

Declining Intramuscular Newborn Vitamin K Prophylaxis:

An Exploration of Parental Decision Making and Influencing Factors

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Abstract

Objective

Newborn infants are at risk of potentially life-threatening vitamin K deficiency bleeding. This is readily prevented with prophylactic vitamin K at birth. In New Zealand, the recommended route of prophylaxis is intramuscular (IM) but the uptake rates are lower than that of comparable countries. This study investigated the reasoning of parents who opted out of IM vitamin K prophylaxis for their newborn.

Study Design

Semi-structured interviews were conducted with fifteen families from the Otago/Southland region of New Zealand about their choice to opt out of IM vitamin K. Interview data was analysed using thematic analysis in order to elucidate themes capturing important aspects of parental decision making.

Results

Parents opt out of IM vitamin K for a variety of reasons. These were clustered into three main themes: parental beliefs and values, concerns about their child's welfare, and external influencing factors. Parents also raised a number of concerns regarding other perinatal and childhood interventions.

Conclusion

This study identified factors that influence parental decision making, and lead to a decision to opt out of IM newborn vitamin K prophylaxis. These findings can contribute to the wider body of literature that informs public health initiatives focused on newborn vitamin K prophylaxis.

Preface

This year I was fortunate enough to undertake a BMedSc(Hons) project and gain exposure to the world of academic medicine. Whilst carrying out a research project, let alone a year-long one, was a new and challenging experience, it has also been incredibly enriching and interesting. For this reason I am extremely grateful to the Faculty of Medicine, for both the opportunity, and the financial support, to undertake this project.

There are a number of people who supported me throughout the year, and I cannot list them all in fear of missing someone. However, first and foremost I would like to thank my supervisors, Dr Ben Wheeler and Dr Nikki Kerruish. I could not have completed this year without your patience, knowledge and enthusiasm. Your support and guidance has been invaluable and I cannot thank you enough.

To all of the families who participated in this project – thank you for offering to speak with me and for sharing your thoughts and opinions. Every interview provided an invaluable contribution to this project and your thoughtful responses were appreciated.

To everyone from Women's and Children's Health: thank you for welcoming me so warmly, and for the advice and support throughout the year. I will miss doing the ODT quiz together every day. I would particularly like to thank Gloria Dainty for your companionship, and for your guidance.

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Presentations

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EXPLORING PARENTAL REASONING BEHIND CHOICES REGARDING VITAMIN K PROPHYLAXIS

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Oral Presentation

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WHY DO PARENTS DECLINE INTRAMUSCULAR VITAMIN K PROPHYLAXIS? AN INTERVIEW-BASED QUALITATIVE STUDY

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Papers in Preparation

WHY DO PARENTS DECLINE NEWBORN INTRAMUSCULAR VITAMIN K PROPHYLAXIS?

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NEWBORN VITAMIN K PROPHYLAXIS: AN ANALYSIS OF INFORMATION RESOURCES FOR PARENTS AND PROFESSIONALS

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List of Abbreviations

APPT	Activated Partial Thromboplastin Time
DHB	District Health Board
IM	Intramuscular
INR	International Normalised Ratio
ISTH	International Society on Thrombosis and Haemostasis
LMC	Lead Maternity Carer
MoH	Ministry of Health
PIVKA	Proteins Induced by Vitamin K Absence (or Antagonism)
PT	Prothrombin Time
QMMC	Queen Mary Maternity Centre
RCT	Randomised Control Trial
UNCRC	United Nations' Convention on the Rights of Children
VKDB	Vitamin K Deficiency Bleeding

Introduction

In 2013, seven infants were admitted to Vanderbilt Children's Hospital in Nashville, Tennessee, with severe vitamin K deficiency¹. Five of these infants were diagnosed with late vitamin K deficiency bleeding (VKDB) – four with intracranial bleeding, and one with gastrointestinal bleeding. Although all the infants survived, two required emergency neurosurgical evacuation of their haematomas, one has severe brain damage (cognitive delays and right hemiparesis), and two have mild to moderate neurological deficits. The parents of these seven infants had all declined vitamin K prophylaxis at birth for their children. Their reasons for doing so included: concern about an increased risk of leukaemia; a belief that the injection was unnatural, and unnecessary for uncomplicated births; and a fear that their infant would be exposed to toxins in the injection. Only one family was aware of the potentially life-threatening nature of VKDB¹.

The above occurred in the context of an increase in infants diagnosed with late onset VKDB in the region and a concern about an apparent rise in the rate of parents declining vitamin K prophylaxis in the surrounding community¹. The same study reported that the rate of local parents declining vitamin K prophylaxis was 3.4%. This is double the rate of declining found in a recent New Zealand study (1.7%)². However, when compared to older New Zealand data from another region, there is a suggestion that the number of New Zealand parents opting out of IM vitamin K has also increased in recent years³.

In conjunction with this, there have recently been a number of studies regarding factors associated with opting out of IM vitamin K^{2, 4-6}. However, it is unknown how these translate into parents' thoughts, feelings and concerns about vitamin K prophylaxis. Additionally, although there is a growing body of literature on all aspects of vitamin K prophylaxis, very little of this data has been qualitative, with no research specifically exploring why parents opt out of IM vitamin K prophylaxis conducted.

Aims of this Thesis

This thesis is a qualitative, exploratory study on the attitudes, opinions and decision making influences of parents who choose to opt out of IM vitamin K for their newborn. It aims to address two key questions. Firstly, why do parents decline IM vitamin K prophylaxis? And secondly, when parents choose to opt out, how should healthcare professionals react? This thesis seeks to achieve these aims through the thematic analysis of interview data, and an analysis of this data using common ethical frameworks.

Outline of this Thesis

Each chapter of this thesis will address different aspects of the study.

Chapter One contextualises vitamin K deficiency bleeding and the use of vitamin K prophylaxis, using the information gathered through an extensive literature review. It will explore: the history of VKDB and vitamin K prophylaxis, the controversies associated with vitamin K prophylaxis, and the current research regarding factors associated with opting out of IM vitamin K. Additionally, it will outline the decision making frameworks that will be discussed in chapter four. Chapter one contains a sizeable amount of technical information. Such information was considered salient to the review in order to provide sufficient context. For ease of reading the key points of such sections will be presented first.

Chapter Two outlines the methods employed for this study.

Chapter Three provides the main results of this research, including demographic information about the study participants, and a description of the themes elucidated from the study interviews. Quotations are included to illustrate key ideas.

Chapter Four discusses the themes described in Chapter Three in depth. It places these in the context of the existing literature, including that related to similar childhood interventions such as newborn screening and immunisation. It also explores ethical questions that result from parents declining IM vitamin K prophylaxis.

The thesis ends with final concluding statements, followed by references and appendices.

Chapter One: Contextualising Vitamin K and Vitamin K Deficiency Bleeding

Michael Obladen's "History of Haemorrhagic Disease of the Newborn" describes reports of spontaneous bleeding in otherwise healthy newborns as far back as 1682⁷. Most of these were singular reports until hospitalisation allowed larger observations to be conducted, and by the end of the eighteenth century it was widely recognised that infants could, and did, bleed without experiencing any trauma⁷. Following this, it was Dr Charles Townsend at the Boston Lying in Hospital who coined the term 'Haemorrhagic Disease of the Newborn' in 1894 to describe fifty cases of spontaneous, transient, neonatal haemorrhages from the GI tract, umbilicus, skin, and seven other locations⁸. He noted that it was distinct from other causes of neonatal bleeding, such as haemophilia, due to: male and female infants being equally affected; the transient nature; and that it occurred only in early life⁸.

Accounts of clinical cases similar to that described by Townsend continued in the following years, and the understanding of neonatal haemorrhagic disease was greatly enhanced by the discovery of the coagulation cascade in 1904⁹. In the years following, Schwarz and Ottenberg noted that infants with haemorrhage had prolonged coagulation times, and concluded that impaired coagulation is the immediate cause of uncontrollable haemorrhages in the newborn¹⁰. Schloss and Commiskey measured coagulation time in infants with bleeds, and suggested that incomplete coagulation is the underlying cause¹¹, and Whipple postulated that melena^a in infants occurred due to a lack of prothrombin¹².

Despite these advances the cause of the bleeding tendency remained unknown until the 1930s when Henrik Dam at the University of Copenhagen described haemorrhages in the skin and organs of chicks fed a diet from which cholesterol and other lipophilic molecules had been removed^{13, 14}. Follow up investigations resulted in the isolation of a fat-soluble substance from hemp seed, alfalfa, and hog-liver that could reverse this bleeding tendency¹⁵. This active substance was subsequently

^a Black stools associated with upper gastrointestinal tract bleeding

named vitamin K (for koagulation, the term for coagulation in German and Scandinavian languages).

The following chapter will cover important aspects of vitamin K and vitamin K deficiency bleeding (VKDB), such as: an overview of vitamin K, including structure, function, and how it is measured in the body; a description of the vitamin K status of infants; a description of VKDB and its subtypes; a discussion of the use of prophylactic vitamin K to prevent VKDB; and a brief description of parental decision making for infants, and its relation to vitamin K prophylaxis.

Vitamin K

Key Points

- Vitamin K is one of four fat soluble vitamins and is most commonly found in leafy green vegetables
- Vitamin K is important for the correct formation of coagulation factors in the blood
- Without sufficient vitamin K, people (including infants) are at risk of vitamin K deficiency bleeding

Molecular Structure

Vitamin K refers to a group of structurally similar fat soluble (lipophilic, hydrophobic) molecules with a common function (also called “vitamers”). In 1939 Edward Doisy was able to elucidate the structure of vitamin K, and found that vitamin K vitamers share a common methylated naphthoquinone ring structure, but have different aliphatic side chains attached at the c3-position¹⁶. The two naturally occurring forms of vitamin K are phyloquinone (vitamin K1) and the menaquinones (vitamin K2).

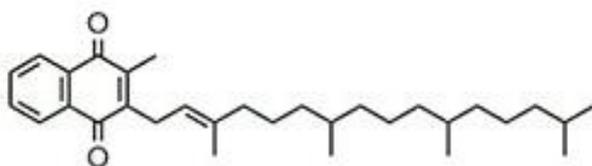


Figure 1: Structure of vitamin K1¹⁷

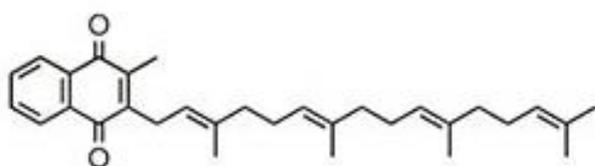


Figure 2: Structure of MK-4 (a form of vitamin K2)¹⁷

Phylloquinone (vitamin K1) was the substance first extracted by Dam in the 1930s. It consists of the naphthoquinone ring structure with a phytyl-side chain at the c3-position¹⁶. It plays a role in photosynthesis and is therefore available in the

largest amounts in green, leafy vegetables such as kale, silverbeet, and spinach; certain legumes; and some vegetable oils¹⁸. Vitamin K1 is the primary source of vitamin K in the human diet¹⁹.

Menaquinones (together known as vitamin K2), also consist of the naphthoquinone ring structure but their side-chain consists of a varying number of prenyl groups. The number of prenyl groups is used to denote the subspecies (MK-n). The most common menaquinone in the human body is MK-4 as it is synthesised from vitamin K1 in the pancreas, testes and arterial walls²⁰. The major dietary sources of vitamin K2 are MK-4 from animal tissue such as meat, eggs, and dairy products; and MK-7 which is synthesised by bacteria during fermentation and is found in a number of fermented dairy and soybean products²¹.

Vitamin K2 can also be synthesised by bacteria that reside in the human intestines (especially the *Bacteroides* group), but there is continued debate over whether this vitamin K is a significant source for humans^{19, 22}. Additionally, there is some evidence of poor bioavailability of this intestinal source of vitamin K¹⁹. This is because bile salts are required for the effective absorption of vitamin K, as it is fat soluble, but these are not present in the colon²³. Nevertheless, insufficient intestinal colonisation by bacteria, and the resultant decreased endogenous production of vitamin K, are still often mentioned to be contributors to clinically significant vitamin K deficiency^{19, 24, 25}.

Vitamin K1 is commercially manufactured for medicinal use under several brand names, but Konakion® is the brand used for newborn vitamin K prophylaxis in New Zealand²⁶. There are also additional, synthetic forms of vitamin K which are used in various industries such as pet food (vitamin K3) and to inhibit fungal growth (vitamin K5).



Figure 3: Konakion vitamin K²⁷

Chemical Function

In the 1970s, forty years after Dam's discovery of vitamin K, Suttie et al and Stenflo et al revealed its molecular function^{28, 29}. They found that vitamin K is a cofactor in the conversion of glutamate (Glu) residues to gamma-carboxylglutamate (Gla) residues²⁸⁻³⁰. These Gla residues are then capable of binding calcium ions, which are required to function by the vitamin K dependent clotting factors - factors II (prothrombin), VII, IX and X³¹.

Before vitamin K can serve as a cofactor in the human body it must first be reduced to vitamin K-hydroquinone. During the gamma-carboxylation of glutamate residues, vitamin K is converted into vitamin K epoxide³². It is then regenerated by the vitamin K epoxide reductase (VKOR). This reduction and subsequent re-oxidation of vitamin K, coupled with the carboxylation of Glu residues is called the vitamin K cycle³². Each vitamin K molecule is thought to be recycled in this manner ~1000 times³³. Certain medications, including antiepileptic drugs and warfarin derivatives, interfere with vitamin K metabolism³⁴. As a result, the infants of mothers taking such medications are at increased risk of early VKDB.

Indices of Vitamin K Deficiency

Various indicators of a patient's vitamin K status are available. Three of the most common indices are summarised below.

Prothrombin Time (PT)

The traditional screening tests for vitamin K deficiency are based on coagulation assays such as prothrombin time (PT), and activated partial thromboplastin time (APTT). Both tests measure the time taken for blood to clot: PT is an indicator of the efficacy of the extrinsic pathway of the clotting cascade, and APPT is an indicator of the efficacy of both the intrinsic pathway and the common coagulation pathway. Functionally active vitamin K dependent pro-coagulation factors are required for both of these pathways³⁵.

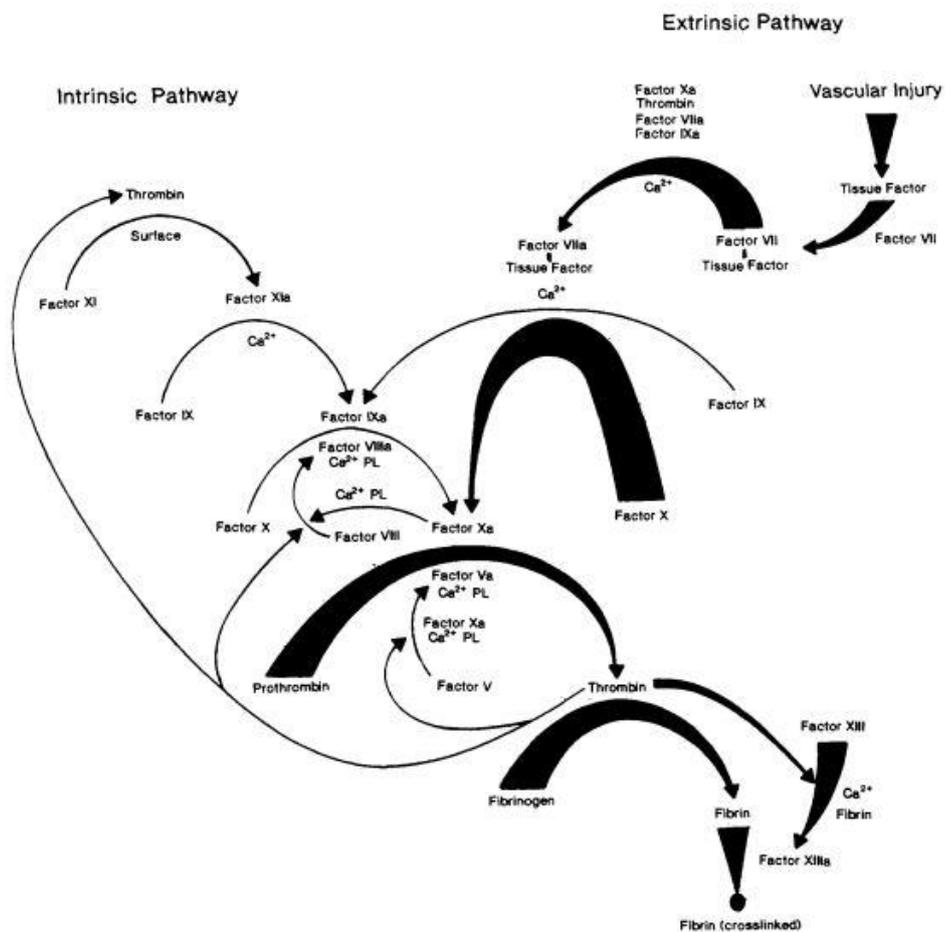


Figure 4: The coagulation pathways. Reprinted with permission from Biochemistry. Copyright 1991 American Chemical Society.³⁵

Whilst these tests are relatively easy to perform, a lengthening in coagulation time is non-specific for vitamin K deficiency. A deficiency is usually confirmed by two or more of the four vitamin K dependent pro-coagulation factors (II, VII, IX and X) being reduced³⁴. Otherwise, normalisation of PT (and coagulation factors) upon vitamin K administration is also considered confirmatory³⁴. However, the PT test is insensitive as it only becomes prolonged once the concentration of prothrombin decreases below 50% of normal³⁶. As a result, the usefulness of the PT test is limited to diagnosing overt vitamin K deficiency, and is not useful for diagnosing subclinical deficiency.

Proteins Induced by Vitamin K Absence or Antagonism (PIVKA)

When there is an insufficiency of vitamin K, non-functional versions of vitamin K dependent coagulation factors are created and released into the bloodstream. These are created due to the inability of the body to carboxylate Glu residues without a vitamin K cofactor. The collective term for these under-carboxylated coagulation factors is PIVKA (Proteins Induced by Vitamin K Absence or Antagonism).

Assays developed to specifically detect undercarboxylated prothrombin (PIVKA-II) have proven to be useful to detect subclinical vitamin K deficiency in infants³⁷. Additionally, the delayed disappearance of PIVKA species after administration of vitamin K, and normalisation of PT time, makes them useful to retrospectively confirm that a bleeding case occurred due to vitamin K deficiency³⁴. However, a disadvantage of such assays is that a clear cut-off point to define a clinically relevant degree of deficiency is difficult to determine^{36, 37}.

Plasma Levels of Vitamin K

The most common circulating form of vitamin K in plasma is phylloquinone (vitamin K1) and its measurement in the blood is a useful indicator of vitamin K status and absorption. As the presence of circulating phylloquinone fluctuates with recent intake, serum concentrations should be determined after an eight hour fast. In healthy (adult) controls, fasting reference values of vitamin K range from 0.2 to 1.0 µg/l with a median of around 0.5 µg/l, and dietary restriction of vitamin K leads to a rapid decrease in these levels within days^{38, 39}.

