

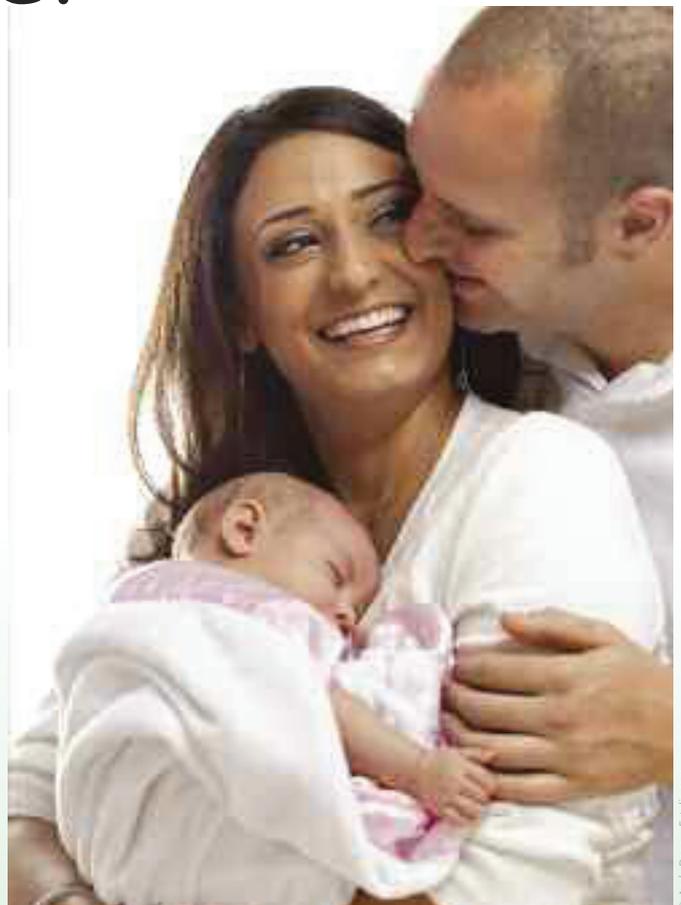


Revisiting vitamin K and the newborn: what have we learned in a decade?

Sara Wickham

This year (2013) sees the 20th anniversary of the Cochrane Collaboration and it is perhaps inevitable that, for some of us who are involved in the generation and evaluation of evidence, the existence of such a notable anniversary has led to personal and shared reflection on how our knowledge in particular areas has changed or evolved over time. It was during my own reflection about how much difference a decade or two can make that I realised it was almost exactly 10 years since I authored an AIMS booklet called *Vitamin K and the newborn* (Wickham 2003), which was designed to offer information to parents seeking to make decisions about a prophylactic intervention that is offered to all newborn babies in the UK and many other countries.

The vitamin K booklet isn't a particularly long or fat one in comparison to some of the titles in the same series, and the decision — and the evidence that relates to it — can be explained in a relatively straightforward manner. As things stood when the booklet was published, the administration of synthetic vitamin K to newborn babies had been shown to be effective at protecting babies from a disorder characterised by unexpected



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bleeding which was formerly known as haemorrhagic disease of the newborn (HDN) and is now more commonly termed vitamin K deficiency bleeding (VKDB). Yet effectiveness is only one element of the decision that parents need to make. VKDB is serious but rare, so several thousand babies need to be given vitamin K in order to prevent one case of VKDB, which means that parents have to weigh up the risks and side effects of vitamin K against the risks and side effects of VKDB. The booklet discusses the different perspectives on the argument, the controversies that were being debated at the time and some of the potentially mitigating factors, for instance whether it was possible to determine that a particular baby was at greater or lesser risk of VKDB, which might help his parents in their decision making.

