates to before or after meals, in order to put in context any out of target BGL readings. Under normal processes of care, patients recorded context-making information, i.e. measurement time, diet/meals, symptoms, and/or other relevant information, in their diaries in an easy to follow and track format for CDE-RNs. Seamless presentation of this information, facilitated rapid perusal and evaluation of the data. However, this aspect of care was disrupted by introducing OHP, as the way OHP was designed created extra work for the CDE-RNs during the process of making sense of the data. The method of automatically uploading data to OHP, rendered the critical data required by the CDE-RNs for clinical care, difficult to interpret, and therefore unreliable, for clinical decision making. In this way, the system design inadvertently created a clinical risk and safety problem.

When one of the patients in the pilot started uploading BGL data more frequently, the CDE-RNs identified problems with matching the uploaded BGL data with the type of meals the readings pertained to. That is, it was difficult to interpret whether a given BGL reading related to pre- or post-breakfast, for example. This prompted the CDE-RNs to make an unplanned phone call to the patient for clarification, which the patient was able to do, because she had kept records on her handwritten logbook, in addition to uploading data to OHP. From the few readings initially identified as problematic, it turned out the rate of mismatch was greater than originally thought. Because this posed a significant clinical safety risk, the CDE-RNs immediately alerted me. Preliminary assessment pointed to a possible issue relating to uploading data to OHP automatically via direct USB connection, as described in section 4.6.1 (page 73) and 4.6.2.1 (page 75). I immediately advised cessation of this method of getting data on to OHP, while I investigated the problem further.

Although some of the early information I used to inform selection of OHP for this study indicated OHP was used by a small number of women with GDM, I postulated that as a system, its design had a predominant focus on type 2 diabetes, where contextualising BGL readings to meals was not as critical as in GDM. Automatic data upload as a design feature of OHP was appealing due to the prospect of reducing human-related manual data entry human errors. However, the automatic data upload feature had the unintended consequence of being discordant with the
realities of people’s lives. The patient in the pilot had meals at varying times on different days, with a corresponding BGL testing schedule. But this was something that the artificial intelligence and decision-making algorithms of OHP, that “decided” when one would normally have a meal, was unable to process reliably; highlighting a mismatch between the technology capabilities and what happened in reality. As an example, when the patient performed a “before breakfast” BGL test at 10.00am which was later than usual, OHP allocated that particular BGL reading to “after breakfast” on upload. The problem of a mismatch in the data then snowballed through subsequent tests for that day. The issue was overcome by resorting to manual data only to OHP, which worked better even though it created extra work for the patient.

The other design issue related to the way data were presented to users for viewing. OHP was designed to provide an output of data in a table list layout (Figure 6) which required more a little more time than usual to appraise and interpret the data. The CDE-RNs were used to the handwritten logbook data layout which allowed, rapid data appraisal with minimal effort. They preferred that OHP had a similar data layout. Although the OHP data layout issue might appear minor, it had implications for scalability. The small amount of extra time expended to review multiple cases on the system would inevitably add up, resulting in a significant burden, thus adversely impacting workflow efficiency; an issue of organisational sustainability [51-53]. Any time saved by making improvements to OHP, however small, would in turn become significantly greater when usage of OHP was scaled up. As such, feedback was provided to the vendor of OHP, who was amenable to making improvements for a data output layout that resembled the CDE-RNs’ favoured view. The result, to the satisfaction of the CDE-RNs, was the layout shown in Figure 7.
<table>
<thead>
<tr>
<th>SELECT</th>
<th>DATE</th>
<th>MEAL</th>
<th>GLUCOSE</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20 Jul 2015 07:41 PM</td>
<td>after breakfast</td>
<td>8.5 mmol/L</td>
<td>4 slices of strawberry toast</td>
</tr>
<tr>
<td></td>
<td>25 Jul 2015 07:40 PM</td>
<td>before breakfast</td>
<td>5.0 mmol/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25 Jul 2015 07:39 PM</td>
<td>after dinner</td>
<td>5.5 mmol/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25 Jul 2015 07:38 PM</td>
<td>after lunch</td>
<td>5.0 mmol/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25 Jul 2015 07:37 PM</td>
<td>after breakfast</td>
<td>6.2 mmol/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25 Jul 2015 07:36 PM</td>
<td>before breakfast</td>
<td>4.0 mmol/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>24 Jul 2015 07:35 PM</td>
<td>after dinner</td>
<td>4.1 mmol/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>24 Jul 2015 11:39 AM</td>
<td>after lunch</td>
<td>4.4 mmol/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>24 Jul 2015 11:38 AM</td>
<td>before breakfast</td>
<td>4.5 mmol/L</td>
<td></td>
</tr>
</tbody>
</table>

Figure 6 Original data table layout on OHP before modifications
The final issue relating to design was the precision of the blood glucose readings. A BGL reading on the OHP output screen was shown as a number with two decimal places, whereas the meter output provided the reading to a precision of a single decimal place. This created a rounding problem for CDE-RNs, particularly when trying to make decisions as to whether a given reading was within or out of treatment target. Again, while seemingly minor, this fed into the issue of overall satisfaction with the system, especially for the clinicians at the coalface of clinical care delivery. Similar to the data reliability issue described earlier, the root of the problem was OHP programing algorithms’ interpretation, and internal conversion, as BGL data were transferred from the meter to OHP, during automatic upload.
The above is an outline and description of some important positives and challenges I identified during the pilot. These had implications that could make or break any further progression of the TeleGDM study. In the concluding section of the pilot chapter below, I summarise the key challenges and discuss remedial changes I made, ahead of proceeding to the exploratory RCT phase of my study.

5.5 Summary of key pilot observations and changes

1. Recruitment process – There is a legal and ethical requirement to afford patients some privacy and confidentiality when navigating through the healthcare system. This extends to research in the health care setting as well, making it imperative to find a location that afforded study patients some privacy. A room was made available at each of the other two campuses. With room availability assured for some weeks at the campus I had to be adaptable in my recruitment process. This meant looking out for a free consultation room during clinicians’ downtime, and negotiating to use the room during these times. However, patient availability did not always coincide with the occasion when a consulting room was available. Some weeks were easier than others, with a room available for use during the entire clinic time.

Furthermore, I observed that on clinic days, patients would quite often spend a considerable time waiting to be seen, especially in between multiple healthcare provider appointments. This provided another opportunity to adapt my recruitment process to engage with the patient for recruitment during this waiting time rather than waiting until the last appointment. After a long day at the hospital, the last thing patients wanted was to spend any more time in clinic, especially for research.

The participant consent and induction part of the recruitment process to use OHP, took approximately 20-30 minutes. Since technology induction was not required for those who would be allocated to the control arm, it was surmised the time required to recruit these and administer baseline questionnaires, would be, at most, half the time required for those assigned to the intervention arm. I observed
that, overall, the two patients who enrolled in the pilot, understood the consent document, and study requirements. Needless to say, it was anticipated disruptions to recruitment were likely to still occur, when clinicians needed to see the patient in the middle of the recruitment process. To overcome this, I negotiated and reached an understanding with the clinicians and patients, that patients could have their clinical consultation slots swapped around to allow continuity in the recruitment process.

2. **Uptake and engagement with data uploads** – Until automatic reminders and alerts were set on OHP and sent out, the volume and frequency of data upload to OHP was less than satisfactory. However, clinicians cautioned that daily reminders could inadvertently become a nuisance, which would ultimately turn the women off acting on the reminders. As a result a decision was made to set the reminders to go out every other day. A decision was made, that, If there was a lack of response to resume data entry after two weeks, in spite of the reminders, the non-responding patient(s) would be considered lost to follow-up for self-monitoring data collection tasks.

3. **Uptake by clinicians** – Perceived clinicians’ roles needed to be considered in the context of the study; not all of them needed to be active participants or had opted to delegate the role of engaging with OHP to the CDE-RNs. Thus, recruiting clinicians to engage with OHP was streamlined to focus on the CDE-RNs as the primary gate keepers and coordinators of the GDM services. Other members of the GDM team (endocrinologists and dietitians), as well as the obstetricians and patient GPs were thus deemed less critical in the scope of the study. As such, the plan to include them as active players in engaging with using OHP was dispensed with.

4. **Automated data uploads** – A mismatch between BGL readings and meal types was identified during then pilot. This posed data reliability issues, hence clinical safety risk. This issue also increased the work of the clinicians during the process of reviewing the data to make clinical decisions. As a solution, consideration was given to meters that had recently entered the market. These meters allowed the user, the ability to input BGL-meal type at the time of testing. However, changing to use this new type of meter required reprogramming OHP to make it compatible,
but the cost and time required made it prohibitive. The next pragmatic solution was to do away with automatic data uploads altogether, and adopt manual data entry, even though this added somewhat to the work patients needed to do for ongoing GDM self-management. The upside was more reliable, and clinically usable data on OHP.

5. **Data view layout** – feedback was passed on to the designers of OHP to change the data view layout to resemble the all familiar paper logbook, and the suggestion was acted upon. However, in order to avoid further delays than had already happened, the implementation proceeded to the exploratory RCT phase while work on the modification was in progress. The discontent with the original data layout (Figure 6) was best summed by the following quoted statement from one of the CDE-RNs, "honestly I don't use it as much, because the way it [the layout] is, it's not useful to me." Following the change, the new layout (Figure 7) was received with great excitement by the team and summed up in the words of some, "it is so much more functional" and "it will make it so much easier and I will use OHP more now."

6. **Precision of readings** – The developers of the OHP re-programmed the system to present readings to one decimal place as required by the CDE-RNs, which was again a very welcome development. However, because of the other issue of the BGL-meal type mismatch (see point 4 above), the reprogramming was nonetheless superseded by the decision to switch from automatic data uploads to manual data entry.

In conclusion piloting the protocol ahead of implementation of the exploratory RCT was an important and valuable exercise, which helped identify a number of critical study implementation process issues. These affected the conduct of the study and also affected the quality of care. As a result of the pilot revealing these early in the study, timely remedial changes were made to the TeleGDM study protocol. Some of the changes were urgently required, and needed to be rectified without delay, because they presented risk to clinical safety. Others relating to system usability, were not so urgent and the study could proceed, while modifications were underway. Yet, other issues, particularly around recruitment challenges, prompted a rethink and presented opportunities to adapt to fit the local context workflow. Lastly, the pilot reinforced the
decision for choosing to use a locally developed telemedicine system, which facilitated access to responsive technical support, when important system changes were needed.

Finally, after the pilot and the resulting changes, I proceeded to the exploratory RCT phase of the TeleGDM study. In the next chapter, I will present the findings of the exploratory trial, reporting both primary and secondary outcomes, as well as reporting on intervention fidelity and other process factors. I then move on to the discussion section of my thesis and then bringing it to a close with a conclusion and implications.
6 Results

6.1 Overview

This chapter presents the results of the TeleGDM study. I start with a general overview, in which I will highlight some minor deviation from my protocol, and discuss the circumstances leading up to these changes, justifying why they were made and outlining their effect on the overall research design. In the early sections I will present underlying population numbers including a Consolidated Standards of Reporting Trials (CONSORT) summary diagram. In subsequent sections, I will present the characteristics of the patients who participated in the TeleGDM study. This is followed by the results of the primary outcome, service utilisation, and quantitative secondary outcomes. I then present a brief section that describes the fidelity of the intervention implementation, in order to aid contextualising the observed quantitative outcomes. Section 6.7 is a presentation and discussion of the process evaluation based on a survey of the CDE-RNs, and findings of the semi-structured interviews with the CDE-RNs and patients.

My published study protocol (methods section 4.9, page 99) indicates that there were two study sites, NH and Bendigo Health. Obtaining ethical clearance at Bendigo Health took longer than planned, and, in the end recruitment and data collection at Bendigo Health could not be included in the analysis, and findings of this thesis. Because of this, I have confined my thesis to presenting and discussing the results for the data I collected on patients and clinicians at NH.

Another aspect of the study that did not go to plan was the randomisation schedule. The intention was for a 1:1 randomisation of patients to the study arms; intervention versus control. Early into recruitment, it became apparent that allocation of patients to the study arms was uneven, with an apparent bias in favour of greater patient allocation to the intervention, rather than the control, group. What contributed to this was the lack of blocking in the randomisation schedule, which was designed with the aim of a recruitment of up to 200 patients. I immediately consulted with my PhD supervisors, and the biostatisticians, and reviewed the literature on the implications of
the issue. I made a decision, informed by the literature and advice, to continue with the existing randomisation schedule. It was evident from advice and the literature [77, 79], that this randomisation issue presented only a minimal impact on the validity of the study. It is not uncommon for RCTs to adopt uneven allocations, although planned in advance, so that more people are allocated to the intervention arm than the comparator. Also, in such instances, sample size estimations take into account the uneven allocation, in order to maintain a desired study power. Despite the uneven allocation in my study, even with my projected study sample size of n=100, study power based on the number of appointments, as an indicator of service utilisation outcome, was maintained. This issue is discussed in-depth in the discussion chapter (strengths and limitations), section 7.6 (page 207).

6.2 Participants

6.2.1 Patients and baseline characteristics

Participant recruitment and data collection commenced on the 30th of August 2014 and the last patient was recruited on the 30th of June 2016. During this period 406 patients with insulin-treated GDM attended the GDM clinics across the three campuses of NH. One hundred and ninety five (195) patients were not approached because they were greater than 35 weeks gestation (n=169), or were missed (n=35) due to recruitment resource limitations. Competing workflows, during clinic times, also contributed to some of these patients being missed for recruitment, particularly on very busy clinic days.

The remaining 211 patients were screened for eligibility, after referral by the CDE-RNs, and/or they were identified from electronic hospital medical records. The CONSORT chart (Figure 8) shows the recruitment flow and 95 (45%) of screened patients were randomised, while 116 (55%) were excluded for reasons as indicated in the CONSORT chart. The main reason for excluding 65 (56%) of the 116 (Figure 8) was a lack of sufficient English language skills, for these patients to adequately undertake study tasks, i.e. completion of questionnaires which were all in English, or engaging with using
the telemedicine system, in the event they were randomised to the intervention. The excluded group’s mean age was 33(5) years of age, median (range) gravidity and parity were 2(1-10) and 1(0-8) respectively. Other than lack of English ability, the excluded group’s characteristics were similar to those for the included patients. In particular, the proportion of patients who had sufficient English skills, but were from a CALD background or an ethnic group considered high risk, in my study sample was 57% overall; indicating the study sample was representative of the GDM population mix at NH (see 4.3.2, page 60). Four patients in the intervention group did not engage with using the telemedicine system beyond the induction, or, when they did, they shared data only for one day. These were considered to have not received the intervention as planned.

**Figure 8 Consort flow diagram of the study based on the primary outcome**
Table 3 shows baseline data and demographic information of patients who took part in the TeleGDM study. Clinicians’ data are presented in a separate section of the results chapter (section 6.7.3.1, page 165).

On statistical comparison, there were no differences between the groups at baseline. As a cohort, the participating women were diagnosed with GDM on average at 20-21 weeks gestation, which was earlier than the consensus to screen at 24-28 weeks [24]. The early diagnosis perhaps reflects the population demographic of the health service’s catchment, which is made up of a high rate of at risk groups for whom earlier screening is advised [24].
Table 3 Baseline and demographic characteristics of patients enrolled in the study

<table>
<thead>
<tr>
<th>Measure</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation, n</td>
<td>61</td>
<td>34</td>
</tr>
<tr>
<td>Age, mean (SD) years</td>
<td>32 (5)</td>
<td>32 (5)</td>
</tr>
<tr>
<td>Gestation at enrolment, mean (SD) weeks</td>
<td>28 (5)</td>
<td>28 (5)</td>
</tr>
<tr>
<td>Parity, median (range)</td>
<td>1 (0-6)</td>
<td>1 (0-3)</td>
</tr>
<tr>
<td>Gravidity, median (range)</td>
<td>2 (1-10)</td>
<td>2 (1-6)</td>
</tr>
<tr>
<td>High GDM risk, % (n)</td>
<td>61 (37)</td>
<td>59 (20)</td>
</tr>
<tr>
<td>GDM Diagnosis:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestation at diagnosis, mean (SD) weeks</td>
<td>21 (6)</td>
<td>20 (7)</td>
</tr>
<tr>
<td>Plasma glucose, mean (SD) mmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting</td>
<td>5.2 (0.6)</td>
<td>5.1 (0.5)</td>
</tr>
<tr>
<td>1-hr</td>
<td>10.1 (1.8)</td>
<td>9.8 (1.8)</td>
</tr>
<tr>
<td>2-hr</td>
<td>8.1 (1.7)</td>
<td>7.8 (1.8)</td>
</tr>
<tr>
<td>Insulin dose, mean (SD) units</td>
<td>9 (7)</td>
<td>8 (5)</td>
</tr>
<tr>
<td>2nd trimester foetal biometry, mean (SD) cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biparietal diameter (BPD)</td>
<td>4.93 (0.45)</td>
<td>4.87 (0.27)</td>
</tr>
<tr>
<td>Head circumference (HC)</td>
<td>18.42 (1.61)</td>
<td>18.20 (1.43)</td>
</tr>
<tr>
<td>Abdominal circumference (AC)</td>
<td>16.19 (1.71)</td>
<td>15.77 (1.17)</td>
</tr>
<tr>
<td>Femur length (FL)</td>
<td>3.53 (0.42)</td>
<td>3.41 (0.24)</td>
</tr>
</tbody>
</table>
6.3 Health Service Utilisation

Summary statistics, median and interquartile ranges, of the measures of service utilisation are presented in Table 4. The absolute total number of appointments for patients in the intervention group was greater than that for the control group, which reflected the difference in the number of patients allocated to each group. The period after enrolment in the study had a greater number of appointments than the before enrolment period. This was consistent with the observed longer follow up, and active time, in the clinic than the period prior; for instance in the period before enrolment, the number of weeks that all participants attended the GDM service was median (IQR) = 3(5) compared to 7(8) weeks for the period after.

Unadjusted statistical comparisons of the group medians and hypothesis testing was performed using the equality of median test. The test results showed that there were no statistically differences between the groups on each of the measures of service utilisation (Table 4), suggesting no association between the intervention and service utilisation.
### Table 4 Median and interquartile range of measures of service utilisation of outpatient GDM clinic

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=61)</th>
<th>Control (n=34)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before enrolment</strong></td>
<td>Absolute total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>appointments</td>
<td>332</td>
<td>221</td>
<td></td>
</tr>
<tr>
<td>Weeks active in clinic</td>
<td>3 (5)</td>
<td>5 (6)</td>
<td>0.391</td>
</tr>
<tr>
<td>Total appointments</td>
<td>4 (4)</td>
<td>6 (5)</td>
<td>0.215</td>
</tr>
<tr>
<td>Scheduled/planned</td>
<td>3 (4)</td>
<td>5 (5)</td>
<td>0.112</td>
</tr>
<tr>
<td>Unscheduled/unplanned</td>
<td>1 (2)</td>
<td>1 (2)</td>
<td>0.914</td>
</tr>
<tr>
<td>Face-to-face</td>
<td>4 (3)</td>
<td>5 (6)</td>
<td>0.407</td>
</tr>
<tr>
<td>Unattended</td>
<td>0 (1)</td>
<td>0 (2)</td>
<td>0.322</td>
</tr>
</tbody>
</table>

| **After enrolment**  | Absolute total      |                |     |
| appointments         | 608                 | 325            |     |
| Follow-up weeks      | 7 (8)               | 8 (8)          | 0.227 |
| Total appointments   | 9 (8)               | 8 (10)         | 0.501 |
| Scheduled/planned    | 4 (5)               | 5 (6)          | 0.096 |
| Unscheduled/unplanned| 2 (4)               | 1 (3)          | 0.130 |
| Face-to-face         | 8 (7)               | 8 (6)          | 0.843 |
| Unattended           | 0 (1)               | 1 (1)          | 0.274 |

Noting that patients had varying lengths of exposure to the intervention (from study entry to end point), through a dose-response relationship with the intervention, follow-up time potentially had an impact on response to intervention, requiring further exploration. A spearman correlation of follow-up time with the total number of appointments was explored, followed by multivariate analysis.

A scatterplot of the relationship between follow-up time and the number of appointments is shown in Figure 9, which shows a strong linear relationship (Spearman’s rho = 0.87, n = 95 and P < 0.001) between appointments and follow-up time. That is,
not unexpectedly, the longer the follow-up time, the greater the number of appointments a patient had.

![Figure 9 Scatterplot with fit line showing correlation between the total number of appointments and follow-up time from study entry](image)

With the above correlation in mind, multivariate analysis was performed to adjust for length of follow up. A Poisson regression analysis was performed with service utilisation variables (the total number of appointments and face-to-face appointments) as dependent variables, and the exposure (intervention=1 or control=0), and follow up time, as predictors, or dependent variables. The results are presented in Table 5. First, statistical assessment of how well the models predict measures of utilisation are provided by the Likelihood Chi square (LR Chi$^2$) and Pseudo R$^2$ values. That is, these statistics indicate how the predicted result, of the outcome of interest (number of appointments in this instance), closely match the observed results in the data [115]. First, the LR Chi$^2 = 230$, and 166 (Table 5) both had p-values <0.00001, indicating that
at least one of the predictor variables (intervention and/or length of follow up) has a significant effect on the number of appointments. Second, the pseudo $R^2 = 0.33$ and 0.27, both with $p$-values $<$0.001, also demonstrate that the models were a good fit for the data; again meaning the model predicted values are a close approximation of observed (real) values. Another, but cautious, interpretation of pseudo $R^2$ is to suggest that 33% and 27% of total appointments and attended appointments is explained by predictor variables, in the respective models. However, caution is advised, because unlike, for example, in linear or logistic regression, pseudo-$R^2$ in Poisson regression is not always an accurate indicator of variance in the outcome attributable to the predictor variables [115, 116].

Although the models performed well as outlined above, the intervention was not a significant predictor (Table 5, model statistics $p$ $<$0.05) for either the total number of appointments, or the number of attended face-to-face appointments, and its effect as indicated by the z values in either case was very small. Thus having telemedicine supported GDM care had no impact on service utilisation. As might be expected, and consistent with the correlation shown in Figure 9, the number of appointments were more related to the duration of follow up time than to telemedicine support.
Table 5 Results of Poisson regression analysis of association between health service utilisation and the telemedicine intervention

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>Independent variables</th>
<th>IRR</th>
<th>Std. Err.</th>
<th>z</th>
<th>P</th>
<th>LR Chi² (2, 92)</th>
<th>Pseudo R²</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of appointments</td>
<td>Intervention</td>
<td>1.04</td>
<td>0.07</td>
<td>0.5</td>
<td>0.596</td>
<td>230</td>
<td>0.33</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Follow-up time, weeks</td>
<td>1.10</td>
<td>1.01</td>
<td>15.6</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Constant</td>
<td>4.00</td>
<td>0.33</td>
<td>16.8</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of attended face-to-face appointments</td>
<td>Intervention</td>
<td>1.09</td>
<td>0.08</td>
<td>1.1</td>
<td>0.257</td>
<td>166</td>
<td>0.27</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Follow-up time, weeks</td>
<td>1.09</td>
<td>0.01</td>
<td>13.2</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Constant</td>
<td>3.8</td>
<td>0.33</td>
<td>15.2</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6.4 Maternal, foetal and new-born clinical outcomes

6.4.1 Glycaemic control

The level of glycaemic control is typically determined from SMBG readings (methods chapter section 4.7.4.3, page 89), and optimum glycaemic control is judged by readings within prescribed glycaemic targets (4.0-5.0mmol/L for pre-prandial SMBG levels and 4.0-6.7mmol/L post-prandial readings). In turn, SMBG readings are a function of insulin dosing. That is, the insulin dose is titrated to reach a satisfactory level of glycaemic control, adjudged by SMBG readings that fall within the desired treatment targets. Two markers of glycaemic control, using SMBG data (percentage of BGLs outside target), and the time to insulin dose stabilisation), were evaluated.