Vitamin K Status of Infants

Key Points

- Vitamin K stores are low at birth, and only small amounts appear to cross the placenta (maternal: foetal gradient is between 20:1 and 40:1)
- Coagulation factors in infants take up to six months to reach adult levels, and in the absence of vitamin K prophylaxis may fall on day two or three of life before increasing again by day six
- Breastmilk has lower amounts of vitamin K than formula (due to formula fortification)
- As a result of the above, exclusively breastfed infants are more likely to have VKDB

Coagulation Factors

The plasma concentrations of vitamin K dependent coagulation factors in infants are 40-60% of the normal adult values and slowly rise during infancy, before finally attaining adult values around six months of age⁴⁰. The infants in such studies had all received 1mg of vitamin K by IM injection at birth, hence it is thought that the low concentrations of coagulation factors are caused by an overall reduced synthesis of the proteins, rather than an absence of the vitamin K cofactor³⁴. However, it is generally accepted that if vitamin K is not given at birth, vitamin K dependent coagulation factors may fall during the first week of life. This results from work in the 1960s by Aballi and de Lamerens, who reviewed studies on the course of prothrombin activity in breast-fed infants not given vitamin K at birth⁴¹. They found that prothrombin activity falls rapidly after birth to its lowest point on the second or third day of life, before returning to its initial concentration by day six. It is thought that this decrease results from a nutritional deficit of vitamin K in early life⁴¹.

Further evidence of the lack of coagulation factors in infants is that PIVKA are found to be above normal levels in umbilical cord blood. One study with full-term infants in Japan reported a prevalence of detectable PIVKA-II in ~20% of infants⁴², and a similar amount was also reported in a study of pre-term babies in England⁴³. Additionally, the use of PIVKA-II assays has shown that some infants still have

inadequate vitamin K at one and two months of age, and that an increased presence of PIVKA-II in plasma is associated with both exclusive breast feeding, and omission of vitamin K prophylaxis at birth^{44, 45}.

Plasma Concentrations and Tissues Stores

Phylloquinone (vitamin K1) is the largest contributor of vitamin K for the human foetus and neonate⁴⁶. This is evident as menaquinones are present in low quantities at birth and take a number of weeks to build up, despite making up over 90% of vitamin K reserves in adults⁴⁶. Additionally, the concentration of vitamin K in cord blood is low compared to the concentration in adult plasma - the best estimates of the maternal/foetal vitamin K concentration gradient are between 20:1 and 40:1⁴⁶. However plasma phylloquinone concentrations are usually detectable in exclusively breast-fed infants from as early as twelve hours after birth, and by three to four days are within the same range as adults⁴⁶. The low amount present at birth, and the time taken to build up stores of vitamin K, means that liver stores of vitamin K in infants are low in comparison with adults. This slow build-up of stored vitamin K2 is potentially consistent with the time taken for bacteria to colonise the infant's gastrointestinal system³⁴. Although, as previously mentioned, there is debate over the importance of bacterial-synthesis of vitamin K2 for human nutrition.

Vitamin K Contents of Breast and Formula Milks

Exclusive breast-feeding is a common risk factor for both idiopathic^b and secondary VKDB⁴⁷. It was first noted in the 1930s that cows' milk offered protection to infants from spontaneous haemorrhage⁴⁸. This led to work by Dam et al who measured the vitamin K content of human and cow milks. This work resulted in values of 15µg/l for breast milk, and 60 µg/l for cows' milk⁴⁹. These values became widely cited in the literature³⁴, and in 1971, the American Academy of Pediatrics used them as the basis for their recommendations for the fortification of infant formulas⁵⁰. Later assays showed that Dam's values were an overestimate, and gave values of 2.1 µg/l from mature human milk, 2.3µg/l from human colostrum, and 4.9 µg/l in Friesian cows' milk⁵¹. A later study, using standardised techniques, found that human hind milk had a higher concentration of vitamin K1 than foremilk⁵². It also found that

^b Of unknown cause

the highest median value of vitamin K1 was in milk produced on the first day of lactation (median value 2.7µg/l)⁵².

As a result of the fortification of infant formula, VKDB typically occurs in exclusively breastfed infants^{3, 53}. In 1991, Greer et al compared the average daily dietary intakes of vitamin K1 of exclusively breast-fed infants and infants fed typical formula milk. They found that although no infants demonstrated obvious vitamin K deficiency, plasma vitamin K1 concentrations in the infants fed human milk remained low during the first six months of life (mean <0.25µg/l) compared to formula fed infants (mean values 5.99µg/l at six weeks and 4.39µg/l at six months)⁵⁴.

Von Kries, et al showed that vitamin K status is related to the infant's total intake of breastmilk in the first week of life⁵⁵. In this study, exclusively breast-fed infants who had increased PIVKA-II, and prothrombin activities of <25% of normal, were shown to have received less than 100ml of milk per day for the first four days of life. Conversely, infants with prothrombin levels >25% of normal on day five, had increased their average breast milk intakes to >100ml per day by days three and four⁵⁵. Motohara et al showed similar findings in that a total intake of 500ml of breast milk during the first three days of life was sufficient for complete gamma-carboxylation of prothrombin – thus ensuring the formation of functional coagulation factors⁵⁶.

Vitamin K Deficiency Bleeding (VKDB)

Key Points

- VKDB is separated into three patterns of onset: early, classical, and late
- Early VKDB occurs during the first twenty-four hours of life, and is typically seen in the infants of mothers taking drugs that interfere with vitamin K metabolism
- Classical VKDB occurs during the first week of life. It is normally not life threatening and affects 1.24/100,000 live births in New Zealand. It typically affects exclusively breastfed infants who did not receive vitamin K at birth
- Late VKDB occurs between eight days and six months of life. It affects 1.4-2.83/100,000 live births in New Zealand. Intracranial haemorrhage occurs in 50-80% of infants with late VKDB

Overview

In 1999 the Pediatric/Perinatal Subcommittee of the International Society on Thrombosis and Haemostasis (ISTH) recommended a change in name from Haemorrhagic Disease of the Newborn (HDN) (as coined by Townsend in 1894) to Vitamin K Deficiency Bleeding (VKDB). The name change was in order to clarify that the etiological basis was solely due to vitamin K deficiency and to include infants who develop VKDB beyond the four week neonatal period⁵⁷.

In 1985, Lane and Hathaway described the three patterns of VKDB, which are stated below⁴⁷. These descriptions are still widely accepted and are recognised by the ISTH Pediatric/Perinatal Subcommittee⁵⁷. It is also usual to distinguish between idiopathic and secondary VKDB. In secondary VKDB there is a known underlying cause, this is usually a previously undiagnosed disease such as a congenital hepatobiliary or malabsorptive disorder, or an effect of drugs given to the mother or infant⁴⁷.

Several countries participating in surveillance programmes for VKDB, including the Netherlands, Germany, Australia, and Switzerland, have agreed upon standardised case definitions of VKDB to allow for international comparison^{58, 59}.

Accordingly, a confirmed case of VKDB should fulfil the criteria of having a PT that is ≥ 4 times the control value, and at least one of:

1. Platelet count normal or raised, and normal fibrinogen, with absent fibrin degradation products
2. PT returns to normal after vitamin K administration
3. Concentration of PIVKA proteins exceeds normal controls

The most recent surveillance data from New Zealand used similar criteria. In this study VKDB was defined as 'spontaneous bruising or bleeding associated with prolonged clotting time, but not due to an inherited coagulopathy or DIC, in an infant <6 months old'³. Cases that met this criteria were reported to the surveillance unit and were confirmed by: the presence of a raised PT time, or international normalised ratio (INR); a normal fibrinogen level and normal or raised platelet count, and correction of the PT and bleeding after administration of vitamin K³. When this study was undertaken, the tests for PIVKA were not routine in New Zealand hospital laboratories, so this measure was not used.

Early VKDB

Early VKDB is bleeding due to vitamin K deficiency in the first twenty four hours of life. It indicates that vitamin K was deficient at birth, usually due to vitamin K deficiency in the mother. Early VKDB is rare and is typically seen in conjunction with the maternal use of drugs that interfere with vitamin K metabolism, such as anticoagulants (warfarin and derivatives), anticonvulsants (phenytoin), and antituberculosis drugs (rifampicin, isoniazid)³⁴. There is no data on the incidence rate of confirmed early VKDB in New Zealand, and in the most recent surveillance study only three potential cases were reported between 1998 and 2008³.

Despite being rare, early VKDB is frequently life threatening due to the common bleeding sites/types. These include the head (cephalhaematoma and intracranial), intrathoracic, intra-abdominal, and gastrointestinal⁴⁷. It has been stated in the literature that it may be more appropriate to classify idiopathic early VKDB separately from cases caused by maternal drugs. This is because classifying early and classical VKDB separately is not always considered necessary as idiopathic early VKDB is rare, and clinically similar to classical VKDB³⁴. In a survey based in an

Ethiopian hospital, the mean age of onset for early VKDB was twenty hours and the clinical features were identical to those found in infants diagnosed with classical VKDB⁶⁰.

Classical VKDB

The bleeding tendency described by Townsend in 1894 is now recognised as classical VKDB. Classical VKDB occurs during the first week of life, and the most common bleeding sites are gastrointestinal, umbilical, skin, nose, and wound post-circumcision⁴⁷. Intracranial haemorrhages may also occur, but are rare⁴⁷. The timing of classical VKDB is relatively well understood and the typical window of presentation between days two and three of life corresponds to the previously mentioned natural decrease in prothrombin activity.

The most recent New Zealand surveillance report regarding VKDB reported eight confirmed cases between 1998 and 2008, with an overall incidence rate of 1.24 per 100,000 births (95% confidence interval 0.54-2.45)³. None of these infants had received vitamin K prophylaxis at birth, and all but one were exclusively breastfed. In New Zealand the majority of infants are given vitamin K prophylactically at birth, however using unpublished data on the number of infants for whom prophylaxis is withheld, the surveillance unit reported the incidence of classical VKDB to be 69 per 100,000 births, or 1 in 1439, for infants who did not receive vitamin K prophylaxis³.

Comparing the incidence of classical VKDB between countries is complicated by differing study designs but a surveillance study from England reported the overall incidence of VKDB as 0.64 per 100,000 births⁶¹, and a study from Canada reported an overall incidence of 0.45/100,000 births⁶². Additionally, the historically suggested incidence of classical VKDB is between 1 in 60 to 1 in 400 breastfeed babies not given vitamin K⁶³ – a much higher rate than that suggested by the New Zealand surveillance data. A number of reasons have been hypothesised for this lower rate³. They include:

- New Zealand babies are not all exclusively breastfed, although breastfeeding rates are high
- And a lack of recognition of the bleeding tendency, or a lack of referral to a paediatrician

However, it is still evident from this study that classical VKDB remains a concern for infants not given vitamin K prophylaxis at birth in New Zealand.

Late VKDB

Late vitamin K deficiency bleeding encompasses bleeding that occurs between eight days and six months⁵⁷, with the peak incidence generally occurring between three and eight weeks of age⁶⁴⁻⁶⁶. Late VKDB almost exclusively occurs in breastfed infants, and occurs at a time when breastfeeding has been well established⁶⁷. The mothers of affected infants usually have normal concentrations of vitamin K in their breastmilk, thus most late VKDB cases are unlikely to be due to insufficient intake⁶⁷.

Late VKDB is relatively rare, with an incidence in New Zealand of between 1.4-2.83 per 100,000 births³. In a 2009 review of vitamin K deficiency bleeding, the incidence rates of late VKDB reported in other developed countries ranged between 0 and 7.2 per 100,000 infants with the lowest rates occurring in countries with IM prophylaxis regimens (0, 0 and 0.3 per 100,000 infants)³⁴. Despite being uncommon, when late VKDB does occur it is usually severe. Intracranial haemorrhages are present in 50-80% of reported cases and as a result, it is often associated with significant morbidity and mortality^{3, 68-71}. However, “warning bleeds” often occur in infants with intracranial haemorrhage from late VKDB⁶⁸. These are non-life threatening bleeds that precede serious bleeding, and in one study were present in 7/10 infants with intracranial haemorrhage caused by late VKDB⁶⁸.

Late VKDB can have similar etiology to classical VKDB (low milk intake, low vitamin K content of milk), but in many cases an underlying condition causing poor absorption is found^{3, 68}. Current evidence points towards an association of late VKDB with hepatobiliary dysfunction³⁴. Due to vitamin K being a fat soluble vitamin, its absorption by the body is dependent on the presence of bile salts and pancreatic secretions. Any reduction in the production and/or secretion of these may then result in vitamin K malabsorption and deficiency⁴⁶. Shearer proposes that the apparently increasing number of infants with late VKDB and hepatobiliary disease is caused by the increasing use of multi-dose oral vitamin K prophylaxis regimens³⁴. He suggests that while these regimes protect healthy babies, it exposes those with hepatobiliary dysfunction who may have impaired vitamin K absorption to some increased risk³⁰. This is supported by a German study in which cholestasis was found in 20/23 infants

with late VKDB⁷². In New Zealand, liver disease was present in 6/9 infants diagnosed with late VKDB between 1998 and 2008³.

Prevention of VKDB

Key Points

- Intramuscular (IM) vitamin K prophylaxis at birth provides infants with almost complete protection against VKDB
- Oral prophylaxis generally offers less protection than IM. Internationally, oral regimens differ in both the timing of administration and the protection offered
- Infants with liver disease who are given oral vitamin K prophylaxis may not be protected from VKDB due to decreased absorption

Overview

In 1939 Waddell and Guerry published that administration of vitamin K to infants shortly after birth could prevent the drop in prothrombin levels that occurs in the first week of life⁷³. A 1944 review published in the *Lancet* stated that administration of vitamin K to mothers immediately prior to birth had a similar effect, and stated that it is “probably advisable to give menaphthone^c either to every mother at or just before the beginning of labour or to every newborn child as a prophylactic against haemorrhagic disease”⁷⁴. Also in 1944, the first trials investigating the usefulness of the prophylactic administration of vitamin K were published. In one trial, vitamin K was administered to the mother prior to birth, with variable results, and another was the first clinical trial investigating the administration of vitamin K to newborns immediately following birth⁷⁵. The version of vitamin K used in these trials was menadione, and while some infants still bled, a 1mg dose was shown to significantly reduce the incidence of bleeding between one and seven days of life⁷⁵. Despite there being no biochemical confirmation that the breakthrough incidences were due to vitamin K deficiency, it was assumed that the dose used had been insufficient to protect all infants and as a result massive doses of up to over 30mg began to be given to infants⁷.

Tragically, in the 1950s it became clear via a series of case reports that the administration of menadione could result in kernicterus and haemolytic anaemia,

^c Menaphthone is a synthetic variant of vitamin K and is also known as menadione or vitamin K3

particularly in preterm infants, and particularly with doses as high as those used⁷⁶⁻⁷⁸. Mary Crosse reported a series of sixty premature infants with kernicterus within ten years: “In 1947, at a total dose of 1-2mg, kernicterus occurred in 0.8% of preterm infants. In 1949, at a dose of 10mg, the incidence was 1.6%, and in 1953 the incidence rose fourfold [to 4.1%] when the dose of vitamin K was increased [to >30mg]”⁷⁷. This effect was noted when menadione was used, but did not occur with other variants of vitamin K. This resulted in a more restricted use of vitamin K, followed by a subsequent increase in the incidence of VKDB⁷⁹. It also resulted in phylloquinone (vitamin K1) become the vitamin K variant most commonly used for prophylaxis, and this is still the variant used in most developed countries.

In New Zealand, the Ministry of Health recommends that all babies should receive vitamin K prophylaxis²⁶. The recommended route of administration is 1mg intramuscularly at birth, or preterm infants may receive 0.5mg. The vitamin K used in New Zealand is Konakion MM[®] (2mg/0.2ml). If parents do not agree to an IM injection, the alternative is for the infant to receive Konakion MM[®], 2mg orally at birth. The infant should then also receive a repeat 2mg oral dose at three to five days, and another at four to six weeks of age²⁶. Uptake rates of vitamin K prophylaxis for the whole country are unknown, however data from a single tertiary birthing unit in Otago between 2009 and 2012 gave an uptake of 92.9% IM prophylaxis, 5.4% oral prophylaxis, with only 1.7% declined². There is evidence that oral vitamin K is becoming more popular, with its use potentially more than doubling since 2008. This is based upon comparing the aforementioned study with unpublished vitamin K uptake rates from another New Zealand tertiary birthing centre between 2002 and 2008 that are mentioned in a surveillance study of VKDB in New Zealand³. This surveillance study stated that 95.9% of infants received IM vitamin K, 2.3% received oral, and 1.8% refused prophylaxis³.

Due to the inability to predict which infants are at risk of VKDB, nearly all developed countries have implemented prophylactic vitamin K programmes. As a result we are able to compare uptake rates in New Zealand to similar countries. Data from New South Wales, Australia between 2007 and 2009 shows a higher rate of IM prophylaxis uptake (96.3%), and corresponding lower rates of oral prophylaxis, and refusal (2.6% and 1.2% respectively)⁵. Data from Alberta, Canada between 2006 and

2012 showed much higher rates of IM prophylaxis (99.3%) and a rate of only 0.4% for oral prophylaxis, and only 0.3% having declined altogether⁴.

Efficacy of Vitamin K Prophylaxis

The implementation of vitamin K prophylaxis and VKDB surveillance programmes in many developed countries allows for comparison between different vitamin K regimens. Ideally the efficacy of a prophylaxis regimen would be confirmed in a randomised control trial (RCT). However, the low incidence of VKDB, and the ethical issues of carrying out an RCT on an intervention already shown to be protective, means it is unlikely that such a trial will ever be performed. Hence data on the efficacy of various regimens are mostly deduced from surveillance studies.

Surveillance studies typically estimate the incidence of a disease by asking doctors to report potential cases. In New Zealand, a surveillance study of VKDB was done by including it on the New Zealand Pediatric Surveillance Unit card between January 1998 and December 2008³. The patients' information and files are then reviewed to confirm or exclude potential cases using the definition of VKDB described earlier. The number of confirmed cases of VKDB is then divided by the number exposed in order to estimate the incidence. For VKDB the number exposed is typically the number of live born infants during that time. However, the number of infants given a certain method of prophylaxis or who refused prophylaxis can also be used to estimate the efficacy of different regimens. The major assumption made by surveillance studies is that there is a direct, and inverse, relationship between the incidence of VKDB and the efficacy of a prophylaxis regimen. Additionally, they assume that other factors including the rate of reporting and recognition, as well as risk factors, are comparably present in populations. The surveillance study of VKDB from New Zealand recognised some of these shortfalls as it stated that a lack of recognition of VKDB (as it is a rarely seen disorder), or a lack of referral to a paediatrician would mean that some cases may not have been captured in the study³.