My interest in this area has continued; I went on to have input into the MIDIRS *Informed Choice* leaflets in this area (MIDIRS 2005, MIDIRS 2008) and revisited the topic with further writing (Wickham 2008a, 2008b), lectures and workshops in several countries. Most recently, I wrote an initially unrelated piece for *AIMS Journal* about the age of research (Wickham 2012), in which I began by lamenting the practice in some universities of expecting students to limit their reference list to information that has been published in the past 5 or 10 years. In arguing that older research often provides valuable contextual information, I used vitamin K as an example of an area in which the volume of articles and studies has tailed off significantly in the past decade, noting that much of what had been written in the 2003 booklet was still valid today. Yet as the 10-year anniversary of this project approached, I felt compelled to search and analyse the literature that has been published in the past decade in order to see exactly how our knowledge has grown, developed and perhaps changed. This article is the result of that exploration, and is based on my analysis of papers published from 2003-2013 found in a bespoke search of the MIDIRS Reference Database. This article is intended to provide an overview of key changes and developments within the area and be a source of further exploration for readers rather than a systematic review of the literature.

Background

For those new to this area, vitamin K is not one discrete substance but a group of fat-soluble vitamins which play an important role in human metabolic pathways and are essential to the production of several substances that are in turn essential to the process of blood clotting. Vitamin K occurs naturally in two forms, and the first of these, vitamin K₁, or phyloquinone, is the 'plant form' of vitamin K. This form is found in abundance in

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leafy green vegetables and some other foods and can be ingested by animals and humans and used directly in the body, but animals can also convert vitamin K₁ into one of a group of substances known collectively as vitamin K₂. Vitamin K₂ is actually a family of compounds termed menaquinones which are made in the gut with the assistance of bacteria. Several synthetic forms of vitamin K are also available as pharmaceutical products, with the synthetic version of vitamin K₁ often being called phytomenadione.

As is explained further in Wickham (2003), phytomenadione is the form of synthetic vitamin K that is offered to newborn babies in order to prevent VKDB. In fact, it is late VKDB which is the primary target of this prophylaxis, as early onset VKDB generally occurs in babies born to women who are taking particular kinds of medication, while classic onset VKDB occurs in a fairly well-defined group of babies and is easy to recognise and treat (Hey 2003a). Late onset VKDB, as above, can be fatal, but the number needed to treat is extremely high. Shearer (2009) compiled data from a number of studies and, while noting that the relative rarity of VKDB negatively affects the accuracy of the data, the incidence of late VKDB in Europe amongst

babies who do not receive prophylaxis is 4–7 cases per 100,000 (The incidence is far higher in some other areas of the world, notably South East Asia). These figures show that this is even rarer than we thought back in 2003 and this data may be more meaningful to parents if expressed as the statement that between 1 in 14,000 to 1 in 25,000 babies who do not receive vitamin K are affected by late VKDB.

Who needs vitamin K?

Some parents and practitioners question the need for vitamin K, in part because of a number of high-profile scares about potential side effects of this substance which were picked up by the mass media in the 1990s, but also because the notion that babies and breast milk are relatively deficient in vitamin K is controversial to some people, who believe that, for the most part, babies are born with what they need and breast milk is the perfect food for babies. This debate has expanded slightly in the past decade. Paediatrician Edmund Hey (2003a) responded to my early writing in this area (in which I had asked whether nature had really got it so wrong (Wickham 2000)) in *MIDIRS Midwifery Digest* by suggesting that, at least in relation to classic-onset VKDB, *'although nature's blueprint is not flawed, the margin of safety is narrow. Babies who do not feed soon, well and regularly are at measurable risk of bleeding once their limited reserves of vitamin K are exhausted'* (Hey 2003a:9). He did not go on to address this ideological question in relation to late-onset VKDB.

Hey (2003a) further concluded that, on the basis of the evidence at the time:

- *'All babies who are not well enough to be fed at birth need a supplement because their vitamin K stores will only last 1-3 days.'*
- *'A few breastfed babies will develop transient VKDB if they are not given a small supplement at birth, probably because early intake is poor.'*
- *'A very small number of breastfed babies risk a sudden serious bleed when 2-12 weeks old if not offered a regular supplement, usually because an unrecognised liver disorder has impaired fat-soluble vitamin absorption.'* (Hey 2003a:12)

