Newborn vitamin K prophylaxis: an analysis of information resources for parents and professionals

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ABSTRACT

AIMS: Vitamin K prophylaxis represents one of the first healthcare decisions families make for their newborn. Information resources are an important component of this process. This study aimed to identify and analyse written information about vitamin K.

METHODS: Resources concerning vitamin K prophylaxis for both parents and health professionals were accessed through tertiary hospitals in New Zealand and Australia, midwives associated with Queen Mary Maternity Centre (Dunedin, New Zealand), antenatal class providers in the Dunedin, New Zealand area, and an online search of Australian and New Zealand government and hospital websites, as well as the Centre for Disease Control (CDC) in the US. These materials were assessed with regard to coverage of information relevant to vitamin K prophylaxis, whether a statement of the recommended option was included, and information concerning parental choice.

RESULTS: In Australia, the majority of centres use the Australian Government National Health and Medical Research Council (NHMRC) resource. In New Zealand, eight different resources are in use. There was variation between resources in all aspects, including use of different incidence rates for vitamin K deficiency bleeding (VKDB). No New Zealand resources were available in languages other than English. The resources for health professionals also varied, and the two available New Zealand consensus statements (Ministry of Health and College of Midwives) differed in terms of their main recommendation.

CONCLUSIONS: Many different information resources are available regarding vitamin K prophylaxis in New Zealand. Standardisation of such information would be more equitable and would facilitate easier review of content and translation into multiple languages.

Vitamin K deficiency bleeding (VKDB) can present as relatively insignificant gastrointestinal or muco-cutaneous bleeding in the first hours to months of life. However, in approximately 50% of late-onset cases, it presents as serious haemorrhage that can result in death or permanent neuro-disability. As a result, many countries have introduced public health programs that offer vitamin K prophylaxis to all babies at birth, with an intramuscular (IM) route generally preferred, partly because of concerns of reliability of administration and partly due to concerns about the efficacy of oral administration. In the presence of IM vitamin K prophylaxis, VKDB is rarely seen with an incidence of approximately 1/100,000 live births, or less, compared to rates of 1/1,500 or more in the absence of prophylaxis. When VKDB does occur, it is almost invariably in children for whom vitamin K has been omitted through error or because their parents withheld consent.

Limited data is available on newborn vitamin K prophylaxis uptake, however, recently published data suggests that New Zealand has considerably lower uptake of IM vitamin K than Canada and Australia. Concern about reducing uptake rates has also been expressed in the US following four recent cases of serious late haemorrhage in previously healthy newborns. Little is known about factors that may influence uptake, but several may be important, including the issue of potential harms. In the early 1990s IM vitamin K prophylaxis
was linked to an increased risk of childhood leukaemia.\textsuperscript{10,11} Although subsequent work has been unable to replicate these findings,\textsuperscript{12,13} these safety concerns appear to remain for some health professionals, as well as for parents. This is highlighted in New Zealand data that compared the attitudes of medical and midwifery staff towards vitamin K prophylaxis. In this study, 16% of midwives were concerned about harms caused by vitamin K prophylaxis, and only 55% stated that they thought all babies should receive it.\textsuperscript{14}

In light of these apparent ongoing concerns about harm caused by vitamin K, some suggestion of declining uptake\textsuperscript{3} and emerging evidence about attitudinal differences between professional groups, we sought to further explore influences on parental and health professional decision-making. To this end information resources available to both parents and health professionals in Australia and New Zealand were analysed and compared with regard to coverage of information relevant to vitamin K prophylaxis (including stated incidence rates and the terminology used to describe VKDB), statement of recommended option/s and information about parental choice.