In 2000 Wariyar et al compared the incidences of late VKDB in various countries with differing prophylaxis regimens⁸⁰. Their results are shown below in Figure 5. The differing incidences that occur in countries with no prophylaxis is potential evidence that the assumptions listed above may not be true for all studies. Figure 5 also shows that IM vitamin K prophylaxis prevents almost all cases of late

VKDB, a single oral dose is not effective in preventing late VKDB, and the efficacy of oral prophylaxis is improved by increasing the number of doses. More recent data also supports the administration of prophylactic vitamin K - in the New Zealand VKDB surveillance study published in 2011, all but one of the VKDB cases had refused prophylaxis³.

It has been suggested that the long-term efficacy of IM vitamin K is due to a depot mechanism, where vitamin K is absorbed slowly over many weeks⁸¹. In support of this theory, PIVKA in one month old infants given IM vitamin K are normally undetectable, and one study showed that the proportion of one month old infants with detectable PIVKA was similar whether the infants were given one dose of oral vitamin K at birth, or no prophylaxis⁴⁵. Additional support for this theory comes from the observation that IV administration of vitamin K also does not offer long term protection against late VKDB, even when given in higher doses than would be given via IM administration⁸².

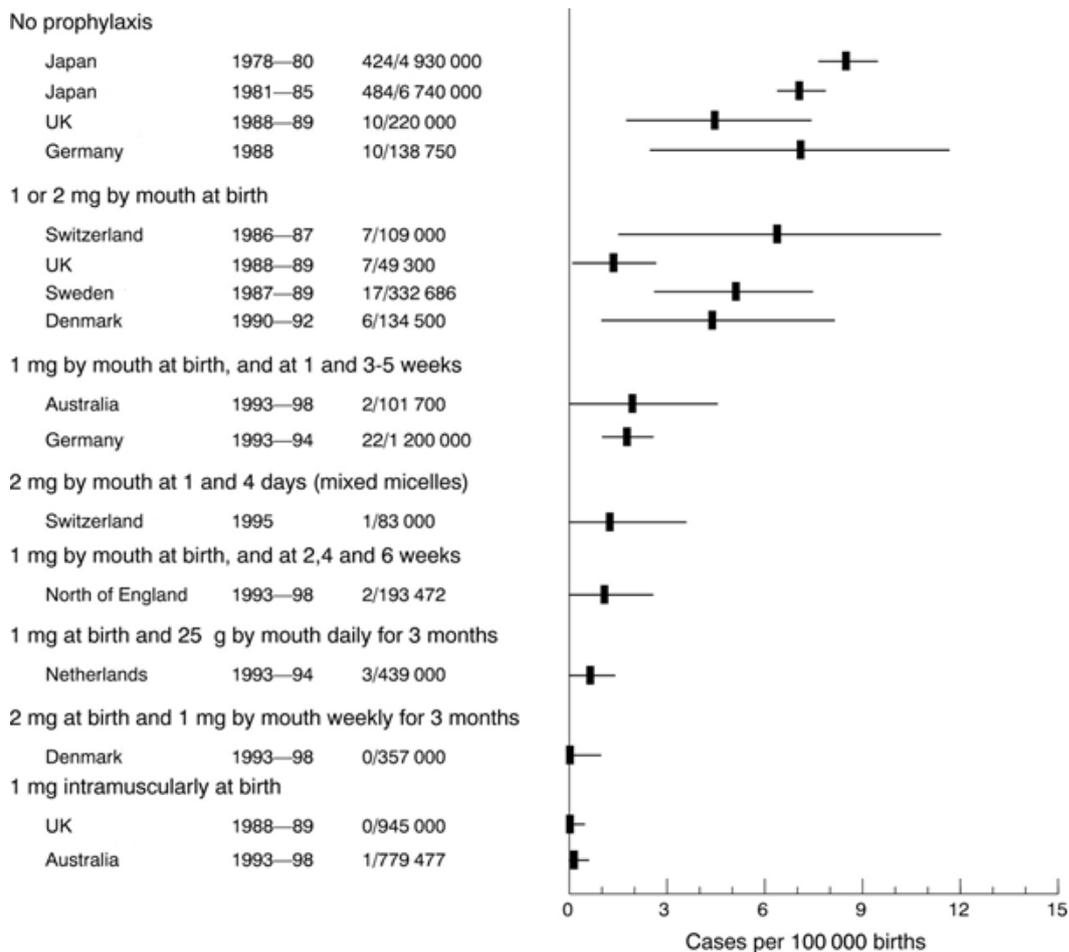


Figure 5: Incidence of VKDB under various prophylactic regimens (Reprinted with permission from Wariyar et al, 2000)⁸⁰

Despite evidence that oral prophylaxis is not as effective as IM prophylaxis, in the early 1990s it had a surge in popularity due to concerns that IM vitamin K was associated with childhood cancer (see later). As a result, paediatricians in a number of countries with VKDB surveillance programmes initiated assessments of the oral prophylaxis regimens used at the time^{59,83}. Germany and Australia both originally followed a three-dose oral regimen with 1mg of phyloquinone given at birth; days four to ten; and days twenty-eight to forty-two, or days twenty-one to twenty-eight, respectively. The total incidence of late VKDB under these regimens was low (2.6 and 2.5 per 100,000 births respectively) but it was still higher than the incidence in infants given IM prophylaxis⁵⁹. In Germany, the oral dose was increased to 2mg in a three dose regimen (almost identical to what is currently used in New Zealand), and this resulted in a decrease in the incidence to 0.72 per 100,000 live births and 0.44 per 100,000 infants who had received all recommended vitamin K prophylaxis doses⁷². Further research from the same group regarding the mixed micellar preparation of vitamin K (the version currently used in New Zealand) showed that the incidence of late VKDB was 0.44 per 100,000 infants compared to 0.72 per 100,000 infants given other preparations⁸⁴. The regimen followed by Denmark at the time was a single oral dose of 1mg of vitamin K at birth. The incidence of late VKDB under this program was calculated as 4.5 per 100,000 infants⁸⁵. However when Denmark later changed to giving a 2mg oral dose of vitamin K at birth followed by a 1mg oral dose weekly for the first three months of life, no cases of any form of VKDB were reported during the seven year observational period⁸⁶. Hence, while there is still debate over which method of oral prophylaxis is best, the three-dose oral schedule currently used in New Zealand appears to be one of the most effective⁸⁷. Nonetheless, IM prophylaxis remains the recommended route of administration in New Zealand due to its increased efficacy, although parents are able to choose the method they prefer.

Barriers to Successful Vitamin K Prophylaxis

A number of barriers to the successful implantation of prophylaxis regimens have been identified. These range from factors affecting the efficacy of regimens, to parents refusing vitamin K prophylaxis for their child. In this section I will describe such factors, starting with the association between liver disease and oral prophylactic failure; then describing the previously mentioned controversy regarding IM vitamin K prophylaxis and childhood cancer; then finally describing more recent research about factors that are associated with parental refusal of vitamin K.

Oral Prophylaxis and Liver Disease

As described above, most oral prophylaxis programmes are less effective at preventing VKDB than IM prophylaxis. From surveillance studies, a number of indicators of prophylaxis failure have been identified. These include: exclusive breastfeeding; non-compliance to the oral regimen; and more commonly, an unidentified, underlying absorptive disorder, of which cholestatic liver disease is the most common^{53, 72, 84, 87, 88}.

Cholestatic liver disease and other absorptive disorders can affect the functioning of the liver, and the production of bile. As previously discussed, vitamin K is a fat soluble vitamin that requires bile salts in order to be absorbed, thus when affected by such disorders, vitamin K is less able to be absorbed from the gastrointestinal tract³⁴. This suggests the lesser protection offered by oral vitamin K prophylaxis is at least partially due to the inability of some infants to absorb it.

Vitamin K and Childhood Cancer

In 1990, Golding et al published a study in the *British Journal of Cancer* about factors associated with childhood cancer in a national cohort study⁸⁹. One of the findings was an association of childhood cancer with vitamin K administration which was “unexpected and fitted no prior hypothesis”⁸⁹. Only one newspaper, the *Guardian*, published any mention of this study (on August 2 1990)³⁴.

Then almost two years later, on May 7 1992, the *Daily Mail* ran a front page headline that read “Vitamin Link to Child Cancer” and the next day a number of newspapers ran articles on the story³⁴. It became evident that the story had leaked from a supposedly closed paediatric meeting where Golding had presented preliminary follow-up data of a larger study to examine the possible link between

vitamin K and cancer. Golding's findings were published in August 1992 – they reported that the risk of leukaemia in children given IM vitamin K at birth was almost double (odds ratio 1.97) but there no increased risk when vitamin K was given orally⁹⁰. This resulted in the British Pediatric Association reviewing their policies and recommending the routine use of oral vitamin K prophylaxis in healthy newborns with IM prophylaxis reserved for those thought to be at the most risk of VKDB⁹¹. There was also a resultant decrease in the use of IM prophylaxis - in 1988 58% of newborns were routinely given IM vitamin K in Britain and this fell to 38% in 1993, the year after Golding's paper was published⁹¹.

Golding's study was the catalyst for a number of studies in numerous countries that tested the association between vitamin K and cancer. Nine studies were carried out between 1992 and 1998, and only one found a potential link. That study suggested that IM vitamin K was associated with an increased risk of developing acute lymphoblastic leukaemia one to six years after birth (odds ratio 1.79)⁹². In 1999 a working group of the WHO International Agency for Research on Cancer (IARC) reviewed the available literature and concluded that there was "inadequate evidence in humans and experimental animals for the carcinogenicity of vitamin K substances"⁹³. Following this publication, in 2002 and 2003 the two most extensive studies on the topic were published. In 2002, Roman et al. combined data from six major case-control studies⁹⁴. In total 2,431 children with cancer and 6,338 children without cancer were included in the studies, and they concluded that the "analysis provides no convincing evidence that intramuscular vitamin K is associated with childhood leukaemia"⁹⁴. In 2003, Fear et al. published an even more comprehensive study. They included 2,530 children with cancer (1,174 of whom had leukaemia) and 4,487 children without cancer. 39% of the children with cancer and 42% of the controls had received IM vitamin K⁹⁵. The study concluded "that there is no convincing evidence that neonatal vitamin K administration, irrespective of the route by which it is given, influences the risk of children developing leukaemia or any other cancer"⁹⁵.

While fears surrounding leukaemia and IM vitamin K have eased since Golding's original papers were published, there is evidence that it still affects the attitudes of both parents and health care professionals towards prophylaxis. A study from New

Zealand published in 2014 showed that some midwives have concerns that prophylaxis may be associated with cancer⁹⁶, and in the report mentioned earlier regarding infants with VKDB in Tennessee, the risk of leukaemia was given by some parents as the reason why they declined vitamin K¹. There is an abundance of information available to parents online about vitamin K prophylaxis (a Google™ search for “vitamin K injection” brings up 1.4 million results) and it is a topic that is often mentioned by blogs and online pregnancy/motherhood forums.

Other Factors Potentially Impacting Vitamin K Uptake

A number of factors have recently been associated with declining IM vitamin K prophylaxis. In a study from Canada, where having a midwife-assisted birth is rare (3% of births), it was found that births attended by midwives were eight times more likely to be associated with vitamin K refusal compared to physician-attended deliveries (risk ratio 8.4)⁴. The same study found planned home deliveries and deliveries in birth centres were also more likely to be associated with vitamin K refusal (risk ratios 4.9 and 3.6 respectively)⁴. Additionally, this study found that parents who refused vitamin K were fourteen times more likely to refuse childhood vaccinations at fifteen months of age (relative risk 14.6)⁴.

This data is supported by three recent studies – two from New Zealand and one from Australia. The first study from New Zealand found a risk ratio of 14.1 for non-immunisation in babies whose parents had refused vitamin K at birth, and a risk ratio of 3.5 for non-immunisation in babies whose parents had chosen oral vitamin K administration⁶. The second study from New Zealand identified a number of perinatal influences on the uptake of vitamin K prophylaxis. This study found that refusal of vitamin K was associated with being of Asian ethnicity (odds ratio 5.87); having a vaginal delivery (odds ratio 2.85); and greater gestational age, per week (odds ratio 1.24)². The same study found Asian ethnicity to also be associated with oral vitamin K prophylaxis (odds ratio 2.61), in addition to: having an obstetric nurse as Lead Maternity Carer (LMC) (odds ratio 2.65); vaginal delivery (odds ratio 2.34); and gestational age, per additional week (odds ratio 1.14)². Interestingly, it was also found that with increasing LMC experience was associated with parents being more likely to accept IM vitamin K as LMC experience, per decade, was associated with choosing oral prophylaxis (odds ratio 0.61)².

The third study, from Australia, also described maternal and infant characteristics by mode of vitamin K prophylaxis. They found that compared to infants who received IM vitamin K, those with oral or no prophylaxis were more likely to have mothers over thirty-five years (odds ratios 1.44 and 1.10 respectively), who had an analgesia free delivery (odds ratios 1.06 and 1.28 respectively)⁵. Additionally oral, or refusal of, prophylaxis was found to be associated with normal, vaginal birth; delivery in a birth centre (odds ratios 2.26 and 2.02 respectively); and planned home birth (odds ratios 5.50 and 23.52 respectively)⁵.

The factors above which have been identified as being associated with opting out of IM vitamin K prophylaxis have also been described as being aligned with a more 'natural' birth without medical interventions^{2, 5}. One study notes that this suggests that IM vitamin K prophylaxis is unappealing to parents who have concerns about the medicalisation of birth and of the risks of the injection⁵. However, despite these postulations, the exact reasons why parents choose to decline IM vitamin K remained enigmatic. Hence, this thesis aims to translate the factors associated with declining IM vitamin K into the actual thoughts and concerns of the parents who make this choice.

Parental Decision Making

The second aim of this thesis is to identify how health professionals should react when a parent chooses to refuse IM vitamin K. Vitamin K prophylaxis, along with other interventions such as immunisation, represent an interesting paradox, as while parents are free to decline, the intervention is strongly recommended²⁶. Ethical literature recognises the parents' right to make decisions for their children, but also recognises that there is a limit to such rights⁹⁷. The limit for New Zealand law is that when parents act in a manner where their child is being, or is likely to be, harmed, the state may intervene⁹⁸. One issue with the concept of "harm" is that it is hard to quantify and differing levels of harm may be acceptable to different people. In order to try and clarify this, a number of frameworks can be used to evaluate whether a parental decision is one that justifies state intervention^{97, 99}. In the discussion chapter of this thesis, the three frameworks described below will be discussed in detail with regards to vitamin K prophylaxis, and whether a refusal of IM vitamin K constitutes a decision that should be overridden.

The Best Interests of the Child

Clinicians have traditionally thought in terms of a child's "best interests" when deciding how to act when parents make a choice for their child that is not in line with recommendations¹⁰⁰. Consequently, the "best interest standard" has become the prevailing ethical standard used to determine when interference is justifiable¹⁰⁰. Acting in a person's best interests has been defined as "acting so as to promote maximally the good of the individual"¹⁰¹, and the best interest standard has been defined as one in which ". . . a surrogate decision maker must determine the highest net benefit among the available options, assigning different weights to interests the patient has in each option and discounting or subtracting inherent risks or costs"¹⁰².

However, acting in a child's best interests all of the time is an exceptionally high standard and one that is not applied to other parental decisions, such as place of residence and choice of school⁹⁹. It also does not allow any interests to be taken into account other than those of the child who is getting treated, such as the interests of the parents or siblings – all of whom have to cope with any potential consequences from the decision made⁹⁹. It is because of these criticisms that other decision making frameworks have found favour more recently.

The Harm Principle

According to the Harm Principle, parental decision making justifies interference if the decision will result in some harm to the child, rather than the decision not aligning with the child's best interests⁹⁷. In order to identify the level of harm that may be tolerated in parental decisions, Diekema has summarised various suggestions about the nature of the harm threshold⁹⁷. He argues that parental decisions that do not significantly increase the likelihood of serious harm compared to other options should be tolerated, and that state intervention to overrule parents should only occur when a child is at probable significant risk of serious harm. As a result, the harm principle accepts decisions that are suboptimal for the child, as long as they are unlikely to result in, or cause, significant harm.

The Zone of Parental Discretion

The Zone of Parental Discretion is a concept developed by ethicists at the Royal Children's Hospital Melbourne (Melbourne, Australia) as a tool to help consider if decisions made by parents should be accepted, even when they are not seen by medical staff to be in the child's best interests⁹⁹. It extends the idea of the harm principle to all situations where parents and clinicians may disagree, with the key idea being that clinicians can accept parental decisions that are suboptimal for the child, so long as the decisions do not involve probable significant harm⁹⁹.

With both the Harm Principle and the Zone of Parental Discretion, it is unclear what exactly the threshold of *probable significant harm* is, and how much risk of harm is acceptable. Thus vitamin K poses an interesting conundrum. As described earlier, the risk of an infant developing VKDB is generally low, and is difficult to accurately quantify for an individual. However when it does occur, the consequences of VKDB can be catastrophic³.

Objectives of this Thesis

As described in the preceding chapter, there are a number of studies that describe factors associated with opting out of IM vitamin K prophylaxis. However, there have been no studies regarding vitamin K prophylaxis that identify parents' specific concerns, or their reasons for opting out. Consequently the first objective of this study is to explore parents' thoughts, feelings, and concerns regarding vitamin K prophylaxis and ascertain the specific reasons why they chose for their child not to receive IM vitamin K.

The second objective of this study is to conduct an ethical analysis of parental refusal of IM vitamin K. The discussion of this thesis will use "ethical tools" to explore whether refusing IM vitamin K prophylaxis is a decision that should be overridden. It will also discuss how clinicians should act in such circumstances in order to both advocate for what is best for the child; and establish, or maintain, a positive healthcare alliance with the family.

Chapter Two: Methods

In order to achieve the objectives of this study, qualitative research methodology was used to explore the perceptions, opinions, and influences of a group of parents who opted out of intramuscular vitamin K prophylaxis for their child. Semi-structured interviews were conducted with participants and the resulting data was analysed using thematic analysis. The details of how I collected, analysed and interpreted the data are described in this chapter, and I also introduce two key ethical questions that will be explored in the discussion chapter.

Study Setting and Recruitment

This study was conducted in the Otago/Southland region of New Zealand (population ~310,000). New Zealand has publically funded maternity and newborn healthcare, and the majority of births for this region occur at the Queen Mary Maternity Centre (QMMC), Dunedin Hospital (Dunedin, New Zealand), the only provider of tertiary maternity and newborn care for the region. There are eleven other birthing units in the region: one secondary level unit based at Invercargill hospital and ten that provide primary maternity services. In addition, approximately 4.3% of births are planned to occur at home¹⁰³.

The key inclusion criteria for the study were:

1. Delivery of a live-born child within the Otago/Southland region
2. A parental decision to decline IM vitamin K prophylaxis for their newborn (either complete refusal of vitamin K or a choice of oral administration)
3. Adequate English (or availability of an interpreter) for an interview

After reviewing the literature and similar qualitative projects, my supervisors and I decided that fifteen interviews were likely to be an appropriate number to produce meaningful results. The number of interviews also had to be achievable within the time allowed for a BMedSc(Hons) project, particularly in light of the fact that only ~7% of births in the region involve a decision to decline IM vitamin K. During the course of the study it was confirmed that a sufficient degree of data saturation had been reached after fifteen interviews as no new themes were able to

be elucidated from the data. Recruitment occurred between 07/03/2015-18/07/15 via a number of pathways, which are outlined below.

