The Hepatitis B Birth-dose Immunisation: Exploring Parental Refusal

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Authors and Affiliations:

1. **Christine E GILMARTIN**
Clinical Trials & Research Pharmacist
The Royal Women's Hospital Pharmacy Department, The Royal Women's Hospital; Parkville, Victoria, Australia
christine.gilmartin@thewomens.org.au
2. **Andrew J DALEY**
Medical Microbiologist & Paediatric Infectious Diseases Physician
Department of Microbiology and Infectious Diseases, The Royal Women's Hospital, Melbourne, Australia
Department of Microbiology, The Royal Children's Hospital, Melbourne, Australia
andrew.daley@rch.org.au
3. **Laura LEUNG**
Clinical Pharmacy Co-ordinator & Antimicrobial Stewardship Pharmacist
The Royal Women's Hospital Pharmacy Department, The Royal Women's Hospital; Parkville, Victoria, Australia
laura.leung@thewomens.org.au

MS. CHRISTINE EMILY-JAYNE GILMARTIN (Orcid ID : 0000-0002-4890-9374)

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Abstract

Background: Hepatitis B Virus (HBV) immunisation is the first vaccine of infant life and one of the most commonly refused immunisations on the Australian Immunisation Schedule.

Aims: To quantify the frequency of declined HBV immunisation birth-doses, investigate reasons for refusal, and determine information sources used by parents.

Materials and Methods: A cross-sectional study using a questionnaire was conducted on postnatal women who declined their newborn's HBV birth-dose immunisation during December 2016 - July 2017 at an Australian tertiary referral hospital. Mothers who were non-English speaking, unwell or medically unstable, or otherwise unavailable were excluded.

Results: 137 of the 1574 (8.7%) eligible reviewed infants had HBV immunisation birth-doses documented as declined. 113 mothers consented to complete the questionnaire. The most common reasons for declining the dose were: "baby too young" (55.8%); preference for 2, 4 and 6-month HBV immunisations only (56.6%); perceived low risk of contracting HBV (45.1%); and a fear of "overloading" their baby's immune system (42.5%). General practitioners or nurse/midwives (43.3%) and the internet/media (33.6%) were the predominant information sources consulted, and 58.4% felt satisfied with the information they received antenatally. 88 of 113 mothers (77.9%) would still consider future immunisations for their infant.

Conclusions: The majority of postnatal women decline HBV birth-dose immunisation for their newborns citing age-related safety concerns and vaccine misconceptions. Informal information sources such as the internet and media are often consulted. Addressing the need for antenatal and health professional education towards the birth-dose may be instrumental in improving uptake.

Introduction

Chronic Hepatitis B virus (HBV) carriage currently affects up to 1.1% of Australia's population and approximately 257 million people world-wide.^{1,2} While some cases of HBV can be asymptomatic, chronic infection can lead to cirrhosis and fatal hepatocellular carcinoma.¹ The rate of progression of acute HBV infection to chronic infection is as high as 90% for those infected perinatally.³ The World Health Organisation (WHO) recommends that all infants receive the birth-dose within 24 hours of birth, then at 2, 4 and 6 months of age.⁴ HBV immunisation coverage for Australian children aged 12 to 15 months was 94.59% in 2018.⁵

It has been argued that antenatal HBV screening using Hepatitis B surface antigen (HBsAg) and vaccination only of high risk or carrier mothers (in conjunction with Hepatitis B immunoglobulin) could suffice as a public health strategy in low prevalence countries such as Australia. However, this approach has inherent vulnerabilities. A notably multicultural nation, many Australians have immigrated from high prevalence countries. Some high risk women may not receive antenatal screening due to late presentation, concealed pregnancies, or socioeconomic barriers to healthcare. Furthermore, some mothers may be unaware of their risk factors or choose not to disclose them. Alternatively, they may acquire HBV after first trimester screening is performed or have a false negative result. Postpartum transmission to infants may also occur via household exposures. The birth-dose aims to provide neonatal protection during the period between birth and 2 months in these scenarios.

All four paediatric doses of the HBV immunisation are included in the Australian National Immunisation Program in line with WHO recommendations.⁶ The HBV birth-dose immunisation is usually offered with parental consent to all infants born at Australian hospitals.