Because of the decreasing number of cases with SMBG data, as GDM management approached end point coupled with data entry attrition, evaluation of glycaemic control using patient recorded SMBG, looked at the first 4 weeks. Mean percentage of readings outside target are presented in Table 6. There were no differences between the intervention and control on the proportion of BGLs outside of target at each time point for each type of BGL measured. The exceptions were the 2-hr post breakfast and 2-hr post dinner readings in week two (Table 6). The intervention had a significantly higher proportion post-breakfast BGLs outside target (suggesting poorer glycaemic control) than controls. For 2-hr post-dinner BGLs the intervention had significantly better glycaemic control marked by the lower percentage of BGLs outside target than controls. The after-lunch BGLs graph shows a decrease in the percentage of outside-target BGLs for the intervention group, suggesting with caution (unadjusted observations) that, sufficiently intensive (i.e. over four weeks), the intervention might be associated with better glycaemic control of post-lunch BGLs. Between groups comparison of the mean percentage of off-target BGLs at each follow-up time point, was statistically significant on the Wilcoxon rank-sum test, with Bonferroni correction, for all the 2hr post meals BGLs (p<0.0001).
<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Week 1</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=52</td>
<td>n=34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-prandial</td>
<td>50.8 (41.5, 60.0)</td>
<td>40.6 (28.8, 52.3)</td>
<td>0.17</td>
</tr>
<tr>
<td>2-hr post breakfast</td>
<td>11.0 (4.1, 17.9)</td>
<td>12.0 (7.8, 16.3)</td>
<td>0.79</td>
</tr>
<tr>
<td>2-hr post lunch</td>
<td>18.1 (10.5, 25.7)</td>
<td>18.5 (11.6, 25.4)</td>
<td>0.93</td>
</tr>
<tr>
<td>2-hr post dinner</td>
<td>22.9 (16.3, 29.5)</td>
<td>26.4 (18.9, 33.9)</td>
<td>0.48</td>
</tr>
<tr>
<td><strong>Week 2</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=40</td>
<td>n=33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-prandial</td>
<td>38.1 (28.7, 47.5)</td>
<td>31.1 (20.1, 42.1)</td>
<td>0.33</td>
</tr>
<tr>
<td>2-hr post breakfast</td>
<td>16.5 (9.4, 23.5)</td>
<td>7.9 (3.6, 12.3)</td>
<td>0.04</td>
</tr>
<tr>
<td>2-hr post lunch</td>
<td>18.9 (10.9, 26.9)</td>
<td>21.5 (14.3, 28.7)</td>
<td>0.62</td>
</tr>
<tr>
<td>2-hr post dinner</td>
<td>19.7 (11.5, 27.9)</td>
<td>31.4 (22.8, 40.1)</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Week 3</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=38</td>
<td>n=33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-prandial</td>
<td>33.7 (23.3, 44.1)</td>
<td>33.2 (25.0, 41.5)</td>
<td>0.94</td>
</tr>
<tr>
<td>2-hr post breakfast</td>
<td>16.2 (9.2, 23.2)</td>
<td>9.4 (4.6, 14.2)</td>
<td>0.11</td>
</tr>
<tr>
<td>2-hr post lunch</td>
<td>17.2 (7.9, 26.6)</td>
<td>21.7 (15.0, 28.4)</td>
<td>0.43</td>
</tr>
<tr>
<td>2-hr post dinner</td>
<td>22.9 (14.7, 31.1)</td>
<td>26.9 (18.4, 35.4)</td>
<td>0.49</td>
</tr>
<tr>
<td><strong>Week 4</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=31</td>
<td>n=31</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-prandial</td>
<td>37.7 (26.7, 48.7)</td>
<td>26.1 (19.2, 33.0)</td>
<td>0.07</td>
</tr>
<tr>
<td>2-hr post breakfast</td>
<td>11.7 (5.8, 17.5)</td>
<td>9.6 (5.0, 14.1)</td>
<td>0.56</td>
</tr>
<tr>
<td>2-hr post lunch</td>
<td>14.1 (4.9, 23.2)</td>
<td>20.0 (13.2, 26.8)</td>
<td>0.29</td>
</tr>
<tr>
<td>2-hr post dinner</td>
<td>20.9 (12.5, 29.3)</td>
<td>28.9 (20.3, 37.4)</td>
<td>0.18</td>
</tr>
</tbody>
</table>
A time to event analysis was performed, to test whether the intervention group reached insulin dose stabilisation quicker than controls (Kaplan-Meier graph in Figure 11). The vertical axis of the graph shows the probability that a patient has not attained insulin dose stabilisation as a marker for optimum glycaemic control. The graph shows that up to about week 15 from study entry, the curve for the intervention group tracked below that of the control group, indicating patients supported through telemedicine had a relatively shorter time to reach insulin dose stabilisation, than those receiving usual care alone. To determine whether this observed difference and variability of the curves was significant, or not, i.e. the survival distribution for telemedicine support versus usual care, the Breslow test showed a statistically significant difference ($X^2(2) = 13.95, p < 0.001$), suggesting there was a difference between the two groups, in the time taken to attain optimum glycaemic control. The median (95% CI) times to reach insulin dose stabilisation from study entry were 3.0 (1.7, 4.3) and 7.0 (4.7, 9.3) weeks, for the intervention group and control group respectively. These were statistically significant on the equality of median test.
While the above univariate analysis (median time to insulin dose stabilisation) showed that intervention had a significant effect on the time to attaining optimum glycaemic control, factors such as baseline (study entry) insulin dose, age, gestation at GDM diagnosis, and at study entry, and GDM risk, may influence the level of glycaemic control, hence the time to attain it as well. That is, these factors are potential confounders for the time it takes to reach insulin dose stabilisation. Therefore to account for these and assess their effect on glycaemic control, a Cox regression analysis was performed with the potential confounders as covariates, or independent predictors, of time to insulin dose stabilisation. All variables were included in the model, and Table 7 shows the hazard ratios and levels of significance. With the exception of GDM risk (hazard ratio=0.84), the hazard ratios of all other predictor variables were greater than one (Model 1, Table 7) signifying that the latter variables reduced the time to insulin dose stabilisation. However, only telemedicine support

**Figure 11 Kaplan Meir graph of time (weeks) from study entry to insulin dose stabilisation**
(intervention, \( p=0.02 \)), and gestation at study entry (baseline gestation, \( p<0.05 \)), were statistically significant contributors. The ensuing model 2 (Table 7) shows that telemedicine support increased the rate of attaining optimum glycaemic control by 71\%, while controlling for baseline gestation. Finally, when baseline gestation was removed from the model, the effect of the intervention was still statistically significant (Cox proportional hazard ratio = 1.76, 95\% CI: 1.14, 2.71, \( z = 2.57, p = 0.010 \)).

| Table 7 Results of cox regression analysis; predictors of time to insulin dose stabilisation |
|---|---|---|---|
| Time to insulin dose stabilisation | predictor variables | Hazard Ratio (95\% CI) | \( z \) | \( P \) |
| Model 1 | Intervention | 1.71 (1.11, 2.65) | 2.41 | 0.02 |
| | Age | 1.01 (0.97, 1.06) | 0.59 | 0.55 |
| | Baseline insulin dose | 1.00 (0.97, 1.04) | 0.12 | 0.90 |
| | Baseline gestation | 1.20 (1.12, 1.29) | 5.14 | <0.001 |
| | Gestation at GDM diagnosis | 1.01 (0.97, 1.05) | 0.65 | 0.51 |
| | GDM risk | 0.84 (0.54, 1.30) | -0.79 | 0.43 |
| Model 2 | Intervention | 1.71 (1.11, 2.65) | 2.44 | 0.015 |
| | Gestation at enrolment/Study entry | 1.21 (1.14, 1.29) | 5.14 | <0.001 |

### 6.4.2 Birthing outcomes

The time of birth marked the end point for this study and overall the patients (women) gave birth at 38.0 ± 1.0 weeks gestation. Women in the two groups delivered at similar gestational age; mean gestation at delivery for the intervention group was 37.9 ± 1.1 weeks versus 38.1 ± 0.7 weeks for the control (Wilcoxon rank-sum test \( z = \), \( p = 0.60 \)).

The incidence of all caesarean delivery, regardless of reason, was higher for the women in the intervention group, 46\% (95\% CI: 33, 59, \( n = 28 \)) versus 32\% (95\% CI: 17, 51, \( n = 11 \)) (Figure 12). However, the 2 x 2 association of the intervention with the incidence of caesarean delivery was not statistically significant (\( X^2 = 1.65, p=0.20 \)).
A further breakdown of caesarean deliveries showed that 18.0% (95% CI: 9.3, 30.0, n = 11) of the intervention group underwent emergency caesareans in contrast with 14.7% (95% CI: 5.0, 31.1, n = 5) for the control group. But similar to the all caesarean incidence, association of the intervention with emergency caesareans was not statistically significant ($X^2 = 0.17, P=0.68$), suggesting that while telemedicine, as a new approach in this instance, resulted in similar rates of caesarean deliveries as usual care.

**Figure 12 Bar graph of showing percentage of caesarean deliveries, “Yes”**
6.4.3 Foetal and new-born outcomes

Summary data and corresponding statistical tests and results for foetal and new-born outcomes are presented in Table 8. Foetal biometry data from the routine care 3rd trimester ultrasound scan results are presented in Table 8. All the biometry variables satisfied normal distribution, $p > 0.05$ on the Shapiro-Wilk test of normality. Therefore, comparisons between groups were made using the independent samples t-test. The result showed no statistically significant difference between the intervention and control (Table 8).

### Table 8 Summary measure of foetal outcomes with statistical comparisons

<table>
<thead>
<tr>
<th>Measure</th>
<th>Intervention (n=61)</th>
<th>Control (n=34)</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3rd trimester foetal biometry (cm), mean(SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BPD</td>
<td>8.4 (0.6)</td>
<td>8.2 (0.7)</td>
<td>0.17</td>
</tr>
<tr>
<td>HC</td>
<td>30.6 (1.9)</td>
<td>30.0 (2.3)</td>
<td>0.15</td>
</tr>
<tr>
<td>AC</td>
<td>29.6 (2.7)</td>
<td>29.4 (3.4)</td>
<td>0.77</td>
</tr>
<tr>
<td>FL</td>
<td>6.3 (0.6)</td>
<td>6.3 (0.6)</td>
<td>0.51</td>
</tr>
<tr>
<td><strong>Birthing outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight (kg), mean(SD)</td>
<td>3311 (445)</td>
<td>3275 (384)</td>
<td>0.69</td>
</tr>
<tr>
<td>Macrosomia, % (95% CI)</td>
<td>4.9 (1.0, 13.7)</td>
<td>2.9 (0.1, 15.3)</td>
<td>1.00</td>
</tr>
<tr>
<td>SCN admission, % (95% CI)</td>
<td>20 (11, 32)</td>
<td>6 (1, 20)</td>
<td>0.08</td>
</tr>
</tbody>
</table>

Although the plan was to use the 3rd trimester foetal biometry to then determine LGA (growth greater than 90th percentile for gestational age), this step was deemed redundant. The reason being, foetal biometry data were extracted from routine care 3rd trimester ultrasound scans, with accompanying reports from the duty radiologist. These reports indicated foetal growth for all participants was within normal parameters, suggesting LGA was a negligible problem among the GDM cohort in my study, and the NH population, leading to an inferred but cautious conclusion, that there was no evidence of association between the intervention and LGA.
The next evaluation was birth weights of the new-borns and macrosomia (birth weight ≥ 4000g). A comparison of the two groups was not statistically significant (Independent samples T-test: t=0.40, df = 93, p = 0.69). In determining rates of macrosomia the overall rate was 4% (4 cases). Within group rates were 4.9% (n=3) and 2.9% (n=1) respectively, for the intervention and controls. As can be noted, the rates of macrosomia were low. Similar to LGA, the lack of statistical significance was more a reflection of the low and negligible incidence of this condition in the NH population.

Overall SCN admission was 15% (14 cases) of the 95 patients in the study. The rate of SCN admission among the intervention and control groups was 20% (12 cases) and 6% (2 cases), respectively (Table 8). The wider confidence interval reflect the low rates of SCN admissions overall. Further, because the control group had two cases, the association between intervention and SCN was performed using the Fisher’s test instead of the Chi-square test of association and this showed a non-statistically significant result; again in all likelihood a reflection of the low incidence of the need for SCN admissions at NH.

6.5 Costs

As indicated in the methods chapter, a cost rate of $280 was applied to each outpatient appointment episode. The 95 patients in the analysed dataset accounted for total of 605 planned appointments (intervention = 378, control = 227) at a total costs of AU$169 400 during the intervention phase. Summary data for the study patients are presented in Table 9. For some background perspective, data are also presented for the period before (Pre) the telemedicine intervention. Without taking into account the length of active time in the service, average costs were similar for the intervention group versus controls (Wilcoxon rank-sum test, P > 0.05).
Table 9 Estimation of utilisation costs pre and post intervention

<table>
<thead>
<tr>
<th>Utilisation Variable</th>
<th>Mean (SD) Estimated Costs, AU$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
</tr>
<tr>
<td>Pre</td>
<td>Total absolute costs</td>
</tr>
<tr>
<td></td>
<td>Total appointments</td>
</tr>
<tr>
<td></td>
<td>Face-to-face</td>
</tr>
<tr>
<td></td>
<td>Scheduled/planned</td>
</tr>
<tr>
<td></td>
<td>Unscheduled/unplanned</td>
</tr>
<tr>
<td>Post</td>
<td>Total absolute costs</td>
</tr>
<tr>
<td></td>
<td>Total appointments</td>
</tr>
<tr>
<td></td>
<td>Face-to-face</td>
</tr>
<tr>
<td></td>
<td>Scheduled/planned</td>
</tr>
<tr>
<td></td>
<td>Unscheduled/unplanned</td>
</tr>
</tbody>
</table>

Post-intervention costs relating to attended face-to-face appointments, which included both planned and unplanned appointments (telephone and walk-ins as previously alluded to in the methods chapter (sections 4.6.1 and 4.7.4.2), were higher for the intervention compared to the control, although not statistically significant (Table 9). When costs were explored looking at only scheduled or planned appointments for the intervention group, the cost was less, but not statistically significant. This non-significant difference resulted in a cost saving of $134.33. This small saving will be discussed further in the discussion chapter (section 7.4, page 201) in the context of a scaled up telemedicine intervention, with a hypothetical scenario of a greater number of patients, to demonstrate health service significance, in the absence of statistical significance.

Similar to the service utilisation outcomes (outpatient GDM clinic appointments), the length of follow-up from study entry to study end point (delivery) was expected to influence the costs. Once the cost variable was calculated, service costs were modelled using Poisson regression analysis. Several other predictor variables (patient
age, gravidity, baseline gestation and GDM risk) were included as predictors in addition to the exposure (intervention=1, control=0) and duration of follow-up. With the exception of follow-up time, all the other predictor variables were not statistically significant predictors of face-to-face service utilisation costs. Modelling was re-run to include only the exposure and follow-up time variables as predictors of costs associated service utilisation. The results of these final models are presented in Table 10. The statistically significant (P<0.0001), Pseudo R² values were 0.66 and 0.62, indicated that either model was a good fit.

The incidence rate ratio (IRR) for the intervention was not statistically significant, indicating that telemedicine support for GDM had no impact on face-to-face, or scheduled, service utilisation costs. Further, Poisson regression analysis looking at scheduled appointments, showed the intervention had a statistically non-significant impact on costs (Table 10). Although not statistically significant, what this meant was that if all the other predictor variables were held constant, telemedicine-supported GDM care would reduce scheduled appointment service utilisation costs by 8.7% [(1-0.913)*100]. The service significance of this will be elucidated in the discussion of costs, using a hypothetical in the discussion chapter (section 7.4, page 201). As might be expected, every one week increase in the duration of follow-up (IRR=1.111) significantly increased scheduled appointment costs by 11.1% (95% CI: 9.0 to 13.2%).

| Table 10 Final Poisson regression modelling of service utilisation costs |
|----------------|----------------|-------|--------|
| **Dependent variable** | **Independent variables** | **IRR (95% CI)** | **P** |
| **Face-to-face appointments** | Intervention | 1.087 (0.937, 1.261) | 0.270 |
| | Follow-up weeks | 1.086 (1.073, 1.098) | <0.001 |
| **Scheduled appointments** | Intervention | 0.913 (0.754, 1.105) | 0.349 |
| | Follow-up weeks | 1.111 (1.090, 1.132) | <0.001 |
| **Model performance, n=95** | **Pseudo R²** | **P** |
| | 0.660 | <0.0001 |
| | 0.618 | <0.0001 |
In summary, the utilisation costs for outpatient GDM care were more influenced by the length of time patients had been attending the GDM service, than by using telemedicine-supported care. While this observation held true from a statistical point of view, cost savings can still be realised from reductions in the number of planned appointments. The latter is still applicable when the cost of patient subscriptions is taken into account. Importantly the cost saving hinges on a high clinic throughput either in the number of patients or volume of appointments.

In the above sections 6.1 through to 6.5, I presented the results of the quantitative evaluation of the clinical outcomes and costs. Sections 6.6 through 6.7 are presentation and discussion of the process evaluation that largely involved qualitative data from semi-structured interviews. However, some of the data and results are quantitative summaries of the actual number of respondents to the survey instrument’s qualitative response items or the items that required numerical responses.

### 6.6 Intervention fidelity

#### 6.6.1 SMBG data volume and patient compliance with BGL monitoring and data entry

Table 11 shows volumes of data (the number of SMBG readings) recorded by the patients. Patients in the intervention arm shared their data via OHP, while those in the control arm provided the data through the handwritten logbook. Although greater in number, patients in the intervention had fewer SMBG data records (as measured by data uploaded to OHP) than patients in the control group (as measured by the volume of records in the handwritten logbook).
The volume of SMBG data was explored further by looking at the period when data recording was performed and this is shown in Figure 13 and Figure 14. The denominators were the expected total number of SMBG data points for the indicated follow-up time category, and the numerator, was the group’s total number of actual or observed SMBG data, for the same period (see section 4.7.3, page 85). Column labels show the number of patients whom the SMBG data pertained to. Both graphs show the trend towards a greater number of patients sharing data, and a corresponding greater volume of shared, data over the first four weeks than subsequent periods. Based on field observations, those patients who dropped out of using OHP to share data reverted to using the handwritten logbook method of data sharing. As can be noted in Table 3, the average gestation at baseline was 28 weeks, and average gestation at delivery was 38 weeks (introductory paragraph of Birthing Outcomes, section 6.4.2, page 140). This meant that the length of follow-up time in the study was 10 weeks, on average.

To further elucidate the decreasing numbers in order to clarify whether numbers decreased as a consequence of reaching study endpoint versus dropout from data sharing, data were charted to look at the number of patients reaching study end point, and this is shown in Figure 15. As the graph shows the decreasing number of

<table>
<thead>
<tr>
<th>BGLs</th>
<th>Intervention (n=61)</th>
<th>Control (n=34)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Readings/patient</td>
</tr>
<tr>
<td>Pre-prandial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-hr Postprandial:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakfast</td>
<td>1560</td>
<td>26</td>
</tr>
<tr>
<td>Lunch</td>
<td>1535</td>
<td>25</td>
</tr>
<tr>
<td>Dinner</td>
<td>1478</td>
<td>24</td>
</tr>
<tr>
<td>All BGLs</td>
<td>6262</td>
<td>103</td>
</tr>
</tbody>
</table>
patients sharing data over time was explained in part by patients reaching study end point, i.e. end of pregnancy.

For patients in the intervention group, the decreasing numbers are also explained by declining numbers of patients engaging with using the telemedicine system to enter and share data, including the four patients who only entered data for 0-1 day (COSORT chart Figure 8). For instance, 19-36 patients in the intervention group reached study endpoint between from weeks 5-8 post enrolment (Figure 15), which would mean the expected number of patients still actively engaged in the study was 25-42 for the same period. However, the real number was 23-24 (Figure 13) suggesting approximately 18 patients did not enter data on the telemedicine system in week 5-8.

It appeared that patients engaged with using the telemedicine system, to enter and share data mainly in the first 4 weeks. The observation suggested that from a patient user perspective, telemedicine to support GDM care was sustained for the first four weeks of the intervention.

Figure 13 Intervention group’s volume of SMBG data uploaded to OHP by weeks of follow-up from study entry
Figure 14 Control group’s volume of SMBG data recorded on paper diaries by weeks of follow-up from study entry

Figure 15 Cumulative number of patients reaching study endpoint
As outlined in the methods, patients were expected to test and keep a record of four SMBG readings daily until delivery (usual care, methods section 4.6.1). Patients in the intervention group primarily entered SMBG data on the web-based personal health record (OHP) and those in the control group kept a handwritten logbook. The product of the daily readings, and the number of days from study entry to delivery, gave the expected number of SMBG entries or records. Percentage compliance was then derived from actual SMBG readings (numerator), and expected SMBG reading (denominator). The resulting measure of compliance was collapsed into categories and the results are presented in Table 12. The control group performed better than the intervention group at maintaining records of SMBG data; 88% of patients in the control group made more than 75% of expected SMBG entries in their paper diaries, compared with 30% for the intervention group (Fisher’s exact test $P < 0.001$). This suggests that, as noted above, sharing data via the handwritten logbook was a more favoured method, particularly that, again as noted above, patients ($n=18$) in the intervention group dropped out of using OHP, and reverted to using the logbook to continue sharing data with clinicians.

**Table 12 Compliance rates for SMBG data recording**

<table>
<thead>
<tr>
<th>Compliance with SMBG entry</th>
<th>Intervention, n (%)</th>
<th>Control, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-25%</td>
<td>28 (46)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>26-50%</td>
<td>7 (11)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>51-75%</td>
<td>8 (13)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>&gt;75</td>
<td>18 (30)</td>
<td>30 (88)</td>
</tr>
</tbody>
</table>
6.7 Process evaluation: patient, and clinician survey and semi structured interviews

6.7.1 Patient satisfaction and diabetes self-efficacy

Client satisfaction and diabetes self-efficacy were assessed with the CSQ-8 and DES-SF at baseline, and at six weeks follow-up. It must be noted that, as described in the methods chapter (section 4.8.1, page 93), client satisfaction related to overall GDM care, before and after the telemedicine intervention was introduced. That is, assessment of satisfaction was not aimed at OHP specifically. Rates of completion for DES were n=92 and n=93 at baseline and follow-up respectively. For the CSQ the numbers were n=93 at baseline and n=94 at follow-up. Three patients were unable to complete the questionnaires face-to-face. These patients needed to leave the clinic in a hurry for other commitments, and they had agreed to send back the completed questionnaires; this did not happen in spite of several attempts of follow up.

At follow-up, questionnaires were completed via a variety of methods. First follow-up made use of face-to-face encounters when patients attended subsequent clinic appointments. This approach yielded a response of 114 (60%) out of the expected total of 190 questionnaires, at 2 questionnaires (CSQ-8 and DES-SF) per patient. The next approach was phoning patients, and completing the questionnaires over the phone, which yielded another 61 (32%) questionnaires. The final strategy was an email out of questionnaires, with SMS reminder follow-ups, which yielded a further 9 (5%). Despite these efforts, there was no response from 3 patients with outstanding questionnaires, and these participants were considered lost to follow up for this data collection component. In keeping with the intention to treat analysis (see methods section, 4.7.4.1, page 87), rather than exclude the missing cases, group means were imputed for the missing DES-SF and CSQ-8 data.

Distributional tests using the Shapiro Wilk test indicated the DES and CSQ total scores did not fit normal distribution (P<0.05) with the exception of the follow-up DES scores (p=0.07). Thus, comparisons were performed using Wilcoxon rank-sum test, and comparative visualisations of the scores are presented in Figure 16 and Figure 17.
Overall both groups showed high levels of self-efficacy and satisfaction, which did not change significantly between baseline and follow-up.