As discussed in the previous section, it has been noted that there is an association between declining IM vitamin K prophylaxis and a preference for factors that are generally associated with “natural” childbirth, such as homebirth and declining immunisations^{2, 4, 5}. Based on this, for initial recruitment I contacted three midwives who are strong advocates for homebirth in the Dunedin area in order to ensure that parents who chose to birth at home were well represented in the study cohort. I asked the midwives to talk about the study to expectant parents in their care who had chosen to decline IM vitamin K, and if they were interested, to pass their details on to me. I made contact with the referred parents and emailed them the study information sheet. If parents then consented to taking part, we organised a time and place for the interview. Four participants were recruited in this manner.

Secondly, I contacted medical staff involved with newborn care at QMMC, this included those conducting new born baby examinations. As with the midwives, I asked them to talk to parents who had chosen to decline IM vitamin K and to pass their details on to me if they were interested in taking part. I made contact with the referred parents and gave them the study information sheet. If parents then decided to take part, we organised a time and place for the interview. Seven participating families were recruited using this method. For these participants, and the four participants recruited by home birth midwives, there is no way to know how many other potential participants the study was discussed with (the denominator of this recruitment method). However a previous study showed that approximately 125 babies did not receive IM vitamin K at QMMC each year between January 2009 and December 2012 (503 in total)². If we use this data to extrapolate, we could expect that approximately sixty infants in the region did not receive IM vitamin K during the five months that we were recruiting and hence the percentage of these families we recruited is 18% (11/60).

Thirdly, invitation letters were posted to a random selection of forty-two mothers identified from electronic maternity records as having declined IM vitamin K prophylaxis between 01/01/2014-08/04/2015 at QMMC. QMMC keeps an electronic maternity database, Maternity Plus 9.42 (Solutions Plus, Auckland, New Zealand),

with data entered throughout the pregnancy, from demographic and health data collected at initial early pregnancy registration by administrative staff, to all pregnancy, labour and postnatal data collected by the LMC or hospital midwifery team. Vitamin K details are added to this system from signed consent and administration forms which are required in all instances of vitamin K administration (or non-administration). If parents wanted to take part in the study after receiving the invitation, they contacted me via email or phone in order to arrange a time and place for the interview. Three participants out of forty-two invitations (7%) contacted me and completed the study using this method of recruitment.

Fourthly, one participant was recruited via a referral from another medical student who knew about the project I was conducting this year. They had a friend who had opted out of IM vitamin K for their children and they contacted the family about the study, who then decided they would like to take part. They gave permission for their contact details to be passed to me, I contacted them and we organised a time for the study interview.

It may be important to note at this stage that unlike many studies there was no incentive offered to participants for taking part. This had positive aspects as it meant that participants were freely giving up their time because they were interested in the study and felt it was important, but also had negative aspects as participants were not offered anything for their time and I may have been able to recruit more participants in less time if I had been able to offer them a reward.

Information about the participants is included in the results chapter.

The Interview Process

Semi-structured interviews were used to explore parental reasons for declining IM vitamin K for their newborn. The questions asked in the interviews centred on a number of key points that were developed through discussions with paediatricians and neonatologists, as well as interviews conducted with ten Dunedin midwives, as part of a prior University of Otago summer studentship completed by another student.

The interviews conducted with midwives centred on the role of the midwife in informing parents about vitamin K prophylaxis. Points raised in these interviews

included: how important they thought it was the parents knew about and gave vitamin K; their opinion on the Ministry of Health guidelines for vitamin K prophylaxis; how they inform parents; what parents already know about vitamin K and how they find information; common parental objections to IM vitamin K; and how they would improve the vitamin K guidelines. Their answers guided a number of the interview questions and ensured that issues central to newborn vitamin K prophylaxis were discussed in the interviews.

The key points covered by my interview guide included demographic data for each participant (including mother's age at interview and age at first child, ethnicity, address to identify their deprivation decile^d, mother's level of education, parity^e, and marital status); an initial description of how they made their decision to opt out of IM vitamin K; when and how they first became aware of vitamin K; information, people and health professionals that influenced their decision; health professional reactions to opting out of IM vitamin K; concerns about giving vitamin K; cultural and religious issues regarding vitamin K prophylaxis; whether they felt any pressure to make their decision a certain way; alternative methods employed to prevent VKDB; and their views about other perinatal health interventions, including immunisation and newborn screening.

The questions in the interview guide were worded to ensure they were not leading questions^f and were as open ended as possible. If participants gave an unclear, or particularly short answer as a response, I would ask them to further clarify or explain their answer. Words that were absolute, or had emotional connotations were avoided in the interview guide to ensure that the answers given by participants reflected their true opinions. The full interview guide is included in Appendix 1.

The semi-structured approach to the interviews allowed extra questions to be asked in response to participants' answers. This meant that any points mentioned as having an influence on a participant's decision were able to be explored further, and that complex discussion regarding each topic could occur. The interview guide was

^d A well described marker of socioeconomic status, according to the New Zealand Deprivation Index¹⁰⁰

^e Parity is the number of pregnancies a woman has carried to over 20 weeks gestation

^f A leading question encourages a certain response due to the way that the question is phrased

not restrictive, but having a number of structured questions gave a framework for each interview and allowed for the generation of comparable data.

The interviews were conducted over a period of five months. Nine were conducted face-to-face in the participants' homes, one interview was conducted in hospital the day following the child's birth, and five were conducted over the phone due to the geographical location of the participant. Eleven of the interviews were conducted with the mother alone and four had both parents present. All participants had the opportunity to ask questions about the study and gave their informed consent to take part.

After the initial interviews had taken place, we had a number of additional questions inspired by the data gathered, and the participants were again contacted in regards to these. These extra questions are also included within the interview guide in Appendix 1.

All interviews were audio-recorded using a digital voice recorder and transcribed to allow for analysis. Total interview times varied in length, the longest interview was seventy-five minutes and the shortest was eleven minutes. The median interview time was twenty-eight minutes and the mean was thirty-three minutes. This variation in time was due to the nature of the semi-structured interview guide and the differing reasons participants had for opting out of IM vitamin K. The shortest interview was also conducted with a family whose child had been born that week and they had limited time for the interview. Following the second round of interviews, my supervisors and I were satisfied that data saturation had been achieved

In anticipation of subsequent thematic analysis I personally transcribed the interviews and each interview was listened to multiple times in order to ensure accuracy and familiarisation with the data. This process took between four and ten hours for each hour of recording as it was dependent on a number of factors. These included: speed of speech, accents, and background noise. It was made clear to the participants that the only people who would see the transcripts were myself and my supervisors. Any potentially identifying information was removed from the transcripts, even before handing on to my supervisors, in order to preserve

anonymity. The raw data, including transcripts and audio recordings have been stored according to University of Otago policies.

Thematic Analysis

Thematic analysis was used to identify themes from the interview data. Thematic analysis is a method to identify, analyse, and report patterns (known as themes) within data and allows researchers to provide a complex account of data gathered, usually via focus groups or a qualitative interview process¹⁰⁴.

In the following paragraphs I will describe the methodology of identifying, analysing, and reporting themes from the interview transcripts. An important informant to this part of my methodology was the paper *Using Thematic Analysis in Psychology* by Braun and Clarke¹⁰⁴, as not only did it discuss instances in which thematic analysis should be used, but it provided a guide to effectively conduct it.

Firstly, each interview was transcribed from the audio recording. This allowed me to both view the data set in a tangible way, and familiarise myself with it. During this stage, I was already able to begin to generate ideas about potential patterns in the data.

Following transcription, the next step was to code the data. Coding is the process of moving the data into meaningful groups¹⁰⁵. Some of these groups followed the questions asked in the interviews but there were also concepts that captured a seemingly important aspect of parental decision making but did not 'belong' to a particular question. It is important to note that identification of a potential theme was not dependent on how frequently it was brought up during the interviews¹⁰⁴, but rather anything discussed in the interviews that represented a seemingly important aspect of parental decision making was explored.

Following coding, the data was analysed further and key themes and subthemes were decided upon through an iterative process that included not only personal review by myself, but additional discussion between my two supervisors and I (one of my supervisors (NK) is a paediatric bioethicist and both are paediatricians experienced in newborn prophylactic vitamin K administration). These themes are presented and described in the next chapter of results along with quotes from the participants that illustrate the essence of each subtheme.

Reflexivity and Researcher Background

Good research should be reflexive. This means that the researcher should regularly assess how they are conducting the research, and the role they are playing in the research process. Thus it is important to note that the development of themes requires personal judgement. It is possible that if the interview transcripts were reviewed by another person, or from a different theoretical position, that this may result in the development of alternative themes to those in this thesis¹⁰⁶. Due to this, before the commencement of the results chapter which includes the outcomes of the thematic analysis, it is important to mention my background and how this may have influenced my interpretation of the data. I am a fourth year university student between my third and fourth years of medical school. This may have had some influence on how I engaged with participants and the themes I identified, however through the processes described above, every precaution was taken to prevent bias in this study. As a result I am not consciously aware of any effect my background had on the project. However, I am aware that it may impact how the information presented is perceived by others.

Ethical Analysis

In addition to presenting the results of the qualitative study described above, I will also examine the following two ethical questions related to IM vitamin K prophylaxis and parental decision making:

1. Does parental refusal of IM vitamin K prophylaxis constitute the type of parental decision that should be overridden?
2. If it shouldn't be overridden (as is current practice) then how should health professionals respond to such a decision that from a standard medical perspective does not appear to be in the child's "best interests"?

These questions will be discussed using the ethical frameworks described in chapter one: The Best Interests Model, the Harm Threshold Model, and the Zone of Parental Discretion. These models will be used to distinguish whether parental refusal of vitamin K is a decision that should be overturned, and to inform a discussion of how health professionals should act when such a decision has been made.

Ethics and Māori Consultation

Ethics approval for this project was sought through the Health and Disability Ethics Committee (Ethics ref: 12/STH/41) and the project was approved on 29 November 2012. Two post-approval amendments were sought after this date: the first was granted in December 2013, and the second was conducted and requested by myself, and granted in March 2015. This included substantial changes to the questionnaire and information sheet, and changes to recruitment that allowed me to invite parents whose children were born at QMMC between January 2014 and March 2015.

Maori consultation was conducted via an application to the Ngā Tahu Research Consultation Committee, and their approval was obtained.

Evidence of the above processes is included as Appendix 2 and Appendix 3.

Chapter Three: Results

The following chapter will describe the main findings from this research project. Firstly I will outline the study participants, including their demographic data. Participants have been anonymised and no identifying data will be provided. Secondly, I will illustrate the themes and subthemes of parental decision making regarding vitamin K prophylaxis that were identified from the thematic analysis.

Participants

Fifteen families were interviewed. Eleven interviews were conducted with mothers, and four had both parents present. Ten families had declined vitamin K prophylaxis for their newborn and five had chosen oral administration. Eight different ethnicities were represented in the study cohort.

The mean age of mothers participating in the study was thirty-four years (range twenty-three to forty-five), and their mean age at the birth of their first child was twenty-nine years (range twenty-one to thirty-six). Nine interviews were conducted with families who had a child born in the previous twelve months and the median age of the families' youngest child at the time of interview was nine months (range one day – thirteen years). The study population was highly educated, with ten mothers holding a Bachelor's degree or higher. Five of the participating families (33%) intended to birth at home, a rate higher than the general population, estimated at 4.3%¹⁰³. In addition, two families chose to opt out of newborn screening, and seven either had already declined, or planned to decline, some or all childhood immunisations.

Demographic data for each participant is presented on the following page in Table 1. Each participant has a corresponding number in the first column (Interview #) which will be used to depict the origin of quotes used in the following thematic analysis and discussion sections.

Table 1: Participant Demographics

Interview #	Method of vitamin K ^g	Ethnicity	Marital Status	Age of mother (years) ^h	Age at First Child (years)	Age of youngest child ⁱ	Parity	Educational Level	Deprivation Decile ^j	Intended Place of Birth	Newborn Screening	Full Vaccinations
1	Oral	NZ European	De facto	24	24	10 days	1	High School	5	Hospital	Y	Y
2	Declined	NZ European	Divorced	44	22	13 years	3	Bachelor's	6	Home	N	N
3	Declined	NZ European	Engaged	23	21	16 days	2	High School	7	Hospital	Y	N
4	Declined	NZ European	De facto	45	33	9 years	2	Bachelor's	6	Home	N	N
5	Declined	NZ European	Married	31	29	1 year 5 months	1	Master's	4	Home	Y	Y
6	Declined	NZ European	Married	32	29	1 year 1 month	2	Doctorate	2	Hospital	Y	Y
7	Declined	Russian	De facto	43	34	9 months	2	Bachelor's	6	Hospital	Y	N
8	Oral	NZ European	De facto	26	20	3 days	2	High School	7	Hospital	Y	N
9	Declined	NZ European	De facto	37	36	1 year	1	Trade cert.	3	Hospital	Y	Y
10	Declined	Dutch	Married	31	25	3 years 4 months	2	Bachelor's	8	Home	Y	N
11	Oral	Sinhalese	Married	34	33	1 year 1 month	2	Doctorate	8	Hospital	Y	Y
12	Declined	English	Married	31	31	1 month	1	Master's	7	Home	Y	Y
13	Oral	American	Married	34	34	1 day	1	Master's	2	Hospital	Y	Y
14	Declined	Japanese	De facto	38	34	6 days	2	Trade cert.	8	Hospital	Y	N
15	Oral	Indian	Married	36	30	1 month	3	Bachelor's	7	Hospital	Y	Y

^g This is the method of administration initially chosen by parents, regardless of if they later changed their mind

^h At the time of the study interview

ⁱ At the time of the study interview

^j For the New Zealand deprivation index, a high score (10) indicates a high level of deprivation and a low score (1) indicates a low level of deprivation

Thematic Analysis

Multiple themes representing important aspects of parental decision regarding vitamin K prophylaxis were present in the data gathered from these interviews. For ease of understanding and reading, these have been clustered into groups of subthemes under the headings of: parental beliefs and values, child welfare, and external influences. These themes are first illustrated with representative quotes in Tables 2, 3, and 4, and are described in full detail in the pages following. Many of these themes are interrelated and a number of quotes could potentially illustrate more than one theme.

In addition, many parents brought up concerns about other perinatal and childhood interventions, and data on this is included in a final section.

Table 2: Themes Related to Parental Beliefs and Values

Theme	Statement (interview number)
Alternative	"I personally would identify myself as more of an alternative person in general . . ."
Lifestyle	<p>I don't always take drugs if I'm feeling bad, I'll find something else or something more natural." (8)</p> <p>"It's always been his belief to keep things as natural as possible...He's very strongly into letting nature take its course, right down to organic foods, soaps, conditioners and it goes as far as avoiding any sort of medical intervention."(3)</p>
Natural Birth	<p>"I just didn't want to interfere with nature that much." (2)</p> <p>"It is quite natural and even though it's quite overpowering it is very natural and your body can do it with or without you complying really." (6)</p>
Questioning Necessity	<p>"I just don't think it's [vitamin K's] hugely important otherwise it would've done it itself naturally." (3)</p> <p>"Why treat something that you can't see or there's no outward sign that she's lacking in vitamin K?"(9)</p>
Questioning of Mainstream Medicine/Science	<p>"We're not a "yes doctor" kind of family, we have some alternative perspectives to what mainstream medicine suggests." (4)</p> <p>"Personally I would try and research it myself as much as I could and then I might still of course follow medical advice depending on the situation." (10)</p>
Intervention Reduction	<p>"I was feeling that the least interventions as possible would have the best outcome." (5)</p> <p>"I think minimal intervention in general about everything, especially when they're little, and they're so new, and their little immune systems are so new." (8)</p>
Medicalisation of Birth	<p>"Birth is terribly over medicalised in the Western world." (2)</p> <p>"In terms of healthy, normal pregnancy I think we probably do maybe intervene just a little bit too much." (8)</p>
Breastfeeding	<p>"If baby really needed more Vitamin K then they'd get it from me." (3)</p> <p>"If he didn't get it through breastmilk naturally then that was another indicator that maybe it was not important to have or might be beneficial to not have it." (5)</p>
Religion/Evolution	<p>"We believe that God created us and knew what He was doing, so why wouldn't there be vitamin K in a baby when it's obviously very necessary in an adult?" (6)</p> <p>"If it had been a big problem in the past then evolution probably would have weeded it out or found some way to deal with it." (5)</p>

Table 3: Themes Related to Child Welfare

Theme	Statement (participant number)
Perceived Risks Outweigh Benefits	<p>“For us it was the risks from [receiving] Vitamin K were higher because he was such a normal, easy birth.” (3)</p> <p>“For me it’s always about risk benefit, so the risk was the bleeding, but what are the risks of giving the intervention?” (4)</p>
Perceived Risk of Leukaemia	<p>“There’s one study out about leukaemia associated with intramuscular vitamin K and even though there is some evidence against that, the fact that it was in the literature was concerning.” (11)</p> <p>“I remember something like if we choose to give through injection there was a little side effect of some leukaemia. So for that reason I thought oral was better.”</p>
Amount Given via IM	<p>“There was also that sort of figure of two thousand times the dose of what an adult would have and it’s like well that’s really, really abnormal.” (2)</p> <p>“I knew that the vitamin K dose is quite high in one go so that led me to want to do the oral dose and spread it out as well.” (13)</p>
Pain	<p>“We didn’t want to have her freshly born and then get stabbed up with a needle.” (1)</p> <p>“Oral is better because baby won’t cry, baby’s not getting any pain.” (15)</p>
Other Side Effect Concerns	<p>“I think we’re a bit naïve to think that is just because it doesn’t have leukaemia that there’s not some other spectrum of issues that can arise.” (2)</p> <p>“I think that children sometimes have allergy because of vitamin K.” (14)</p>
Perceived Low Risk	<p>“For most women, it means nothing. Not doing vitamin K does not mean your baby will likely die. It’s such a low percentage of babies that will be affected.” (2)</p> <p>“If it’s like that for lots of kids, if there’s no risk factor for them other than the fact that they’re being born, then maybe it’s the way it should be or it’s safe enough to risk not giving it to them.” (5)</p>
Changing Mind Depending on Circumstances	<p>“I would’ve reconsidered if there’d been anything abnormal in the labour or birth.” (2)</p> <p>“Because of [baby]’s birth we decided the risks of not having vitamin K because he was bruised... were higher.” (3)</p>
Deciding Between Oral and IM	<p>“It was never really a question of not getting it done, it was just how to have it done.” (13)</p>

Table 4: Themes Related to External Influences

Theme	Statement (participant number)
Influence of Midwives	<p>"She [the midwife] said that it's recommended for all babies but she told us she didn't feel it was necessary in every case." (3)</p> <p>"She [the midwife] had her own views but she probably didn't tell us them she kept it quite neutral." (9)</p>
Influence of Medical Professionals	<p>"I think when a doctor or a medical professional presents you with 'this is available but it is not compulsory' you think 'well if it's not compulsory then it can't be actually necessary.'" (6)</p> <p>"If a medical professional tells us "this is needed" we'd probably take it without any qualms." (6)</p> <p>"There was that one doctor that drove me nuts... she was basically making us feel like we were really bad parents because we didn't do it." (9)</p>
Information Sources	<p>"I found the pamphlets that they gave out from the hospital...they expected that you would do it. It wasn't exactly giving you the option...if we'd only seen those pamphlets we probably would have just done it." (3)</p> <p>"I tried to get my information from people that I thought were knowledgeable about this and also just books, I always checked out the studies at the back about it, so looked at the references and made sure that it wasn't just someone's opinion." (10)</p>
Celebrities	<p>"Jacqui Brown...did a pregnancy book and there was quite a bit of information in there about Vitamin K...it was the book that made me wonder whether or not we even needed it, pretty sure in the book she chose not to give it [vitamin K] to her son." (3)</p>
Family	<p>"Mum mentioned that when I had it when I was a kid that I had it orally... and she said that it all went fine...it didn't make any difference...so it was good to have a first-hand experience" (8)</p> <p>"I wanted to check with my sister in law. I asked her, she said she also gave oral [vitamin K] for her kids." (15)</p>
Friends	<p>"I remember asking other mums, so friends who'd had kids already, asking them if they'd done it and what their thought process was around it." (5)</p>

Parental Beliefs and Values

The following themes were included under parental beliefs and values because they are representative of incompatibilities between deeply held parental beliefs and/or values and the administration of IM vitamin K prophylaxis to their baby.