**Methods**

**Sourcing materials**

Printed and electronic resources concerning vitamin K prophylaxis were requested from multiple sources including all 28 Level 3 Neonatal Intensive Care Units (NICUs) in Australia and New Zealand (while NICUs were the access point for this information, the resources provided were not confined to NICU practice but were also those utilised by the relevant antenatal services), all 65 independent midwives undertaking deliveries at Queen Mary Maternity Centre (QMMC) via an anonymous online questionnaire (QMMC being the only hospital birthing unit in the city of Dunedin, New Zealand) and the two antenatal class providers for Dunedin. This collection strategy was supplemented by online searches for vitamin K resources from Australian and New Zealand government and hospital websites, as well as the Centre for Disease Control (CDC) in the US.

**Evaluation process**

In order to analyse and compare these information resources, we developed an analysis tool based on a literature review pertaining to public health interventions in childhood. The criteria within the tool were fully determined prior to analysis of information resources, which was undertaken independently by two authors (HM and NK). Where variation in scoring between the two researchers existed, differences were discussed until consensus was reached. The tool is reproduced in Appendix 1 and the three key elements are described below:

1. **Information coverage**

   The New Zealand Ministry of Health (Medsafe) guideline was used to determine the range of headings reasonably discussed in an information resource.\textsuperscript{15} Areas covered were: What is vitamin K?; What is VKDB?; Prophylaxis options (IM/Oral/None); timing of prophylaxis; benefits of prophylaxis; and potential harms of prophylaxis.

   Each component was assessed on a scale from zero to three, meaning not covered at all (0), minimally covered (1), moderately covered (2) or extensively covered (3). In addition to the above areas covered in the analysis tool we also recorded some specific aspects of content, such as quoted incidence rates of VKDB, and terminology used that clearly differed between resources.

2. **Recommendation**

   Resources were assessed with regard to whether or not they reflected the following Medsafe recommendation: “All babies should receive vitamin K prophylaxis. The recommended route of administration is intramuscular.”

3. **Parental choice**

   Parental choice was scored from one to three, where no mention of parental choice (implication or statement that this is routine, expected) scored 1, mention of parental choice alongside a recommendation for IM vitamin K scored 2 and a statement that prophylaxis is entirely parental choice scored 3.

**Results**

A summary of all the information resources collected and their analysis is included as Table 1 (full results in Appendix 2).
One hundred percent (6/6) of New Zealand NICUs provided parental information, all of which were different and created by the individual hospital or district health board (DHB). Sixty-four percent (14/22) of Australian NICUs responded and all of these units used the Australian NHMRC brochure. In addition, a resource created by the Waitemata DHB was found online, and North American education material created by the CDC was included for international comparison. The information resources accessed through NICUs were also used by their relevant antenatal service.

The response rate for the midwifery survey was 45% (29/65). Fifteen (52%) used the QMMC vitamin K pamphlet and 13 (45%) “Vitamin K: Does my Baby Need it?” published by the Women’s Health Action Trust,16 which was also used by one of the antenatal classes contacted. Of note, this resource was the only one found in our study with an associated cost to the health provider (~$1/pamphlet). A number of midwives stated that they often provide more than one type of brochure and a number also recommended other information sources. These included various articles and pamphlets available from the Maternity Services Consumer Council website,17–19 and an article from the magazine ‘Kiwiparent’.20

* This resource stated that New Zealand health professionals recommend vitamin K but not that intramuscular is the preferred route.
consensus statements (Ministry of Health and College of Midwives), Australian NHMRC guidelines and the CDC information sheet.

Analysis

In 91% of cases, both reviewers (HM and NK) assigned the same score. In the 9% of cases where variation existed, differences were discussed until consensus was reached.

Parent resources

Table 1 demonstrates that the level of information covered in different brochures varied significantly (for parent information resources scores ranged from 9 to 17 out of a possible 18). This was true for all aspects of the information, including discussion of potential harms and benefits (for full results refer to Appendix 1).

Other key differences in content included stating different incidence rates of VKDB from “approximately one in 10,000 babies” (Canterbury DHB) to “less than one in 1,000 babies” (Southern DHB). Some brochures broke this information into the three categories of VKDB with the Women’s Health Action Trust pamphlet stating that “classic VKDB...occurs in the first week of life in 0-0.44% of healthy infants”—equivalent of up to one out of 227 infants. In addition, the terminology used to describe VKDB varied, with a minority of resources still using the outdated term “Haemorrhagic Disease of the Newborn” (HDN).