The mean DES-SF score for the intervention group at both baseline (34.1 ± 4.5) versus 33.2 ± 3.4), and follow-up (34.1 ± 3.9 versus 33.3 ± 3.9), was only marginally greater than the mean for the control group. These results were not statistically significantly different at either time point; baseline, z=1.2, p=0.23 and follow-up z=1.1, p=0.27. Similarly CSQ-8 scores for the intervention group at baseline (29.4 ± 2.4 versus 28.3 ± 3.6), and follow-up (29.2 ± 2.7 versus 28.2 ± 3.9), were not statistically significantly different; baseline z=1.7, p=0.098, and follow-up z=0.9, p=0.35. The findings suggest patients’ similar, and higher, levels of diabetes self-efficacy, and satisfaction with their GDM care at the point of study entry. Introducing the telemedicine support in particular had no impact on this level of self-efficacy and satisfaction with the service. In spite of this though, based on the distributional plots the intervention, would appear to have been associated with reducing the low outlier scores measured by the DES-SF.
Figure 16 Distributional scatterplots of DES-SF scores with red showing the mean
Figure 17 Distributional scatterplots of SCQ-8 scores with red line showing the mean.
6.7.2 Survey of CDE-RNs on system satisfaction and use

System use and satisfaction of CDE-RNs were surveyed using the Canada Health Infoway System and Use Assessment Survey. The survey questionnaire assessed clinical staff (CDE-RNs) on the usability of the telemedicine system, (OHP) which was chosen for this study. Five CDE-RNs engaged in using the OHP to provide support and care to patients in the intervention group, and all five responded to the survey questionnaire that was emailed to them. The responses are summarised and discussed in the following subsections beginning with overall satisfaction.

6.7.2.1 Overall satisfaction

Only two out of the five CDE-RNs were moderately satisfied with the system (OHP) overall. The remaining three were either neutral or moderately dissatisfied with OHP in general (Figure 18). A similar pattern of responses was noted in relation to the system’s impact on work flow (Figure 19). Recognising that data related to a small, but representative, number of CDE-RNs in the GDM service, none of the CDE-RNs felt that using OHP improved sharing of information, and nobody felt it made their job easier.

The survey provided space to record free text. Analysis of the written responses to contextualise the above observations, and identify the reasons behind them, showed that there was discontent with the layout and organisation of information on the system pages. This invariably impacted on system navigability, and how quickly data or information could be accessed. For instance, accessing patient GDM self-monitoring data in a logbook layout, which was the most familiar and preferred view (pilot chapter, section 5.4, page 119, and Figure 7), was a three step rather than a single step process. Upon log on and selecting the required patient, the default view that came up on OHP first was a calendar view. Next, the user had to click on a different tab to access GDM self-monitoring data, which presented the data as a list in a table. Finally, another tab click navigated to the logbook view preferred by clinicians. As a consequence, accessing data in a user friendly format for review and clinical decision making, as well or messaging, became more burdensome than
simply using the handwritten logbook. Appreciably, the time required to execute these steps adds up, when multiple patients are involved.

Another issue that impacted on productivity was the OHP alert feature. When it worked well, email messages were sent to the CDE-RNs when readings that breached target levels were entered. However, partway through the study, this feature became unreliable, and alert emails were sent to the CDE-RNs for all BGL data entered, regardless of whether readings were off-target or not, taking away the ability to streamline decisions about logging into OHP to review data. Plus, the unfiltered emails meant the CDE-RNs’ email inboxes were inundated with a high volume of these unfiltered “alerts.” As a result, I had to turn off the alert feature which meant the CDE-RNs had to always log on to OHP.

Finally, as described in the pilot chapter (section 5.3, page 115), other members of the GDM care team ended up not being part of the intervention. The protocol was, therefore, modified to exclude the endocrinologists and dieticians from being active participants in the study. This meant that CDE-RNs, as service care coordination, had no ability to share information with these other members of the team via OHP, leaving them to still encourage patients to use the handwritten logbook to facilitate data sharing with the other members of the team, including the obstetricians. Concurrent use of the OHP and the logbook created double handling, which contributed to burdens on CDE-RNs productivity and the work patients had to perform.
Figure 18 General satisfaction with the telemedicine system (OHP)

Figure 19 Levels of agreement with system impact on work flow
6.7.2.2 System and information quality

Levels of acceptability of the system quality (top panel, Figure 20), and responses to questions about information (bottom panel, Figure 20), mirrored those of overall satisfaction (Figure 18). None of the CDE-RNs felt using OHP integrated into their workflow. Written responses from the CDE-RNs indicated that the factors that contributed to and explained the observations reflected in both panels in Figure 20, were unavailability or no updated data shared by patients at the time they needed to review the data, and the time expended navigating through different screens and pages to review data. The following quotes from the CDE-RNs, illustrate some of the above issues:

CDE-RN3: “If all the data are entered correctly by patients, using comments when required, it helps. Otherwise, we had to telephone patients to find out some additional information before making any clinical decisions.”

CDE-RN1: “I do not think the system makes our job any easier as the logging in and navigating around the system can be time consuming.”

The CDE-RNs also bemoaned the lack of a system design feature that allowed filtering of inactive patients so that only active patients could be viewed in OHP. Another issue around design was the non-integration of OHP with existing hospital-controlled eHealth systems, particularly the hospital electronic medical record. Being a standalone application or system, meant clinician users had to move between OHP and other hospital control health systems.

CDE-RN4: “... when the platform [OHP] was open you can’t access CPF [the hospital controlled electronic medical record] so in fact you often have to write down clinical information prior to reviewing the BGLs ... or you have to keep shutting down OHP to then reopen CPF.”

CDE-RN5: “Also the listing of all names – there was no way of identifying who were the current patients – so in many ways I found it more time consuming to work out who was current or not.”
In spite of the above issues, the CDE-RNs showed trust and confidence in the system’s security (bottom panel, Figure 20). All five CDE-RNs responded with strongly or moderately agree to the item about acceptability of system security. Also, three out of five CDE-RNs found the OHP was easy to use and reliable (bottom panel, Figure 20).

Three CDE-RNs indicated the quality of the information shared via OHP was acceptable (top panel, Figure 21) and relevant (bottom panel, Figure 21). Completeness of the information, availability when needed, and the speed with which the information was provided to the CDE-RNs were an issue. Written responses and field observations indicated that the main contributing factor to these issues was the level of patient engagement performing data sharing via OHP. That is, patients often updated data later (or not at all) than the time CDE-RNs logged in OHP; also noting that at some point the CDE-RNs no longer had the option of logging in when they needed, to due to reliability issues with the alert system described above.
Figure 20 Acceptability of system quality
6.7.2.3 Quality of service and system usage

In the survey, the quality of service referred to the training provided to the CDE-RNs on using the telemedicine system, technical support and implementation process. In line with the principles espoused by the cognitive participation and collective action...
elements of the NPT the GDM clinical care team, including the CDE-RNs, attended demonstration presentations in the formative stages of the project. The CDE-RNs also underwent an induction prior to commencement of the trial. These activities were aimed at engaging and preparing the CDE-RNs in using the telemedicine system. Views of the CDE-RNs regarding service quality and usage were assessed during the survey and are summarised in Figure 22. The inference which could be drawn from the results shown by these figures, is that for the most part the CDE-RNs were satisfied with the level of quality of service they received in relation to training, implementation and technical support.

![Figure 22 Acceptability of quality of service](image)

*Figure 22 Acceptability of quality of service*
The CDE-RNs provided written responses to questions about frequency of usage. Four of the five CDE-RNs used the system once a day with one using the system twice a day. Usage frequency reported by three CDE-RNs, was generally one day per week. The remaining two reported a usage frequency of two days per week. In addition this reflected the trial protocol expectation of system access for data review at least once to twice weekly (methods chapter, section 4.6.3, page 78).

In conjunction with the final comments relayed by the CDE-RNs during this survey, the findings presented and discussed above highlighted the importance of the interplay between the human and technological factors. For instance technology design features, and other technology capabilities, may act as barriers or enablers in the use of telemedicine, either in GDM specifically, or the wider application of telemedicine as a concept in general. During the semi-structured interviews, some of the CDE-RNs intimated the potential time saving aspects of telemedicine. In spite of this, some of the responses from the CDE-RNs’ survey indicated that, from a technical perspective, the telemedicine system’s speed of navigability and speed of information access, in a fast paced clinical environment, posed a workflow efficiency problem, casting aspersions on the potential of telemedicine. The human impact aspect emanated from behaviour, in relation to performing data entry by patients. The CDE-RNs also relied on patients engaging in using the telemedicine system (OHP) to enter and share GDM self-monitoring data. Failure to enter the data, or delayed data entry, contributed to rendered the system less useful to clinicians.

Finally, the following quote stresses the potential limitation of technology, and highlights the CDE-RNs views of how telemedicine as an intervention approach, may not completely replace usual care processes, e.g. face-to-face interaction between patients and their health care professionals. Instead, telemedicine could perhaps provide a supportive role rather than a substitute for orthodox health care provision.

CDE-RN5: “there are many other personal factors needing consideration that a [telemedicine] system alone will not address. For example there can be several reasons a blood glucose result is elevated; including, diet, illness, stress, medications, and lack of sleep or exercise. All these factors should be addressed prior to making
insulin adjustments and this can only be achieved when there is direct involvement with a person and a conversation takes place, either in a clinic situation or via phone."

6.7.3 Evaluation of patient and clinician experiences with using OHP and telemedicine support

This section of the process evaluation, is a concurrent presentation of the results and discussion from the semi-structured interviews. I report on the interview process, characteristics of the interviewees, and the themes from the semi-structured interviews supplemented with field notes. I then provide an interpretation of each theme, and include supporting interviewees’ quotes.

I have described the rationale for choosing a mixed methods design in the methods chapter of my thesis (section 4.1, page 54): i.e. the limitations of using quantitative methods alone, and the combined strength and value of using both quantitative and qualitative methods [71, 72]. I used semi-structured interviews to supplement the quantitative evaluation of my study. It emerged from the pilot experience and my observations during the study that some patients engaged well with using OHP while others showed low levels cognitive participation. A lower level of cognitive participation was also noted among some of the CDE-RNs, which contrasted with the greater enthusiasm and demonstration of greater participation noted during the pilot phase (section 5.2, page 115). This potentially reflected research participant burden once the study was under way, i.e. “the time and effort required” of participants to be involved in research [117, 118].

Observations such as highlighted above, relate to experiential questions and qualitative phenomena which quantitative methods alone could not provide answer for. Hence, I performed semi-structured interviews to explore patient and clinician experiences of using telemedicine, as an overall concept, and OHP as the chosen telemedicine system, to support GDM management. The analysis made use of the framework approach guided by the domains of the telehealth evaluation framework (Appendix 4) [51, 52], while also being open to identifying new concepts or themes that did not fit the framework domains.
6.7.3.1 Description of the interview process and characteristics of the participants

I drafted the interview schedule and discussed it with my supervisors, with a focus on improving and framing the questions. Subsequent to this, I listened to recordings of the first two interviews together with my main supervisor, who provided feedback and suggestions for further improvement ahead of the next interviews. Altogether I interviewed eight patients and four CDE-RNs following the schedules shown in Appendix 14 and Appendix 15, as general guides and prompts. I used a free smartphone app to make digital audio recordings of the interviews for later transcription. However, one CDE-RN provided a written response to the interview schedule in lieu of a sit-down interview.

The first of the clinician interviews was conducted face-to-face, individually with a CDE-RN1 in her clinical consulting room during work hours. A patient had cancelled her consultation appointment, which provided the opportunity to conduct the interview. The second interview, with CDE-RN2, was in the form of a written response, because it was difficult to find a suitable time for the interview, due to an often busy clinic schedule, and also the interviewee expressed personal discomfort with a face-to-face interview. She completed the interview schedule questions during work hours in between patient consultations. The third (CDE-RN3) and fourth (CDE-RN4) interviews were conducted jointly with the two CDE-RNs, due to busy clinic schedules hampering scheduling time for individual interviews. This took place in their administrative office away from the clinical area during their lunch break. The fifth CDE-RN could not be interviewed due to the inability to find a mutually agreeable suitable time for the interview. Where CDE-RN5’s views are included, these were based on field notes or free text responses to the clinician survey described in section 4.8.2 (page 95).

I have elected to adopt a more general and cautionary approach in describing the characteristics of CDE-RNs. The reason being, the CDE-RNs were very few in number and hence, any detailed description linking them to the participant IDs and interview responses, could easily breach the ethical requirement to protect participant privacy.
and confidentiality. The age of the four CDE-RNs I interviewed ranged from 30s to 50s. Between them, the CDE-RNs had over 55 years of clinical experience in diabetes care. Besides GDM, the CDE-RNs provided diabetes education across other types of diabetes, both in the in-patient and out-patient settings. Some were endorsed to prescribe insulin in the scope of their practice as CDE-RNs.

A total of 20 patients, who were in the intervention arm of the TeleGDM study, were approached over the phone for a phone interview, and eight (P1 to P8) were subsequently interviewed. The rest (12) either declined or it was difficult to find a mutually agreeable time to conduct the interview. Eight interviews were conducted, seven were audio-recorded. Recording failed for the eighth interview, leaving only handwritten notes I took during the interview. The interviews were conducted between September 2015 and May 2016 and they took place between two and eight weeks following the birth of the baby. Interviewee P8 was the exception, as I interviewed her approximately four weeks before her estimated due date. The reason for this was, she was the only one with low usage of OHP available and willing to be interviewed. It was particularly challenging to find patients with less than 30% compliance with using OHP to share GDM self-monitoring data. At that stage P8 had stopped entering data on OHP after only four weeks, and during that time she entered 77 (22%) of an expected total of 356 BGL readings. The characteristics of patients I interviewed are presented in Table 13.
Table 13 Characteristics of interviewed patients/women

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Measurement summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>8</td>
</tr>
<tr>
<td>Age, mean (SD) years</td>
<td>34 (6)</td>
</tr>
<tr>
<td>Gravidity, median (range)</td>
<td>2 (2-6)</td>
</tr>
<tr>
<td>Parity, median (range)</td>
<td>0 (0-3)</td>
</tr>
<tr>
<td>OHP SMBG data entry compliance, Mean % (95% CI)</td>
<td>70 (44, 96)</td>
</tr>
<tr>
<td>Highest level of education, n:</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>2</td>
</tr>
<tr>
<td>Post high school/tertiary</td>
<td>6</td>
</tr>
<tr>
<td>Self-rated general technology awareness, n:</td>
<td></td>
</tr>
<tr>
<td>Previous health monitoring or wearable personal monitoring devices</td>
<td>1</td>
</tr>
<tr>
<td>General home usage or work</td>
<td>8</td>
</tr>
</tbody>
</table>

6.7.3.2 Concepts and themes

Table 14 is a summary of the framework analysis showing the key themes and concepts from the CDE-RNs and patient interviews, mapped to the domains of the telehealth evaluation framework. A brief description of these domains is provided in section 2.2.3 (page 32). In addition to the themes I have mapped to the framework, I identified the following three themes listed below, which fell outside the categories of the framework:

- A telemedicine approach requires engaged clinicians and patients for greater cognitive participation
- Telemedicine was a potential threat to personal relationship dynamics of GDM care
- CDE-RNs use of telemedicine may be constrained by patient compliance
Each theme is discussed in detail with supporting quotes from the interviewees. Where relevant I also include field notes and observations in my discussion of these themes. For readability and/or understanding of specific contexts, I have inserted some words and/or phrases in square brackets in the quotes, while careful not to change the ideas and views expressed by the interviewees.
Table 14 Summary of concepts/themes from semi-interview transcripts mapped to the telehealth evaluation framework

<table>
<thead>
<tr>
<th>Telehealth evaluation framework domain</th>
<th>Themes</th>
<th>Clinicians</th>
</tr>
</thead>
</table>
| **Patient control** | • Telemedicine-supported GDM care has the potential for  
  o facilitating timely and personalised care  
  o convenience for working pregnant women to continue to balance work with access to healthcare  
  o saving patients the need to travel to attend GDM appointments in person  
  • Engaging with using the telemedicine system was an effort intensive exercise | • Using telemedicine to support GDM care was believed to facilitate patient empowerment towards self-management |
| **Clinician quality of care** | • Using technology may be good but clinician support and advice are what matter the most to women for GDM outcomes | • Complexity of care in insulin-treated GDM may require a careful section of patients for a telemedicine intervention to be effective  
  • Telemedicine may be less preferred compared to face-to-face contact in relation to making medication alteration decisions to drive improved outcomes |
<p>| <strong>Organisation sustainability</strong> | | • There was a mixed response regarding the impact telemedicine on workflow and efficiency |</p>
<table>
<thead>
<tr>
<th>Telehealth evaluation framework domain</th>
<th>Themes</th>
<th>Clinicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology capability/capacity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Patients                              | • The system was user friendly, easy to use and navigate, even for those reporting basic computer awareness/literacy  
• Lack of a supported smartphone application  
• The design of OHP and time required to enter data made engaging with using the telemedicine system (OHP) effort intensive | • The system was generally easy to use  
• Lack of integration with existing ehealth systems other technologies was problematic  
• As a telemedicine system, OHP potentially has scalability issues with handling a large number of patients  
• System design factors were potential barriers to uptake |
6.7.3.3 Patient Control

6.7.3.3.1 Telemedicine may facilitate timely and personalised feedback

Although some of the CDE-RNs reported were that the GDM population targeted for the TeleGDM study may not have been suitable, some patients expressed the view that the concept of telemedicine and using OHP in particular was a good means of supporting GDM care. Some patients who received support through this approach, reported that they received faster responses from the CDE-RNs on what actions to take for ongoing GDM care. Furthermore, the features of OHP that allowed patients to graphically manipulate, and visualise BGL data trends, provided them with personalised feedback.

P1: “You’ve got good feedback straight away on your levels, when you put them in. Even though you generally have that guide in the book of what they say but it sort of shows you straight away...It was easy to see at a glance where you’re at, rather than looking back through the book; I like having the option to have a look at the graphs and stuff, look at it in a different way.”

P2: “…because you’ve got the charts and you understand it more visually, you can see it more that it is going up all the time; it’s not just an amount on paper.”

It is worth noting that both P1 and P2 were among the high users of OHP for data entry and sharing. They respectively entered 75% and 70% of their expected SMBG data in to OHP.

Graphical visualisation of data trends seemed to facilitate behaviour change, in relation to actions that patients needed to take to better manage GDM. Some patients reported using the graphing feature of OHP to construct BGL data trends over time. They then used the information around instances of better BGL control in the trends, for personal reflection on what might have worked and attempt to replicate that for ongoing GDM self-management. Engaging and responding to the intervention in this way, suggested a potential empowering aspect of the
P5: “I actually found it really good because you could always go back and look at what your other glucose readings were; previous days, previous weeks. So when you went on you sort of knew, ok like, I’ve had this many, you know, over the average readings so maybe I need to up my levels of insulin or maybe I need to go speak to someone or something like that. So you can bring up the history you can actually see what the next step was what you could do, if it was stable, and you could also see what you’ve eaten, so you could try and match, oh yeah I ate this this day when this reading was this so um maybe I will eat the same today or something like that.”

Besides the potential for personalised feedback, as reported and described above, using the telemedicine approach appeared to promote more timely feedback to patients from the CDE-RNs. Some patients reported that after sharing their self-monitoring data via OHP there was a faster turnaround in received feedback from the CDE-RNs, relative to what they experienced before, through usual care, when they generally waited for their next clinic appointment for review and feedback.

P5: “…good to get that feedback straight away and get those comments straight away rather than waiting until I’ve got another appointment or something like that.”

P2: “the people that deal with my levels going up and down and with medication and things like that. They were able to see it pretty much the next day and then they could judge if I needed to put the insulin up…”

6.7.3.3.2 Using telemedicine to support GDM care was believed to facilitate patient empowerment towards self-management

Although expressed from a clinicians’ perspective, using telemedicine was considered a facilitator of patient empowerment. This was an especially important factor in the context of the GDM service strategy and goal of promoting self-management amongst patients. Some of the patients who received telemedicine support were reported, or observed, to proactively engage in self-management through their use of OHP. An empowered patient takes responsibility over their health,
making choices and decisions which are health promoting [119, 120]. The following quotes illustrate how some the CDE-RNs felt about telemedicine; noting CDE-RN5’s views are based on field observations, as opposed to an interview.

Also, this was consistent with the reports noted from some CDE-RNs that using telemedicine may be empowering for the women to proactively engage in self-management.

CDE-RN1: “I thought it was very good and I found it was some way of empowering women [with GDM]; you know giving them a bit of ownership of putting their data on the website rather than us following them all the time and telephone contact and things like that.”

CDE-RN5: “…regularly entering the data [on OHP] was a very good idea. It was a very good step towards self-management.”

6.7.3.3.3 Telemecine could provide a convenient way of accessing healthcare for working pregnant women

Continuing care for GDM requires a significant investment of time by patients. Based on my observations of the clinic processes, a significant number of the women in the GDM service were still working and had to take time off work to attend their appointments, either for GDM management or obstetric reviews. Appointment days also involved spending a considerable amount of time at the health service, waiting between consultations, and navigating through multiple appointments. While efforts were made to schedule all the various appointments on the same day, some women indicated they would appreciate any convenience that saved the need to set aside time from work to attend clinic appointments in person.

Some of the patients who participated in the TeleGDM study, and received telemedicine-supported care, felt that the approach saved them from taking time off work in order to attend some of their clinic appointments in person or they believed the intervention had the potential to reduce the frequency of GDM clinic attendances. Patients indicated that the ability to share data, and maintain communication and contact with the CDE-RNs, as facilitated by telemedicine-
supported care, provided them the degree of convenience they wanted to balance work with their healthcare needs.

P5: “…at the time I was working full time so it was really difficult…because of the GDM, I had to take [some time off]. Every fortnight, I had to take a morning or something off to be able to go into my appointment and I find if I didn’t have to do that I wouldn’t have to have that time off and would make things probably so much easier…having that fortnightly, I guess visit into the clinic, you know in to Craigieburn Health Service it was quite frustrating because obviously I’m working I have to take time off that sort of thing. It would be good, if you could actually do everything online and then maybe even receive a phone call every fortnight rather than having to go in because at the end of the day, you’ve got your results online, you guys would just jump on and just while discussing over the phone, you could sort of get away with that. A lot better I think, for people who work anyway or people who are busy…"

P1: “Rather than having to take time [time off work]; especially I was working so it’d mean taking more time off work to come in to see the girls [CDE-RNs] for no reason, if you know what I mean, when it wasn’t necessary. So I found that [telemedicine] much more convenient.”

The above benefit was reported at an individual level. However, overall, as demonstrated by the quantitate data (Table 4), the effect was not significant.

6.7.3.3.4 Telemedicine may save patients the travel time to attend clinic appointments

Some of the catchment for NH extends to rural towns beyond the boundaries that define the catchment area (section 1.1.2, page 13). This meant, some patients travelled in excess of 45-60 minutes from adjacent regional towns to access GDM services at NH. For patients who could access care via telemedicine during the study, some reported that telemedicine-supported care reduced the frequency of their face-to-face GDM clinic attendances. This illustrated by the following quote from patient P5, who resided about an hour’s travel by car from one of the NH campuses;

P2: “They were able to do things a little bit quicker and [I did] not have to always go down there [to clinic] every time something was going on….For me it worked out
because I just can’t run down to Craigieburn [CHS] every second day when my levels are going up more.”

Not only was a potential saving on travel expressed by those who lived farther, but some patients who lived less than 30 minutes, and some as little as 5 minutes, from clinic locations also indicated they were in favour of not travelling to clinic if it were possible. In spite of this, there were some patients for whom the supposed convenience of reduced frequency of face-to-face face appointments and time saving, were not important factors. The observation suggested that, telemedicine-supported GDM care, was preferred by some, but not all patients. This seemed to be consistent with the issue of patient population suitability, raised by some of the CDE-RNs (see theme discussed in section 6.7.3.4.2, page 176).

P8: “I had my booked appointments so it didn’t really bother me to come in and see the dietitian for example [in lieu of remote support],”

The above reflects the views of patients and clinicians under the telehealth evaluation framework dimension of patient control. While there was a mix of views, for the most part, these views were positive about utility of the concept of telemedicine in supporting GDM care. However, patients expressing these view, were by and large a self-selected (for the interviews) group, and were high users who had demonstrated greater levels of compliance with engaging with the intervention, especially using OHP. The next section explored the views that aligned with the clinician quality of care dimension of the evaluation framework.