The term vaccine hesitancy (VH) describes the refusal or delay in vaccine acceptance and use.⁷ The cause of this phenomenon may vary with the culture, media, influential leaders, government policies, and pharmaceutical industry of a geographic area.⁷ A 2015 study of vaccine hesitant families at a Victorian paediatric referral hospital revealed that the most frequently omitted vaccines of the 2, 4 and 6-month schedule was the HBV immunisation at 66%.⁸ While some published studies have previously explored VH for

childhood immunisations,⁸ the birth-dose of the HBV immunisation is unique in that it is the first vaccine of an infant's life. This occasion may require a parental decision based on reasoning possibly differing to that of general VH and may affect future immunisation decisions. There are currently no published studies of parental vaccine hesitancy for the HBV birth-dose immunisation in Australia.

The aim of this study was to describe the frequency and reasons for declined Hepatitis B immunisation birth-doses, identify information sources consulted, and determine if patients felt they had received satisfactory information prior to being offered the dose.

Methods

A cross-sectional study was conducted at an Australian tertiary referral obstetric hospital. Medicine charts of infants admitted to postnatal wards during the convenience period of 1st December 2016 to 26th July 2017 were reviewed for HBV birth-dose immunisation status. Mothers who had not consented for their baby to have this immunisation had "declined" documented by the midwife on the neonatal medicine chart order. The number of all reviewed infants, declined doses, and infants born to HBsAg positive mothers was recorded to describe the frequency of immunisation refusal. As local protocol permits vaccination delay for clinically unstable babies, those who were admitted to the Special Care Nursery or Neonatal Intensive Care Unit after birth did not have their charts reviewed and so were excluded from these counts. Similarly, infants discharged or transferred before their medicine chart could be reviewed were also excluded from these counts. The mothers of otherwise eligible babies who had declined immunisation were asked by a hospital pharmacist to complete a voluntary and anonymous questionnaire whilst they were on the postnatal ward during their inpatient stay (see Appendix). Non-English speaking women, those with complex ongoing medical or social issues, and those already discharged or otherwise unavailable were excluded, and thus, not asked to complete the questionnaire (see Fig 1). Demographic information, gravida para status, and hepatitis B serology status was collected using questionnaires and medical records for this subset of mothers who had both declined their eligible baby's immunisation and completed the questionnaire. Gestational age, birth weight, and health concerns documented at birth were collected for their infants via medical records.

Questionnaires were paper-based and written in plain-language English, with

multiple-choice options and free-text fields provided where required for participant responses. Multiple-choice options pertaining to reasons for immunisation refusal were selected to reflect common concerns of vaccine hesitant parents revealed by the 2015 Forbes et al study.⁸ Participants were asked to indicate the reason for their decision, their satisfaction with the immunisation information provided antenatally, other information sources used, how comfortable they felt discussing concerns with healthcare providers, and whether they would consider future infant immunisations. Participant responses were de-identified and data was pooled. Data was analysed using the statistical software SPSS Statistics 22 (IBM) and expressed as mean $\pm$ standard deviation (SD). This study was approved by the site's Human Research Ethics Committee as meeting the National Health and Medical Research Council requirements for a quality assurance audit (reference: AQA16/01).

Results

The medicine charts of 1,574 infants on postnatal wards were reviewed during the study period (See Fig. 1). Of all reviewed infants, 25 (1.6%) had HBsAg positive mothers. One hundred and thirty-seven (8.7%) infants, including two pairs of twins, had not received the birth-dose because their mother had declined it. All 137 infants who had declined birth-doses were born to HBsAg negative mothers, although one of the 135 mothers who declined was hepatitis C virus seropositive.

One hundred and thirteen of the 135 women (83.7%) who declined their infants' birth-dose consented to participate in the study. Of the remaining 22 women, one was non-English speaking. As one of the 113 participating women had given birth to twins, 114 infants were included in the study (Table 1). The average maternal age was approximately 34 years (Table 2) with over half having given birth to their first child. The majority of participants were highly educated and spoke English at home. The cohort possessed significant cultural diversity, with 38 (33.6%) mothers born internationally. Nine women (8.0%) were born in countries where Hepatitis B is considered endemic.⁹

All 114 infants who had had their birth-doses declined (including the pair of twins), were delivered at term (≥ 36 weeks gestation) (Table 1). Forty-four of 114 (38.6%) infants had

one or more documented medical issues (eg. hypoglycaemia, respiratory distress, bruising, growth restriction, etc) requiring investigation, monitoring or treatment, but not admission to the special or intensive care units.