It is clear that only a tiny proportion of babies would experience VKDB in the absence of prophylaxis, but as we have no effective means of establishing who those babies are, we currently have no option other than to offer prophylaxis to all. The debate is compounded by concerns around whether giving vitamin K to the tens of thousands of babies who would not have succumbed to VKDB has adverse effects. Although there is by no means universal acceptance of the validity of these concerns (as evidenced by a recent paper by an American nurse (Burke 2013) which uses rather aggressive language to describe the case of a baby who became ill after his parents chose a home birth in water and then declined vitamin K and several other

interventions) some of the literature of the past decade implies an increased understanding of other views in this area. In 2010, Clarke acknowledged the potential normality of the allegedly 'low' level of vitamin K in the fetal period, noting that, *'very low vitamin K levels in the human fetus appear to be physiological because overt manifestations of antenatal deficiency, such as fetal intracranial haemorrhage, are reported only extremely rarely'* (2012:17). As a purely observational statement, I would say that this is one example of an important but almost imperceptible shift. When I was reading the literature in the early 2000s, there was an undercurrent of emphasis on the 'low' levels of vitamin K in newborn babies and breast milk. A decade later, I would say that the emphasis has shifted subtly from the 'deficient baby' to the 'dangerous postnatal period', the latter being an alleged source of multiple threats to the breastfed baby's ability to maintain adequate vitamin K stores.

What hasn't changed?

It may be worth noting, albeit briefly, some of the areas where we haven't really moved on in our knowledge. It is always interesting to read papers that document and consider elements of the history of this area, such as those by Robertson (2003), Zetterstrom (2006) and McNinch (2010) but they do not always teach us anything new. Ten years ago, Hey (2003b) observed that policies around vitamin K administration had been dictated more by what manufacturers decided to market than by any kind of informed understanding of what babies need. While I found no papers specifically relating to this area, anecdotal discussion with interested colleagues would suggest that this remains unchanged.

A number of commentators have considered the issues and maintained that universal prophylaxis is best, despite ongoing safety questions (Hey 2003a). However, as many of these writers note, safety is an extraordinarily difficult thing to prove with certainty and, as was discussed recently in this journal (Wickham 2013), guarantees are rather difficult to come by. Some are more willing to go out on a limb; Clarke and Shearer (2007) noted that, *'no convincing new evidence has emerged in the last 15 years to support the cancer link, particularly with respect to providing any biochemical plausibility for carcinogenicity of vitamin K1, and of course today's MM preparation has safer excipients'* (742). No research has been carried out to determine whether vitamin K has other unwanted effects on newborn babies, or to explore the questions that some midwives have long been asking about whether and how this intervention might be linked to increasing levels of jaundice that were noted when oral regimes changed (Wickham 2003).

Sutor (2003) was among those who acknowledged the need to *'search for methods of identifying early the few infants destined to bleed so that targeted prophylaxis can replace the current "prophylaxis for all"'* (373), but our knowledge has not really

moved on in this area either and many other reviewers continue to reiterate the *status quo*: that vitamin K is necessary as routine prophylaxis for all and that the real question is which route was the most appropriate. A whole raft of reviewers have continued to identify huge gaps in our knowledge about the comparative effectiveness and safety of different routes, alongside vast international, national and even local differences in the dosage, route and frequency of administration (Sutor 2003, Tandoi *et al* 2005, Harvey 2008, van Winckel *et al* 2009, Clarke 2010, Greer 2010).

Perhaps unsurprisingly, most Western countries have continued to produce guidance recommending vitamin K (eg AAP 2003, NICE 2006). In the UK, for example, NICE (2006) recommended that all parents be offered vitamin K which:

'Should be administered as a single dose of 1 mg intramuscularly as this is the most clinically and cost-effective method of administration [but] if parents decline intramuscular vitamin K for their baby, oral vitamin K should be offered as a second-line option. Parents should be advised that oral vitamin K must be given according to the manufacturer's instructions for clinical efficacy and will require multiple doses' (32).

I will return to the question of oral prophylaxis later.

What has happened in practice?