6.7.3.4 Clinician quality of care

6.7.3.4.1 Using technology may be good but clinician support and advice are what matter the most for GDM outcomes

One patient raised an important issue relating to the role of technology in clinical care and health service provision. For instance, in relation to the impact of technology on personal GDM care, one interviewee indicated that even though she embraced the idea of technology to support GDM care, she was of the view that technology in this
instance had no direct influence on her GDM outcomes. She indicated that, ultimately, clinical advice was what impacted BGL control, not the technology.

P3: “Fair enough, I’m inputting all the information but at the end of the day what I eat, is what I eat...I don’t think it [OHP] would have had an impact, it was just me keying what I ate and stuff. The dietitian she helped me, she told me what to eat and stuff like that, that helped [with my blood sugars] but putting the information on the computer, I don’t think it helped in a way, sort of thing, like on its own. In a way it was good to do but then again if I didn’t do it, I would have been alright as well.”

The above view highlighted an important observation and appreciation, that not everyone is able to see “the worth” in the intervention and “make sense” of it (see theoretical frameworks description on NPT, section 2.2.2, page 28); or there may have been shortcomings in the work that went into addressing these issues at the start and/or during the intervention. Nevertheless, the above quote also suggested that the idea of using technology, such as OHP, may be acceptable, but it was only one element in the complex process of GDM management. Having a clinician on hand to interpret the data shared by patients, and provide clinical support and advice, are what impact clinical outcomes. This reiterates the views of some of the CDE-RNs that telemedicine may be a supportive supplement rather than a replacement of usual care processes. Using technology, such as in my study, has no direct influence on the biological process of a health condition, like a prescribed drug would directly alter the biological course of the disease. But the key role of using technology, as the intervention in my study, is to influence user behaviour for improved disease management [121, 122], with the flow-on effects on the biological or pathophysiological outcomes.

6.7.3.4.2 Complexity of care in insulin-treated GDM may require a careful selection of patients for a telemedicine intervention to be effective

The central feature of the telemedicine intervention was data sharing in a patient population with insulin-treated GDM. The effectiveness of GDM care relies in part on availability of patient data, in order for CDE-RNs to make clinical decisions. Overall, patients in the intervention arm of the study, shared fewer data via OHP than patients
in the control arm, who used the handwritten logbook method to share data with the CDE-RNs (Table 11). On other occasions, data on OHP were not entered or updated as often as CDE-RNs expected. The CDE-RNs suggested that lower levels of engagement with data entry in OHP, may in part have been due to the type of patients who were selected and targeted for the telemedicine intervention.

The TeleGDM study was aimed at patients with insulin-treated GDM. The CDE-RNs indicated that adding insulin to managing GDM, added another layer of complexity to an already complex disease management process. They therefore suggested that as population group, patients with insulin-treated GDM were perhaps not the right target population for telemedicine-supported care, making this approach less effective. The expectation was that, as a generally younger population group, pregnant women would embrace technology [42]. However, the addition of technology potentially contributed to care burdens, rendering telemedicine unsuitable for the GDM group and less effective on outcomes in this instance.

CDE-RN3: “The idea of TeleGDM program is ok in theory but I think you have to be very specific in what area you use it in...These women literally are insulin naïve when they go on insulin. You’re pregnant, now you have gestational diabetes...we have been given them instructions to walk every day, eat properly, ring us etc. and now you need insulin which is very scary and we want you to do this thing online and I think it’s too much. So from that point of view, your target audience is not right.”

CDE-RN4: “I think possibly the wrong patient group...It’s time critical with gestational diabetes to make [clinical] decisions that affect BGLs. Whereas if you had someone with type 2, it’s an ongoing issue, so it doesn’t necessarily have to be done every two or three days. So you probably have a little more time up your sleeve to make [clinical] decisions.”

Furthermore, the above quote from CDE-RN indicated the paradox of in this clinical and health service environment. The clinical process required rapid decision making but introducing technology with the view to facilitating this, inadvertently slowed down the process, due to patient behavioural issues, e.g. data entry issues discussed above, or the technology capability limitations, some of which are described and discussed in section 6.7.3.6.2 (page 183).
6.7.3.4.3  **Telemedicine may be less preferred to face-to-face contact in relation to making medication alteration decisions to drive outcomes**

Outcomes, such as BGL control, are influenced in part by the decisions around medication changes that CDE-RNs make in collaboration with the patient. The decisions are based on the data that patients avail to the CDE-RNs. Some CDE-RNs expressed views about acceptability of telemedicine. These related to the completeness of the information or the data they needed to make clinical decisions, aimed at improving patient clinical outcomes. The CDE-RNs felt that, telemedicine as concept in GDM management could not replace existing process of care. Rather, they viewed it as a process that augmented usual care, because, as the CDE-RNs indicated, they accessed additional information, e.g. diet, through usual care processes, which most patients in the intervention group tended to not record on OHP. This information was a crucial part of explaining anomalies in BGL readings.

CDE-RN3: “… when they [patients] bring their blood glucose diaries we say to them, if you have a reading above target you need to write what you ate for that meal. Anything out of the ordinary you need to write down. And I think they are better at doing that than doing the online recording.”

Even, though the CDE-RNs expressed challenges to availability of data via OHP, there was acknowledgement this also happened with usual care. Therefore potentially indicating a wider patient attitude and behaviour change towards self-management issue; a factor not necessarily peculiar to engaging with using technology to support GDM management.

CDE-RN3: “However, we get a lot of people turning up with their blood glucose diary with multiple elevated readings with no explanation or diet recorded or anything in it, it may come back to the patient group.”

In the real word, new interventions “compete” with existing ways of working, which are usually deeply entrenched, or as NPT describes, are normalised [49, 58, 59]. Workers or actors in such entrenched practices tend to have “propensities to work within already normalized frames of knowledge and practice” [49] rather than new ones. If the new intervention is not seen to confer advantages it has little chance of
competing effectively. There was an indication that some CDE-RNs preferred direct face-to-face or even telephone contact with patients (as usual care processes provided) to the telemedicine approach, in making decisions that affected outcomes. The reasons for this were personal comfort and familiarity with usual care, and greater confidence in clinical safety from providing care through usual care. In a way, this suggested health practitioner readiness to change [123-125], which NPT describes as “readiness of actors to accept” (new) practice [49, 57]. It underscores an important element in the implementation process which can be change at the individual’s level, i.e. the CDE-RNs or organisational level (NH) [57]. Readiness is discussed further in the chapter seven (section 7.5, page 204).

CDE-RN4: “I don’t know how it’s [OHP] used in other situations. I feel uncomfortable changing medication doses without that [face-to-face] interaction.”

CDE-RN4: “I still would prefer current methods maybe its generation because I’m a bit older but anyway that’s just what I’m used to. I think maybe it is a generational thing, younger health care workers brought up in the IT age might be more comfortable with these sort of [telemedicine] processes but I’m very hands on and I like to speak to my patients and see patients face.”

While the above sentiments and queries about the suitability of the patient population might appear to contradict the views of patients who embraced telemedicine, they highlight an important issue of patient selection. There were some patients whose views indicated they liked the idea of telemedicine and therefore, showed high levels of cognitive participation. However, there were those who did not, as was apparent in the quantitative results on fidelity (section 6.6.1, page 146), which suggested some patients dropped out or did not engage with the key element of the intervention (sharing data via OHP). From this, it may be inferred that telemedicine requires a careful selection of patients rather attempting to engage everyone in it and this might an area of future research.
6.7.3.5 Organisation sustainability

6.7.3.5.1 There was a mixed response regarding the impact telemedicine on workflow and efficiency

Opinions on the impact of telemedicine on GDM service workflow and productivity were divided. For instance none of the CDE-RNs felt that using telemedicine made their job easier while one felt it improved her productivity, and two felt it enabled them to coordinate continuity of care (Figure 19, page 157). The outcome of the semi-structured interviews reflected a similar pattern.

Some CDE-RNs were of the view that using the telemedicine approach for clinical care might have saved them time, been an efficient way to mitigate failed clinic attendance and that it facilitated continuity of care. The reasons for these views were that by having the patients upload GDM self-monitoring data to the OHP, it facilitated better use of clinician’s time, i.e. rapid review of data and feedback to the patient. A faster turnaround time to get feedback from the CDE-RNs, was reported by some patients (see theme at 6.7.3.3.1, page 171). Under usual circumstances CDE-RNs often spent time attempting to call, or actually interacting over the phone with patients for follow up. It would appear telemedicine reduced the need for these calls in some instances.

CDE-RN1: “It saved me a lot of time because some of the time if their blood sugars are all good I could just go on the website and just check them and then just send them an sms which would take a few seconds rather than telephone conversations or trying to contact them.”

CDE-RN2: “I love the idea as it saved time rather than phoning them.”

CDE-RN1: “And in terms of people coming for appointments it is a lot of time-the clinician’s time and also the patient’s time and if they fail to attend then that sort of delays the care whereas if they are entering data online then I think the care carries on continuously [there is continuity of care]. In terms of care I find it’s [telemedicine] a very efficient way of doing things.”
Despite the views expressed above, some of the clinicians reported differing opinions and experiences, in relation to the impact on workflow. Their experiences with, and views on, using the telemedicine were that it was time consuming, and that it increased the work they had to do. Tasks such as logging into OHP, navigating through the system pages, reviewing the data, and then having to make a follow-up telephone call to the patient, added extra layers of work. They reported that, since they still had to call the patient they could have saved time by going straight to the telephone and getting all the necessary information that way. This was particularly pertinent when patients did not upload data to the telemedicine system as expected.

CDE-RN1: “Sometimes the women who were recruited to the study to log in their data and then when we keep looking at the data it's not there, then we would have to the call, or contact the women… I found that was a bit frustrating…”

CDE-RN4: “…removing old patients is something that needed to happen. Even though we didn’t have hundreds but if I did find it difficult to work out who were the current patients or who had completed. I found it annoying to have to scroll through every single name…it takes up valuable time”

The paradox of proponents of telemedicine in relation time saving for the CDE-RNs, on one hand and the detractors because of the time expended, on the other, suggested that, similar to patients, clinicians may need to be selected. Alternatively, induction and training may need to a review to seek better ways to increase cognitive participation of the clinicians, as actors in this context.

6.7.3.6 Technology capability/capacity

6.7.3.6.1 The system was user friendly, easy to use and navigate, even for those reporting basic computer awareness/literacy

Notwithstanding some technical features of OHP that are discussed below, as potential barriers (section 6.7.3.6.2, page 183; section 6.7.3.6.5, page 186), patients reported finding the telemedicine system user-friendly and likeable. Such user friendliness related to the easiness of data entry, information organisation, navigability
through the system pages, and correction of data entry errors. Further users considered the system easy to use for those with basic computing skills.

P1: "It was easy to mark whether it was after breakfast, after lunch; but having it specifically after the meals, made it easy to know which one, you were keying in where, rather than trying, like I don't know if it was time based or whatever."

P5: "I just found, like say for example, it wouldn't record my entry of my glucose levels or insulin levels, I would just delete it and do it again. It was pretty easy yeah. To rectify."

P1: "...you're able to choose which insulin you were on so that was nice and easy too...I found it all easy to switch between the screens."

P3: "...it's pretty basic to be honest, for me that's hard to say because I'm bad with computers and I managed to do it so."

At recruitment, and at the start of the intervention, patients underwent an induction that included practicing the tasks they were expected to perform independently. It appeared the induction was an important factor in the ability of patients to use the telemedicine system. In particular, two aspects of the induction highlighted by two interviewees were, the clarity of information and instructions provided and practice to cement learning.

P2: "Once I started entering I didn’t have any problems. It all ran pretty smoothly for me..."

P3: "Well she wrote it down step by step what to do and I followed it so it was easy."

Similarly clinicians’ views suggested the system (OHP) was easy to use which was enabled by the system demonstration and training provided. This highlights the importance of equipping users with the necessary skills to be able to interact and engage with using the telemedicine system of choice. Also, results of the clinician (CDE-RNs) survey (Figure 20) showed that three out of the five CDE-RNs indicated that the system (OHP) was easy to use.

CDE-RN4: “And some of the early things doing demonstrations of the technology. I think that was fine, we were certainly clear on how to use it and the hand-outs. It’s not a difficult system and it’s not complex.”
6.7.3.6.2 Lack of integration with existing ehealth systems other technologies was problematic

One of the issues that emerged from the pilot phase and field observations, as well as the interviews was the lack of integration of OHP into existing ehealth systems. Having been procured through a third party without involvement of the health service IT unit meant OHP had to be accessed independent of existing hospital ehealth systems, such as the electronic medical record. This meant clinician users had to use separate login information to access data on OHP, then copy the data to paste into the patient’s hospital-controlled electronic medical record. It must be noted this was something I had no control over changing.

Closely related to integration was adaptability. One of the important factors that have been highlighted as important, and influential, in the implementation of technology based interventions is the ability of the system to be adapted to the local setting [126]. I noted during the course of the TeleGDM study that some CDE-RNs became innovative and adaptive due to the limitations in the way data were shared via OHP. This is demonstrated by the quote below.

CDE-RN2: “I use photos now. Patients take photos of their diary and send them by SMS [MMS] and I find this is even easier. I started this two months ago, around October 2015 and has evolved into a research project. The TeleGDM approach was restricting when there was no data uploaded. So it was a much quicker response to text message. And there was no need to log in with regards to MMS and it instant response back to the patients.”

The key feature of the intervention in my study was data sharing between patients and clinicians. Thus, CDE-RNs and patients came up with their own innovative parallel process, of sharing copies of handwritten logbooks via photos, which they viewed as faster than what OHP offered. They felt that MMS way of sharing data also provided a different option to overcome the data sharing limitations of OHP;

CDE-RN2: “A patient not in the study couldn’t use the phone at work and during short breaks [she] would send photos instead. I thought this was a quicker way to share data than entering it [on OHP].”
Besides the automatic data upload from the glucose meter to OHP via USB connection, which was abandoned for the TeleGDM study (see 4.5 Summary of key pilot observations) patients had to manually enter GDM self-monitoring data shared over OHP. Implicit in the above quote and as perceived by the CDE-RN, was the idea that the one-dimensional data sharing capability of OHP was a barrier which was perhaps ameliorated by alternative options to achieve the intended objective of data sharing. Hence, as the CDE-RNs at one campus of NH discovered the versatility of sharing data via smartphone SMS/MMS, the process became embedded into usual care. In some way this demonstrated the NPT’s “reflexive monitoring” [54]. The clinician appraised the capability of OHP, identified a limitation, and in collaboration with a patient, came up with an alternative way to the work. First what this highlights is the limited capability of OHP to adapt and integrate different ways by which data could be shared. Second, it underscores consideration for telemedicine to be the overarching concept within which are different, flexible elements of data sharing capabilities in the context of GDM.

6.7.3.6.3 As a telemedicine system, OHP potentially has scalability issues with handling a large number of patients

The telemedicine system (OHP) was designed in such a way that a full list of all enrolled patients would come up on the screen, from which a clinician could then select the patient to review. The list included current patients, as well as those who had reached study end point. The CDE-RNs reported that the list became too cumbersome, once more patients were enrolled, and it became a challenge to distinguish current patients from non-active ones. The issue was not identified during the pilot, therefore not anticipated because the pilot only trialled two patients. But as more patients were enrolled during the study, this presented a scalability issue during the study, as well as an organisational sustainability issue.

CDE-RN4 “…removing old patients is something that needed to happen. Even though we didn’t have hundreds but if I did find it difficult to work out who were the current patients or who had completed. I found it annoying to have to scroll through every single name…"
In reference to the same foreseeable issue of scalability with an increasing number of patients using OHP;

CDE-RN3 “…we didn’t have huge numbers and because I know our GDM population very well and at a glance I know who was currently attending clinic. It wasn’t a huge problem but ongoing I could imagine that could be a big problem.”

6.7.3.6.4 Lack of a supported smartphone application

Furthermore, some of the women indicated that using a smartphone based application (app) to access OHP to perform data entry, rather than using an internet browser on their smartphones, would have made the process easier. While OHP offered the ability for cross platform access, i.e. via mobile devices and computers, based on field observations and interviews, a lot of patients relied on using their smartphones to access OHP. Doing so meant using an internet browser on a small phone screen, hence with a small text view which patients surmised could have made the process easier if there was a smartphone app.

P2: “Doing an app and as a reminder or something each day for the future, that will probably get more people doing it [data entry], you know every day…if I used the app I reckon I would’ve done it [data entry on OHP] every day.”

In spite of the above views, there was an app, iHealth (see section 4.6.2.1, page 75) which patients were not made aware of. The reason for this was that reliability of the app could not be guaranteed, as it had not been updated for a long time, and hence patients were not explicitly made aware of its existence. Also, the lack of a well-supported app highlighted the limitation of a lack of flexibility in the technology design, thereby making it incumbent upon users to fit in with the technology, as opposed to a responsive patient-centred technology, that is adaptable to user needs. However, adapting technology to fit users is often constrained by costs.
6.7.3.6.5 System design factors were potential barriers to uptake

A number of factors relating to the design of OHP and human factors emerged as barriers to uptake of the telemedicine concept, and use of OHP. In spite of general sentiments that OHP was user-friendly and liked, there were some design features that also made it unlikeable at the same time. For instance, during the pilot phase, data output layout made it difficult for clinicians to rapidly review and appraise data. Even though satisfactory improvements were made, some more complex changes required time and costs. The latter became ongoing barriers, leaving the clinicians with less than positive experiences. For instance, as pointed out earlier (see 6.7.3.4.3, page 178), clinicians indicated they needed additional information about diet, and other information, that could elucidate out-target readings before they could make clinical decisions. Although patients provided this information on occasions, it could not be integrated for simultaneous view in the electronic logbook format of OHP, thus requiring navigation away from the electronic logbook for viewing in isolation of the BGL readings. Another example of this was the lack of integration of OHP into existing systems which is discussed above (section 6.7.3.6.2, page 183).

The first quote below shows how there were some adverse sentiments for the data layout at the start, but these changed after modifications were made. The second illustrates some of the CDE-RNs views relating the isolated review of data, which made it a challenge to consider the data in the bigger picture, and contextualised for informed clinical decision making.

CDE-RN2: “I didn’t like the idea initially. But once the logbook display was fixed the program was good.”

CDE-RN3: “…it [BGL readings OHP] was just numbers, not enough for us to glean useful information…”

One of the main sources of discontent among the CDE-RNs was the navigability of the system. In particular, OHP was set up as a series of web-pages, such that one had to navigate to a different web-page in order for one to access other functions, or information different from what one might be viewing at the time. For instance, if one was viewing the logbook of SMBG data, one had to navigate to a different page, in
order to message the patient whose data were under review. Based on the dissatisfaction expressed by the clinicians, it would appear they preferred a system that provided all crucial information and functions on one page, rather than having to navigate through a series of pages to view the information, or access required functions.

CDE-RN2: “It became inconvenient when sending messages as you can’t access their BGLs at the same time…in order to view one you have to navigate away from the screen of the other. So it would have been easier if you could still have a view of the BGLs while messaging at the same time.”

Having been procured for the purpose of the trial, OHP was a standalone system that was not embedded in routine hospital applications. As a result, accessing OHP required separate logon credentials to access patient health information recorded on OHP, i.e. GDM self-monitoring data. First, this added an extra layer of work that was not particularly pleasing to the CDE-RNs and second the data had to be copy transcribed from OHP onto the separate, hospital-controlled electronic patient medical record. The indication from the CDE-RNs was that this was double handling and inefficient.

CDE-RN2: “Some double handling in relation to transcribing data on OHP onto patient’s hospital record. No need to log on with regards to MMS and instant response back to the patient for e.g. to change insulin.”

6.7.3.6.6 The design of OHP and time to enter data made engaging with using the telemedicine system (OHP) effort intensive

Whilst overall, patients reported some positive experiences with using OHP, and the telemedicine concept, in supporting GDM care, patients indicated that using OHP was effort intensive and often inconvenient. The repetition and frequency of the tasks (BGL and insulin dose data entry, free text entry of diet, and symptoms), that needed to be completed were also slowed down by the way OHP was designed. Once logged into OHP, the data entry process included selecting the correct date, meal type, entry of the BGL reading, and saving that entry to enable upload to the server. There was a brief time lag between saving the data and the system being ready for
entry of the next reading and related data. The process had to be repeated for every single BGL reading, noting that some patients elected to perform all data entry at the end of the day, while others did so with every BGL test. Patients were expected to perform four BGL tests per day. Patients found this particularly burdensome in the setting of other competing demands such as such work.

P8: “Just going in entering the date and then one by one and then putting in what you’ve eaten and stuff, I don’t know, I just found it, recording what I eat, I found is a drainer.”

P2: “I would say [data entry] was a little bit more [work], that I had to make sure I actually sat down and did it; put it into the computer...Doing an app and as a reminder or something each day for the future, that will probably get more people doing it, you know every day...if I used the app I reckon I would’ve done it every day.”

P3: “It was a bit annoying to do it every day, for me I just got a bit annoyed, if you know what I’m saying. So it was easy, basic but to do it every day was like a chore...I was tired from work, I had to work full time, I was tired but in three days I’ll do it. I couldn’t do it every day.”

P5: “Sometimes if you went through and updated too quickly the site itself was a bit slow and so it wouldn’t record properly. Like it would record the previous entry, if that makes sense. So you know you just had to go back and redo it which was fine. But sometimes the site itself was a bit slow, sometimes it would freeze and stuff like that. That doesn’t necessarily mean that any impact on the trial, the technology was a bit, it would freeze and sort of wouldn’t record it and that sort of thing.”

Through the telemedicine approach, patients could communicate and engage specifically with the educators. However, other important specialties in GDM care continued to engage via face-to-face, and relied on the hand written logbook record of self-monitoring data. This, coupled with the fact that the intervention which involved telemedicine as an adjunct to usual care, meant that patients had to perform double data entry adding to the issue of the increased work demands of the intervention. This is embodied in the view expressed below in relation to clinicians that were not signed up to use OHP:
P5: “...you need to obviously have the book and write down what your readings were as well because the clinician, the clinic actually look at the book more than what they would look at online obviously. They didn’t really, look at online at all, so you needed something to actually show them so that they were satisfied that everything was going well. They didn’t ask about the trial or anything like that so I actually told them I’m actually doing the online trial da da da da da but they didn’t really ask. They just basically when they called you in, they wanted to look at the book to see how everything was going.”

6.7.3.7 Other identified themes

6.7.3.7.1 A reciprocal relationship between patient and clinician is essential for greater cognitive participation in a telemedicine approach

A mutually reinforcing relationship needs to happen between patients and clinicians for telemedicine to gain traction and work for either actor. The views of the CDE-RNs have already been established in relation to shortcomings of the intervention, when often patients did not enter data on OHP as expected (e.g. theme at 6.7.3.4.2, page 176), leading to disruption of care and some degree of consternation among clinicians.

CDE-RN1: “Sometimes the women who were recruited to the study to log in their data and then when we keep looking at the data it’s not there, then we would have to the call, or contact the women...I found that was a bit frustrating...”

On an individual level, some patients engaged well with using OHP and where this was the case, there were some positive affirmations of the intervention concept from the CDE-RNs as well; as reflected in some of the views highlighted in 6.7.3.3 under the patient control theme. However, on a more general group observation level as seen through the eyes of the clinicians, lower compliance by patients in engaging with data sharing via OHP, posed limitations to the use of the telemedicine system by the CDE-RNs. As noted in the quantitative part of this study on the volume of data entered on OHP (section 6.6.1, page 146), average follow-up time was 10 weeks. This
translated to an expected average number of BGLs of 280. However, patients in the intervention arm entered an average 103 BGL readings. The implication is there were occasions when patients did not enter data or they updated the data later than expected, hence there were no data in such instances, for clinicians to review and make clinical decisions.

CDE-RN2: “It is difficult when no data is uploaded-[we had to do] follow up via text message [on OHP] or call [but we were] not always able to get through. [Therefore] impact[ing] on care effectiveness....”

Sometimes CDE-RNs found continued access of OHP when no new data were available an injudicious use of their time, which contributed to reduced frequency of access to review data and often imposing additional work from following up patients through other means.

CDE-RN3 “…it became more labour intensive for us to be checking, or wondering, to see if someone had entered the data and then they hadn’t and we had to contact them…it ended up doing my head in, basically.”