All resources, except that from the Women’s Health Action Trust, stated that IM vitamin K was recommended for all babies. seven of the nine Australasian parent resources scored 2 in the parental choice category (meaning that while it was acknowledged that parents could make their own decision concerning vitamin K, they also recommended IM vitamin K prophylaxis) while one brochure made no mention of parental choice, and one portrayed the choice as entirely the parents responsibility without relaying the standard recommendation (refer to Table 1 and Appendix 1 for scoring).

No New Zealand parent brochures were available in languages other than English, in contrast to the Australian NHMRC brochure, which is available in seven different languages.

Health professional resources

Information coverage varied significantly between the consensus statement from the New Zealand College of Midwives and the other consensus statements, although it is acknowledged that the midwifery statement does not purport to be a resource concerning clinical aspects of vitamin K and includes a list of references. The midwifery statement was alone in not making the recommendation of IM vitamin K being the preferred option, instead emphasising parental choice (Table 1). In contrast, the CDC resource made no mention of parental choice.

In addition, the CDC health professional resource stated that “in the majority of cases of VKDB, there are no warning signs before a life-threatening bleed occurs”. This is in contrast to the New Zealand Medsafe data sheet, which states “most cases of severe VKDB are preceded by ‘warning bleeds’”.

Discussion

This is the first study to identify and analyse key information resources available to parents and professionals about newborn vitamin K prophylaxis. The key findings are that in Australasia, there are a large number of such resources available to parents and health professionals, particularly in New Zealand. Some of these vary significantly with regard to all aspects studied, including content, message and tone. This may have important implications for the parental decision-making process. While only resources related to vitamin K were analysed in this study, the problems discussed are likely to be relevant to many other health interventions.

In relation to information coverage, it is widely acknowledged and incorporated in the New Zealand code of patient rights, that patients (or their parents) have a right to be provided with good quality information, especially if written, increases recall. It has also been shown that providing patients with good quality information, especially if written, increases recall. In this study we have not attempted to articulate the ‘right’ amount of information to provide to patients, rather we aim to highlight the significant variation that exists in this regard. We do however, agree with the New...
Zealand Medsafe guideline that acknowledges that where there has been significant debate and uncertainty (as there was in the last two decades over the safety of vitamin K), it is particularly salient to provide adequate information, and further information should be available should a patient feel they need it.\(^\text{15}\)

A lack of information, or a perception of this, has also been associated with patient anxiety in a number of healthcare areas. With immunisation, this perception has led to negative attitudes by families towards immunisation and even towards healthcare providers.\(^\text{23}\) There does however, exist a tension between providing patients with enough information to facilitate informed decision-making without overwhelming them with excessive or irrelevant information.\(^\text{24}\) Aspects of information provided to parents, such as incidence of an illness or serious outcomes, are important and should ideally be reproducible between all sources of information. However, these often varied considerably. While we acknowledge there are difficulties in determining an exact figure for the incidence of VKDB, it is potentially confusing for both parents and professionals to be exposed to such widely differing statistics, particularly when data sources are not referenced. This confusion comes in part from the literature, which is also not clear on this subject, and differs between papers depending on the country of origin, the definition of VKDB used and whether the data comes pre- or post-introduction of vitamin K prophylaxis. The most recent figures available for New Zealand come from surveillance of neonatal VKDB between 1998–2008 when the overall incidence of classic VKDB (in the presence of an established public health prophylactic programme) was found to be 1.24/100,000 live births. These authors also postulate a figure of or approximately one in 1,439 for the incidence of VKDB in infants not receiving prophylaxis.\(^\text{3}\)