Multiple reasons for declining were often reported per participant, with 103 of 113 (91.2%) participants citing two or more reasons. There was significant diversity of responses and frequent overlap in themes (Table 3a). The five most common reasons given included:

- Having a specific plan for receiving 2, 4 and 6-month immunisations only (56.6%)
- Feeling their baby was “too young” (55.8%)
- Perceiving their infant to be at “low risk” of contracting HBV and therefore did not consider it necessary (45.1%)
- reporting a fear of “overloading” their baby’s immune system (42.5%), and
- feeling concerned about the risk of a serious side-effect of the immunisation (35.4%).

Less common reasons (Table 3b) included:

- A fear of their baby acquiring a developmental delay (17.7%),
- A mistrust of information available (15.0%),
- A preference for the use of natural or alternative medicines for immunity (12.4%), and
- The impression from health professionals that it was either not necessary and/or too stressful a decision to make soon after birth (2.7%).

Regarding information sources used by participants, 66 of 113 (58%) women felt satisfied about the immunisation information received antenatally from their healthcare providers. Seventy-six of 113 (67%) felt comfortable discussing vaccine concerns with their healthcare providers. Participants appeared to consult multiple information sources before making their decision, the main sources being General Practitioners (GPs) and/or midwives for 49 of 113 (43%) participants, and more informal sources such as internet and media for 38 of 113 (33.6%) participants. While a few women appear to have conscientiously researched the topic before making a decision, some seeking expert opinion and reviewing medical literature, 31 of 113 (27.4%) sought the advice of friends and family. Eighty-eight of 113 (77.9%) participants expressed that they would still

consider future immunisations for their infant, with 5 (4.4%) stating that they would not. Of the remaining women, 18 of 113 (15.9%) were still undecided and two (1.8%) did not disclose their plan for future immunisations.

Discussion

Available Australian data regarding HBV birth-dose specific coverage rates is limited, but information from other demographics suggests a lower uptake than that demonstrated in this study. The WHO reports that in 2017, despite 105 countries having implemented birth-dose immunisation, worldwide Hepatitis B immunisation coverage was only 43%.¹⁰ The US-based Centers for Disease Control and Prevention reported a 73.6% birth-dose coverage rate among American children aged 19-35 months in 2017 following their National Immunisation Survey.¹¹ Other studies have shown an association with timely completion of other scheduled vaccines amongst infants who received their first HBV immunisation dose at birth.^{12,13}

While some concerns regarding HBV immunisation mirror that of previous studies of childhood vaccines in general, there are a few specific objections that clinicians can address. A 2012 national online survey completed by Australian parents similarly found that the perception of vaccines were unsafe was a significant factor in non-uptake of immunisation.¹⁴ It is apparent that despite multiple robust studies refuting the claim that vaccines are associated with autism, many parents still fear developmental consequences of immunisation suggested by the since-retracted 1998 Wakefield et al article originally published in *The Lancet*.^{15,16}

Another significant area of parental concern about the birth-dose revealed in this study is the perception that newborns are “too young” and too fragile to tolerate immunisation. Of the infants whose birth-dose had been declined, a notably high proportion had medical concerns of some description documented at birth (see Table 1). Reasons for this observation are unclear. It is possible that immunisation refusal may be more likely in infants with identified medical conditions, however minor, as parents may be more inclined to avoid interventions perceived as risky at a time of heightened concern for the vulnerability of their infant. However, this avoidance is usually needless. Previous

studies have demonstrated that infants can respond appropriately and safely to as many as 10 different antigens administered at the same time and there is currently no evidence that scheduled vaccines can “overwhelm” the infant immune system.¹⁷ Furthermore, the reasoning that infants’ immune systems are not robust enough to cope with immunisation underscores the rationale for timely birth-dose immunisation; babies are most vulnerable to contracting communicable illnesses at this early stage of life.¹⁷