Themes include: beliefs from an evolutionary or religious perspective, an identity with an “alternative” lifestyle, and beliefs that birth is a natural process that we should not “interfere” with.

Alternative Lifestyle

For a number of participants, declining IM vitamin K prophylaxis for their newborn aligned with their own personal choices to live a self-described “alternative” lifestyle. This is illustrated in the following quotes:

I was a little bit anti-conformist, can you tell? (Participant 2)

It's always been his belief to keep things as natural as possible...he's very strongly into letting nature take its course. Right down to organic food, soaps, conditioners and it goes as far as avoiding any sort of medical intervention. (Participant 3 speaking about her fiancé)

Our kind of social cultural perspective is one of holism and not blind faith in the medical system. (Participant 4)

I personally would identify myself as more of an alternative person in general . . . I don't always take drugs if I'm feeling bad, I'll find something else or something more natural. I took a lot of natural remedies whilst I was pregnant. (Participant 8)

For these parents, opting out of IM vitamin K fits within their worldview and is aligned with their personal beliefs. As one would expect, these beliefs guided many aspects of their lives, not just their decision about vitamin K (evidence for this is present in the answers given over many of the following sections).

Natural Birth

Participants that spoke of a natural birth often spoke of it in the context of having a “trust of nature” and believing that having as few interventions as possible would result in the best outcome. Such participants also often spoke of a preference for home and/or analgesia-free birth. Several quotes illustrate this theme:

I just didn't want to interfere with nature that much. . . I had a trust of nature which showed through in my births as well because they were all completely easy, normal births. (Participant 2)

I remember someone saying to me once 'How do you get comfortable with the whole being at home and not being so afraid?' and it's like well to be honest I'm more afraid of walking through the doors of the hospital and being confronted with all the stuff that can happen there. (Participant 4)

It is quite natural and even though it's quite overpowering it is very natural and you know your body can do it with or without you complying really but I think the more we try to intervene the worse it goes often. (Participant 6)

Right from the start I felt that birth is just a completely natural thing that women's bodies are designed to do and I felt totally confident that I could do it without assistance or intervention and I think that I'm not massively keen on the hospital environment either...I'm very into the idea of the fourth trimester and I just wanted as peaceful as birthing experience for her as possible and for me being injected wasn't part of that. (Participant 12)

Again for these parents opting out of IM vitamin K for their baby fits with broader beliefs, this time concerning childbirth being a “natural process” with no necessity for medical intervention

Questioning Necessity of Vitamin K Prophylaxis

Parents who questioned the necessity of vitamin K prophylaxis did so for a variety of reasons. Some considered the research about VKDB to be out of date and thought it was not applicable in a modern clinical setting, or that VKDB is actually a problem created by medical interference at birth. Others considered that because all babies are born with low levels of vitamin K, there must be a reason for this, or it must not be important for them to have.

The fact that they're born with a low dose and that there's a low dose available, it builds up as they get older, I just don't think it's hugely important otherwise it would've done it itself naturally. (Participant 3)

I come from a place of feeling that much of the data and research and stuff is done around medicalised birthing and based on historical situations where mothers and babies were separated a lot more. . . I would love to see a study on babies that have had absolutely no separation from their mothers and complete physiological birthing. What's the incidence of Vitamin K deficiency bleeding? (Participant 4)

Why treat something that you can't see or there's no outward sign that she's lacking in vitamin K? . . . Vitamin K is like the only one that stands out as being something not obviously necessary. (Participant 9)

Others felt protected by having a 'normal' pregnancy and birth with a baby that did not show any sign of bruising.

*They were all completely normal births, I just didn't see the point.
(Participant 2)*

*For a full term uncomplicated normal birth it didn't seem appropriate but in another situation I totally thought it was a good option.
(Participant 4)*

Furthermore some parents also felt that if they were eating a diet rich in vitamin K that prophylaxis was not needed.

My diet was actually naturally high in vitamin K and I also take a supplement which had more than your daily allowance of vitamin K in it or more than your suggested daily intake of vitamin K in it so I figured that [baby] would've got vitamin K from me anyway in the womb so I didn't feel she'd be deficient. (Participant 12)

Questioning of Mainstream Medicine/Science

A number of participants brought up that they have a scepticism, or questioning attitude towards mainstream medicine and the healthcare system as a whole. This was then reflected in their decision regarding vitamin K prophylaxis. Some participants stated that they felt it was best to do their own research as well as taking into consideration medical advice, rather than being totally against, or totally for, medical recommendations.

We're not a yes doctor kind of family. We have some alternative perspectives to what mainstream medicine suggests. (Participant 4)

I think not just blindly accepting what doctors and science tell me. . . I like to do my own research find out my own stuff. If I agree with it yes, if I don't that's ok too, and so yeah I'm definitely a bit more open and alternative. (Participant 8)

I don't just trust any doctors saying something but I've had bad experiences with that anyway. Personally I would try and research it myself as much as I could and then I might still of course follow medical advice depending on the situation. (Participant 10)

Intervention Reduction

One of the most common reasons stated by parents for opting out of IM vitamin K was the idea of avoiding interventions not just in their pregnancy and labour but also more specifically for their child.

We wanted to where possible minimise the level of intervention that he needed. . . He has had so many interventions while he was in utero because of our risk history. So I think I'm glad that he had one less injection and one lower level of intervention than he might otherwise have had. (Participant 11)

For me personally I was feeling that the least interventions possible would have the best outcome . . . every intervention has potential to lead to another intervention. (Participant 5)

I think minimal intervention in general about everything, especially when they're little, and they're so new, and their little immune systems are so new. (Participant 8)

The Medicalisation of Birth

A similar theme to wanting to reduce interventions were parents feeling that birth is “over medicalised” and that we unnecessarily interfere with the process. Parents spoke of feeling that while some interventions are necessary, and justified, it is also sometimes a question of whether they are really needed, or are merely “convenient” for the parents and/or healthcare staff.

Birth is terribly over medicalised in the Western world. (Participant 2)

I think it's a balance. . . It's whether it's really needed or whether it's just convenient. Like this time with my gestational diabetes I was on insulin injections but after the birth I had quite a few doctors tell me that they wouldn't have considered me as a gestational diabetes case because my numbers were so borderline. . . like they probably didn't need to interfere, I didn't need the insulin. (Participant 3)

There are times when you totally need the intervention. . . but I think in terms of healthy, normal pregnancy I think we probably do maybe intervene just a little bit too much. It's such a natural thing it can definitely be done without all the extras. (Participant 8)

I definitely would not judge any woman's choice, however they want to give birth they should be allowed to and respected for that, but I do think there is quite a lot of fearmongering and the feeling that if you don't birth in hospital you are risking yourself and your baby, I think that's still very present. (Participant 12)

Breastfeeding

Another theme present in the interviews was the belief that if their infant *really* needed vitamin K, it would be present in, and passed through, their breastmilk. The majority of these parents knew that vitamin K was only present in low levels in breastmilk, and took this as a sign that it was not as necessary for their child. Such

parents considered breastmilk to be a whole food with everything present that their child would require.

I suppose it goes right back to the natural side of things. If baby really needed more Vitamin K then they'd get it from me but I don't think he needs it. . . I honestly believe that if baby really needed that high of dose of vitamin K then it would be available to them through the breast milk. (Participant 3)

If he didn't get it through breastmilk naturally then that was another indicator that maybe it was not important to have or might be beneficial to not have it. (Participant 5)

We thought that Mother Nature supplies her with everything she needs. (Participant 7)

Even orally my concern was that it's still something other than breast milk and it's something, artificial is possibly the wrong word, but it's still something that is introduced to the infant rather than something the infant chooses to have. (Participant 11)

Religion and Evolution

Two families brought up similar points regarding their faith in human creation. Whilst one family spoke of this faith in terms of divine creation, and one spoke in terms of evolution, the main point for both families was their faith in the system of creation (by whichever means) and how if vitamin K was necessary for infants, they would be born with it.

A belief that God created everyone and will have created us perfectly was stated by the family with the divine creation viewpoint. For this family, they believe that if God creates babies to have low vitamin K in their system at birth, there must be a reason why. This was illustrated by the following quote:

We believe that God created us and knew what He was doing so why wouldn't there be vitamin K in a baby when it's obviously very necessary in an adult or in a person living in the world? (Participant 6)

The second family stated their belief that if all babies have lower levels of vitamin K in their system at birth, and a decreased ability of blood to clot, then it has probably evolved that way for a reason. They also stated that if VKDB has been a problem for infants in the past, we would have evolved to overcome this problem.

If it's something that across the board kids do have a lower or babies born do have a lower level of then perhaps it's kind of evolved to be like that for a reason ,maybe they need less clotting in their blood post birth. . . If it'd been a big problem in the past then evolution probably would've weeded out or found some way to deal with it. (Participant 5)

Child Welfare

While parental beliefs and values were important factors for decision making, the majority of parents also brought up concerns regarding balancing the risks and benefits of administering vitamin K to their baby. These concerns related to: a perceived low level of necessity, potential pain, and worries about risks and side effects. The following section will describe common themes that parents brought up as objections to IM vitamin K prophylaxis and provide quotes to illustrate each theme.

Perceived Risks outweigh Benefits

All the participants who took part in the study spoke about their perception of the potential risks for their child if they received IM vitamin K prophylaxis. A number of participants went on to speak about how they weighed these risks against the benefits their child would receive.

For us it was the risks from vitamin K were higher because he was such a normal, easy birth. (Participant 3)

For me it's always about risk benefit, so the risk was the bleeding, but what are the risks of giving the intervention? . . . There's always the unknown and so the need to do something has to be strong enough to override those potentials from my perspective. (Participant 4)

Concern about Amount Given

One concern given by parents for opting out of IM vitamin K was the amount given in the injection.

I think there was also that sort of figure of two thousand times the dose of what an adult would have and it's like well that's really, really abnormal. (Participant 2)

For some parents, this high dose was one reason that they chose oral administration of vitamin K, as in their opinion it was preferable to spread out the amount given.

I knew that the vitamin K dose is quite high in one go so that led me to want to do the oral dose and spread it out as well. (Participant 13)

Pain

For those who opted for oral prophylaxis, perceived pain for their newborn emerged as a very important factor, and was highlighted by the majority as their foremost reason for choosing oral over IM.

We just wanted to go for the oral first... we didn't want to have her freshly born and then get stabbed up with a needle. (Participant 1)

I didn't want my baby to have an injection as their first experience of being in the world. . . I just thought it'd be traumatising for her to have an injection as soon as she was born. (Participant 12)

Oral is better because baby won't cry, baby's not getting any pain. (Participant 15)

However, in contrast to the above, one mother questioned the idea of declining IM vitamin K to avoid causing pain, by comparing it to the experience of being born.

Really they've just been through a much more painful traumatic experience than having a needle. I mean going through a birth canal is not going to be comfortable so really a needle prick that lasts a few seconds is much less and they probably don't notice it, and they don't notice it once they start feeding again which they do straight away. (Participant 6)

Risk of Leukaemia

Concerns about side effects or more serious harms were also significant factors for some parents. In particular, this was a perceived increase in risk for childhood leukaemia, which, as mentioned in the introduction, is a result of two studies from the early 1990s.

There's one study out about leukaemia associated with intramuscular vitamin K and even though there's some evidence against that, the fact that it was in the literature is concerning. (Participant 11)

I remember something like if we choose to give through injection there was a little side effect of some leukaemia. So for that reason I thought oral was better than injection. (Participant 15)

Concerns of Other Side Effects

In addition to leukaemia, other potential side effects were also of concern, both at the time and in the future. Parents sometimes acknowledged that while there are

no known common side effects, they were also concerned about unknown things that could arise.

I think we're a bit naïve to think . . . just because it doesn't have leukaemia that there's not some other spectrum of issues that can arise. (Participant 2)

I looked at a couple of, I can't remember unfortunately the journals they were in, but a couple of medical studies on vitamin K and the potential side effects and that made me sure that I've made the right decision. (Participant 12)

I think that children sometimes have allergy because of vitamin K. (Participant 14)

Low Risk of VKDB

For some parents, their decision not to give vitamin K was also based on how uncommon VKDB is. They felt that due to the already low risk, an intervention to further reduce it was not needed, or that they could reduce the risk through other means, such as a 'natural' birth and eating vitamin K rich foods.

For most women, it means nothing. Not doing vitamin K does not mean your baby will likely die. It's such a low percentage of babies that will be affected. (Participant 2)

If it's like that for lots of kids, like if there's no risk factor for them other than the fact that they're being born, then maybe it's the way it should be or maybe it's safe enough to risk not giving it to them. (Participant 5)

However, parents were also understanding of the importance of vitamin K prophylaxis as a public health intervention, even if they chose to decline it for their own children.

It didn't feel appropriate for us to give it to our baby but I totally understand the perspective of 'of all these babies some are going to get it and we don't know which ones so let's protect all the babies to reduce the risk'. (Participant 4)

Changing Mind Depending on the Circumstances

It is important to note that child welfare works both ways for IM vitamin K, and for three participants who originally opted out of IM vitamin K, following an instrumental birth, they opted back in. In these instances, they felt the risk benefit ratio was altered.

Because of [baby]'s birth we decided the risks of not having vitamin K because he was bruised . . . were higher. (Participant 3)

Additionally, other parents who had declined vitamin K also spoke of potentially changing their decision if the birth required intervention.

I would've . . . reconsidered if there'd been anything abnormal in the labour or birth. (Participant 2)

So we thought given that that's the way we're designed, that's the way we're made, unless there's a reason to intervene we'd just let their bodies do what they naturally would do and so we thought we wouldn't intervene unless there was some reason why we'd need to as in they got cut during birth or bruised or had some accident. In which case we're perfectly happy for it to be supplied. (Participant 6)

That was our caveat that if there was anything that was either untoward in his presentation or in his delivery or in any other information that we had we would switch to intramuscular. (Participant 11)

Deciding Between Oral and IM Vitamin K

For two of the study participants who chose oral administration, they stated that for them it was not a question of whether or not their child would have vitamin K prophylaxis, but rather their main decision was deciding how to give vitamin K.

I don't see a reason why you wouldn't want to give your kid vitamin K... their blood can't clot without it. (Participant 1)

I did do a bit of research myself and knew the possibility of bleeding into the brain, brain bleeds and things like that...so it was never really a question of not getting it done it was just how to have it done. (Participant 13)

External Factors

In addition to parents' philosophies about pregnancy and birth, and their concerns about the risks and benefits of vitamin K, external factors that had influenced their decision were brought up. These will be described in the following section and include the influence of health professionals; information sources used to research vitamin K prophylaxis and VKDB; and celebrities, family, and friends.

Midwifery Influences

All parents talked about how their midwife had the greatest role in informing them about vitamin K prophylaxis. The majority of parents then went on to do their

own research, but in a minority, the verbal information from the midwife, and any information pamphlets she chose to give, were all they based their decision on.

Thirteen out of fifteen study participant first found out about vitamin K prophylaxis from their midwife and usually this occurred in the third trimester when participants were creating their birth plan. All participants felt that this was a good time to bring up vitamin K and most also felt that they had enough information provided to them by their midwife.

I wasn't quite aware about the vitamin K deficiency and the bleeding before my midwife educated me about that, she gave me a leaflet and I read through it and then I decided. (Participant 15)

However, one participant in particular did not feel that she was provided with enough information from her midwife to make a decision.

If I didn't do my own research I wouldn't have known anything about it. My midwife . . . she didn't go into it without prompting and I probably wouldn't have known anything about it without having done my own research. (Participant 8)

Our data also shows that midwives sometimes share their own views of vitamin K prophylaxis, which are not always supportive.

She [the midwife] said that it's recommended for all babies but she told us she didn't feel it was necessary in every case. (Participant 3)

However, not all midwives did so:

She [the midwife] had her own views but she probably didn't tell us them she kept it quite neutral . . . She didn't bias either way. (Participant 9)

Nevertheless, the majority of participants spoke highly of their midwives and appreciated their support and the close relationship they were able to create.

I feel that the midwifery system is very good because I feel a personal relationship with my midwife. A doctor will maintain a professional distance with her clients . . . but with my midwife I feel very personal with her and I had the choice of choosing a midwife who will come home and visit me so these kind of things make me feel the midwifery system's very good. (Participant 15)

Medical Influences

Whilst all participants had a midwife LMC, ten had planned hospital births and so had contact with a doctor at some point post-delivery. No parents described a medical professional as having an influence on their decision. However, a number did talk about how doctors were not supportive of their decision to opt out of IM vitamin K, and tried to change their mind.

I had an experience when I was pregnant with my second child and I had to take my first child to a paediatrician and I was heavily pregnant and the doctor told me, because we explained that we hadn't given Vitamin K to our first baby, and this paediatrician told me that I should be very afraid because of all the babies that she saw with haemorrhagic disease of the newborn which really pissed me off. I walked out of there just furious that this woman would tell a pregnant woman to be fearful. I thought that was a really poor approach. (Participant 4)

There was that one doctor that drove me nuts . . . She was basically making us feel like we were really bad parents because we didn't do it. (Participant 9)

Another talked about how if a doctor says that an intervention is optional, such as vitamin K prophylaxis, then it makes it seem less important.