Our study has also shown that there is consensus across all documents, except the New Zealand College of midwives, that vitamin K is recommended for all babies and that IM prophylaxis is the recommended route. This deviation is important to note, as evidence suggests that when health professionals recommend such interventions, this is likely to influence parents. For example, a recent report concerning parental attitudes to vaccination found that most parents (87%) stated that they usually follow their health care provider’s advice.\(^\text{25}\)

However, recommending vitamin K to parents does not imply that parents’ choices should ultimately be constrained. While our study found a high degree of consistency with regard to the recommendation, there was some variation in how parental choice was approached. In particular there were subtle but potentially important differences between the various consensus statements. The Medsafe statement 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”,\(^\text{15}\) the NHMRC statement says “Parents should receive written information during the antenatal period about the importance of vitamin K prophylaxis”\(^\text{26}\) and the midwifery consensus statement states that “Midwives should ensure the woman is informed and supported to reach her own decision on whether vitamin K is to be given intra-muscularly, orally or not at all”.\(^\text{3}\) These differing wordings may affect how the decision is portrayed to parents. They may also reflect a deeper divide—in recent New Zealand data, only 55% of midwives thought that all babies should receive vitamin K, compared to 100% of medical staff.\(^\text{14}\)

Again, in this paper we are not attempting to articulate the most ethically acceptable approach to parental choice in this context but rather to raise concerns about the lack of clarity that currently exists. Highlighting this variability may provide an opportunity for practitioners and professional groups to further reflect, decide upon a preferred approach and articulate this clearly in policy, as has occurred with immunisation and the “Immunisation Handbook”.

A particular strength of this study is the involvement of midwives in sourcing documents used in a real world setting. This is important as in New Zealand, midwives provide the primary maternity care for the majority of pregnant women. The high response rate from NICUs (100% in New Zealand) is an additional strength, ensuring an appropriate snapshot of what information is being provided to parents through
major centres in the antenatal and postnatal periods in both countries. However, we did not contact smaller maternity units in New Zealand or Australia, or specifically target homebirth midwives, and only approached the two community antenatal education providers in Dunedin rather than conducting a nationwide survey. It is therefore possible that the number and variety of resources included in this study is an underestimate of the true total. If this was the case, it would add further weight to our argument that it would be beneficial to further standardise the information available. Similarly, although our study has determined that no New Zealand parent brochures were available in languages other than English, we did not assess how health professionals respond to this difficulty with families of different ethnicities.

In conclusion, many different information resources on newborn vitamin K prophylaxis are available. In New Zealand, this is a particular problem, where multiple resources are in use with often subtle but important differences in content and overall message. Ideally, especially for New Zealand, and to bring vitamin K prophylaxis more into line with comparable interventions such as immunisation and newborn screening, more standardised information regarding newborn vitamin K prophylaxis should be available. A standardised brochure would facilitate easier review of content, ensuring information remains up to date, accessible and aligned with best practice. More importantly, this would ensure all parents receive the same information, regardless of language, location or place of birthing.

Competing interests:
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Appendix 1: Assessment instrument.

<table>
<thead>
<tr>
<th>Organisation producing pamphlet</th>
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<tr>
<td>Title of pamphlet</td>
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<td><strong>Completeness of information</strong></td>
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<td>What is vitamin K?</td>
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<tr>
<td>What is VKDB?</td>
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<tr>
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<tr>
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<tr>
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Appendix 2: Complete data.

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<th>Organisation</th>
<th>Completeness of information</th>
<th>Parental choice</th>
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<td>What is VKDB?</td>
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<tr>
<td>Counties Manukau DHB</td>
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<td>2</td>
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<tr>
<td>Southern DHB</td>
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<td>3</td>
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<td>Waikato DHB</td>
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<tr>
<td>Australian Government NHMRC</td>
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<td>1</td>
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<tr>
<td>CDC</td>
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**Abbreviations: * DHB—District Health Board; NHMRC—National Health and Medical Research Council; CDC—Center for Disease Control.**

**This resource stated that New Zealand Health Professionals recommend vitamin K but not that intramuscular is the preferred route.**