Surveys of what is happening in practice have also consistently continued to show this wide variation. Ansell *et al* (2004) surveyed paediatricians in 20 large maternity units in the UK and reported that there had been frequent policy change between 1977 and 2002. Busfield *et al* carried out a related study in 2007, looking firstly at the current use of vitamin K prophylaxis in the UK and then relating this to the effectiveness of the regimens used. While we will return to the question of effectiveness below, their study also revealed wide variation in the form of vitamin K offered where babies had been born at term following uncomplicated births, with 60% recommending intramuscular prophylaxis, 24% oral vitamin K and 16% offering both routes. All units offering intramuscular vitamin K in this study gave a single dose, most commonly 1 mg of Konakion Neonatal. There was considerable variation in the timing, dosage and frequency of the oral regimens that were offered (Busfield *et al* 2007). This problem is international; Guala *et al* (2005) found wide variability in procedures between different nurseries in Italy and, in New Zealand, Robertshawe's (2009) audit unearthed variations in the way that vitamin K was prescribed and its administration documented.

The British Paediatric Surveillance Unit carried out two surveys in the past decade which showed that the number of cases of VKDB was reducing and the effectiveness of oral regimens had improved (McNinch *et al* 2007). Back in New Zealand, Darlow *et al* (2011) found that, of nine confirmed cases of late-onset

VKDB, eight had received no vitamin K, eight were fully breastfed and six had liver disease, while an Australian study demonstrated that, compared to neonates receiving intramuscular vitamin K, those with oral or none were more likely to have vaginal births without medical interventions at birth centres or planned home births (Khambalia *et al* 2012). In what seems to be a worldwide trend, authors of such papers are consistently criticising parents who are choosing not to give their babies vitamin K, and all of the authors above have, in one way or another, stated that parental refusal of prophylaxis has become more problematic. The literature contains a number of case studies of babies who have had VKDB, often with a moral undertone about the fact that the baby's parents declined (often the more confrontational term 'refused' is used) vitamin K (Thomas & Gebara 2004, Brousseau *et al* 2005). Other studies highlight the continuing problem of VKDB in countries where parents do not get to make a choice, because prophylaxis is either not available or is too expensive (Danielsson *et al* 2004).

Oral vitamin K

We do seem to have moved forward a little in our knowledge of what constitutes effective oral prophylaxis for those parents who want prophylaxis but would prefer not to have vitamin K injected into their baby. There is now concurrence that, in order to be effective, oral vitamin K needs to be multi-dose (Busfield *et al* 2007, Shearer 2009, van Winckel *et al* 2009, Laubscher *et al* 2013) and that the dosage and frequency may need to be higher than was the case in initial regimens. A Danish study revealed no cases of VKDB in about 396,000 babies who received weekly oral prophylaxis of 1 mg per week from birth until they reached three months of age (Hansen *et al* 2003). This finding was further supported by the findings of a Dutch study (Ijland *et al* 2008) which evaluated the practice of giving breastfed babies 1 mg of vitamin K orally at birth, followed by a daily dose of 25 micrograms of vitamin K from 1 to 13 weeks of age for breastfed infants and found that, while this reduced VKDB, it did not eradicate it.

Clarke and Shearer (2007) distinguish these doses, describing the lower Dutch dose as physiological and the Danish dose as pharmaceutical. They further note, especially in relation to the lower dose, that the absorption of vitamin K is greatly enhanced by the presence of other fats (which partly explains the success of artificial milk as a vehicle for vitamin K administration). Both they and McNinch *et al* (2007) note the increased effectiveness of the oral regimens offered in the UK in the past few years, while also discussing the issue of compliance, which (they suggest) may be more problematic if not for the fact that many of the parents who are choosing oral vitamin K are motivated, breastfeeding and perhaps more inclined than average to give the appropriate dosage at the appropriate times. This is further supported by the findings of the Swiss Paediatric Surveillance Unit (Laubscher *et al* 2013), who monitored the incidence of VKDB from July 2005 until

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June 2011. They found that, compared with historical controls who had received two oral doses of vitamin K, the incidence of VKDB was significantly lower in babies who had received three oral doses.

What else have we learned?

There are a couple of other areas in which our knowledge has grown, at least in theory. Costakos *et al* (2003) highlighted concerns about preterm babies receiving higher levels of vitamin K than was ideal and, in 2010, Greer (one of Costakos' co-authors) again reiterated how, because of multiple sources of vitamin K intake, preterm babies can end up with vitamin serum concentrations a hundred times higher than those found in adults and 10 to 20 times greater than those found in term formula-fed infants (who are already receiving considerable daily supplementation). Both papers argued that this warrants further study and/or changes to the nutrition that preterm babies receive, although it is worrying that an issue first raised in the literature in 2003 did not seem to have been addressed in practice by 2010.