I think when a doctor or a medical professional presents you with 'this is available but it is not compulsory' you think 'well if it's not compulsory then it can't be actually necessary' . . . but certainly if a medical professional tells us 'this is needed' we'd probably take it without any qualms. (Participant 6)

One participant of Indian ethnicity compared the healthcare systems in New Zealand and India and spoke of how the patient autonomy-focussed system in New Zealand actually made it more stressful for them to make a decision.

In India the doctors make a decision and they decide and they say that this is best for you and they do that but here they leave it to the choice of the patient. It's good in one way but we were a little confused about whether to choose this or that and it was a little bit stressful for us to decide about it. (Participant 15)

In addition, parents spoke about differing attitudes towards opting out of IM vitamin K between midwifery and medical staff. In general, midwives were described as much more accepting of their decision, whereas doctors were often described as trying to change their mind about vitamin K prophylaxis. These differences in

medical and midwifery actions were noted to sometimes be confusing and are described below in a quote from participant 15.

I felt that there was quite a lot of difference in opinion between the midwives and the doctors there, even among the doctors there were differences in opinion, but especially between the midwives and the obstetricians. (Participant 15)

Information Sources

The majority of participants had done their own research on vitamin K in addition to the verbal and written information provided by their LMC. A number of barriers to finding unbiased and factual information were noted, including that much of the information available to them online was from blogs and opinion-based pieces; and that a lot of the information available from sources such as the government, and hospitals, appeared biased towards vitamin K prophylaxis.

I found the pamphlets that they gave out from the hospital . . . they expected that you would do it. It wasn't exactly giving you the option . . . if we'd only seen those pamphlets we probably would have just done it. (Participant 3)

We got one set of pamphlets that were standard government ones and kind of gave all the information and said your choice at the end but the way it was set out definitely suggested that you should do it. (Participant 5)

A lot of it was opinion based, there didn't actually seem to be that many with studies and stuff attached to them so it wasn't easy to find them. A lot of them were just people saying they didn't agree with it and stuff but I'd still read those because it is interesting to see why they didn't. (Participant 8)

Some participants spoke about ensuring that they were looking at information that had studies to back it up, or was peer reviewed, to ensure that what they were viewing was legitimate.

I tried to get my information from people that I thought were knowledgeable about this and also just books, I always checked out the studies at the back about it, so looked at the references and made sure that it wasn't just someone's opinion. (Participant 10)

I think I went to the most academic seeming or peer reviewed, I don't think I was looking at things from online baby groups or anything like that they were proper medical articles I think I was looking at. (Participant 12)

One participant spoke of information bias and how beliefs someone already holds will affect the manner in which they approach and view available information.

You can find anything out there that's going to go against something that's beneficial, but on the same token you can find lots of information on things that maybe aren't so good for them and it makes it seem good. I think it depends on the person and what they believe I guess. The information's there it's just a matter of how you look at it and what kind of research you do. (Participant 13)

Celebrities

One participant noted the influence of celebrities, or well-known people, on her decision regarding vitamin K. She read a baby book written by a New Zealand television personality which made her start thinking about whether she would choose vitamin K for her own child.

It's by Jacqui Brown she's like a TV [personality], she did a pregnancy book and there was quite a bit of information in there about Vitamin K. . . That book made me think about it in the first place because I read that before I even spoke to the midwife about it and it was the book that made me wonder whether or not we even needed it. Pretty sure in the book she chose not to give it to her son. (Participant 3)

Family

A number of participants spoke about asking family members, particularly their mothers, for their opinion and about the method of prophylaxis they had chosen. While the parents I interviewed did not always think that this influenced their own decision, they did speak of feeling surer in their decision after knowing someone else who had had a healthy infant after opting out of IM vitamin K.

Mum mentioned that when I had it when I was a kid that I had it orally . . . and she said that it all went fine . . . it didn't make any difference and stuff like that so it was good to have a first-hand experience. (8)

I wanted to check with my sister in law. I asked her, she said she also gave oral for her kids . . . that did not really affect my decision but I just wanted get a second opinion from her. (Participant 15)

However, whilst the opinion of family members was asked, it did not always have an influence on the final decision.

I talked to my mum about it. She actually doesn't agree with me she thought we should've had vitamin K for both kids and definitely should've right from the start but that's her opinion. (Participant 3)

Friends

In addition to asking family members for their opinion on vitamin K, participants also spoke of asking friends who had previously had children.

I remember asking other mums, so friends who'd had kids already, asking them if they'd done it and what their thought process was around it. (Participant 5)

In a similar way to asking family members, the opinions of friends did not necessarily alter the decision that participants ultimately made.

Concerns Regarding Other Perinatal and Childhood Interventions

In addition to their decision about vitamin K, participants were also asked about other healthcare interventions that they had concerns about, particularly those for children and pregnant women. A number of concerns were brought up, and these often existed as part of a wider family hesitancy towards medical intervention. These concerns resulted in 7/15 participants planning to, or already declining immunisation; 2/15 declining newborn metabolic screening; as well as 5/15 opting for home birth.

The following section will describe interventions and concerns raised by parents, in conjunction with quotes that illustrate these concerns.

Immunisation

In this study we had a high number of parents who had opted out of some, or all childhood immunisations (7/15). A number of concerns were raised, often centred on the safety of the vaccine, not wanting to 'overload' their system, and avoiding causing pain.

I'm just not a huge fan of injecting any child with anything. I mean, my first was never immunised. (Participant 8)

When I was pregnant I read the handbook from the ministry about vaccines . . . And I had many, many, questions about that and lots of things did not quite make sense to me. I also read some anti stuff and yeah I'm more inclined to lean towards the anti-vaccine but I'm not sure yet either. (Participant 10)

I think that with something so little and so new that they can have too much at one time and so I'd already considered when the baby is due for vaccinations at six weeks to try and have them spread out. (Participant 13)

However, these views were not universal, and in contrast, some parents who had declined vitamin K prophylaxis were strongly in support of immunisation.

They are both on track with their immunisations...Very keen on immunisation. Can get pretty angry with people who don't immunise their kids basically. (Participant 6)

We've had her first immunisations, I feel that's important. (Participant 12)

Newborn Screening

For newborn screening parental reasons for declining included that they didn't feel it was necessary after a healthy pregnancy, and that they had a faith, or trust, that things would be normal.

A large amount of it was the trust in the normal . . . there's always risk in life and they're incredibly low for the diseases that are screened for. (Participant 2)

Our first born we didn't actually do that we were again like this from that perspective of checking her for all these potential diseases didn't quite fit where we were but with [second born] because complications had arisen and things had gone a bit askew it was a bit more like why is all this happening? . . . Yes let's check if there's anything else here that might be an underlying issue. (Participant 4)

Folic Acid Supplementation

One participant raised concerns regarding folic acid supplementation that were related to supplementation not being necessary for the entire population.

Here we are fortifying foods for the whole population but actually some of us don't need that stuff because we eat food that's got it in it naturally. (Participant 4)

Antenatal Classes

Friends and social norms influence many aspects of a pregnancy, and we found that this included attending antenatal classes. The majority of study participants who brought up antenatal classes did not find them particularly useful but said that they attended them because they felt it was expected of them.

Everyone's going 'you have to do antenatal classes so that you're prepared' but it didn't actually prepare us for anything. . . We can't do anything with our weekends now because we've got a baby but our very important two weekends before she was born was used up learning about nothing, but we did it. (Participant 9)

Scans

Two participants brought up concerns about the number of ultrasounds that pregnant women are given. These concerns were centred on potential long-term risks for both the mother and the child. They felt these had not been adequately researched.

I think I'm quite firmly against ultrasounds unless that there's something in the pregnancy that indicates that there is a reason for ultrasounds . . . to just routinely scan people and not knowing the actual long term possible risks like it hasn't been researched properly from my understanding what the long term risks might be so therefore I think that it should not be used. (Participant 10)

Well I definitely wouldn't have wanted all the scans but I had to because . . . it was quite a complicated pregnancy but I would've preferred not to have ultrasounds. (Participant 12)

Summary

It is obvious from this chapter that there are a large number of reasons why parents choose to opt out of IM vitamin K – this is the first qualitative study to identify, and examine these. From the data it can be seen that many themes overlap and are interrelated. As a result, some quotes may be relatable to a number of themes, and not just those they are used to illustrate in the preceding chapter. For instance, a large number of the themes related to parental beliefs and values centred upon keeping the birthing process as “natural” as possible. This was the main value that underlied themes such as natural birth, intervention reduction and the medicalisation of birth.

The core value of the themes related to child welfare was reducing any potential harm to the child. For some parents this meant that they chose oral prophylaxis over IM prophylaxis in order to prevent pain, and for others this meant that they wanted to avoid any perceived potential side effects of IM administration.

Finally, the key concepts related to the external factors on parents' decisions mostly related to the information that parents were given and how this information influenced their choice. A common concern brought up by parents was the need for unbiased, neutral information regarding vitamin K prophylaxis and how they often felt that such information was difficult to find. This highlights the need for a

nationwide information programme similar to that in use in New Zealand for immunisation, and similar to that used in Australia for vitamin K prophylaxis¹⁰⁷.

In the next chapter, the discussion, the themes described above will be discussed in depth. The themes will be compared and contrasted to existing data regarding other childhood interventions such as newborn screening and immunisation. Following this, ethical questions that result from parents declining IM vitamin K prophylaxis will be discussed. These questions include: Should the choice to decline IM vitamin K for a newborn be accepted? And if accepted, how should health professionals act in order to advocate for what is believed to be in the “best interests” of the child while still maintaining an effective therapeutic relationship with the parents?

Chapter Four: Discussion

Disagreements between parents and health professionals about a child's medical treatment represent some of the most challenging issues in clinical paediatrics and bioethics. A significant body of literature exists concerning parental refusal of healthcare interventions^{108, 109}, and a wide range of diagnoses and interventions have received attention, including refusal of: blood products by Jehovah's Witness parents¹¹⁰; immunisation¹¹¹; and newborn screening¹¹². Interestingly, despite being one of the very first healthcare interventions recommended in infancy, administration of prophylactic vitamin K at birth has received relatively little attention.

The following chapter will firstly discuss the data produced by this study, as well as place it in context with the existing literature, and evidence concerning parental decision making for similar childhood interventions. It will then examine the ethical concepts underlying parental decision making about vitamin K prophylaxis by employing a contemporary ethical framework.

Parents' Reasons for Opting Out of Intramuscular Vitamin K

This project has been the first to examine parental reasons for opting out of IM vitamin K, the earliest, and one of the most prevalent public health intervention in early life in New Zealand. The key findings are the identified themes influencing this decision making process, including the importance of: underlying parental beliefs and values; concerns about risks/benefits; and external influences. A number of the themes were similar, or the same, as those described in a systematic review of qualitative research concerned with why parents opt out of immunisation, further emphasising the relationship between these two childhood interventions¹¹³.

Underlying Parental Beliefs and Values

As mentioned in Chapter One, a range of studies have now associated refusing IM vitamin K with factors aligned with parental, and/or health professional preferences and attitudes towards 'natural birth', including both local and international data^{2, 4, 5, 96}. These preferences for a more 'natural' birthing experience are consistent with the themes from our data, such as: not wanting to interfere with

nature; questioning of the medical field and the medicalisation of birth; living an 'alternative' lifestyle; and avoiding interventions during birth and pregnancy. For many participants, these beliefs informed not only their views about pregnancy and childbirth, but many areas of their life. For example our data highlighted that many participants expressed hesitancy towards other perinatal interventions, with high rates of non-immunisation and declining newborn screening as well as opting for home birth compared to the general population (33% of participants chose a home birth compared to 3.6% of all babies born in the Otago/Southland area)¹⁰³.

Supporting the data from this study, many of the themes identified relating to parental beliefs and values have also been described in an analysis of qualitative research regarding parental attitudes and beliefs about immunisation. These similar themes include: distrust of the medical community, preferring to rely on a child's natural immunity or alternative methods of protection, and religious reasons¹¹³. The identification of these similarities is important as the literature suggests that the two interventions are connected. Recent studies have shown that parents who decline IM vitamin K for their children at birth are fourteen times more likely to opt out of immunisations at eighteen months of age^{4, 6}.

Concerns About Child Welfare and Perceived Risk Associated with Prophylaxis

From our data it is evident that parental perception of risk has a major effect on vitamin K prophylaxis uptake. This was described in a number of subthemes:

Firstly, the perceived low risk of VKDB was a driver towards declining IM prophylaxis for parents. Study participants spoke of the low risk posed by VKDB to their child and how it seemed to be a "minor decision" compared to every other decision one has to make whilst pregnant. For some of these parents, the intervention was considered unnecessary and they also spoke of their perceptions that a "normal" delivery and/or pregnancy reduced their need for vitamin K prophylaxis, despite there being evidence that prevalence of low vitamin K levels does not differ between 'low' and 'high' risk deliveries¹¹⁴. This opinion has also been seen in the attitudes of midwives as a study found that 45% of midwives thought that only babies 'at risk' should receive vitamin K prophylaxis. In this study, "at risk" infants included: prematurity, instrumental or surgical delivery and the infant having a bleeding disorder⁹⁶.

The above perceptions of vitamin K prophylaxis not being necessary due to the low risk are perhaps best paralleled with parental beliefs regarding newborn screening programmes. The diseases screened for have a very low prevalence in the population and the majority of infants screened will not test positive, however the risk to the child of not identifying a disease early can be devastating. This is similar to vitamin K prophylaxis as although the risk of a child having VKDB is low, the resultant consequences can include death and significant permanent disability³. In such instances where the initial risk is low, but the resultant harm is significant, it can be hard to quantify the actual risk associated – a point that will be further discussed in the ethical analysis.

Secondly, parental fears of perceived pain were shown by our data to be a common reason for opting for the oral vitamin K preparation. Such concerns regarding pain were hypothesised by a recent study to be a possible reason for the association between Asian or Indian ethnicity and declining IM vitamin K². Due to this hypothesis, it was important to us to have a variety of ethnicities represented in our study cohort as we were interested in exploring any potential effect of ethnicity on this decision. Interestingly, supporting the aforementioned hypothesis, of the three participants in our study of Asian or Indian ethnicity, two raised concerns about pain from the injection as a reason for opting out of IM vitamin K. One of the mothers for whom pain was a concern stated that although their nuclear family isn't "culturally bound", she is "aware that in my family, children's satisfaction and comfort is held as really important". However this association is impacted by our small study numbers and further research would be needed to identify how applicable the association of pain and Asian or Indian ethnicity is in a wider context.

Parents declining interventions in order to avoid causing pain to their child is also an important issue in immunisation and newborn screening^{113, 115, 116}. Neonatal pain reduction is an expanding field, and evidence currently exists for a number of interventions that may be applicable to IM vitamin K prophylaxis. For instance, Leite et al. found that breast feeding before and after blood drawing for newborn screening decreased indices used to measure pain (facial actions, sleep-wake state, heart rate, and sucking)¹¹⁷, and Reis et al. found the use of a combination of sucrose, oral tactile stimulation (with a pacifier or bottle), and parental holding significantly decreased

the duration of crying in infants receiving multiple immunisations¹¹⁸. The effectiveness of these interventions for infants receiving IM vitamin K prophylaxis is unknown and could be explored in future studies. It is possible that parents who decline IM vitamin K due to beliefs about natural birth may also be opposed to using a bottle or sucrose to decrease pain as it is not in line with other associated ideals such as exclusive breastfeeding. However, these parents may be able to use a combination of the above two methods, such as breastfeeding and skin-to-skin contact or parental holding. Regardless, our interview data suggests that there is potential to increase parents' acceptance, and possibly uptake of IM vitamin K prophylaxis if we are able to overcome the common barrier of avoiding pain.

Thirdly, it is evident from this study that parental concerns about potential adverse effects are also contributing to IM vitamin K prophylaxis refusal. The most common adverse effect mentioned by parents was childhood leukaemia, which as described in the introduction, originated in the early 1990s from two studies that linked an increased rate of childhood leukaemia to IM vitamin K administration^{89, 90}. Despite the findings not being replicated in subsequent work^{95, 119, 120}, it is clear that they are still having an impact on parents' decisions regarding vitamin K prophylaxis.

These fears are not only confined to parents but also seen in a minority of health professionals, in particular midwives. This has been highlighted in a recent survey of midwifery and medical attitudes towards vitamin K in New Zealand⁹⁶. This survey identified professional concerns regarding vitamin K, and found that 3.5% of midwives were concerned that prophylaxis was associated with cancer, 15.6% were concerned about other possible harms resulting from prophylaxis, and over 50% of midwives responded that they have concerns that naturally low vitamin K levels may have a physiological purpose we are unaware of. It is unknown how exactly these midwifery concerns affect the information that is given to expectant parents. Data from this study indicates that the majority of midwives make their patients aware that vitamin K is recommended for all babies, but then fully accept and support whatever choice is made, whether or not it aligns with this guideline. This is perhaps best illustrated in a quote from participant three which clearly shows the differing attitudes between their midwife and the medical staff involved in her birth:

We made the decision not to have it. We still had about four different doctors and paediatricians and nurses question us 'Do we realise what decision we're making?' I did feel pressured...They [the medical staff] did try and convince us to change our minds. My midwife was wonderful with that though she was very supportive of whatever we wanted to do. (Participant 3)

However, generally high uptake rates of vitamin K prophylaxis in New Zealand suggest that it must be an issue that is regularly discussed and promoted by LMC midwives^{2, 6}.

The studies and ongoing concerns regarding IM vitamin K prophylaxis and leukaemia strongly parallel issues related to measles mumps and rubella (MMR) immunisation and autism. In 1998 a publication by Andrew Wakefield proposed links between the MMR immunisation, autism, and bowel disease. Unlike the work on vitamin K, Wakefield's work was found to be falsified and was later retracted^{121, 122}. However, like vitamin K, it resulted in an initial significant drop in uptake¹²³, and now almost two decades later, a number of parents (not to mention many books, blogs and websites) still continue to report concerns about this link¹²⁴. Strengthening the relationship between these two interventions further, are the two recent studies showing that parents who decline vitamin K prophylaxis are fourteen times more likely to decline immunisations^{4, 6}.

External Influences

External influences were also described by many parents as having an effect on their decision making, including the opinions of family members, the choices made by other pregnant women within their social circle, influences by the media and the internet, and as described previously, the opinions of medical and midwifery staff. Such psycho-social factors and media portrayal have been previously shown to have effects on parental decision making for immunisation¹²⁵⁻¹²⁷, but prior to now no studies have linked this with vitamin K. As described by our data, these factors can influence parents both towards and away from an intervention. As an example, some participants spoke about a family member recommending vitamin K and how this influenced their decision towards it:

*My sister's just finished dietetics . . . and she was like yup do it.
(Participant 9)*

While others spoke of how knowing someone who had declined IM vitamin K with no problems made them feel okay about declining as well:

Mum mentioned that when I had it when I was a kid that I had it orally . . . and she said that it all went fine . . . so it was good to have a first-hand experience. (Participant 8)

As touched on earlier, the attitudes and values of a family's health professional/s are also important influences on vitamin K prophylaxis uptake. Differing opinions between midwifery and medical staff regarding the important of vitamin K have been highlighted in a recent study showing that all medical staff but only 55% of midwives think that all babies should receive vitamin K⁹⁶. As previously mentioned, our data shows that these differences in attitudes between medical and midwifery staff may result in differences in tone and content with what patients are being told. This is supported by a study from a Canada where midwife-assisted deliveries were eight times more likely to be associated with vitamin K refusal than physician-attended delivery⁴. Interesting, another study from New Zealand, where the vast majority of LMCs are midwives, found that opting for oral vitamin K was also associated with decreased LMC experience, per decade², perhaps suggesting that the more experience a midwife gains, the more likely she is to follow Ministry of Health guidelines. Or, this might reflect a change in the way newer midwives are trained.