However, similarly, some patient who were motivated to engage with using OHP, felt they did not see reciprocated levels of engagement from clinicians. A key aspect of the telemedicine intervention in my study was timely availability of GDM self-management data via the telemedicine system (OHP). By participating and sharing data in this way, patients considered this an important part of GDM care. The level of importance and “sense making” was also apparent from having telemedicine support embedded in the GDM clinics. Thus, patients expected and hoped that all clinicians would be active partners, and would equally consider this approach important too. But, as I have pointed out in the pilot (section 5.3, page 115), not all clinicians used OHP to review patients’ data and instead, they relied on the handwritten logbook to monitor progress in GDM management. This led to some patients questioning the importance of using OHP, when there was limited uptake by other clinicians, such as the endocrinologists, dietitians. Patients believed they invested a lot of time and effort in entering the data on OHP for sharing with CDE-RNs in particular, and they would have appreciated acknowledgment and recognition from other clinicians that their efforts were clinically valuable. Reliance, by other clinicians on the handwritten logbook, made patients question the need to continue
using the telemedicine system (OHP). This contributed to a decrease in cognitive participation in using OHP to share data, as illustrated by the view expressed by patient P8, who was one of the lowest users of OHP;

P8: “Well when I had my appointments here and I was bringing my book in anyway, I also thought is there a point doing it [OHP data entry] or are they [clinicians] checking it online, when they are checking my book anyway? I didn’t know if anyone was checking it or not because they were always looking at my book anyway.”

In linking this to the “reflexive monitoring” dimension of the NPT [43, 44, 48] patient evaluate, both patients and CDE-RNs evaluated whether the work of intervention, in this instance, was worth doing by the reciprocity of each other’s actions.

Nonetheless, the issue of compliance was not unique to patients in the intervention arm of the study. Based on field observations, patients receiving care via usual care also kept a record of their data irregularly although overall less so that patients receiving telemedicine. But a human behavioural factor (patient compliance) conspired with technological factors (design features of OHP) in vicious circle making technology less desirable in some instances.

### 6.7.3.7.2 Telemedicine was a potentially threat to personal relationship dynamics of GDM care

During the course of clinical care clinicians and patients form relationships; a concept which in psycho-behavioural sciences is referred to as a therapeutic relationship [127]. The relationship is about patient–clinician rapport, and associated with better adherence to therapy, leading to better outcomes [127, 128]. CDE-RNs indicated that the face-to-face aspect of GDM care usually involved a personal human interaction that was as much part of care as was the therapeutic clinical elements. The CDE-RNs reported this was mutually beneficial to them and the patient regardless of whether the interaction or exchange was directly related to GDM, or not, but nevertheless, indirectly affected outcomes. The potential for telemedicine-supported care to curtail face-to-face interactions was perceived as a threat to this dynamic.

CDE-RN3: “…there is a job satisfaction issue. I think the number of times when you speak to a patient is not necessarily for diabetes. But something of significance is often
brought up. It could be a social work issue or a blood sugar issue or whatever it maybe they just happen to tell us and that’s fine.”

CDE-RN4: “But I just think that [relationship] will never happen if you’re just relying on information [provided via the telemedicine system] too much.”

CDE-RNS: “… when dealing with pregnant women we do not simply rely on numbers. A blood glucose result alone is not enough information on which to make changes to insulin regimes. There are many other personal factors needing consideration that a system alone will not address.”

In concluding the results chapter, I have presented the results from my mixed methods evaluation of the TeleGDM study. Informed by previous studies and the findings of my systematic literature review, I had hypothesised that the intervention in my study will at the least, show no differences in outcomes compared to usual care (section 4.2.2, page 57). Consistent with this hypothesis, and in answer to my research questions, the data showed no significant differences in service utilisation, which was the primary outcome of my study, when the intervention was compared to usual care. Similarly, there were no differences in both maternal and foetal or new-born clinical outcomes, costs and levels of satisfaction. Despite the lack of significant difference, in general, telemedicine support was significantly associated with a shorter time to reaching optimum glycaemic control. In terms of the intervention fidelity, compliance with data entry and data sharing via the telemedicine system was less than expected. In effect, as a means of sharing data with the clinicians, patients in the control group (usual care) demonstrated greater fidelity with recording and sharing data in the handwritten logbook. Interviews and surveys elicited varied responses ranging from some positive affirmations on the utility of telemedicine as a concept, to the human behavioural factors and technological limitations that adversely affected productivity and workflow. The next chapter is a summary and discussion of the key findings overall, relating these to existing literature, as well as the strengths and limitations of my study, before finally concluding my thesis.
7 Discussion

The increasing incidence and prevalence of GDM and associated burdens [8, 10, 18], calls for innovative ways of service provision. The Telemedicine for Gestational Diabetes Mellitus (TeleGDM) study was an exploratory pilot randomised control trial, with supplementary qualitative process evaluation. It was an innovative use of current technologies, in response to an identified clinical and health service need to mitigate the burdens of high GDM prevalence, on the background of limited outpatient services. The intervention in the TeleGDM study relied on reliable, and acceptable technology, for efficient data sharing between patients and clinicians. Underpinning the intervention was the idea that, telemedicine provided the platform for engagement and interaction between the patient and clinician, independent of face-to-face visits. The intervention incorporated some elements which are typical for web-based interventions, e.g. self-management, communication and individualised feedback [129].

My study built on the preliminary limited evidence on the potential benefits of telemedicine intervention, particularly a reduction of service utilisation measures, in GDM care [67]. The study involved the implementation of an adjunct telemedicine, or telehealth approach to support management of insulin-treated gestational diabetes (GDM). The intervention in this study made use of a web-based patient controlled health record (OHP), as a telemedicine platform to facilitate timely sharing of self-monitoring GDM management data, and communication between patient participants and the diabetes educators (CDE-RN). The study sought to explore the effect of this approach on a number of health service performance indicators, maternal and foetal/new-born outcomes, patient quality of diabetes care, user satisfaction, and health provider costs. In addition to these a supplementary qualitative evaluation focussing on both patient and clinician (CDE-RN) user experiences of the telemedicine approach was performed.
7.1 Summary of findings

The main findings of the quantitative evaluation summarised under the key domains of the telehealth evaluation framework [51, 52] were:

i) Patient Control/Use/Accessibility: Adjunct telemedicine support for GDM had no impact on the number of outpatients GDM clinic appointment, whether face-to-face, planned or unplanned appointment.

ii) Clinician Quality of Care – The intervention produced maternal and foetal, or new born clinical outcomes that were similar to the usual care approach. Importantly there was no evidence of adverse outcomes from telemedicine support. In spite of this, and judged by insulin dosing, patients who were supported through telemedicine reached glycaemic stability over a significantly shorter time (median of 3 weeks vs. 7 weeks) than patients supported through usual care process alone.

iii) Organisation sustainability: Closely related to the number of appointments, there was a null finding in relation to health service provider costs. Whilst statistically there was no significant difference in costs, scaled up modelling of costs is likely to produce a significant cost saving from a health service perspective. This is illustrated and discussed further in the discussion chapter (section 7.4, page 201).

iv) Technology capability: Although there were more patients enrolled in the intervention of the study than in usual care, patients in the intervention shared fewer GDM self-monitoring data, i.e. SMBG, via OHP, than was the case with the usual care means of sharing data (handwritten logbook). Some of the reported key issues around technology capability were the lack of a smartphone application which would have made data entry possible, and easier away from a desktop computer, and lack of integration of OHP to existing hospital-controlled ehealth systems, which inevitably created some degree of added work for users. As the number of patient users increased on OHP, it became cumbersome to distinguish active patients from non-active ones, potentially creating an issue for scalability.
I have outlined and discussed the findings of the process evaluation elsewhere in my thesis (section 6.6 through 6.7). Nevertheless, some of the views expressed by patients and clinicians, in relation to the potential benefits of telemedicine in supporting GDM care were:

- Empowerment of patients to engage in GDM self-management;
- Saving of clinician time owing to timely access of patient shared data, hence less need to call patients frequently; and
- A decrease in the need for patients to travel to the clinic particularly when living further from the health service or while still working during pregnancy.

One of the advantages of telemedicine-supported care was the technological capabilities of OHP, allowing graphical visualisation of data. Some patients used this feature to manipulate their personal data to show graphical trends of BGL control. This personal graphical feedback enabled some patients to reflect on their BGL patterns, adjust behaviour and replicate actions that led to better control. Use of images for feedback has been reported to have a potentially positive impact on health [130, 131]. A pilot study [130] exploring visual feedback using personal retinal photographs in patients with diabetes, suggested this may lead to better diabetic control, i.e. reduction in HbA1c. Hollands et al [131] undertook a systematic review of literature on the use of visual images to effect health behaviours change. Although there were fewer available studies, and, other limitations notwithstanding, the review showed that use of images as a feedback tool to explain health risk to patients, appeared to be associated with an increase in health promoting behaviours, or a decrease in behaviours averse to health in some instances; e.g. cardiovascular disease and skin care [131].

There were also some technical design issues and human factors that posed as barriers to telemedicine as a concept in the management of GDM or OHP as the selected telemedicine system. These were mainly the additional work needed to engage with using OHP, and the query as to whether the insulin-treated GDM patient population was suitable for telemedicine. The question of suitability of patients, related to adding a complex intervention in the form of telemedicine to a patient group.
already burdened with a plethora of complex demands of managing GDM through usual care processes.

7.2 Similar outcomes from adjunct telemedicine as usual care

I had hypothesised that the primary outcome for my study, health service utilisation as measured by the number of outpatient GDM clinic appointments, would be lower as a result of the telemedicine intervention compared to usual care. As the results showed, the number of outpatient GDM clinic appointments were not significantly different when the telemedicine intervention was compared to usual care processes. The lack of observed significant differences in service utilisation was incongruent with the finding that, telemedicine support was associated with optimising glycaemic control faster than usual care, hence an expected reduction in the frequency of appointments (discussed in 6.3).

Furthermore, the lack of difference on utilisation in my study, contrasts with previous findings that women undergoing telemedicine-supported GDM care had 44% fewer clinic visits than those supported through conventional care [45]. Another study showed that compared to usual care using telemedicine in GDM reduced clinic visits; average of 4 versus 6 face-to-face clinic visits [76]. These latter two studies differed from my TeleGDM study in a number of ways which may in part explain my different findings. These differences are discussed below in the following paragraphs.

The study by Dalfra et al [45] investigated telemedicine as a substitute intervention. It would appear the study’s protocol determined the frequency of follow-up appointments (once monthly) for patients receiving care via telemedicine, whereas those in the control group (standard care) were scheduled to attend fortnightly. With such an approach, it becomes difficult to attribute and distinguish how much of the difference in the number of clinic visit was due to the intervention or a planned, protocol driven decision to determine the number of appointments. Further, although the intervention had a comparator, patient allocation was non-randomised thereby raising the possibility of selection bias. In the TeleGDM study on the other hand, a number of factors contrasted it with the Dalfra et al study: i) telemedicine was
implemented as an adjunct to usual care, ii) the study was randomised and iii) decision about follow-up clinic appointments was a patient-centred clinical decision, rather study protocol driven. Having telemedicine as an adjunct to usual care may have led to unconscious bias on the part of the clinicians to continue scheduling appointments the same way they had been practicing rather than making this a data informed decision potentially resulting in no difference in the frequency of appointments. Notably Dalfra et al [45] reported that participants who received telemedicine in their study, had 44% fewer clinic appointments than controls. It was unclear whether this was a raw percentage based on the raw number of visits, or whether it was standardised to make the groups comparable, in the light of the differences in study arm allocations (telemedicine n=88, control=115) [45]. Also, this study reported the outcome as the mean number of appointments, whereas my study compared the outcome using the median. Being a count variable, the number of appointments is expected to be positively skewed, making the use of the mean as a central measure problematic.

Not only was there no difference found in primary outcome in terms of the GDM outpatient clinic appointments, but this was observed for other outcomes as well. With the exception of optimum glycaemic control marked by insulin dose stabilisation, all other clinical and quality measures were also similar for telemedicine as usual care. These findings were consistent with our systematic review and meta-analysis [67] (copy appended in section 3.2, page 43), the general findings of a more recent systematic review [46] and the individual studies included in the latter reviews [44, 45, 47, 76, 132].

A finding of no difference in clinical outcomes, such as rates of caesareans, macrosomia, and special care nursery admissions, was still important in relation to quality of clinical care. Higher rates of these outcomes, associated with poorly controlled hyperglycaemia in GDM, are indicative of adverse or undesirable pregnancy outcomes [7, 11, 14, 89, 133]. A reported estimated prevalence of macrosomia in GDM was 15-45% [134]. Rates of undesirable outcomes in a group of women receiving standard treatment for mild GDM were 14.3% for macrosomia, 14.5% for LGA and 33.8% for caesarean deliveries [63]. An Australian study [135] reported a significantly higher rate of caesarean delivery 19.8% in GDM vs. 15.6% in women without GDM, although this difference diminished once factors such as age and parity
were considered. Compared with normoglycaemia in GDM, high maternal fasting BGL has been associated with a 6.7 odds of macrosomia [14]. Using a composite measure of the adverse outcomes, Langer et al [136] reported an incidence of 59% in untreated GDM, 18% in treated GDM and 11% in those without diabetes. Whilst these studies are not an exhaustive presentation, they are a snapshot of the epidemiology of adverse outcomes in in GDM.

Compared with the above findings, my TeleGDM study cohort showed caesarean delivery rates of 46% (intervention) vs. 32% (control) and macrosomia rates of 4.9% (intervention) vs. 2.9% (control). Statistically there were no differences in the latter outcomes, potentially attributable to only a small number of patients impacted (11 caesarean cases and 4 for macrosomia), making these numbers too small for an appreciable difference to be realised. The lack of difference in clinical outcomes suggested telemedicine-supported GDM care did not compromise clinical quality of care. The implication is that telemedicine would be a viable approach to supporting GDM care, if a cost advantage over usual care could be demonstrated. However, notwithstanding the possible reasons for this as discussed above, with no significant change in the frequency of appointments from the adjunct telemedicine intervention in the TeleGDM study, it followed that a cost saving was not realised. Cost is discussed in a separate section of this chapter.

The other outcomes that showed no difference between the groups were self-efficacy and satisfaction with care. Both groups had higher scores at baseline to begin with. Patients enrolled in the TeleGDM study at 28 weeks gestation on average, while GDM diagnosis occurred at approximately 20 weeks gestation. At the time of enrolment into the study, the patients had had a few weeks to settle into the GDM service, to build up their self-efficacy and satisfaction with care which was not impacted by the intervention. In their evaluation of the psychological impact of a GDM diagnosis, Spirito et al [137] concluded that patients adapted well to the diagnosis and initiation. In spite of this reported successful adaptation, my field observations were that a small number of patients who were earmarked for recruitment at insulin initiation, were overcome with emotions, which led to deferment of recruitment.

The DES-SF and CSQ-8 Scores at baseline were closer to the maximum possible for either outcome; DES-SF intervention=34, control=33 out of a possible 40 and CSQ-8
intervention=29, control=28 out of a possible 30) with only a marginal 1 point change for either group at 6 weeks follow-up. Standardised questionnaires measurements reach a point where assessed subjects no longer improve or have reached the maximum possible score (or close to it) while in reality participants may still have further capacity for improvement. That is, the instrument ceiling effect phenomenon [138-140]. As an instrument property, rather a patient related attribute, the lack of further changes in both self-efficacy and satisfaction respectively on the DES-SF and CSQ-8 as an issue of instrument ceiling effect cannot be discounted. Data on responsiveness of the original 28-item DES is available, while there is none for the DES-SF. The closest to assessing responsiveness of the DES-SF is the Health Empowerment Scale (HES) [141, 142] which is an adapted version of the DES-SF. Based on the HES the DES-SF has been inferred to have a ceiling effect in the order of 20% of respondents [141]. However, it is possible that the adaptation process changed the psychometric and construct properties of the DES-SF, especially that, reference to diabetes was replaced with health and the questionnaire testing was administered in an older populations [141, 142]. Lastly and to a lesser extent, the six week follow-up time may have been too short to achieve a significant change.

Finally, one of the notable limitations of the studies of telemedicine in GDM was the smaller sample sizes. My study recruited n=95 patients and previous RCTs recruited n=57 [32], n=80 [47], and n=97 [44, 76]. Another more recent RCT with similar intervention to my study (telemedicine adjunct to usual care) had a sample n=50 [132]. Notwithstanding the fact that some of these were feasibility or exploratory studies, the numbers underscore the possibility of difficulties in recruiting patients with GDM for research, making it difficult to conduct large scale RCTs and generate rigorous evidence. In fact, challenges recruiting pregnant women and their under-representation for clinical trials in general have been documented. Some of the factors which contribute to research participation barriers, include the historical exclusions of pregnant women from clinical research, due to the potential or uncertainty of harm to the foetus [143] although this mostly affects clinical drug trials. Being time poor and other pregnancy issues [144], are reasons that have been attributable to non-participation and these were certainly issues I noted when attempting to recall women to the hospital specifically for the study, i.e. recruitment, when they had no scheduled appointments at the hospital.
The implication of the above issue is that researchers need to consider innovative ways of reaching pregnant women for research, i.e. use of technology such as social media, and mobile telephony [143, 145, 146], to recruit and engage the women in research. Furthermore, smaller sample sizes result in studies that are inadequately powered to detect small differences and effect sizes as would be expected with the clinical outcomes in GDM. This too, potentially explains the lack of significant differences in my study and others; a consideration for future trials is to make concerted efforts to recruit larger sample sizes in order to facilitate definitive conclusions on the effect of telemedicine interventions in GDM. One way this may be achieved is though multicentre clinical trials.

7.3 Faster time to optimum glycaemic control advantage with telemedicine support

Assessment of effectiveness of therapeutic interventions depends on reliable and valid measures. Several measures and indicators of glycaemic control and variability exist for use in both clinical practice and research in diabetes in general and in GDM. These include SMBG, continuous glucose monitoring (CGM), HbA1c [5], the standard deviation method and the CGM derived mean amplitude of glycaemic excursion (MAGE) [147-149] amongst others. Ultimately selection of which outcome measure to use is dictated by a balance between reliability, validity and responsiveness [78, 150] on the one hand and practicality, completion burden, and costs [138] on the other.

Wojcicki et al [151] used the mean of blood glucose (MBG) levels and J-index (a measure of variability) in their study of telemedicine in type 1 diabetes. They found no differences between the intervention and controls on MBG, HbA1c or the J-index, perhaps due to either low sensitivity of these measures in pregnancy or low study power secondary to a smaller sample size (n=15 per study arm). However, significant differences in favour of the telemedicine intervention were found using the standard deviations of the MBG and J-index.

In my study I considered two markers of glycaemic control, the percentage of SMBG readings outside target and the insulin dose stabilisation (methods section 4.6.1, page
The percentage of out-target BGLs was only significantly different for post-lunch readings over a four week period with unadjusted univariate comparison favouring the intervention for lower BGLs. However, this result is treated with caution because it was an unadjusted association and its significance is uncertain. Although I did not collect data on specific insulin regimens speculation might be that the result could be explained by variability in insulin regimen.

The mean percentage of out of target SMBG for the intervention was similar to the controls while time to insulin dose stabilisation for patients receiving telemedicine support was shorter (approximately 4 weeks vs. 8 weeks). The finding demonstrates an important advantage of the telemedicine intervention for my study, granted all other outcomes were similar. Logically it would follow that as patients reach optimum glycaemic control and no longer required insulin dose titrations, they would not need to be seen as much in the outpatient GDM clinic. Notably though, attaining glycaemic control did not have a corresponding decrease in the number of appointments. The likely explanation for this lies in the multifactorial aspects at play; the technology, and the human behavioural factors (patients and CDE-RNs). One of the views expressed by the CDE-RNs during the interviews was the preference for face-to-face contact which was based on justifiable reasons in some ways and resistance to changing practice in the other ways.

Whilst a significant finding, caution needs to be exercised, because as a marker selected on face validity for the TeleGDM study, insulin dose stabilisation has not had reliability and construct validity testing. Despite this, it offers an opportunity for a simple marker of glycaemic control based on readily available clinical data. However, further evaluations would be needed to validate it as an outcome in insulin-treated GDM care and assess its value in relation to maternal and foetal outcomes.

**7.4 Potential for cost-saving advantage from telemedicine**

One of the questions I aimed to address in my study was whether a cost saving would be realised through the telemedicine-supported GDM care. Similar to nearly all the other outcomes the result was not statistically significant. The average cost face-to-
face appointments were $2506 (intervention) and 2305 (control). For scheduled appointments the average costs were $1735 for the intervention and $1869, which, being less than the cost of patient subscription to use OHP, gives a cost difference of $54 per patient. When modelled using Poisson regression analysis, on average the intervention potentially increased the face-to-face appointment costs by 8.7% while it decreased scheduled appointment costs by the same margin, noting none of these observations were statistically significant. The main difference between these indicators of services costs was that scheduled appointments were determined by the clinicians and as defined in my study, excluded walk-ins and telephone based consultations. Telemedicine support may appear to contribute to curtailing unscheduled appointments. Based on regression analysis, by investing $80 per patient (the market cost of the OHP subscription at the time), the cost saving could potentially be $24.36 per clinician contact (8.7% of the appointment rate of $280).

None of the studies in our systematic review and meta-analysis [67] (section 3.2, page 43) included cost analysis, which is one of the criticisms of studies in telemedicine in general [28]. Likewise a more recent systematic review of telemedicine intervention in diabetes in pregnancy [46] could not evaluate costs because none of the included studies include an economic evaluation. In spite of this costs savings have been reported elsewhere following telemedicine or telehealth approaches, e.g. in type 1 or type 2 diabetes [152, 153] and in oncology [154] mainly due to reductions in patient-related travel expenses. Another RCT [155] reported a cost saving of US$142 in differential costs when patients shared their diabetes monitoring data via a modem service (telehealth) compared to a usual care control in a cohort of younger patients with type 2 diabetes. These studies were in different populations to that studied in the TeleGDM study and telemedicine was implemented as a substitute service. Despite these differences, and lack of definitive evidence for cost saving in GDM, telemedicine as a concept shows promise as a costs saving approach to service provision.

The cost evaluation result of my study as discussed above, should be viewed with a cautionary note, that, statistically there was no significant difference between telemedicine and usual care. However, from a service perspective these figures could translate into significant findings from a scaled up telemedicine-supported service perspective; provided scaling up issues of technology systems such as OHP are
addressed. To illustrate the health service significance, the 95 patients in the TeleGDM study together had a total of 933 (intervention=608, control=325) appointments attributed to them, regardless of attendance or not. With a cost saving of $24.36 per clinician appointment, n=24 (usual care patients) at an average of five scheduled appointments per patient translates to a saving of approximately $4140 over an average of 10 weeks (study entry to study endpoint, see section 6.6.1, page 147). Historical data from NH (section 1.1.2) showed there were approximately 400 patients with GDM at NH in calendar year 2012. The number is projected to increase with the increasing population and number of births in the catchment. Maintaining the same frequency of appointments, n=400 patients translates to an approximate saving of $46 920 per annum which for a mid-tier tertiary healthcare service provider such as NH could be a significant amount.

The above illustrates that in spite of lack of statistical significance as my study found, significant cost saving may be realised by scaling up telemedicine support in GDM care. However, this will need to go hand in hand with practice changes, such as selection of clinicians that technology ready, and the patients to match. As previously pointed out, there was reluctance to change practice relating to face-to-face appointments. One of the views expressed by the CDE-RNs was the need for continued direct in person interaction with the patient because of the personal aspects of care that technology was unable to provide. This highlights the need to explore practitioner behaviours and practices which may be barriers to realising some of the expected benefits of telemedicine interventions, whether in GDM or the health conditions.