This study also revealed how frequently parents justify omitting the birth-dose due to the low perceived risk of their infant contracting HBV in their particular family environment. There is no published data of HBV transmission rates for the patient population of this study. Some geographical areas of Australia have HBV carriage rates exceeding the estimated 1.1%, such as the cohort of this study which had a carriage rate of 1.6%.² Complicating further, it has been estimated that only 56% of the HBV-positive population of Australia have been diagnosed and made aware of their infection.² It is also difficult to accurately estimate a single family’s risk, as spouses and other household members are not required to be tested. There is currently limited information to quantify the risk of neonatal HBV transmission in families in which the mother is HBsAg negative. However, while perinatal transmission most often occurs vertically from mother to infant, evidence of horizontal HBV transmission between family members of households, including spouses, suggests that the risk of early childhood infection cannot be eliminated if mothers are HBsAg negative.⁸⁻²⁰ Transmission of HBV can occur through mucosal or percutaneous exposure to infected blood and other body fluids.²¹ HBV can also survive at least seven days outside the body on contaminated surfaces, requiring only 4×10^{-5} mL of infected blood to cause infection.²¹ Inpatients or employees of health care services are also at risk of contracting HBV from contaminated multi-patient-use equipment, with HBV outbreaks linked to diabetic and dialysis patient units.^{21,22}

While some women appear to have researched their decision thoroughly, over 40% felt that they did not receive satisfactory information antenatally and so may have been poorly prepared to make a decision in the time given. This finding reveals a need to review antenatal education and prioritise informed discussion about immunisation to reduce reliance on possibly erroneous information sources such as family, friends, and the internet. Informal sources have been found to be associated with more frequent

rejection of basic immunisation science, the emphasis of risks rather than benefits, and greater levels of concern.^{23,24}

A number of women in this study reported feeling uncomfortable communicating immunisation concerns to healthcare providers. Substantial trust and rapport between parent and practitioner is influential to immunisation uptake.¹⁴ It has also been shown that timely discussion with healthcare providers is important, with vaccine-hesitant parents twice as likely to begin their decision making about immunisation in the antenatal period as opposed to parents agreeing to immunisation.²⁵ It is therefore imperative that health professionals take care to impart consistent, up-to-date, impartial, and evidence-based recommendations. Concerned parents are increasingly extrapolating uncorrected vaccine misconceptions and fears to other routine preventative perinatal care.²⁶ This has been observed in studies of prophylactic intramuscular Vitamin K injection uptake at birth, where refusal has been associated with rejection of the Hepatitis B immunisation birth-dose.^{27,28} Conflicting impressions or lack of confidence perceived by patients from different healthcare providers about early-life public health interventions can further negatively impact uptake. Highly skewed proportions of women rejecting the intramuscular dose have been found to be receiving care from the same maternity health professional personnel, suggestive of meaningful negative influence on parental decision-making.²⁹

While this study is the first Australian publication to offer insight into the parental reasoning behind refusal of the HBV birth-dose immunisation, there are several limitations. Participants included only English speaking mothers of newborns. Exploring paternal or familial demographics and influences may also be revealing of parent's immunisation preferences. Also, only term infants were investigated. The relationship between refusal of the birth-dose and refusal of other coinciding routine neonatal interventions such as prophylactic Vitamin K administration were beyond the scope of this study and therefore not investigated. Lastly, this study principally focused on HBV immunisation refusal; authors emphasize that all identified HBsAg positive women consenting to immunise their baby was an encouraging outcome.

In conclusion, there is a need to review education given antenatally about the HBV birth-dose, and by extension, scope to investigate the relevant knowledge, information sources

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and attitudes of maternity healthcare professionals. All clinicians involved in perinatal care should be aware of the risks and benefits of early-life immunisations and to be able to communicate them to expecting patients.

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Table 3. Infant demographics

Table 1. Infant de

Gestational age (weeks+days)		
Mean ± SD	39+3 ± 1+3	
Range	36+0 – 42+3	
Weight (g)		
Mean ± SD	3441.7 ± 470.7	
Range	2338 - 4752	
Gender		
Female	52 (45.6%)	
Male	62 (54.4%)	
BSL monitoring (for maternal diabetes, hypoglycaemia)	14	31.8
Respiratory (eg. distress/ effort/ tachypnea/ dusky /cyanotic episode)	10	22.7
Minor congenital abnormalities (eg. cleft palate, dimple, skin tags)	11	25.0
Bruising, abrasions, & birth trauma	8	18.2
Prematurity & growth restriction	7	15.9
GBS sepsis / presumed sepsis	4	9.1
Shoulder dystocia	3	6.8
Cephalohaematoma	3	6.8
Tachycardia / abnormal cardiotocography	2	2.3
Jaundice	2	2.3
Poor tone / “floppy”	1	4.5
Abnormal thyroid hormone levels	1	25.0
Undescended testes	1	15.9