The differences in attitudes between the medical and midwifery professional groups have previously been postulated to be partially accounted for by discrepancies in their guidelines⁹⁶. For example, the current New Zealand Ministry of Health vitamin K guideline states that "it is the responsibility of the lead maternity carer (LMC) to discuss vitamin K prophylaxis and ensure that parents are aware of the recommendation that all babies should receive vitamin K prophylaxis"²⁶. In an important contrast, the New Zealand College of Midwives published a consensus statement in 2000 which states that "midwives should ensure the woman is informed and supported to reach her own decision on whether Vitamin K is to be given intramuscularly, orally or not at all"¹²⁸. These differences may both explain, and reflect some of the discrepancies between midwifery and medical views on vitamin K prophylaxis.

On a positive note, the uptake rate of vitamin K prophylaxis in New Zealand is high, as over 92% of infants receive IM vitamin K², and it appears clear that the majority of health professionals, whatever their field of practice, are discussing this intervention with their patients. Data on New Zealand midwives highlights this, as the majority consider that it is important that babies receive a dose of vitamin K⁹⁶. A study published earlier in 2015 noted that 92.9% of infants born in the Otago/Southland region between 2009 and 2012 received IM vitamin K, 5.4% oral vitamin K, and only 2.4% no prophylaxis². Whilst these rates of uptake are high, they are lower than comparable countries such as Canada and Australia. Uptake rates in Alberta, Canada have been published as 99.7% uptake of both IM and oral, and only 0.3% receiving no vitamin K⁴, and rates in New South Wales, Australia have been published as 96.3% IM uptake, 2.6% oral uptake, and 1.2% receiving no vitamin K⁵. As mentioned in Chapter One, there is also potential evidence that IM prophylaxis rates in New Zealand are declining³. If these numbers are indeed representative of declining uptake of vitamin K prophylaxis, it is important to understand why parents are choosing to opt out. It is in this context that the data from this study is essential as being aware and empathetic of parents' specific objections and questions means that clinicians are in a better position to overcome them.

The above data and a potential link between healthcare provider attitudes and vitamin K prophylaxis uptake is supported by studies regarding immunisation that show strong associations between a recommendation of the intervention by a physician and subsequent uptake^{129, 130}. There is also data regarding differing approaches that a physician may take and the effect that this has on uptake. For example, initiating vaccine recommendations with a presumptive approach (e.g. "Well, we have to do some shots") rather than a participatory approach (e.g. "What do you want to do about shots?") resulted in significantly lower odds of resisting vaccine recommendations¹³¹. It is possible that this knowledge of different approaches could be useful when recommending vitamin K prophylaxis, however the authors of this research also recognised that while using a presumptive approach may increase uptake in that session, it may not be beneficial for future healthcare decisions as parents do not have the opportunity to voice their concerns. In such instances, it has previously been noted (albeit in the context of newborn screening) that when parents feel pressured to make a decision against their personal wishes, it may polarise their

future attitudes towards healthcare, thus making future consultations more difficult – a concept that will be explored in depth in the next section of this discussion.

The Ethics of Parental Healthcare Decision Making

In recent times there has been a shift in healthcare across the Western world, away from a model of medical paternalism, toward a patient-centred approach which places high value on a patient's autonomy¹³². In New Zealand, the right of a patient to be fully informed, and the right to make an informed choice are recognised as two central tenets of healthcare¹³³. This attitude also translates to children's health where the concept of family-centred care, a model that incorporates shared decision making, is a central tenet of modern paediatrics¹³⁴. In terms of ethics, children's bioethics has now been recognised as a specialist field, although some of the key dilemmas have long been debated in general bioethics. The key advantage of viewing paediatric bioethics as a specialist field is the ability to highlight some of its common and fundamental ethical principles⁹⁹. Perhaps the most central of these, at least in relation to very young children, are the concepts of parental autonomy and the best interests of the child. The following sections will discuss these concepts and how they may operate in relation to parental decisions concerning newborn vitamin K prophylaxis.

Parental Autonomy

The importance of parental autonomy^k is widely recognised in both bioethics literature and in the practice of clinical paediatrics. In the majority of clinical situations it is assumed that parents naturally have the authority to make decisions for their children¹³⁵, and various justifications for this authority have been described. Diekema argued that parental autonomy should be respected for a number of reasons⁹⁷:

1. Most parents care about their children and will therefore desire what is best for them, and make decisions which are beneficial to them.
2. The interests of family members may conflict or compete and parents are usually better suited than people outside the family unit to compare such interests and make a final decision

^k The right of parents to make medical decisions for their children

3. Parents should be able to raise their children how they see fit, according to their own values and philosophies

Salter also describes additional reasons why parents' decisional authority should be respected¹³⁵:

- Parents are generally in the best position to know what decision the child would make if they were mature, and are the most knowledgeable about their child's interests
- Parents themselves are the ones who bear much of the primary burden and consequences of medical decisions that are made for their child

Limits to Parental Autonomy

For all of the above reasons, most ethical analyses, and clinical paediatrics, assume that a child's parents are the people best suited, and most likely, to act in the best interests of the child⁹⁷. However, this decision making entitlement is not absolute and parental autonomy is bounded by certain limits. A significant body of literature exists concerning the circumstances in which a health professional can ethically justify overriding parents' medical decisions¹³⁶, and New Zealand law states that when parents act in a manner where their child is being, or is likely to be harmed, the state may intervene⁹⁸.

Most contemporary frameworks permit parental discretion when making decisions unless there is a *significant risk of harm* to the child^{97, 99, 137}. Examining parental refusal of IM vitamin K prophylaxis using such models highlights some interesting underlying questions, the first of these is whether it represents the type of parental decision that should be overridden? I will discuss this question using the framework of two commonly used models: The "Best Interests" of the Child, and the "Harm Threshold" Model, and one more recently developed model: The "Zone of Parental Discretion".

The "Best Interests of the Child"

The "best interests" doctrine is used throughout the world in many contexts, including legal and bioethical discourse and clinical decision making¹³⁵. Arguably one of the most important and influential documents regarding the treatment of children, the United Nations' Convention on the Rights of Children (UNCRC), also uses the

concept of the “best-interests” of children. The UNCRC is the human rights treaty outlining the rights of children, including those of a civil, political, economic, social and cultural nature, and article three of the Convention states that “in all actions concerning children . . . the best interests of the child shall be a primary consideration”¹³⁸. Additional to this, clinicians have traditionally thought in terms of a child’s best interests when deciding how to act when parents make a choice for their child that is not in line with their recommendations, and the “best interest standard” has become the prevailing ethical standard used to determine when interference is justifiable¹⁰⁰.

Acting in a person’s best interests has been defined as “acting so as to promote maximally the good of the individual”¹⁰¹ and the best interest standard has been defined as one in which “. . . a surrogate decision maker must determine the highest net benefit among the available options, assigning different weights to interests the patient has in each option and discounting or subtracting inherent risks or costs”¹⁰². Both definitions require the surrogate decision maker/s to always make the decision which is most favourable to the child. Therefore, if we examine the choice to decline newborn IM vitamin K prophylaxis using the best interests standard from a medical viewpoint, it could be argued that opting out is not in the infant’s best interests as the intervention reduces the risk of VKDB to close to zero with few potential side effects, thereby maximising their potential wellbeing³. However, the interview data presented in this thesis shows that many parents who opt out of IM vitamin K prophylaxis also believe that they are acting in their child’s best interests. Such parents place greater value on the avoidance of any potential side effects for their child, or on a completely ‘natural’ birth with few interventions, or on one of the other benefits they describe in the previous results section, than they place on the benefits gained from IM vitamin K prophylaxis.

This conflict between two different ideas of what constitutes a child’s best interests illustrates two of the major criticisms of this model. The first being that in many situations it is difficult to precisely define and determine the course of action that is in the child’s best interests⁹⁷. In the context of vitamin K prophylaxis, one could argue that IM vitamin K maximises the child’s wellbeing as it is the most effective means of preventing VKDB, however one could also argue that oral vitamin

K maximises the child's wellbeing as it prevents any pain or distress to the newborn, despite potentially being not as effective³.

The second point raised by this example is that the idea of "best interests" is inherently dependent on an individual's values. All of the parents interviewed considered themselves to be acting in their child's best interests and hence overriding their decision would involve assessing which values should be considered the most important and whose idea of the child's best interests should prevail⁹⁷.

Other criticisms also exist as to why the best interest's model is insufficient for the complexities involved with paediatric decision making. These include the inability to acknowledge the family as a unit and that it does not allow the parents to take into account interests other than those of the child who needs treatment; and that it is also an incredibly high standard to hold parents to, one that is generally not expected for other choices such as schooling or place of residence^{97, 99, 135}. As a result of these criticisms, some ethicists have moved towards using the principle of harm and the idea of a 'harm threshold' to assist with clinical decision making^{97, 100, 139}.

The Harm Principle

In the context of paediatric healthcare, the harm principle has been put forward as a test for justifying state intervention when parents refuse medical treatment for a child¹³⁶. According to the harm principle, the feature of parental decision making that justifies interference is not that it does not align with the child's *best* interest, but rather that the decision poses some harm to the child⁹⁷.

In his writing about the harm principle, Diekema summarises various suggestions about the nature of the harm threshold in order to try and identify the level of harm to be tolerated in parental decisions⁹⁷. He states that parental decisions that do not significantly increase the likelihood of serious harm compared to other options should be tolerated, and that state intervention to overrule parents should only occur when a child is at significant risk of serious harm. He proposes eight conditions that must be met before state inference with parental decision making can be justified⁹⁷:

1. By refusing to consent are the parents placing their child at significant risk of serious harm?

2. Is the harm imminent, requiring immediate action to prevent it?
3. Is the intervention that has been refused necessary to prevent the serious harm?
4. Is the intervention that has been refused of proven efficacy, and therefore, likely to prevent the harm?
5. Does the intervention that has been refused by the parents not also place the child at significant risk of serious harm, and do its projected benefits outweigh its projected burdens significantly more favourably than the option chosen by the parents?
6. Would any other option prevent serious harm to the child in a way that is less intrusive to parental autonomy and more acceptable to the parents?
7. Can the state intervention be generalised to all other similar situations?
8. Would most parents agree that the state intervention was reasonable?

There is an evolving consensus among ethicists that harm is the central moral concept when judging the appropriate threshold for overriding in parents' medical decision making¹³⁶. Given this widespread acknowledgement that the harm principle is a more appropriate way of analysing parental decision making, I will now examine the parental decision to decline IM vitamin K prophylaxis with reference to Diekema's eight criteria:

1. By refusing to consent are the parents placing their child at significant risk of serious harm?

VKDB is a relatively rare condition, with the classical version affecting approximately 1/1500 infants not given prophylaxis³. Hence one could state there is not a *significant* risk of harm by declining IM vitamin K prophylaxis. However, Diekema states that the salient point is whether a choice increases the likelihood of harm compared to **other** treatment options. As the likelihood of VKDB is reduced to near zero in the presence of IM prophylaxis, it could be argued that there is a significant increase in harm by declining and as approximately 50% of all late onset cases of VKDB result in disability or death, the harms resulting from VKDB can indeed be *serious*^{3,69}.

2. Is the harm imminent, requiring immediate action to prevent it?

Again there is a degree of subjectivity in gauging whether or not any harm related to refusal of vitamin K is “*imminent*”. However, given that VKDB typically occurs within the first week to six months of life (unless the mother has been taking medication that interferes with vitamin K metabolism) it would be difficult to argue that vitamin K needs to be administered *immediately* to avoid harm.

3. Is the intervention that has been refused necessary to prevent the serious harm?

It is not possible to pre-determine which babies will develop VKDB and for each individual there is a relatively low chance that they will have VKDB, even without prophylaxis. Thus it would be difficult to argue that the intervention is *necessary* to prevent the serious harm, but it does reduce the risk.

4. Is the intervention that has been refused of proven efficacy, and therefore, likely to prevent the harm?

The *efficacy* of newborn vitamin K prophylaxis in preventing VKDB has been firmly established¹⁴⁰

5. Does the intervention that has been refused by the parents not also place the child at significant risk of serious harm, and do its projected benefits outweigh its projected burdens significantly more favourably than the option chosen by the parents?

IM vitamin K prophylaxis does not place the child at significant risk of serious harm and its projected benefits clearly outweigh its projected burdens, although some authors do argue that a small risk of an increased likelihood of childhood leukaemia cannot be excluded⁵³.

6. Would any other option prevent serious harm to the child in a way that is less intrusive to parental autonomy and more acceptable to the parents?

There are two options of administration of vitamin K prophylaxis (IM and oral) so it may be that parents who have declined IM prophylaxis would find oral prophylaxis more acceptable. Given that oral vitamin K provides similar levels of protection as IM vitamin K as long as it is correctly administered

(including that all three doses are received) this may be an acceptable alternative to parents who are concerned about pain¹⁴¹.

7. Can the state intervention be generalised to all other similar situations?

The state intervention in newborn vitamin K prophylaxis could potentially be generalised to all births.

8. Would most parents agree that the state intervention was reasonable?

There is widespread acceptance of IM vitamin K prophylaxis with over 90% of parents choosing to give this to their children, so arguably they find the intervention itself reasonable². Whether they would agree that state intervention to overrule parents who wish to decline is reasonable is unknown.

While there may be debate about some of the above criteria in relation to IM vitamin K prophylaxis it is clear that all eight are not met. It follows then that under the Harm Principle a parental decision to opt out of IM vitamin K prophylaxis would not normally constitute a decision that is justifiably overridden. Exceptions may however exist, including for preterm infants, or those with cholestatic disease, as they may be particularly vulnerable to developing a functional vitamin K deficiency¹⁴².

The “Zone of Parental Discretion”

I turn now to a third framework for paediatric healthcare decision making. The Zone of Parental Discretion is a concept developed by ethicists at the Royal Children’s Hospital Melbourne (Melbourne, Australia) as a tool to help consider if decisions made by parents should be accepted, even when they are not seen to be in the child’s best interests by medical staff⁹⁹. The Zone of Parental Discretion extends the idea of the harm principle to all situations of disagreement between parents and clinicians, not just those where state intervention is being considered. The key idea is that clinicians can accept parental decisions that are suboptimal for the child, so long as the decisions do not involve probable significant harm to the child.

The use of the Zone of Parental Discretion consists of two stages of consideration: the first being the harm from the parents’ decisions and the second being the harm from overriding the parents’ decision. Stage one is similar to the harm principle described above and determines whether the decision will result in

probable significant harm to the child. If the decision will not result in probable significant harm, then the decision lies within the Zone of Parental Discretion. Stage two requires determining the effects of overriding the parental decision and determining whether this would in fact cause greater harm than the harm expected from the original decision.

The Risk of Serious Harm Associated with Refusal of IM Vitamin K

The issue of what constitutes probable significant harm to a child is at the heart of both Diekema's harm principle and the Zone of Parental Discretion. Some situations in paediatric care clearly require intervention, such as when parents make a decision that will definitely result in the child's death when another option exists that would cure them. Conversely, some situations clearly do not require intervention and the parents should be able to make decisions at their discretion, such as when there is a range of treatment options and none offer any obvious advantage over the others. However, refusal of IM vitamin K prophylaxis poses a difficult question for these models: the risk of harm occurring from refusing vitamin K is relatively low, but the consequences may be very serious. With any threshold or zone there are likely to be "grey areas" around the edges and it seems that vitamin K prophylaxis may fall within such an area. Refusal of newborn screening poses similarly low levels of risk of serious harm¹¹².

The Risk of Overriding Parental Refusal of Vitamin K

The second stage of the Zone of Parental Discretion is particularly important in vitamin K prophylaxis as how physicians react to this first healthcare decision may 'set the scene' for any future interactions those parents have with the healthcare system. This is because healthcare decision making is a long-term process and it is important that consideration is placed upon not just how an action will affect the current doctor/patient relationship, but also how it will affect a patient's (or in this case the parents') views of healthcare in the future. Newson notes that forcing parents to make a decision that opposes their personal beliefs may polarise their views towards healthcare¹¹², and as vitamin K prophylaxis is often the first medical choice the majority of parents will make for their newborn, it may be particularly important that this decision making experience is positive and leaves parents feeling empowered.

Concern about the future risks to the doctor/patient relationship and how it will affect conversations about healthcare decisions in the future may contribute to the current reluctance to overrule parents who opt out of IM vitamin K prophylaxis.

Current Practice

As reflected in most information sheets for parents and policy documents^{26, 143, 144}, it has become accepted practice to permit parental refusals of IM Vitamin K prophylaxis. This is likely based on the concepts noted above, that it is difficult to reach a consensus regarding whether refusal constitutes significant risk of serious harm, and that the harm associated with overruling parents may be substantial. Similar arguments about accepting parents' decisions, even when they are contrary to medical recommendations, have been made regarding newborn screening, another intervention in the neonatal period which carries a similar level of risk¹¹².

How Should Health Professionals Respond When Parents Decline Vitamin K?

Despite the evolving consensus among ethicists that harm is the key ethical concept when judging the appropriate threshold for state intervention in parents' medical decision making, there is much more controversy regarding how to respond to disagreements that fall around the margins of that threshold¹³⁶. It remains unclear how health professionals should respond when they think a parent is making a decision that is significantly suboptimal from the child's perspective, but does not involve the serious, imminent harm that justifies state intervention. In such cases, is it always ethically appropriate for health professionals to question parental decisions, or try to persuade a parent? There is significantly less literature available concerning how such situations should be managed. None of the models discussed above give explicit direction on this as they are focussed on the context at the time of the decision, rather than a longitudinal approach that acknowledges the long term nature of the doctor/patient (or parent) relationship. As a result it is at this stage that our interview data and knowing specific reasons why parents choose to opt out of IM vitamin K prophylaxis is useful.

Taking a tailored approach to consultation depending on the parents' reasons for hesitancy is one option. This has been previously recommended for immunisation¹⁴⁵, an intervention similar to vitamin K prophylaxis, and may be applicable to how clinicians approach parents with concerns regarding IM vitamin K

prophylaxis. For example if the parents' major concerns relate to child welfare, specific steps could be taken to educate and reassure parents, and/or pain management methods could be employed. Another study involving parents who were hesitant to immunise showed that when parents are given specific time to voice their concerns at a specialist immunisation clinic the likelihood of immunising their children increases¹⁴⁶. Measures such as these, coupled with an acknowledgement that the parents' decision, while not optimal from a medical perspective, falls within their discretion, arguably both respects parental autonomy, and enables the health practitioner to act in an ethically appropriate and professional manner.