Finally the inclusion of a cost analysis in my study was in itself a strength, granted that studies of telemedicine interventions in GDM do not tend to consider this aspect of evaluation. Limitations include the fact that my study limited itself to cost minimisation evaluation from a provider perspective only. Even then, costs associated with telephone consultations as a service provision were not included, although in reality the infrastructure and clinician time are an expense to the healthcare service provider.
7.5 “Readiness of actors” to change

Normalisation Process Theory describes how actors in the implementation process may be deeply set in the way they perform their work in relation to practices that are already normalised [43, 51, 52]. Introduction of new practice, such as telemedicine in this thesis, requires readiness on the part of the clinicians and “to accommodate changes” [57] and embrace new ways of working. Readiness to change is considered a crucial step in the implementation of complex healthcare interventions [57, 125]. That is, for the new intervention to normalise, the actors (clinicians) need to buy in (NPT’s “cognitive participation”) and the organisation, also needs to provide an enabling environment (NPT’s “collective action”) [48, 52]. Thus readiness to change is integral to cognitive participation and collective action; as oftentimes, failure of interventions in effectiveness, may be due to failure to normalise in practice, in part attributable to resistive tendencies on the part of the actors [55].

For the most, the quantitative evaluation component of my study showed that, the telemedicine intervention produced outcomes that were not significantly different, when compared to usual alone (results chapter; section 6.3 through 6.5). A number of factors and limitations e.g. sample size, instrument properties as well as clinician behavioural and entrenched practice factors that potentially contributed to similarities of outcomes between the telemedicine intervention and usual care in my study, have been discussed. Some of the CDE-RNs, who were important actors in the intervention, expressed views that were suggestive of low readiness to change practice, e.g. the view of CDE-RN3 in section 6.7.3.4.3 (page 178). For instance, some of the CDE-RNs indicated they preferred usual care to the telemedicine approach in the context of GDM management. This presented challenges, that potentially impacted outcomes, because telemedicine had to compete with the CDE-RNs’ preferred way of working.

The NPT [57] and Weiner [125], discuss readiness in the context of organisational readiness to change, defined as “…organizational members’ shared resolve to implement a change (change commitment) and shared belief in their collective capability to do so (change efficacy).” Implicit in the definition is a conscious active decision and willingness on the part of members of an organisation to be active
participants in the change process. The NPT [57] and Weiner [108] go on to outline factors that determine readiness to change, namely “task demands, resource availability, and situational factors” [57, 125].

In the context of the TeleGDM study clinicians (GDM care team) were both the members of the organisation and individuals that I engaged with to facilitate implementation of the complex telemedicine intervention to support GDM care. In the formative stages the members of the GDM care team showed high levels of commitment and enthusiasm for the study. During the pilot (reported and discussed in chapter four) as the “task demands” of the intervention became clearer and the work imposed by technology, perception of roles shifted and I determined the CDE-RNs were the better placed members of the GDM care team to engage with in implementation of the intervention. Other clinicians were supportive but opted to be non-active participants and were perhaps less inclined to change and embrace using technology (OHP) in managing GDM. The consequence for this was, continued use of handwritten log books by patients which ultimately contributed to some patients in the intervention reverting to this mode of data sharing in lieu of using OHP.

As it emerged from the interviews some CDE-RNs expressed views in favour continued face-to-face mode of providing follow-up care to patients. Notwithstanding some of the limitations of the technology (OHP), other issues of readiness to change and embrace a different way of supporting care via telemedicine were demonstrated by the mixed responses relating to views around the impact of on workflow. Some CDE-RNs viewed the telemedicine intervention as time saver while others expressed views that focussed more on the additional work the intervention created making for less that positive experiences. Thus, some of the CDE-RNs were perhaps not ready to embrace telemedicine and it associated disruption to the way they delivered care in GDM.

Granted current evidence of telemedicine in GDM is limited, it is possible that clinicians may have been sceptical and did not have sufficient trust in the intervention to change their practice in relation to potentially reducing unnecessary face-to-face appointments in response to telemedicine support. Furthermore, implementing telemedicine as an adjunct to usual care provided no real incentive for clinicians to reduce face-to-face appointments when the usual care process was still at their disposal. Lastly the difficulties experienced with using OHP early on may have also
contributed to clinicians’ bias towards usual care practices getting in the way of readiness to change.

Although formally assessing readiness to change was outside the scope of my TeleGDM study, it is nonetheless a concept worth considering in implementation. For the purpose of the TeleGDM study engaging the NH remained at the endocrinology and obstetrics team level. However, beyond this study, future translation to practice would require engagement at higher organisational levels so that support for the necessary human resources, i.e. nurse informatician, technology infrastructure and ensuring that enabling policies and procedures are in place to facilitate implementation.

7.6 Strengths and limitations

The main strengths of the TeleGDM study included implementation of the study in a real world clinical setting with a limited budget and innovative use of current technology. The study involved a mixed method design to facilitate the richness of data collected, a balance of primary and secondary data collection methods to minimise participant burden, especially the use of secondary data for the primary outcome thereby reducing data reliability issues that would have otherwise been associated with recollection should the data have been collected primarily from patients. Also the TeleGDM study considered costs, an often overlooked outcome in studies of telemedicine in GDM or diabetes in pregnancy. Furthermore, the evaluation aligned with the proposed framework for evaluating telehealth interventions in Australia [51].

A few previous studies [32, 44, 47, 76] have specifically explored telemedicine in the management of GDM. These studies found better service utilisation in the form of fewer face-to-face appointments and better diabetes psychological self-efficacy. My study differed from these studies in two critical ways.

Firstly, my study used technologies (broadband internet and the ubiquitous internet connected smartphones) which were not previously available. Use of current technology meant a greater and faster reach compared to the technology used in
the previous studies. As such my study was both innovative and novel in relation to use of technology.

Secondly, I implemented telemedicine as an adjunct to usual care. In the studies that met the inclusion criteria for my systematic literature review, telemedicine was as a substitute, alternative approach to usual care. In my exploratory RCT usual care as described in my thesis was the current standard of care. Therefore implementing a telemedicine based intervention as a wholly alternative, substitute service would have been tantamount to denying patients an established service approach, hence unethical. However, the adjunct nature of the intervention meant concurrent elements of usual care were still available to the intervention group thereby potentially confounding the intervention.

I set out to conduct the TeleGDM study aiming for a 1:1 randomisation of patients to the study arms using an independently designed STATA 11 (StataCorp LP) randomisation schedule. Once the trial was underway, it appeared more patients were getting allocated to the intervention than the control group. I identified an error in the form of a lack of blocking in the randomisation schedule. Blocking is a means of ensuring that allocation of participants to trial arms is balanced [77]. Also the number of participants used in the scheduled was the projected 200 based on the GDM clinic throughput at NH. Both of these factors contributed to this apparent uneven allocation of participants with bias toward the intervention with the final sample of n=61 for the intervention group and n=34 for the control group. As previously indicated rather than revise the randomisation schedule, the decision was to continue.

Typically, clinical trials adopt a 1:1 random allocation, and departures from to uneven allocation have implications for study power [79, 156]. As such sample sizes need to be recalculated to factor in uneven allocation. For instance studies with participant allocations of 2:1 and 3:1 will respectively require 12% and 33% more participant recruitment for the same study power and treatment effects as a similar study designed with a 1:1 allocation [79]. That is, if the necessary recruitment sample size is not factored into the design of uneven allocation, the consequence is reduced study power. But clinical trials using uneven participant allocation to study arms, planned in advance, are not unusual, e.g. in early phase and exploratory RCTs [77, 79] where there is a greater allocation to the intervention arm than control. Amongst others,
some of the reasons that investigators may use uneven group allocations include reduction of trial costs, improvement of study power in three-arm trials, counteracting an anticipated higher dropout rate in the arm with a higher allocation, especially when new interventions are trialled, or the plan is to gather more data, particularly around safety of new interventions [79, 156]. The counter side of the argument is the ethical query of exposing a greater number of participants to a new (experimental) intervention [79] where the comparator is perhaps an established treatment approach. Whether planned or not, sample size implications for uneven allocations are not as profound for 2:1 allocations as they are for 3:1 allocations [156].

My study concluded with almost twice as many patients in the intervention group as the control group. However, my sample size projections as per the protocol [80] (copy in section 4.9), were such that despite this inadvertent departure from the 1:1 allocation, there was only minimal impact on the study power and no need to drastically alter the recruitment target. The decision was affirmed by a second opinion from one the biostatisticians I consulted.

Other limitations have been discussed in the different sections of this chapter and are summarised below.

- During recruitment, 65 (56%) of the women with GDM who were excluded prior to randomisation (n=116) had limited English language ability (section 6.2.1, 127). This represents a significant proportion of women who are typical of the ethnic diversity of the catchment population who are at risk of GDM. The exclusion of these women adds some selection bias to the recruitment process, hence although acceptable for an exploratory study, the results need to be interpreted with caution as they may not be generalisable to the catchment population.

- As described in section 4.6.1, there was lack of standardisation of SMBG after the plan to use the same make and model of glucometer was abandoned. Thus although pragmatic under the real world condition of my study, the use of different glucometers by the patients most likely introduced random errors in the BGL data. Reliability of SMBG measurement is an important factor in diabetes care and management; SMBG results inform clinical decisions and outcomes [157]. Studies have demonstrated great variability in the accuracy
and agreement of different glucometers [157, 158], with variations ranging from approximately 6% to 21% [158]. Therefore the unstandardised measurement of BGLs may have introduced random errors that contributed to some degree of variability in the SMBG data. Even though there was no significant difference finding from SMBG data in my study, the influence of glucometer variability cannot be ruled out.

- There was greater compliance with SMBG data entry in the first four weeks of enrolment in the study; in part due to women reaching study end point and decreasing compliance with data entry to OHP. Efforts such as automated reminders, and direct phone contact or SMS to the women to encourage engagement with the data entry task. Despite these attempts, compliance with data entry to OHP remained poor beyond the four weeks, in particular became poorer in the later stages of pregnancy. This presented a major limitation to the analysis of the glycaemic control using SMBG data beyond four weeks follow up. Given some of the women reverted to using the handwritten record when they ceased electronic data entry to OHP, a post-hoc analysis using data from handwritten diaries may be useful.

- Costs were only considered from a provider perspective, limited to billable consultations for pragmatic reasons in relation to the scope of the study. The cost evaluation approach was very simplistic versus robust methods such as cost-effectiveness analysis. However the analysis was informed by a recognised method of health economic evaluation, i.e. “cost minimisation”[99, 159], despite its limitations. The simplicity posed methodological limitations as it does not reflect the true costs of healthcare provision; the unit cost price was based on a nominal fee that the health service charged. The evaluation excluded other costs, particularly patient related costs, such as travel to clinic, parking, GDM management consumables and cost burden on the wider healthcare system, considering consumables for self-monitoring are subsidised. Further attaining optimum glycaemic control has implications for continued testing and costs associated with this. As such a comprehensive economic evaluation that takes into account other costs could be a future consideration.

- OHP had a number of technical and functional limitations which as both patients and CDE-RNs pointed out imposed extra work for sharing and review
processes. In addition to this high dropout rates in sharing data and sporadic data entry rates in the later stages of the trial limited the ability to explore the full potential of the web-based data sharing approach.

- Although use of secondary data was a strength for evaluation of service utilisation, as it represents real world practice, it may be a limitation as well. Factors around data collection process, e.g. data definitions, purpose for collection, collection methods, and data verification and completeness, may be crucial to the interpretation of the data[160] but users of secondary data are not always privy to these. As an investigator I relied on routine care data, for some outcomes and measurements, e.g. attendances, with limited ability to verify the quality of such data.

- Even though the DES-SF and CSQ-8 questionnaires are recognised standardised instruments, they may have ceiling effects, reducing their ability to detect change.

- Whilst my sample size aligned with the exploratory nature of my RCT and was sufficiently powered for the primary outcome, the sample size was nevertheless too small to detect significant differences in the secondary clinical outcomes. These outcomes formed the basis for evaluating clinical quality of care. As result the finding of no impact on quality of care needs to be interpreted with caution. This underscores the need for further research before definitive conclusions can be drawn. In spite of the sample size limitations, the secondary outcomes data may be useful for estimating power and sample sizes for such future definitive trials.

- Clinicians in my study were responsible for the decisions about appointment scheduling but it was impractical blind them to the allocation of patients to the study arms. Blinding or masking of clinicians in randomised controlled trials is a possible safeguard against the risk of conscious or sub-conscious bias that may influence the study outcomes (ascertainment bias) [161, 162]. Although my study protocol did not expressly direct clinicians to alter appointment scheduling, it cannot be unequivocally ruled out that decisions about appointments were not made to influence the course of the primary outcome.
To conclude, my research took place in a real-world health care environment and I had to negotiate with clinicians whose primary responsibility and duty was to deliver care to the patients they cared for in what was a very busy clinic environment. Navigating such a system required negotiations and compromises to keep interference with the clinic flow to a minimum. This invariably affected recruitment especially since that, with limited funding, I had to also depend on clinicians to carry out some of my study tasks. Patient clinical care for the purpose of the study, had to be performed by the same clinicians that were subject of the research as well. This again reflected the limitations of funding, where I was unable to employ clinicians independent of the health service to carry out elements of the intervention.

7.7 A reflection on conducting the research

Prior to undertaking my PhD, I had previously coordinated and/or undertaken various research projects. While some of the fundamentals of the research are similar across different research projects, conducting my PhD research had its own highlights that were both fulfilling and challenging.

My study did not begin as a GDM research topic. Originally, my plan was to pursue a research topic that focused on a different area of diabetes research, i.e. to support management type 2 diabetes through telemedicine. As perhaps happens typically in the PhD journey, a topic can evolve and/or change from the original idea. After consulting and reflecting on advice, I opted to focus my topic on different type of diabetes, GDM. The reason behind this balancing my topic of interest with what was feasible and achievable in the finite time of undertaking a PhD.

Selecting a PhD topic quite often involves carving out a component and developing a research topic out of an already established and funded research program. In my case, I joined my university department brining along an independently conceived research idea rather than following the latter path. This meant that save for a much appreciated small research grant and in-kind support, my study was largely unfunded. As such, I relied on myself to do all the work of managing and coordinating my study activities, although I was able to secure limited research assistance for a brief period.
Lack of funding meant I could not afford pay for assistance. I had to travel and coordinate recruitment and data collection across three campuses of one health service. When recruitment at this main health service became challenging in terms of getting the number of participants consideration had to be given to other research sites. It became a near impossibility for me, as a solo operator, to take on more study sites. As it was, I was already spread too thin. The consequence was that recruitment took longer than envisaged.

In my thesis I indicated that my study was novel. At conception there were no known studies that explored telemedicine or telehealth specifically in the management of GDM in the Australian context. However, by the time I wrote my thesis, I was aware of at least one other study in Australia. In the landscape of research delays can often lead to the study being overtaken by events.

There were moments of personal frustration when things did not go to plan, e.g. failure by patients to upload data, or not honouring appointments or due to the general process and progress of the study. Despite this, I had to continually adapt and cast aside my frustrations and realise that although the research was important, the patients were doing me a favour. Being adaptable was an important attribute for research because at the end of the day conducting research on patients was a privilege and a great opportunity. The research process requires continually reflecting and reviewing progress and making necessary adjustments, albeit exercising caution not to interfere with the fundamentals of the research trial.

Finally, delays in conducting a study can sometimes leads to other events overtaking the study. This is even more the case, in studies that have technology as a central feature because technology changes at a rapid pace. For instance, partway through the TeleGDM study, clinicians discovered an alternative means for patients to share their GDM self-monitoring data. This involved patients taking photos of their handwritten diary and sending the photos to the CDE-RNs via smartphone messaging. Although this approach was not used by all patients, it nevertheless altered usual care practice from what it was when I started my trial. While none of the patients I recruited

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2 Kaplan R, Leader L, Nathan S, and Lau A. SugaMama – Can eHealth enable supported self-management of gestational diabetes mellitus (GDM) for public outpatients?
in my study were affected by this, it potentially created a disincentive for the CDE-RNs to change their practice to suit the expectations of my study’s intervention. This however, made me question whether I had failed at getting the CDE-RNs to buy in to my endeavours and made me doubt my belief in “the worth” of my intervention. But I drew strength and courage from the support of my supervisors and the views of those who still saw some worth in my pursuit.
8 Implications & Conclusion

8.1 Implications for policy, practice and research

Telemedicine as a concept shows much promise in general and specifically in GDM care. However, the full potential for telemedicine in GDM is yet to be realised. In view of my study findings and observations throughout the trial, I outline and discuss three areas of policy and practice implication, with a specific focus and relevance to GDM care, but potentially transferrable to telemedicine in general. While some of these may not have been explicitly explored in my study, they are implicit in the opinions and observations from the qualitative evaluation. These include:

- Investment in human and technological resources,
- Expansion of health funding schedules to include non-videoconference telehealth modalities,
- Cooperation between technology systems/solution developers and clinicians.

Notwithstanding the exploratory nature of my study, and hence the limitations of this approach, I finish with a discussion of the implications for future research.

8.1.1 Investment in human and technological resources

My study was implemented in a real world practice setting and some of the study data were critical clinical data which informed clinical care. As such I trained the CDE-RNs to be the primary gate keepers of the telemedicine system for clinical care and coordination. While the CDE-RNs were the GDM clinic care coordinators, adding coordination of telemedicine was outside their scope of work. But this role was as much a study function as it was a clinical coordination role. The CDE-RNs accessed the telemedicine system to review patient data, provide clinical feedback to patients and/or liaised with other members of clinical care team. In addition to this they also
followed up patients for compliance with the important task of data entry as lack of data disrupted continuity of care. As such, future implementation to embed telemedicine in GDM care will need to consider investing in up-skilling and building the capacity of the CDE-RN workforce to interact with technology.

The telemedicine coordination role was additional to CDE-RNs’ usual role and was within existing workloads and capacity. This provides an opportunity to either expand the scope of practice for the CDE-RNs to include health informatics, or invest in developing a new role e.g. nurse informatician to coordinate GDM telemedicine services. Granted, as the researcher I provided first level technical support, this role could also become the responsibility of a specifically skilled CDE-RN or the nurse informatician.

One of the issues that emerged from the study pilot and process evaluation was the inability of the chosen telemedicine system (OHP) to integrate with existing eHealth system within NH. This was one of the barriers expressed and observed by the rest of the GDM care team who opted out of using the telemedicine system and it was reiterated by the CDE-RNs. Non-integration into existing systems such as hospital-controlled electronic medical records and the birthing outcomes system, was a contributing factor to dissatisfaction and the extra work imposed by telemedicine. While there was capability for integration this required financial investment for the initial work and ongoing support; a consideration for future implementation. Furthermore, consideration should be given to organisational policies and governance processes to put in place, an enabling environment for this integration work, and adoption and normalisation of telemedicine in GDM care and practice. These will go a long way in increasing clinician uptake, further enhancing clinical care access and continuity.

Lastly because of the rapidly evolving landscape of technology, industry needs to invest in modular systems to enhance their capability in terms of adaptability to patient needs, different population groups or the local setting. For instance, a substantial number of patients in the catchment of my study location came from a CALD background and communicated in languages other than English. Their involvement in the trial was limited because the system was all in English. Some patients in the study reiterated the need for a smartphone application to enhance user experience and accessibility. It is recognised that rigid systems have their place
but flexible systems that are capable of modification and adaptability are likely to be scalable and attract more interest, greater adoption and enhance the chances of being normalised into the healthcare system.

8.1.2 Expansion of health funding schedules to include non-videoconference telehealth modalities

Current Australian Medicare funding schedules only provide for a fee for service for telemedicine that includes videoconferencing. As such, care provided through the telemedicine approach, such as that in my study, attracts no payment from Medicare. Although billing and its impact was not explored in my study, current MBS limitations may create a disincentive for the members of the GDM clinical team, e.g. the endocrinologists, some of whom may engage in private practice, to actively engage in using telemedicine to provide GDM care. Healthcare peak bodies and representatives of healthcare services, will need to lobby government to expand fee schedules to consider evidence-based non-videoconferencing telemedicine services in general and in GDM care.

Extending the fee for service payment to telemedicine similar to that in my study, is likely to widen uptake and usage of telemedicine, given the preliminary findings that indicate telemedicine for GDM care may not compromise clinical quality of care and scaling up the service may have some health service cost savings, while facilitating access to health services.

8.1.3 Cooperation between technology systems/solution developers and clinicians

Experiences from the pilot and the process evaluation of the TeleGDM study, highlighted some deficiencies in the selected telemedicine system which required input from a clinician’s perspective to enhance user-friendliness and acceptance. Traditionally developers operate in an independent technological ecosystem with limited appreciation of or familiarity with the workings of the healthcare ecosystem.
The consequence is creation of systems which from a technology perspective, are intuitive but from a clinical perspective, are less intuitive, with limited usability. For instance, OHP was designed in way that was less favourable to what the CDE-RNs preferred; tabular data format as opposed to the preferred layout resembling the handwritten logbook to facilitate rapid data review and clinical decision making. This underscores the need for cooperation and collaborative engagement between developers/vendors and clinicians in developing systems fit for the express purpose of enhancing healthcare provision.

The advent of a national digital health strategy in Australia, provides a great opportunity for telemedicine system developments. Consideration for cooperative strategies is imperative to harmonise the technology and health care system to maximise applicability, adoption, technological capability and eventually access, with follow on benefits to clinician quality of care, and operability, either in GDM specifically or other areas of health care need. At the time of writing my thesis, four key highlights of the strategy [163] were that:

- At least 80% of surveyed persons believed digital technologies will transform and improve healthcare
- Four times as many people responding to the strategy surveys expressed the desire to be able to access their own personal health information on their smartphone than those who actually did.
- 45% have of the respondents expressed difficulties with accessing healthcare when they needed it. This underscores the partnership in development telehealth systems that enhance patient access to health care.

Trends in digital or telehealth pursuits are not limited to Australia. Other jurisdictions and agencies [164] also recognise the capabilities of telehealth whether at device level, individual disease outcomes, or health system-wide transformation.

### 8.1.4 Future research

The TeleGDM study was exploratory, thus together with the preliminary evidence from previous studies has paved the way for future, more definitive trials. Given the potential selection bias in the current study, future trials should consider more culturally
appropriate interventions. Also, because of the limitation relating to small sample size and recruitment challenges, future studies of telemedicine in GDM need to consider large scale multicentre trial approaches to be sufficiently powered to generate conclusive evidence. This will require substantial resources. To navigate the resourcing issue, consideration should be given to collaborative partnerships between government, industry, healthcare settings and/or academic institutions.

Furthermore, future research opportunities for telemedicine in GDM need to consider economic evaluation. This was an area of marked limitation of all the previous studies of telemedicine in GDM. Intervention that demonstrate cost effectiveness gain more traction with healthcare stakeholders, especially government as the main healthcare funder.

Finally, secondary to limited evidence, more robust research is still needed to specifically evaluate the effects of telemedicine in the short term period around pregnancy. The intent of the TeleGDM study was to involve general practice but because of logistical reasons and the fact that GPs were not active participants in the TeleGDM study, this element was omitted. Therefore future research in telemedicine needs to consider:

- General practice and primary care in the management of GDM in terms of collaborative shared care supported by telemedicine. The projected increases in population and births means tertiary healthcare service capacity to provide care will continue to be stretched. Other types of insulin-treated diabetes are increasingly being managed in general practice. Hence expanding primary care in general practice to include insulin-treated GDM, may be the next domain for general practice, warranting further research. In addition to this GPs are well placed to continue care for women who had a GDM complicated pregnancy. Therefore involving GPS in telemedicine-supported interventions and research in GDM needs to be considered.

- Investigating the long term impacts of telemedicine on the metabolic and/or diabetes and health status of mother and child beyond the immediacy of pregnancy. This is a pertinent topic noting that GDM has long term implications for the health of both the mother and child.
• Innovative and adaptable (beyond the traditional) methods to recruit, retain and engage pregnant women in research. As technology increasingly makes more and more inroads into clinical care systems and health settings, generating good quality evidence is paramount; especially in areas where very critical outcomes are at stake, i.e. foetal and neonatal well-being. This can only be achieved through robust, representative studies.

• Investigating factors that will facilitate identification of patients most likely to take up telemedicine interventions, so that such interventions are better targeted and streamlined. This is on the background that some patients curtailed their level of engagement with the intervention and that some CDE-RNs suggested that perhaps the target population in my study might not have been suitable.