Greer has also added to our knowledge about vitamin K in breast milk. This is a controversial topic because some of the research cited to support the claim that breast milk contained 'low' levels of vitamin K (a term that always begs the question of exactly what breast milk is being compared to as a standard) was carried out at a time when women were not being supported to breastfeed in ways that are now considered optimal. Although Greer (2004) argued that the levels are still not high enough (which again could be said to fuel the notion that the postnatal period is dangerous for babies), he did demonstrate that levels were about twice the average of some of these earlier reports. In the same year, a Japanese study (Kojima *et al* 2004) found that the concentration of vitamin K in breast milk varied according to the diet of the women concerned, implying that maternal nutrition may be a factor.

As well as the standpoints which I have described as the dangerous postnatal period and the deficient baby hypothesis, there also exists the view that the tendency to VKDB may be iatrogenic and the result of medicalised birth. Expressed more in verbal conversation, on internet blogs and in discussion articles, one recently published example can be found where Cranford (2011) questioned whether modern birth practices stress the clotting system of the newborn, arguing that trauma caused by medicalised birth, limited early breastfeeding and practices such as early cord clamping and circumcision can deplete a newborn of its clotting factors. While some of these arguments (namely limited early breastfeeding and circumcision) are already widely accepted to be risk factors for VKDB and early cord clamping is considered by a number of people to be a likely culprit, research is needed to support or refute the idea that other practices can lead to VKDB. It is important to note that some of the babies who

have gone on to develop VKDB have been born physiologically, at home and outwith the presence of medical intervention (Brousseau *et al* 2005).

Supporting parents' choice

The AIMS booklet that inspired this article was written in the hope of helping parents make the decisions that were right for them, and it is only fitting that this should be the final area for consideration. The vitamin K decision continues to be a difficult one for some parents, principally because our lack of knowledge about which babies might benefit from vitamin K leaves a fairly stark choice. Sadly, some fairly anti-parent stances persist, especially in relation to those parents who make the choice to decline vitamin K. Clarke and Shearer's (2007) suggestion epitomises what happens to many parents in practice:

'We believe refusal should trigger involvement of a senior paediatrician to explore parental concerns and discuss all available options. Infants who suffered VKDB not uncommonly feature among medicolegal cases so meticulous documentation is imperative.' (Clarke & Shearer 2007:743)

Around the time of publication of the original booklet from which this article stemmed, two articles were published in *AIMS Journal* (Bevan 2003) and *Midwifery Matters* (Neiger 2004), both demonstrating how women often received little information in this area and frequently did not realise they had a choice about whether or not their baby received vitamin K. It is notable that the literature search carried out for this article found no recent research or articles exploring what parents want or need in this area and no evidence of parents' voices in the literature. Rather strangely, one study that purported to have evaluated the acceptability of a new oral vitamin K preparation and which concluded that this regimen *'is well tolerated and acceptable to midwives and parents'* (Strehle *et al* 2010) actually only sought midwives' perceptions of parents' views. While many midwives will have parents' concerns at the forefront of their minds, it is hard to see how researchers can justify the claim that a group feel a particular way about something without having been asked themselves.

The next 10 years?

In the introduction to this article, I reiterated my viewpoint that much of what was written in the original booklet I wrote on vitamin K is still valid. While this is true, it is not necessarily valid for the right reasons, and the fact that 10 years can pass without any significant changes to our thinking about or understanding of an area is itself quite telling. The professional approach to the topic of vitamin K administration seems largely to be characterised by acceptance (or perhaps apathy) that, although this intervention is metaphorically a sledgehammer (in relation to the number needed to treat), it is probably not *too* harmful and we

should therefore keep calm and carry on. And, indeed, many parents seem happy to do this. Yet the parents who have concerns are facing a continued lack of knowledge and, even more sadly, a continued lack of effort in relation to carrying out research that might help us learn more. We can only hope that the next 10 years will bring increased insight.

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