If underlying parental beliefs and values are the major determinant in a parental decision to opt out of vitamin K, further education concerning child welfare may be less helpful. It is important that such parents do not feel pressured to make a decision contrary to their personal wishes because as mentioned earlier, this may polarise their future attitudes towards healthcare¹¹². This is reflected in one paper which showed that some methods employed by clinicians to convince parents to immunise can actually 'backfire' and further decrease intent to immunise¹⁴⁷. It has also been argued in the context of newborn screening that while some degree of encouragement is important, there is a definite difference between advocacy, and forceful attempts to coerce parents¹¹². In such instances, a clear acknowledgement of the moral weight accorded to parents as decision-makers for their child, coupled with continued explanation that healthcare professionals remain concerned about the potential harm to the child, may help maintain a therapeutic alliance with the family.

In this section we have made some preliminary remarks about how to manage parental refusal of IM vitamin K, a decision that while suboptimal from the child's perspective, does not appear to reach an appropriate threshold of "serious imminent harm" that justifies state intervention. However, this area remains significantly under-studied and we suggest the need for further research both in relation to vitamin K specifically, and "sub-optimal" decisions more generally.

Study Strengths and Limitations

The use of qualitative research methodology and thematic analysis was a specific strength of this study as it enabled in-depth exploration of themes and experiences as well as a detailed analysis of parental decision making. Furthermore,

having a large percentage of participants opting to give birth at home (5/15) compared to the regional average of 4.3% meant that we were able to elucidate the concerns of this group particularly well¹⁰³. As participants for studies involving maternity care, including the main data on uptake of vitamin K prophylaxis, are often drawn from hospital records, those who birth at home are excluded unless they end up in hospital. As a tendency towards “natural birth” appears to be an important determinant of vitamin K uptake, including the views of those who birth at home is vital. In fact, if we allow for this effect, and a resultant lower uptake of vitamin K prophylaxis for infants born at home, the total uptake rates of vitamin K prophylaxis around the country may be even lower than currently thought

As always with studies of this nature, sample size is a weakness. While we cannot claim that the results of this study include all possible factors that influence parents’ decisions regarding vitamin K, the themes identified were relatively consistent in that common themes were brought up time and again without new ones appearing in the final interviews. Additionally, despite the smaller sample size, we had a large number of ethnicities represented (eight). This was vital as certain ethnicities have previously been associated with opting out of IM vitamin K, and we were interested in any effect that ethnicity may have on parental choice. Ideally future research on this would focus even more closely on these groups, something that was not possible in the time frame allowed for a BMedSc(Hons) project

Due to this study using qualitative research methodology which examines views within a particular context (in this case only one DHB in New Zealand – albeit the largest geographically), generalisability of these findings to another time and/or place may be problematic. Future research looking at national datasets on uptake would be beneficial, however this is hampered by the fact that the Ministry of Health (MoH) does not routinely collect data on the uptake of vitamin K prophylaxis, despite it being a universally recommended intervention. Continued efforts to encourage the MoH to collect this data are required, particularly given that concerns about safety continue to be raised in our data, and by others⁹⁶.

However, despite the potential issue of generalisability, the themes identified in this study are consistent with those brought up by parents declining similar childhood interventions in other parts of the world. In the future, this work can serve

as a springboard for additional semi-quantitative research that can explore the issues raised over a wider setting, thus confirming and/or providing evidence of wider applicability.

Conclusion

Parental acceptance or refusal of IM newborn vitamin K prophylaxis is the first healthcare decision most families make for their newborn and is also an indicator of the uptake of subsequent health interventions. This work is significant as it has been the first study to closely examine factors that influence parental decision making and lead to a decision to opt out of IM newborn vitamin K prophylaxis. The key findings are that while there are a large variety of reasons why parents decide to opt out of IM vitamin K, they can be grouped into three main themes: parental beliefs and values, child welfare, and external factors.

By knowing what influences parental decision making regarding vitamin K, health professionals can not only gain a deeper understanding of parents' concerns, but may also be able to provide interventions that will potentially maintain and/or improve uptake. However, it is important to consider how such interventions will impact the doctor/patient relationship. Parental beliefs and values may remain steadfast despite intervention by health professionals, however taking the time to understand parents' reasons may help build the relationship and provide opportunities for discussions in the future about other health interventions. Parental concerns regarding child welfare, and the external influences on decision making may be targets for intervention – particularly the management of pain from IM vitamin K and understanding attitudinal differences between health professionals and the impact that these may have on parental decision making. Further exploration of other factors that have been identified to impact on uptake (such as ethnicity) also appears to be important, particularly given the increasingly multicultural nature of New Zealand's population.

Ethical analysis of parental refusal of newborn IM vitamin K prophylaxis highlights that while this decision probably falls within a "Zone of Parental Discretion", it is close to the margins. It is therefore suggested that in practice health professionals should attempt to encourage parents to choose vitamin K for their child but should not be coercive. An understanding of parental reasons for hesitancy is critical to appropriate tailoring of such approaches.

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Appendix 1: Interview Guides

Questionnaire - Vitamin K choices of New Parents

Name/s:	Ethnicity:
DOB:	Address:
Occupation:	Highest educational level:
Marital status:	Number of children of father:
Gravida:	Parity:
Babies DOB:	Type of birth:
Gestation at birth:	Birth weight:
LMC: midwife / doctor	Vitamin K: Oral/Declined
Intended place of birth:	

We're interested in finding out about how parents decide whether or not to give vitamin k to their baby

Can you tell me about your Vitamin K decision, starting from when you first found out about Vitamin K?

How did you come to this decision and what were your reasons for opting for the method of vitamin K that you chose?

1. Information

- When and how did you first become aware of vitamin k?
 - *E.g. midwife, antenatal class, brochure, pregnancy book, own research*
- What information were you provided with about Vitamin K?
 - Was any further information suggested to you?
- Did you talk to anybody other than your LMC about Vitamin K?
 - Who? Suggested by midwife, or found yourself?
- Did you seek out extra information yourself?
 - *i.e. website, book, pamphlet, etc.*
- Which sources of information did you use in your decision about vitamin K?
 - Hospital pamphlet
 - Womens Health action group Pamphlet on vitamin K
 - Antenatal classes
 - Healthcare professional – midwife/LMC/GP/O&G, etc.
 - Internet, if so which site.
 - Book, if so which one
 - Other mothers/fathers/friends/family members
 - Other (ask what)
- Do you feel you were given or had access to enough information about Vitamin K?
- Did/do you and your child's other parent have similar or different views about Vitamin K?

2) Choice

- What are your concerns about giving vitamin K by injection/orally?
- Are there any specific issues related to vitamin K from your or your family's perspective?
 - cultural / religious / family / personal
- Did you feel any pressure whilst making your choice?
 - i.e. from midwives, doctors, nurses, etc.

3) After the choice

- How do you feel about your decision now?
- How does the other parent feel about the decision now?
- Have you tried any alternative means to reduce the risk of vitamin K deficiency bleeding in your baby?
 - i.e. naturopathic products, increasing maternal intake, etc.
- If you have other children – did they receive vitamin K?
- Are there any other health interventions for your baby you have concerns about?
 - Do you plan to immunise your child?
 - Do you plan for your child to undergo newborn metabolic screening?

Do you have any other comments you would like to make?

Thank you for your time and input. It is greatly valued.

Vitamin K choices of Parents – Extra Questions

1. During the interview we spoke about information sources you used and you mentioned that you searched about vitamin K on the internet and looked it up via other methods.
 - Can you tell me in what ways the websites and other sources and the information you found there influenced your decision? Did they promote or oppose vitamin K?
 - In what ways did media/other information sources have an influence on your decision about vitamin K? Did it promote or oppose vitamin K?
2. What influence did your partner have on your decision about vitamin K? Did they promote or oppose vitamin K?
3. What influence did your family have on your decision about vitamin K? Did they promote or oppose vitamin K?
4. What influence did your friends or other pregnant women have on your decision about vitamin K? Did they promote or oppose vitamin K?

There are often many healthcare professionals involved in pregnancy.

1. How did you choose your LMC?
 - Do you consider that they have similar values to you?
 - Is it important that they do (have similar values)?
2. Can you tell me if any doctors involved in your care:
 - Knew of your decision to opt out of IM vitamin K? What was their reaction?
 - Did they influence your decision? How?
 - Did they attempt to further educate you on vitamin K?
 - Did they attempt to change your mind? How?
 - Did they state to you that vitamin K is recommended for all babies?
3. Can you tell me if any midwives involved in your care:
 - Knew of your decision to opt out of IM vitamin K? What was their reaction?
 - Did they influence your decision? How?
 - Did they attempt to further educate you on vitamin K?
 - Did they attempt to change your mind? How?
 - Did they state to you that vitamin K is recommended for all babies?
4. Can you tell me if any nurses involved in your care:

- Knew of your decision to opt out of IM vitamin K? What was their reaction?
 - Did they influence your decision? How?
 - Did they attempt to further educate you on vitamin K?
 - Did they attempt to change your mind? How?
 - Did they state to you that vitamin K is recommended for all babies?
5. Can you tell me if any other practitioners (naturopaths, homeopaths, chiropractors, etc.) involved in your care:
- Knew of your decision to opt out of IM vitamin K? What was their reaction?
 - Did they influence your decision? How?
 - Did they attempt to further educate you on vitamin K?
 - Did they attempt to change your mind? How?
 - Did they state to you that vitamin K is recommended for all babies?

A number of parents have said that their decision for vitamin K would change depending on the risk of Vitamin K Deficiency Bleeding posed to their child. If this applies to you:

- Can you describe the level of risk needed for you to give your child prophylactic vitamin K?
- What do you think would change this risk? (i.e. mode of birth, instruments used at birth, etc.)

Thank you for your input. It is greatly valued.

Appendix 2: Ethics Approvals



Health and Disability Ethics Committees

1 the Terrace
PO Box 5013
Wellington
6011

04 816 2403
hdec@mh.govt.nz

29 November 2012

Dr Ben Wheeler
PO Box 913
Dunedin 9054

Dear Dr Wheeler

Re:	Ethics ref:	12/STH/41
	Study title:	Attitudes to Vitamin K and subsequent immunization by new parents declining vitamin K at Birth: Do choices on Vitamin K at birth predict immunization uptake later and what informs parents' decisions on these issues?

I am pleased to advise that this application has been approved by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at a *given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

3. The Committee suggests rewording study aim number 1 on page 1 of the PIS to "Explore choices made by parents regarding intramuscular Vitamin K for babies"
4. The Committee feels that the research would be enhanced by including both families who did and did not choose to inject Vitamin K.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Participant access to ACC

The Southern Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Ms Raewyn Idoine
Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

19 December 2013

Dr Ben Wheeler
PO Box 913
Dunedin 9054

Dear Dr Wheeler

Re: Ethics ref:	12/STH/41/AM01
Study title:	Attitudes to Vitamin K and subsequent immunization by new parents declining vitamin K at Birth: Do choices on Vitamin K at birth predict immunization uptake later and what informs parents' decisions on these issues?

I am pleased to advise that this amendment has been approved by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

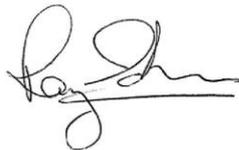
Non-standard approval conditions

The Committee suggested the following change to the participant information sheet:

1. Page 1 under the heading 'What is the aim of the project?' Please consider rewording the first paragraph to simply state "Babies have a deficiency of vitamin K at birth and Vitamin K is offered to all new born infants".

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely



Ms Raewyn Idoine
Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

31 March 2015

Dr Ben Wheeler
PO Box 913
Dunedin 9054

Dear Dr Wheeler

Re:	Ethics ref:	12/STH/41/AM03
	Study title:	Attitudes to Vitamin K and subsequent immunization by new parents declining vitamin K at Birth: Do choices on Vitamin K at birth predict immunization uptake later and what informs parents' decisions on these issues?

I am pleased to advise that this amendment has been approved by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Ms Raewyn Idoine
Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix 3: Māori Consultation

NGĀI TAHU RESEARCH CONSULTATION COMMITTEE *TE KOMITI RAKAHAU KI KĀI TAHU*

Tuesday, 20 November 2012.

Dr Benjamin Wheeler,
Dunedin School of Medicine - Paediatrics and Child Health,
DUNEDIN.

Tēnā Koe Dr Benjamin Wheeler,

Attitudes to Vitamin K and subsequent immunization by new parents declining vitamin K at Birth: Do choices on Vitamin K at birth predict immunization uptake later and what informs parents' decisions on these issues?

The Ngāi Tahu Research Consultation Committee (The Committee) met on Tuesday, 20 November 2012 to discuss your research proposition.

By way of introduction, this response from The Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum it states "Ngāi Tahu acknowledges that the consultation process outline in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago". As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGechan:

"Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal."

The Committee notes this is Southern District Health Board research.

The Committee considers the research to be of importance to Māori health.

The Ministry of Health website <http://www.health.govt.nz/publications> contains a list of Māori health publications. The Committee recommends you review the Māori health publications on this website, eg. Unequal Impact II: Māori and Non-Māori Cancer Statistics by Deprivation and Rural-Urban Status 2002-2006 and Tatau Kahukura: Māori Health Chart Book 2010. Another Publication, Hauora: Māori Standards of Health IV (2000-2005), has its own website, <http://www.hauora.maori.nz/>. These publications provide information on a range of Māori health issues and will assist in ensuring your research has an appropriate Māori health focus.

The Committee suggests that in some regions including the Southern region of New Zealand Māori immunization rates are higher than non-Māori. The Committee

The Ngāi Tahu Research Consultation Committee has membership from:

*Te Rūnanga o Ōtākou Incorporated
Kāi Huirapa Rūnanga ki Puketeraki
Te Rūnanga o Moeraki*

NGĀI TAHU RESEARCH CONSULTATION COMMITTEE
TE KOMITI RAKAHAU KI KAI TAHU

suggests contacting the Māori Women's Welfare organisation who have an interest in this area.

The Committee suggests dissemination of the research findings to Māori health organisations regarding this study.

We wish you every success in your research and the Committee also requests a copy of the research findings.

This letter of suggestion, recommendation and advice is current for an 18 month period from Tuesday, 20 November 2012 to 6 May 2014.

Nāhaku noa, nā



pp. MRC

Mark Brunton
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The Ngāi Tahu Research Consultation Committee has membership from:

Te Rūnanga o Ōtākou Incorporated
Kāiti Huirapa Rūnaka ki Puketeraki
Te Rūnanga o Moeraki

Appendix 4: Poster

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PARENTAL REASONS FOR DECLINING NEWBORN IM VITAMIN K PROPHYLAXIS

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Background

Vitamin K deficiency bleeding is a potentially life-threatening disorder for which all infants are at risk. Prophylactic Intramuscular (IM) Vitamin K is recommended at birth to prevent this. A three-dose oral alternative is also available. IM Vitamin K uptake in NZ appears to have declined in recent years, and no research exists into how parents make this decision.

We aimed to identify common themes as decision-making factors for parents who opt out of IM Vitamin K for their infant.

Methods

Participants were identified prospectively by healthcare professionals at Dunedin Hospital and Dunedin homebirth midwives, and retrospectively through Queen Mary Maternity Ward records from 1/1/2014 – 08/04/2015.

Semi-structured interviews with parents were used to explore decision making, followed by thematic analysis.

Results

12 interviews were conducted. For their most recent birth, nine participants initially opted to decline Vitamin K and three participants chose oral. However, due to adverse birthing circumstances four families changed their initial decision: three opted for IM and one oral.

The mean age of mothers at time of interview was 33.6 (range 23 to 45). The median time from the interview to most recent delivery was 1y1m (range 3d to 13y2m). Six participants were living in a de facto relationship, five were married and one was divorced. Mean parity was 1.8 (range 1 to 3). Regarding socioeconomic status, the mean NZ dep. index of participants was 5.7 (range 2 to 8) and nine mothers had a bachelor's degree or higher. Eight intended to birth in hospital and four at home. The main themes with various subthemes have been displayed in table 1. It should be noted that parental decision making regarding Vitamin K can involve multiple reasons from different themes.

Table 1: Decision-making factors from interviews

Theme	Statement
Alternative Lifestyle¹	
Identity of being alternative	"I was a little bit anti-conformist, can you tell?" "He's very strongly into letting nature take its course, like right down to organic foods, soaps, conditioners"
Questioning of mainstream medicine	"The idea that we would need to inject something into all babies...just didn't really sit with my more holistic perspective on things" "I'm quite firmly against ultrasounds"
Natural Birth²	
Intervention reduction	"We wanted to where possible minimise the level of intervention that he needed where we could" "I was feeling that the least interventions as possible would have the best outcome"
Decreasing medicalisation of birth	"Birth is terribly over medicalised in the Western world" "I think it's a balance...it's whether it's really needed or whether it's just convenient"
Birth as a natural process	"I sort of just didn't want to interfere with nature that much"
Breastfeeding as optimum nutrition	"If baby really needed more Vitamin K then they'd get it from me" "If he didn't get it through breastmilk naturally then that was another indicator that maybe it was not important to have or might be beneficial to not have it"
Questioning Necessity³	
Concern about amount given	"There was also that sort of figure of two thousand times the dose of what an adult would have and it's like well that's really, really abnormal"
Religious reasoning	"We believe that God created us and knew what He was doing so um that's why we sort of looked into well why wouldn't there be Vitamin K in a baby?"
Evolutionary reasoning	"If it had been a big problem in the past then evolution probably would have weeded out or found some way to deal with it"
Avoidance of pain to child	"We didn't want her to come straight out and have a jab straight away" "We were wary of giving her distress by giving her an injection"
Thinking risks outweigh benefits	"For us it was the risks from Vitamin K were higher because he was such a normal, easy birth"
Worry of risk of leukaemia	"Even though there is some evidence against that, the fact that it was in the literature was concerning"
Concern of unknown effects	"I think we're a bit naïve to think that is just because it doesn't have leukaemia that there's not some other spectrum of issues that can arise"
Non-concern due to perceived low risk	"If you have a consent form it implies that it's far more important than it is" "It seemed like a fairly minor decision compared to everything else that was going on"

¹ Alternative Lifestyle included families who identified that opting out was consistent with their general view of opting for less 'mainstream' alternatives

² Natural Birth included families who opted out due to beliefs that birth is a natural process that should have as few interventions and medicalisations as possible

³ Questioning Necessity included families who opted out due to specific concerns such as potential side effects, the amount given, or how necessary the injection is for their child

Conclusion

We have identified several common themes that influence the choice of parents to decline IM Vitamin K prophylaxis. Developing an understanding of parental decision making and concerns regarding IM Vitamin K may assist health professionals to understand and communicate with parents when discussing this important public health intervention.