8.2 Conclusions

The incidence and prevalence of GDM are on the rise. This coupled with a higher number of affected women requiring insulin to control hyperglycaemia in GDM is putting a strain on currently available healthcare resource. Telemedicine offered an opportunity to enhance service provision and mitigate service demand burdens, while maintaining if not enhancing quality of clinical care. Telemedicine or telehealth is a rapidly evolving landscape in healthcare provision. Advancements towards cheaper, faster and more ubiquitous technologies, and the wider interest of government, motivated by decentralisation of care and accessibility of patient centred healthcare, clinical quality of care, and sustainability, particularly costs efficiency are the key enablers.

Further to the above, telemedicine proffers the potential opportunity to keep patients connected and engaged with the healthcare system regardless of geographical bounds, for timely access to clinical care and reductions in the need for in-hospital care when it can be avoided. In spite of many trials of telemedicine in general and the few in GDM care, translation and embedding of telemedicine in routine care has been progressing at a slower pace. Contributing to the slow uptake are the mixed and often inconclusive evidence, implementation issues, entrenched behaviours and
practices, organisational readiness to change, sociodemographic and economic factors, as well as limitations of technology itself, particularly the dissonance between technology and existing healthcare ecosystems.

Specifically in GDM evidence for telemedicine holds much promise but evidence is limited. I conceived, implemented and evaluated an exploratory randomised control trial with the view to answering questions around innovative use of current technology to support clinical care in the management of GDM a real world setting. The intervention was telemedicine adjunct to usual care. The intervention was complex, involving a web-based telemedicine system (patient controlled personal health record) for patients to enter and share GDM self-monitoring data with the GDM clinical care team and an induction/training for both patients and clinicians to capacitate interaction and engagement with the telemedicine system.

My study investigated the effects of the intervention on a range of health service indicators and a range of maternal and foetal clinical outcomes including supplementary quality and process evaluation. The overall findings was that telemedicine implemented to support care in the management of insulin-treated GDM produces similar outcomes as usual care processes. There was one but important demonstrable advantage that patients supported through telemedicine reached insulin dose stabilisation earlier as a proxy marker of optimum glycaemic control. Furthermore, while not superior to usual care in terms of all other outcomes, importantly, albeit with caution, there was no evidence that telemedicine compromised quality of care in GDM, suggesting it may be a safe approach for supporting GDM care. Nonetheless effort is needed to develop integrated technological systems or solutions that are, user friendly, and keep the work of using technology to the minimum. These would need to be supported by the implementing organisation’s systems and processes that provide an enabling environment for readiness to change to embrace telemedicine.

Finally, as packaged intervention telemedicine will need to be cost effective while enhancing access to healthcare, inclusive of patients from all sociodemographic and economic backgrounds. Telemedicine will need to be scalable, organisationally sustainable and at the very least maintain clinician quality of care.
In closing, my thesis and the study central to it have demonstrated that telemedicine used to support GDM care is a complex intervention involving a coalescence of technology, the healthcare system or organisation, clinicians and patients. Despite the complexity telemedicine can play an important role in supporting the management of GDM in that while it does not alter the course of outpatient clinic visits, it provides clinical quality of care which is as good as usual care processes. My findings also underscore the need for further research definitive trials for conclusive evidence of telemedicine for the management of GDM.
REFERENCES


72. Bowling A. Research Methods In Health. Investigating Health And Health Services [Book]


12/17/received


APPENDIX 1. SYSTEMATIC LITERATURE REVIEW PROTOCOL

Literature Search

I performed an electronic search of the literature for English publications across multiple databases; MEDLINE, EMBASE, PUBMED, CINAHL, the Cochrane Central Register of Controlled Trials and the World Health Organisation International Clinical Trials Registry Platform. The search will use Medical Subject Headings (MeSH) and free text to cover the various synonyms of the search terms outlined in Appendix 1. Bibliography and reference lists of included studies will be scrutinised for further relevant studies. The search will be limited to publications from 1st January 1990 to 31st August 2013. The rationale for this search start date is that results of a systematic review of telemedicine [28] showed that the publications on telemedicine in chronic disease management emerged in 1990. Literature screening will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2009) [165] (Appendix 2).

Inclusion Criteria

The criteria for inclusion of literature will be publications on telemedicine interventions in women with GDM. Such interventions would be implemented for the purpose of monitoring, consultation and proving feedback to patients and will include use of telephone, video-conferencing, mobile short message segments (SMS), or web-based interfaces and other remote wireless relay systems. Experimental, quasi-experimental and non-experimental design studies will be included. Owing to possible paucity of the literature, non-English publications will be included and translated.

Exclusion Criteria

Exclusions are literature pertaining to other forms of diabetes or other population groups or studies whose aim is to assess reliability and validity of telemedicine modalities.

Study Selection

A search of the literature will be performed by TR according to the search strategy outlined above. TR and IB will primarily independently screen studies for inclusion. JF
will assist IB in the screening process. Uncertainties to include or exclude a study will be resolved by consensus between TR and IB. Non-consensus will be resolved by an arbiter, KL and if a decision cannot be reached the publication in question will be excluded. At the outset titles and/or abstracts will be used to identify relevant papers. Where the latter identification process is inconclusive, identification proceeds to reviewing full text articles of the publication in question, for relevance and inclusion or exclusion. Full text articles in the final list will be obtained for quality assessment, data extraction and synthesis. Attempts will be made to contact authors should further data be required.

Outcomes

The systematic review will explore the following outcomes:

Primary outcomes

i. Service utilisation and costs
ii. Blood glucose control
iii. Neonate birth weight

Secondary outcomes

i. Mode of delivery
ii. Gestational age at delivery
iii. Macrosomia
iv. Neonatal intensive care admission
v. Quality of life

Included papers will be assessed for methodological quality using the Downs and Black [166] checklist (Appendix 3). The checklist was developed as a tool to assess the quality of studies that use randomised or non-randomised designs. The tool is a 27 item checklist with five sub-scales; reporting, external validity, internal validity (bias), internal validity (confounding/selections bias) and power, aggregated to give a possible best score of 32. The checklist has no indicated cut offs to decide whether a given study is of a high or low quality but the authors reported an overall mean (sd) of 14.0(6.39) for RCTs and 11.7 (4.64) for non-randomised studies. Hence for the purpose of this review
scores greater than these reported averages will be classified as being of higher methodological quality.

**Literature Search Terms**

The following subject search terms (based on general knowledge and perusal of key literature key words) and their variants using wildcards will be used in combination with “Gestational Diabetes” or “GDM”:

- Telemedicine OR Tele-medicine
- Telehealth OR Tele-health
- Telemonitoring OR Tele-monitoring
- Telecare OR Tele-care
- Electronic monitoring
- ehealth OR e-health
- Wireless
- Technology
- SMS, Short message
- Videoconferencing, Video-conferencing
- Telephone

**Data Analysis and Synthesis**

The systematic review was developed and presented following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2009) guideline [167].

A quality index based on the Downs and Black checklist will be computed for each included study and an overall mean (sd) of the studies will be calculated. A meta-analysis of RCTs and quasi-experimental studies will be performed. The $I^2$ statistics will be used to assess consistency of study findings[168]. The suggested cut-off levels for quantifying inconsistency (heterogeneity) in meta-analyses are low ($I^2=25\%$), moderate ($I^2=50\%$) and high ($I^2=75\%$). Where there is evidence of too much inconsistency in my analysis, defined as $I^2$ statistics equal or greater than 75%, results will be presented as descriptive statistics and narrative in lieu of pooled data meta-analysis. Non-experimental or observational studies will be presented as a narrative summary.
Data analyses will be performed using RevMan 5 (The Cochrane Collaboration, Copenhagen). Continuous outcomes data will be evaluated as mean differences. Odds ratios will be calculated for dichotomous variables. Effect size of each outcome outcomes will be calculated and results graphically presented as forest plots. Data will be pooled regardless of the type of telemedicine approach. However, subgroup analysis will be performed according to 1) type of GDM treatment (insulin vs. other (oral hypoglycaemic agents or lifestyle modification)), and 2) high quality studies based on the quality index cut off stated above.
June 20, 2014

A/Prof. K. Lim
NORTHERN HEALTH

Dear A/Prof. Lim,

Subject: PO11/14 – TELEMEDICINE FOR INSULIN TREATED GESTATIONAL DIABETES MELLITUS (TeleGDM)

The Northern Health HREC at its meeting on June 17, 2014 considered your subject study.

The Committee has ratified this study until December 2015. Could you please correct No. 3 para 3 in the PICF by reversing 'current your' and could you please advise what safety/warning procedures are in place should the mother accidently enter the wrong data and receive inappropriate advice re her treatment?

To enable the Committee to fulfill its obligations in relation to monitoring the program, you are asked to provide a report within 12 months (due July 1 annually), or on completion of your project whichever is earlier.

You must also inform The Northern Hospital Human Research and Ethics Committee immediately of any matter, which arises that, may affect the nature of the approved program. Should you require any further assistance please do not hesitate to contact Cheryle Williams, Secretary HREC on 8405 2918.

Yours sincerely,

Prof. Peter Brooks AM MD FRACP FAFRM FAFPHM FRCP (Glas, Edin)
MD Hon Causa (Lund)
Executive Director Research
NORTHERN HEALTH

Northern Health
The Northern Hospital
Pine Health Service
Craigieburn Health Service
Broadmeadows Health Service
Bundoora Extended Care Centre

The Northern Hospital
185 Cooper Street
Epping Victoria 3076
Phone: 8405 2918
Fax: 8405 2930

www.nh.org.au
26th August 2015

Dear Kwang,

Re: Amendment form dated: 16 July 2015

Type of review: Human Research Ethics Committee

HREC Reference Number: P/11/14
SSA Number: N/A
Protocol Number:

Study Title: Telemedicine for insulin treated gestational diabetes mellitus (TeleGDM)

I am pleased to advise that the amendment to the above project has been reviewed and approved by the Northern Health HREC on 24th August 2015.

Approval Period: Extended till 31 December 2016

Approved Documents:

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<tr>
<td>Patient Information &amp; Consent Form</td>
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<td>Protocol</td>
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Noted Documents:

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Please refer to the Northern Health Office for Research & Ethics website to access guidelines and other information and news concerning research at: [http://www.nh.org.au/research/ethics](http://www.nh.org.au/research/ethics)

For any queries about this matter, please contact Ms Rita Wong on 8405 2918 or via email on: rita.wong@nh.org.au.

Yours sincerely,

Mr Kollen Sussman
Director Education & Research

Acting Chair, Northern Health Human Research Ethics Committee

Copy: Tshepo Rasekaba
APPENDIX 3. DOWNS AND BLACK CHECKLIST FOR MEASURING STUDY QUALITY

Reporting

1) Is the hypothesis/aim/objective of the study clearly described?

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2) Are the main outcomes to be measured clearly described in the Introduction or Methods section? If the main outcomes are first mentioned in the Results section, the question should be answered no.

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3) Are the characteristics of the patients included in the study clearly described? Are the interventions of interest clearly described? In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

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4) Are the interventions of interest clearly described? Treatments and placebo (where relevant) that are to be compared should be clearly described.

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5) Are the distributions of principal confounders in each group of subjects to be compared clearly described? A list of principal confounders is provided.

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6) Are the main findings of the study clearly described? Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

| Yes | 1 |
7) Does the study provide estimates of the random variability in the data for the main outcomes? In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

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8) Have all important adverse events that may be a consequence of the intervention been reported? This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

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9) Have the characteristics of patients lost to follow-up been described? This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no, where a study does not report the number of patients lost to follow-up.

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10) Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?

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**External validity**

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11) Were the subjects asked to participate in the study representative of the entire population from which they were recruited? The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from
which the patients are derived, the question should be answered as unable to determine.

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12) Were those subjects who were prepared to participate, representative of the entire population from which they were recruited? The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

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13) Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive? For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

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**Internal validity - bias**

14) Was an attempt made to blind study subjects to the intervention they have received? For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

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15) Was an attempt made to blind those measuring the main outcomes of the intervention?

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16) If any of the results of the study were based on “data dredging”, was this made clear? Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

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17) In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

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18) Were the statistical tests used to assess the main outcomes appropriate? The statistical techniques used must be appropriate to the data. For example nonparametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

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19) Was compliance with the intervention/s reliable? Where there was non-compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

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20) Were the main outcome measures used accurate (valid and reliable)? For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

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**Internal validity – confounding (selection bias)**

21) Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

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22) Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

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23) Were study subjects randomised to intervention groups? Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.

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</table>

24) Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.
25) Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In nonrandomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

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</table>

26) Were losses of patients to follow-up taken into account? If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

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Power

27) Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%? Sample sizes have been calculated to detect a difference of x% and y%.

<table>
<thead>
<tr>
<th>Size of smallest intervention group</th>
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<tbody>
<tr>
<td>A &lt;n₁</td>
<td>0</td>
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<tr>
<td>B n₁-n₂</td>
<td>1</td>
</tr>
<tr>
<td>C n₃-n₄</td>
<td>2</td>
</tr>
<tr>
<td>D n₅-n₆</td>
<td>3</td>
</tr>
<tr>
<td>E n₇-n₈</td>
<td>4</td>
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<tr>
<td>F n₈+</td>
<td>5</td>
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</table>
## Appendix 4. Summary Table of the Telehealth Evaluation Framework

Table 1: Proposed framework for telehealth evaluation in Australia

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<tbody>
<tr>
<td></td>
<td>Changes in individual’s productivity</td>
<td>Number of days of leave for health reasons</td>
<td>Changes in an individual’s productivity, and days of leave for health reasons, can be a simple and clear measure of improved quality of life.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Changes in access to required healthcare service</td>
<td>Number of in person appointments, number of telehealth appointments</td>
<td>Access to required healthcare services is proposed to be a significant benefit of implementing telehealth. Time and cost savings may not be accurate measures. However, a change in the number of in person appointments could help in explaining whether or not telehealth has improved access to healthcare.</td>
<td></td>
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<td></td>
<td>Mortality rate</td>
<td>Number of deaths of patients using telehealth in comparison to in person delivery of care</td>
<td>This is a vital measurement of how safe and effective the treatment provided via telehealth is to the patient. This is an important determinant of the quality of care provided via telehealth.</td>
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<td></td>
<td>The accuracy of a key measure in any illness – BP, blood sugar, physical activity, movement etc.</td>
<td>Clinical indicators</td>
<td>This criterion accommodates for changes to various determinants of good health. These determinants will vary across specialities, but provide a good way to measure the effectiveness of diagnostics / treatment provided via telehealth consultations.</td>
<td></td>
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</table>

**Patient Control**
- Responsiveness: Healthcare service is patient oriented. The client is treated with dignity, confidentiality and encouraged to participate in choices related to their care.
- Accessibility: People can obtain healthcare at the right place, at the right time irrespective of incomes, physical location and cultural backgrounds.
- Continuity of care: Ability to receive uninterrupted coordinated care or service across programs, practitioners, organisations and levels over time.
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<tr>
<td>Organisation sustainiability</td>
<td>Efficiency &amp; Sustainability: Achieving desired results with most cost effective use of resources. Capacity of system to sustain workforce and infrastructure, to innovate and respond to emerging needs.</td>
<td>Cost to run the telehealth service for healthcare provider.</td>
<td>Fixed Cost in comparison to alternative modes of treatment. Variable Cost in comparison to other modes of treatment.</td>
<td>Fixed costs, such as capital investment in equipment and variable costs include maintenance and repairs, telecommunication costs, administrative support and supplies, training, wages to technicians and clinical staff. Measuring both these fixed and variable costs will provide an overall picture of how much has been invested into the telehealth project.</td>
</tr>
<tr>
<td>Technology capability/capacity</td>
<td>Link to ACRRM telehealth advisory committee standards framework (2012): Technical aspects of telehealth: Adequate performance: equipment works reliably and well over available network and bandwidth. Equipment is compatible with equipment used at other sites. Standards relevant to security of storage and transmission are met. Peripheral devices are fit for purpose. Commissioning of equipment: Equipment installed according to producer’s guidelines. Equipment and connectivity are tested with other participating healthcare organisations. Risk management: Risk analysis is performed. Procedures for detecting, diagnosing and fixing equipment are in place. Technical support services are available. Backup plan to cope with equipment or connectivity failure.</td>
<td>Reliability</td>
<td>Number of successful consultations.</td>
<td>The reliability of telehealth technology must be evaluated as it can affect the quality of care. The number of successful consultations is a good measure of the impacts of speed, distance and connectivity.</td>
</tr>
<tr>
<td></td>
<td>Data quality</td>
<td>Number of instances data was re-sent during/after teleconsultation (post measure).</td>
<td>The quality of the data being transmitted, whether it be audio, or images, is important as it can have an impact on the decision making and quality of care. A simple measure, that is not technical in nature, can be used to measure data quality: the number of instances when data was re-sent during/after the teleconsultation.</td>
<td></td>
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</table>
APPENDIX 5. PARTICIPANT INFORMATION AND CONSENT DOCUMENT

PARTICIPANT INFORMATION & CONSENT FORM (PICF)

**Project Name:** Telemedicine for Insulin Treated Gestational Diabetes Mellitus: An Exploratory Pilot Randomised Controlled Trial

NH HREC No: PO11/14

**Principal Investigator:** A/Prof Kwang Lim; Mr Tshepo Rasekaba;

**Other Investigators:** A/Prof John Furler; Dr Irene Blackberry

Participant’s Involvement in project –

Start Date: 30/06/2014

Finish Date: 31/12/2016

Participant Information:

1. Introduction

You are invited to take part in this research project. Your diabetes nurse educator passed on your information to us to contact you about the project. This is because you have been diagnosed with pregnancy related diabetes or gestational diabetes mellitus (GDM). The research project aims to understand whether using an internet and/or mobile phone based facility to send blood sugar, diet and insulin information to your care team can improve the management of GDM. Specifically we wish to understand whether the impact of this
approach on clinic attendance, blood sugar control and pregnancy outcomes, and your satisfaction with this approach to service.

This Participant Information and Consent Form tells you about the research project. It explains what is involved to help you decide if you want to take part.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local health worker.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to be involved in the procedures described;
- consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. **What is the purpose of this research project?**

High levels of blood sugars associated with pregnancy (gestational diabetes mellitus (GDM)) affects a significant number of women. There is a high demand for GDM services at the Northern Hospital. Telemedicine is viewed as possible way of managing GDM but its use in GDM is less understood. Therefore we would like to trial telemedicine using Online Heath Portfolio (OHP) in at least 100 pregnant women with GDM and are treated with insulin.

In addition to helping improve services for pregnant women at Northern Health, this project forms part of study for Tshepo Rasekaba to obtain a higher research degree (PhD). It is funded by the Northern Health.

3. **What does participation in this research project involve?**

You will monitor your blood sugars, diet at home according to normal care and advice from your diabetes care team. The study is what is referred to as a randomised controlled trial, meaning one group of women will be continue to receive current normal care while the other group will receive normal care plus a new approach (TeleGDM) briefly explained below.

What is new is that instead of waiting to show your diabetes care team the logbook of the results you will use OHP over the internet or mobile phone to send this information daily and before your scheduled appointment. Note that this applies to when you are assigned to the TeleGDM group. We will assist you with getting set up on OHP at no cost to you. OHP also allows you to keep in contact with your health carers.

At six weeks after joining the study we will ask you to complete a questionnaire that takes about 10minutes. The other thing we would like to ask is your permission for us to get additional information from your medical records. This information is about previous
pregnancies, how your current baby is delivered (that is whether by caesarean or other methods), the weight and size of the baby, and the care the baby receives following delivery.

Overall your involvement in the study will start from when you agree to participate until your baby is born. After your baby is born we can close your OHP account if you let us know. However, you are free to continue using the account for free for 12 months from the time you join the study. After the twelve months any plans to continue using OHP will be a matter between you and the company that we use to provide OHP.

4. **What are the possible benefits?**

You will have access to an online facility (OHP) for free for 12 months to assist you manage diabetes. Also by participating it means you can get early advice about managing GDM, should this be required, instead of waiting for your appointment.

5. **What are the possible risks?**

There are no foreseeable major risks other than minimal inconvenience to your time to discuss participation in the study, completing the questionnaire and devoting time to upload data on the internet.

If you become upset or distressed as a result of your participation in the research, the researcher is able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team.

6. **Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage.

If you decide to withdraw, please notify a member of the research team. This notice will allow that person or the research supervisor to inform you if there are any special requirements linked to withdrawing.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the researchers or Northern Health or the University of Melbourne.

7. **How will I be informed of the final results of this research project?**

A summary report can be provided at the completion of the full research in 2016 and you will be informed by email when it is ready.

8. **What will happen to information about me?**

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as permitted by law.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

9. **Can I access research information kept about me?**

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you.
Please contact one of the researchers named at the end of this document if you would like to access your information.

In addition, in accordance with regulatory guidelines, the information collected in this research project will be kept for at least 5 years. You must be aware that the information collected about you may at some point not be able to be identified once the identifying information has been removed.

10. **Is this research project approved?**

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of Northern Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.
11. Consent

I have read, or have had this document read to me in a language that I understand, and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I agree to participate in this research project, as described.

I understand that I will be given a signed copy of this document to keep.

Participant’s name (printed) .................................
Signature ......................................................... Date

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher’s name (printed) .................................
Signature ......................................................... Date

Note: All parties signing the consent section must date their own signature.
12. Who can I contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact Tshepo (the student researcher) on 0417 129 946 or any of the following people:

Name: A/Prof Kwang Lim
Role: Principal researcher
Telephone: 8405 2018, email: Kwang.Lim@nh.org.au

For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name: Ms Cheryle Williams
Role: Ethics Secretariat and Governance, Northern Human Research Ethics Committee
Telephone: 8405 2918, email: nhresearch@nh.org.au
For Questions & Queries Contact:

Tshepo Rasekaba
Email: tshepo.rasekaba@nh.org.au
Tel. 0417 129 946

TeleGDM Project:
Using technology to assist you manage diabetes in pregnancy better

What is the TeleGDM project?
A Northern Health study involving women diagnosed with diabetes during pregnancy (GDM). It is a randomised controlled trial (RCT), meaning some women who agree to participate will be assigned to trial an online system to send their blood sugar readings, information about insulin dose, diet and symptoms ahead of their clinic appointment. The other group of women will continue to use the paper diary to record their GDM management information. We hope this will keep you in regular contact with your healthcare providers even when you are not attending the clinic and may improve GDM management and improve pregnancy outcomes.

Who is eligible to participate?
Any woman who is
• Up to 35 weeks pregnant,
• Has been diagnosed with GDM,
• Is currently using insulin,
• Understands English
• Has access to a computer with internet and/or smartphone

I am interested who can I contact?
Talk to your GDM health care provider or contact the researcher below.

Researcher and trial coordinator:
Tshepo Rasekaba
Email: tshepo.rasekaba@nh.org.au
Tel. 0417 129 946
APPENDIX 7. LOCAL NEWSPAPER MEDIA PROMOTION

Whittlesea Leader 23 December 2014. Page 11

App for easier delivery

EXPECTANT mums with gestational diabetes mellitus can be taking part in an innovative trial that monitors their health without the burden of attending regular obstetrician appointments.

The groundbreaking free TeleGDM trial at Northern Health uses a smartphone app to manage diabetes in pregnant women.

The trial participants save time and interruption to their day by not needing to attend the gestational diabetes clinic, instead entering their data electronically into an online system that is monitored by the care team and raises alerts for timely corrective action.

Craigieburn resident and mum of two with another on the way Lisa McNally, 33, (pictured) said the trial was a time saver.

“I didn’t have diabetes with my first (baby), this is my first time,” she said.

Ms McNally uses the app to log her glucose readings, when she uses insulin and occasionally her food intake.

“If people use a lot of technology like I do, it’s heaps easier to keep in contact with the dietitian but also my obstetrician,” she said.