*including one pa

**some infants ha

Table 2. Maternal participant demographics

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Age (years)		
Mean ± SD		33.7 ± 4.3
Range		22 - 45
Parity (after this birth)		
Mean ± SD		1.7 ± 1
Range		1 - 6
Parity = 1	63	55.8
Highest level of education		
Primary	0	0.0
Secondary	10	8.8
Tertiary	97	85.8
Other	4	3.5
(Not disclosed)	2	1.8
Country of birth		
Australia	75	66.4
Europe	10	8.8
Asia	10	8.8
New Zealand	6	5.3
UK	6	5.3
Africa	3	2.7
Russia	2	1.8
Canada	1	0.9
Language spoken at home		
English	102	90.3

Immunisation safety concerns		
"I was concerned about "overloading" my baby's immune system"	48	42.5
"I was concerned about a risk of my baby having a serious side-effect from the immunisation"	40	35.4
"I was concerned about the ingredients in the injection"	31	27.4
"I was concerned about my baby developing a long term condition or developmental problem from the immunisation"	20	17.7
Timing concerns		
"I did not want the HBV birth-dose immunisation given, but plan for my child to receive the 2, 4 and 6 month HBV immunisations"	64	56.6
"I felt that my baby was too young to have an immunisation"	63	55.8
"I preferred to delay immunisation until I saw my GP / family doctor"	34	30.1
"I felt that my baby had received too many injections/needles already"	19	16.8
"I needed more time to think about whether I wanted my baby to have the HBV immunisation"	14	12.4
"I felt that my baby was not well enough after birth to have an immunisation"	2	1.8
Concerns about the need for the HBV birth-dose immunisation		
"I do not believe my child is at high enough risk of Hepatitis B infection to receive the immunisation"	51	45.1
"I do not fully trust the information I receive about the HBV immunisation and the need for it"	17	15.0
"I prefer to use natural or alternative medicines for immunity"	14	12.4

Table 3a. Participant reasons

“I do not believe that the HBV immunisation is effective”	3	2.7
“I do not believe the illness the immunisation prevents (Hepatitis B) is severe”	2	1.8
“I prefer to rely on herd immunity (protection from living in a population that is mostly immune)”	1	0.9

Cites a lack of evidence describing necessity at the newborn stage, specifies low risk at birth specifically	9	8.0
Identifies as pro-immunisation, not anti-vax, pro-delayed immunisation, agrees with the need – but still considers it “too early”	5	4.4
Concerned about post-immunisation temperature spikes resulting in administration of empirical antibiotics	4	3.5
Prefers to wait until the baby is more “accustomed to life”/ recovered from birth	4	3.5
Believes “we do not know enough” about short term and long term side effects. Keen for more information, more evidence, to feel convinced of need and safety.	4	3.5
Was given the impression/suggestion from health professionals on site that it was not necessary or too stressful a decision soon after birth	3	2.7
Concern about adjuvants and “metals” in the vaccine, specifically aluminium	3	2.7
Believes the birth dose of HBV immunisation only intended for babies with Hepatitis B positive family members	2	1.8
States pharmaceutical companies are motivated by generating profit rather than health	1	0.9
Religious reasons (unspecified)	1	0.9
Wants to minimise unnecessary vaccinations	1	0.9

Table 3b. Participant reasons cont.

States baby has “no immune system until 7 months of life” and therefore cannot yet produce an immune response	1	0.9
Prefers to receive the immunisation themselves and pass protection into the breast milk	1	0.9
Feels judged for raising objections	1	0.9
Concern that mother has MTHFR gene mutation	1	0.9
Awaiting consultation with other health care personnel, eg. “biobalance doctor”, clinical nutritionist, to advise on “readiness for vaccination”	1	0.9
Believes we should revisit the immunisation schedule and question the practice	1	0.9
Belief that risk of contracting Hep B in metropolitan Melbourne is low	1	0.9
Previous children did not receive birth-dose	1	0.9

Figure 1. Study flow diagram

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Author/s:

Gilmartin, CE;Daley, AJ;Leung, L

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