Expectant mothers with gestational diabetes accessing Northern Health maternity services can participate in the trial by phoning Tshepo Rasekaba on 8405 8999 or email tshepo
rasekaba@nh.org.au
APPENDIX 8. OUTLINE OF PATIENT INDUCTION CHECKLIST AND PATIENT HAND-OUT

A. Participant Induction Checklist

Number:_______  Group:_____________  Date:_______________

☐ PICF

For those randomised to use OHP:

**Sign up**

☐ Username and password

☐ Given list of clinicians

☐ Explained no cost to participant to use OHP

**Data upload**

☐ Manual upload – BGL, Insulin, Diet, Symptoms

☐ Data upload frequency (daily)

☐ Messaging and SMS

☐ Alerts and reminders

☐ Practice data entry – Glucose, Insulin, My Nutrition

**Clinician invitation**

☐ Tshepo Rasekaba (Clinical Research)

☐ Diabetes Nurse Educators at TNH GDM-DE (First Name: Diabetes Nurse Educators, Last Name: TeleGDM, Practice Name: Northern Health)

☐ Diabetes Nurse Educators at BHS and CHS (First Name: CDE, Last Name: BHSCHS, Practice Name: Broadmeadows and Craigieburn Health Services)

☐ Endocrinologists (First Name: Endocrinology, Last Name: TeleGDM, Practice Name: Northern Health)

☐ Dietitian (First Name: Dietitian, Last Name: TeleGDM, Practice Name: Northern Health)
Obstetrician (First Name: Obstetrician, Last Name: TeleGDM, Practice Name: Northern Health)

Comments:______________________________________________________________
____________________________________________________________________
B. Patient hand-out

1. Signing Up on OHP
   - Online Health Portfolio webpage: www.onlinehealthportfolio.com
   - Ensure and/or guide the participant through the sign-up process

2. Go to <PATIENT SIGN UP>
   - Check “I agree to terms and conditions”
   - Next

3. Creating OHP account
   - Choose “Gold Service Package”
   - (Reiterate to participant the indicated cost will be covered by the study)
   - Enter all required information
   - Note:
     - Mobile to be entered starting with 4
     - Time zone: (UTC+10:00) Canberra, Melbourne
   - Next, then login into OHP

4. Add healthcare/medical care professionals (see clinicians under checklist)
   4.1. This allows healthcare professionals and researcher to view data and communicate with participant
   4.2. Go to:
      - Personal Data and Settings
      - My Carers
      - Add Medical or Healthcare professional
      - Type in details to search for appropriate carers:
        - Tshepo Rasekaba (Clinical Research)
        - Diabetes Nurse Educators at TNH GDM-DE (First Name: Diabetes Nurse Educators, Last Name: TeleGDM, Practice Name: Northern Health)
        - Diabetes Nurse Educators at BHS and CHS (First Name: CDE, Last Name: BHSCHS, Practice Name: Broadmeadows and Craigieburn Health Services)
        - Endocrinologists (First Name: Endocrinology, Last Name: TeleGDM, Practice Name: Northern Health)
        - Dietitian (First Name: Dietitian, Last Name: TeleGDM, Practice Name: Northern Health)
Obstetrician (First Name: Obstetrician, Last Name: TeleGDM, Practice Name: Northern Health)

- Select and save each carer

5. Data Entry

5.1. Measurements

5.1.1. Glucose

5.1.2. Add New

5.1.2.1. Practice data entry using previous day's data and current day's date from log book

5.1.2.2. Ensure selection of appropriate meal times from the drop down box and selection of correct units (mmol/l) to right of the BSL reading box

5.1.2.3. Notes Box: enter meals/dietary information, symptoms or any information you deem important to relay to carers.

5.1.2.4. Once all BGL data are entered, save

5.1.3. Insulin

5.1.3.1. It follows similar format to glucose

5.1.3.2. Enter actual number (ONLY) of units of insulin administered and when taken (the day's meal it corresponds to, i.e. before breakfast, dinner, after dinner or night)

5.1.3.3. Select the type of insulin for the drop down box. The most commonly used insulin are listed. If not, select "Other" and specify the adjacent box.

5.2. My Nutrition

5.2.1. Add new-micronutrients or calories as indicated if applicable. Otherwise, entry of actual meal (e.g. piece of toast, boiled egg and fruit for breakfast) in 'Notes Box' is sufficient.

6. Data View

6.1. Table View/Logbook View

6.1.1. Table view is the default view for Glucose and Insulin data

6.1.2. Below the table is a list of tabs one of which is "Logbook View". Clicking on this tab allows 7-day data view in a logbook format. Selection can be made back or forward.

7. Finally:
- Remember to enter your data daily data entry. Tailored, relevant support for GDM management relies on regular data availability.
- We will give you a courtesy call after approximately two days to ask if “everything is going well with data entry or check if you have any have any questions” or
- We will also call you if we note that you have not entered new data and work to out what issue you might experiencing”
- If you need reminders remember alerts/auto-reminders can be set up to remind you to test and enter data.
APPENDIX 9. NORTHERN HEALTH GDM SCREENING POLICY/GUIDELINE

Document Type: Level 2 – NH Policy & Procedure
Department: O&G Services
Section: NH – Clinical Manual
Subject: Screening and Management of Diabetes Mellitus in Pregnancy
Approved by: Chief Executive Officer

PURPOSE & SCOPE
To advise all Antenatal Clinic Staff on:
1. Screening for gestational diabetes during pregnancy
2. The Model of Care for Women with Gestational Diabetes

DEFINITIONS
- Pre-pregnancy Diabetes Mellitus - present before pregnancy:
  - Can be Type 1 or Type 2 in nature
  - If not diagnosed pre-pregnancy, diabetes mellitus diagnosed prior to 20 weeks gestation may be pre-pregnancy diabetes mellitus

- Gestational Diabetes:
  - Develops in pregnancy when pancreatic function is not sufficient to overcome the insulin resistance created by diabetogenic hormones secreted during pregnancy

- GTT consists of a 75g glucose load after an overnight fast, Fasting, 1 hour and 2 hour plasma glucose levels are measured

OUTCOME
To effectively diagnose and manage diabetes in pregnancy to decrease the risk of:

- Obstetric complications:
  - Polyhydramnios
  - Hypertension and Pre-edampsia
  - Operative delivery
  - Post partum haemorrhage
  - Perinatal mortality

- Neonatal sequelae:
  - Fetal hyperinsulinaemia → Neonatal hypoglycaemia
  - Hypocalcaemia/hypomagnesaemia
  - Macrosomia
  - Birth trauma
  - Polycythemia and jaundice
  - Respiratory distress syndrome

POLICY
The Northern Health policy on the Screening and Management of Diabetes Mellitus in Pregnancy is:-

SCREENING FOR DIABETES IN PREGNANCY:
- GTT at booking visit for women with any of the following risk factors for GDM:
  - Past history of GDM
  - Ethnicity: Asian (including Indian, Pakistani, Bangladeshi, Sri Lankan South Asians), Aboriginal, Pacific Islander, Maori, Middle Eastern, non-white African
  - Maternal age ≥ 40 years
  - Family history DM (1st degree relative with T2DM or a sister with GDM)
o BMI >35
o Previous baby >4500g
o Past history of Polycystic Ovarian Syndrome (PCOS)
o Medications: corticosteroids, antipsychotics

GTT at 24-28 weeks’ gestation for all remaining women, and those with a negative early GTT

GDM diagnosed if:
- Fasting glucose >= 5.1 mmol/L
- 1-hr glucose >= 10.0 mmol/L
- 2-hr glucose >= 8.5 mmol/L

GCT has poor sensitivity and specificity and should not be used.

ANTENATAL MANAGEMENT OF DIABETICS IN PREGNANCY:

1. Communication of abnormal results:
   - Positive GTT results to be reported from pathology laboratory to a DNE who is to then arrange:
     - an initial education session with the patient within 3 days
     - an obstetrics appointment at any campus within 1 week
     - and an appointment with a dietitian at BHS or TNH within 1 week

2. Model of care:
   - All women with pre-pregnancy Type 1 or Type 2 Diabetes Mellitus, or early diagnosis (prior to 20 weeks’ gestation) gestational diabetes mellitus to be treated in the Diabetes antenatal clinic at TNH
   - All women with GDM to be managed in the obstetrics care model
   - Women are to transfer to the Diabetes ANC at TNH for consideration of Metformin or Insulin therapy if they have 2x BSLs greater than target levels in one week AND/OR if they have macrosomia with an AC or EFW >90th centile

3. Home blood glucose monitoring:
   - Patient is to undertake home glucose monitoring of fasting and 2 hour post prandial BSLs
   - BSL targets are fasting BSL of <5.1 and 2 hour post prandial BSL of <6.8

4. Fetal surveillance:
   - Women need to be reminded of the need to monitor fetal movements and to report decreased fetal movements
   - Fundal Height and Blood Pressure is to be measured at every ANC visit
   - Third trimester USS to be ordered at ~36/40 to assess for macrosomia, or at other times +/- repeated if there is concern re: IUGR
   - Antenatal CTG is not routine in GDM. CTG to be ordered in the event of decreased fetal movements, suspected or ultrasound defined IUGR. Consider CTG in the event of large insulin requirements, macrosomia or poor glycaemic control.

TIMING OF DELIVERY:
- Women with diet-controlled GDM with no complications should be induced at 40 weeks’ gestation
- For women requiring insulin, with suspected fetal macrosomia, with other obstetric complications, or with poorly controlled GDM, induction may be considered from 38 weeks’ gestation
- Women having an elective caesarean section should have this booked for 38 weeks’ gestation
INTRAPARTUM MANAGEMENT:
- Obstetric registrar to be informed
- Continuous CTG
- If insulin requiring GDM or T2DM – withhold insulin
- Check BSL on admission and then hourly
- Treat with 4 hourly doses of Actrapid according to sliding scale if needed:
  - BSL 0-6 = 2 Units Actrapid
  - BSL 7-10 = 4 Units Actrapid
  - BSL >10 = 6 Units Actrapid
- 2nd stage management to anticipate shoulder dystocia
- Active management of 3rd stage

POST PARTUM:
- GTT at 6 weeks postpartum with classification according to the WHO criteria
- If GTT at 6 weeks is normal, women should have repeat GTT at least every 2 years due to 40-60% risk of developing T2DM within 10-15 years

ASSOCIATED PROCEDURES
Insulin infusion guidelines for Type 1 Diabetes in labour
Hypoglycaemia in newborn infants

KEY PERFORMANCE INDICATORS/ COMPLIANCE/EVALUATION
Percentage of women receiving adequate screening at booking and at 24-28 weeks’ gestation

AUTHORS
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Dr Alexis Shub (FRANZCOG, MFM subspecialist, senior lecturer),
Dr Suresh Varadarajan (Endocrinologist)
Dr Alex Teare (Obstetrician and Gynaecologist, Clinical Director Obstetrics and Gynaecology, TNH)

REFERENCES
- TNH ‘Management of Diabetes in Pregnancy’ Policy created 2010 and last reviewed 2011

FURTHER INFORMATION
- Diabetes Nurse Educators at Northern Health
- ADIPS
APPENDIX 10. TELEGDM SCHEMATIC

Patient home self-monitoring (Home)

Patient data entry devices (Home)

Wireless/network data relay

Data collection repository & server

Urgent SMS Feedback

DNE +/- Endo Data Evaluations

Information sharing

General Practice

Network relay

Hospital Access Station

Patient level self monitoring

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APPENDIX 11. CLIENT SATISFACTION QUESTIONNAIRE-8 ITEM (CSQ-8)

Please help us improve our service by answering some questions about the help that you have received. We are interested in your honest opinions, whether they are positive or negative. Please answer all of the questions. We also welcome your comments and suggestions. Thank you very much. We appreciate your help.

CIRCLE YOUR ANSWERS

1. How would you rate the quality of service you received?

<table>
<thead>
<tr>
<th></th>
<th>4 Excellent</th>
<th>3 Good</th>
<th>2 Fair</th>
<th>1 Poor</th>
</tr>
</thead>
</table>

2. Did you get the kind of service you wanted?

<table>
<thead>
<tr>
<th></th>
<th>1 No, definitely not</th>
<th>2 No, not really</th>
<th>3 Yes, generally</th>
<th>4 Yes, definitely</th>
</tr>
</thead>
</table>

3. To what extent has our service met your needs?

<table>
<thead>
<tr>
<th></th>
<th>4 Almost all of my needs have been met</th>
<th>3 Most of my needs have been met</th>
<th>2 Only a few of my needs have been met</th>
<th>1 None of my needs have been met</th>
</tr>
</thead>
</table>

4. If a friend were in need of similar help, would you recommend our service to him or her?

<table>
<thead>
<tr>
<th></th>
<th>1 No, definitely not</th>
<th>2 No, I don’t think so</th>
<th>3 Yes, I think so</th>
<th>4 Yes, definitely</th>
</tr>
</thead>
</table>

5. How satisfied are you with the amount of help you received?

<table>
<thead>
<tr>
<th></th>
<th>1 Quite dissatisfied</th>
<th>2 Indifferent or mildly dissatisfied</th>
<th>3 Mostly satisfied</th>
<th>4 Very satisfied</th>
</tr>
</thead>
</table>

6. Have the services you received helped you to deal more effectively with your problems?

<table>
<thead>
<tr>
<th></th>
<th>4 Yes, they helped a great deal</th>
<th>3 Yes, they helped somewhat</th>
<th>2 No, they really didn’t help</th>
<th>1 No, they seemed to make things worse</th>
</tr>
</thead>
</table>

7. In an overall, general sense, how satisfied are you with the service you received?

<table>
<thead>
<tr>
<th></th>
<th>4 Very satisfied</th>
<th>3 Mostly satisfied</th>
<th>2 Indifferent or mildly dissatisfied</th>
<th>1 Quite dissatisfied</th>
</tr>
</thead>
</table>

8. If you were to seek help again, would you come back to our service?

<table>
<thead>
<tr>
<th></th>
<th>1 No, definitely not</th>
<th>2 No, I don’t think so</th>
<th>3 Yes, I think so</th>
<th>4 Yes, definitely</th>
</tr>
</thead>
</table>

WRITE ANY COMMENTS OVERLEAF

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TMS:100
**APPENDIX 12. DIABETES EMPOWERMENT SCALE-SHORT FORM (DES-SF)**

The 8 items below constitute the DES-SF. The scale is scored by averaging the scores of all completed items (Strongly Disagree =1, Strongly Agree = 5)

Check the box that gives the best answer for you.

In general, I believe that I:

<table>
<thead>
<tr>
<th>Item</th>
<th>Statement</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>...know what part(s) of taking care of my diabetes that I am <strong>dissatisfied</strong> with.</td>
<td>[ ] 1 Strongly Disagree</td>
</tr>
<tr>
<td>2.</td>
<td>...am able to turn my diabetes goals into a workable plan.</td>
<td>[ ] 1 Strongly Disagree</td>
</tr>
<tr>
<td>3.</td>
<td>...can try out different ways of overcoming barriers to my diabetes goals.</td>
<td>[ ] 1 Strongly Disagree</td>
</tr>
<tr>
<td>4.</td>
<td>...can find ways to feel better about <strong>having</strong> diabetes.</td>
<td>[ ] 1 Strongly Disagree</td>
</tr>
<tr>
<td>5.</td>
<td>...know the <strong>positive</strong> ways I cope with diabetes-related stress.</td>
<td>[ ] 1 Strongly Disagree</td>
</tr>
<tr>
<td>6.</td>
<td>...can ask for support for having and caring for my diabetes when I need it.</td>
<td>[ ] 1 Strongly Disagree</td>
</tr>
<tr>
<td>7.</td>
<td>...know what helps me stay motivated to care for my diabetes.</td>
<td>[ ] 1 Strongly Disagree</td>
</tr>
<tr>
<td>8.</td>
<td>...know enough about myself as a person to make diabetes care choices that are right for me.</td>
<td>[ ] 1 Strongly Disagree</td>
</tr>
</tbody>
</table>
### Appendix 13. Canada Health Infoway System and Use Assessment Survey

#### Section 1. Overall User Satisfaction

1. In general, how satisfied are you overall with the Online Health Portfolio (OH) system you are currently working with or previously worked with? By “system” we mean, the ease and functionality of the OHP system itself, the quality of the information given and the quality of the services provided for the system.

<table>
<thead>
<tr>
<th>Highly satisfied</th>
<th>Moderately satisfied</th>
<th>Neither satisfied nor dissatisfied</th>
<th>Moderately dissatisfied</th>
<th>Not at all satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Please indicate your level of agreement or disagreement with each of the following statements below.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Moderately Agree</th>
<th>Moderately Disagree</th>
<th>Strongly Disagree</th>
<th>Not Sure</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) The system improves my productivity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) The system improves the quality of care I can provide</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) The system makes my job easier</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) The system enhances our ability to coordinate the continuity of care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) The system improves our sharing of patient information amongst providers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) The system</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
enhances the efficiency of ordering lab tests, X-rays, prescriptions, etc.

g) The alerts, reminders and order set features (i.e. support tools) improve the quality of my decision-making

3. Are there aspects of the system that you would change, and if so, which ones would they be? Please describe your comments.

4. Do you have any experiences with the system where it has supported the provision of care? Please describe your comments.

SECTION 2. SYSTEM QUALITY

5. Based on your experiences to date with the system, how acceptable is the quality of the system itself (as described by the specific characteristics listed below)? Would you say it is;

<table>
<thead>
<tr>
<th>Highly acceptable</th>
<th>Moderately acceptable</th>
<th>Neither acceptable nor unacceptable</th>
<th>Moderately unacceptable</th>
<th>Not at all acceptable</th>
</tr>
</thead>
</table>

6. Please indicate your level of agreement or disagreement with each of the following statements below.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Moderately Agree</th>
<th>Moderately Disagree</th>
<th>Strongly Disagree</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) The system is easy to use</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) The response time is acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) The system is integrated with my workflow</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) The system security is acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) The system features enable me to perform my work well</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
f) The system is reliable in its performance

<table>
<thead>
<tr>
<th>Highly acceptable</th>
<th>Moderately acceptable</th>
<th>Neither acceptable nor unacceptable</th>
<th>Moderately unacceptable</th>
<th>Not at all acceptable</th>
</tr>
</thead>
</table>

SECTION 3: INFORMATION QUALITY

7. In general, when thinking about the quality of the information provided by the system, do you find the quality of the information to be;

<table>
<thead>
<tr>
<th>Highly acceptable</th>
<th>Moderately acceptable</th>
<th>Neither acceptable nor unacceptable</th>
<th>Moderately unacceptable</th>
<th>Not at all acceptable</th>
</tr>
</thead>
</table>

8. Please indicate your level of agreement or disagreement with each of the following statements below.

<table>
<thead>
<tr>
<th>a) The information is complete</th>
<th>Strongly Agree</th>
<th>Moderately Agree</th>
<th>Moderately Disagree</th>
<th>Strongly Disagree</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>b) The information is quickly provided</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) The information provided is accurate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) The information provided is relevant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) The information is available when I need it</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) The format and layout of the information is acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4. SERVICE QUALITY

9. In general, when thinking about the quality of the services (i.e. technical support and training services) provided for the system, do you find the quality of these services to be;

<table>
<thead>
<tr>
<th>Highly acceptable</th>
<th>Moderately acceptable</th>
<th>Neither acceptable nor unacceptable</th>
<th>Moderately unacceptable</th>
<th>Not at all acceptable</th>
</tr>
</thead>
</table>
10. Please indicate your level of agreement or disagreement with each of the following statements below.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Moderately Agree</th>
<th>Moderately Disagree</th>
<th>Strongly Disagree</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) The implementation process at this Hospital or Centre was acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) The current level of training is acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) The level of on-going support provided is acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 6. SYSTEM USAGE

11. In a typical day, how many times do you use the system?

___________Number of times, a day

Always..............

Rarely..............

12. In a typical week, please indicate the number of days in which you use the system.

___________Number of days, a week

13. Please estimate the percentage of your patients that you use the system for?

___________% patients (FILL IN)

Don’t know .............

14. How likely are you to recommend the system to other healthcare providers at other Hospitals or Centres?

| Definitely | Probably | May or may not | Probably Not | Definitely not |
|------------|----------|----------------|--------------|---------------|---------------|

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15. Given a choice, would you like to increase or decrease your future use of the system that you are currently working with? Would that be a significant or moderate increase / decrease, or would you like your future use to stay the same?

<table>
<thead>
<tr>
<th>Significant Increase</th>
<th>Moderately Increase</th>
<th>Moderately Decrease</th>
<th>Significant Decrease</th>
<th>Remain the Same</th>
</tr>
</thead>
</table>

16. How would you describe your “use” of the system? (Check all that apply)

- I use the system for clinical decision making ...........................................
- I use the system to both access patient information and in clinical decision making ...........................................
- I use the system to access patient information and support the clinical decision maker ...........................................

SECTION 7. OTHER COMMENTS

17. Do you have any other comments you would like to make regarding the system?
APPENDIX 14. CLINICIAN INTERVIEW SCHEDULE

As a clinician who had the opportunity to use telemedicine/telehealth in the TeleGDM trial your views on this approach are very valuable. I would like to hear of your experiences, i.e. the good, the bad and the not so good about using telehealth to support women with GDM. These are experiences about providing clinical care, impact on your workflow, usability of the technology (OHP) and its features, how your patients used the telehealth system and how you interacted with them.

The following questions are only a guide but are not intended to limit your views. Feel free to provide as much information and details as possible.

1. During the TeleGDM trial you used a telemedicine/telehealth using OHP to support women with GDM. Can you tell me:
   a. Your overall experience with using telemedicine for the management of GDM?
   b. How confident did you feel accessing data online?
   c. Was using OHP convenient or inconvenient and whether it was or not, how so?
   d. What problems and frustrations did you encounter and how did you deal with them?
2. What are your views of:
   a. Using telemedicine (OHP) compared to usual care alone?
   b. How different or similar was this to usual care?
3. How did using telehealth impact your workflow, patient scheduling and clinical decision making?
4. How often did you:
   a. Access the system?
   b. Interact with patients over the system, i.e. messaging?
   c. Your views on safety and effectiveness of providing care and support via telemedicine?
5. Is telemedicine an approach for everyone or what groups of patients could this be suitable for?
6. What do you think would make clinicians embrace and take up telemedicine in GDM care?

7. If in the future, you had the option to provide care and support via telemedicine or usual care,
   a. What would you choose and what factors would you consider in making the decision/choice?

8. Going into the future what are your suggestions on how we can improve providing GDM management support via telemedicine and what elements/features or improvements of the web-based system do you think might make it better/easier and useful?

9. Please tell me about any other thoughts you haven’t expressed already.

10. Finally, are you okay for me to contact you for some follow-up questions?
APPENDIX 15. PATIENT INTERVIEW SCHEDULE

As you might recall you were a participant in the TeleGDM study, and used Online Health Portfolio to help you manage diabetes during pregnancy or GDM. The purpose of this interview is to get as much of your story as possible on how you found using OHP to manage the diabetes and how you found OHP itself. So there are no right or wrong answers; it’s about your views and experiences noting we have no personal/vested interests in OHP.

1. So to start off tell me about managing GDM itself, how do you think you went with
   a. Managing the diabetes
   b. Insulin
   c. Getting help from the clinicians; and who was involved?
      (That is, what was good, or bad; what worked or didn’t work for you)

2. Let’s focus on the technology/OHP itself. How did that go (again the good, the bad and the bad)
   a. How did it help or didn’t help you manage GDM
   b. Getting support from the clinicians
   c. Attending appointments
   d. Entering data (frequency, confidence, convenience)
   e. What did you use to enter you data, (Smartphone, tablet, Windows computer, Mac)?

3. Tell me about any problems or issues you came across using OHP (what were these problems and how did you deal with (resolve) them?)

4. What suggestions do you have which might help us improve providing GDM management and support via technologies like OHP?

5. If in the future, you were given the opportunity to use telemedicine to support you manage GDM or use the usual way, which would you choose and why?
   a. While we provided OHP free for you to use during that time, what impact would cost have on your choice/decision whether to use technology like OHP?
   b. What other factors would influence your choice?

6. I have a few more general background questions to finish with...If it’s alright,
• Have you had experience with using technology for health, work or on a personal level? (E.g. this may include health consultations, sharing health information, making appointments online, self-monitoring devices e.g. fitbit® and the like etc.)
• How far do you live from the clinic?
• What is the highest level of education you have achieved?
Author/s:
Rasekaba, Tshepo Mokuedi

Title:
Telemedicine for Insulin treated Gestational Diabetes Mellitus (TeleGDM): an exploratory randomised controlled trial of the effects of a web-based GDM support system on health service utilisation, maternal and foetal outcomes, costs and user experiences

Date:
2017

Persistent Link:
http://hdl.handle.net/11343/207988

File Description:
Complete thesis

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