AIMS For a better birth...

Vitamin K and your Newborn Baby

This article replaces the AIMS book, "Vitamin K and the Newborn"

What is Vitamin K?

What we refer to as Vitamin K is an important group of chemicals which help our blood to clot. There are several different types of Vitamin K and these different types all have different effects on the body. The only effect that is being considered when Vitamin K is offered to your baby is its role in reducing the chance of complications from excessive bleeding known as Vitamin K Deficiency Bleeding (VKDB). VKDB was previously known as Haemorrhagic Disease of the Newborn (HDN) and the two names refer to the same condition. VKDB is very rare but it can be very serious, which is why the parents of all babies in the UK are offered an injection of Vitamin K for their baby, just after birth, even though almost all of those babies will not benefit from it. If parents decline the injection they should be offered an oral dose given several times over a few weeks.

Types of Vitamin K Deficiency Bleeding (VKDB)

There are three recognised types of VKDB:

- Early Onset, which occurs within 24 hours of birth
- Classic Onset, which occurs 2-7 days after birth (some researchers define classic onset as 2-14 days after birth)
- Late Onset, which occurs between 8 days and 3-4 months after birth (or 2 weeks onwards for those who define classic onset as being 2- 14 days after birth).

Early Onset VKDB is almost always caused by medications taken by the baby's mother such as some epilepsy drugs, and anticoagulants which have passed to the baby before they were born and stopped the baby's body from being able to clot their blood properly. It is the Classic Onset form of VKDB for which artificial Vitamin K supplementation is most effective – almost all babies who are given the supplement *do not* experience VKDB. Late Onset VKDB is often caused by an underlying problem in the baby such as a liver condition, but, for most babies, Vitamin K supplementation at birth stops Late Onset VKDB.

Consequences to babies of Vitamin K Deficiency Bleeding

VKDB is extremely rare, but it can be very serious. While most babies, if treated quickly, will recover, some babies will have permanent damage, and very rarely, a baby will die. The type of damage that a baby has after such a bleed will depend on where the bleeding happens and a bleed in the brain may cause

significant brain damage. Some babies may experience excessive bleeding due to Vitamin K deficiency following an operation such as circumcision and, in this case, babies can lose a dangerous amount of blood.

How Common is Vitamin K Deficiency Bleeding?

Because artificial Vitamin K is given to so many babies, and because VKDB is extremely rare even if babies are not given Vitamin K, it is very difficult indeed to get a clear picture of how common VKDB actually is.

Some numbers of babies who experience VKDB when *not* given Vitamin K supplementation, which come from various studies which refer to developed countries like the UK are:

1/10,000 (McNinch and Tripp 1991, Von Kries and Hanawa 1993, Passmore et al 1988)

5.8 to 17.8/100,000, which is between 1/17000 and 1/5500, so consistent with the 1/10000 (Sanker 2016)

1/14,000 – 1/25,000, which is also consistent with the above numbers. This is looking at LATE onset only, not early onset or classic onset (Shearer 2009)

It is clear from these numbers that the risk to any individual healthy baby experiencing VKDB is very low. It may be higher in at-risk babies (see below).

***Do* babies have low levels of Vitamin K?**

Babies are born with lower levels of Vitamin K compared to older children and adults. It is not understood why this is, and it may be important for a process that we don't yet understand. It might be that giving additional Vitamin K to babies through any method – injection, oral drops or high levels in artificial baby milk (formula) - may cause harm that we don't yet know about. We don't have any evidence of this – but then there are no long term studies on the potential health impacts (risks or benefits) of giving Vitamin K either. So, while you might be told that there is no evidence of long term harm, it is also the case that equally we have no evidence of its long term safety. We have just not looked at either safety or harm.

We are sometimes told that breastmilk has 'low levels' of Vitamin K when compared to formula, but this actually makes no sense. Formula has high levels of Vitamin K only because this is what is added into the product. It's rather like adding food colouring to formula, then saying that breastmilk has low levels of food colouring compared to formula! However, the additional Vitamin K that is added to formula does mean that those babies whose bodies do need extra Vitamin K will normally get it from the formula, whereas breastfed babies will receive the biologically normal amount, which in the rare case of a baby needing extra, may not be enough to stop them from experiencing VKDB.

Although most of our Vitamin K needs come from food (so, for babies, their milk), Vitamin K is also

manufactured in the human gut. It may be that babies have lower levels of Vitamin K because their gut needs to start working efficiently in a way that it didn't need to do in the womb. This might take longer for some babies than others. We do know that breastfed babies who experience VKDB, and who were not given Vitamin K, very often have not fed well from birth, so it's possible that the cause of the VKDB was that they were not receiving enough milk. This is one reason why early and effective breastfeeding after birth is important; if a woman decides to give formula, feeding should also start as soon as the baby shows an interest.

Methods of giving Vitamin K to babies

1. Intramuscular (IM) injection

This is an injection given to the baby, usually shortly after birth although it can wait for a few hours so that the mother can first spend time getting to know her baby, have plenty of skin to skin and hopefully initiate breastfeeding – all of which are likely to reduce the chance of VKDB.

The injection is very effective against Classic Onset VKDB. It is extremely hard to obtain accurate figures as to the effectiveness of the injection. This is because different studies look have very different methodologies. However, evidence from the UK shows that with this injection the rates of VKDB drop to below 1/100,000.[1]

2. Oral

This is where the Vitamin K liquid is put into the baby's mouth. Vitamin K is a fat soluble vitamin and so it is considered important to give the doses of oral Vitamin K immediately after a feed of breastmilk or formula because the fat in the milk helps the Vitamin K to be absorbed.

There is no good evidence to show how much Vitamin K to give, and how often to give it, however in the UK it is normal for 3 doses to be given although this might differ from product to product so always check for the correct information for the Vitamin K product that you are using. For some products, babies who are formula fed may not be offered the third dose. Babies may spit up the oral dose, often making it impossible to know whether or not they've swallowed any, and if so, how much.

There is no evidence that we have been able to find which looks at whether the oral version of Vitamin K affects the baby's gut bacteria.

Deciding to not give Vitamin K

Some parents choose to not give their baby Vitamin K, and it is their legal right to decide this provided that they have parental responsibility for their child, and that there is no court order stating that someone else has responsibility for medical decisions. Health Care Providers are not allowed to try to coerce or force parents into giving any intervention, treatment or prophylaxis. Instead they should offer balanced information to support the parents' informed decision making, which they should then support.

If this doesn't happen, you can remind them of their obligations to provide information and then support your decision.

One option that some parents choose is to make the decision to have Vitamin K only if their baby shows signs of having a liver condition, or if they are not feeding well and they become concerned, bearing in mind that injury from VKDB can occur before symptoms show. Another situation may be that the baby needs a tongue tie revision (snip) and some practitioners who treat tongue ties will not do so if the baby hasn't had Vitamin K. In this case, it is usually possible to obtain the Vitamin K through the GP, although a few areas of the UK have reported that the local NHS Trust is not allowing this. While this could be challenged, it might be worthwhile finding out in advance how open your local Trust is to this option as fighting it when feeding is going badly is likely to be incredibly stressful. Another option is to attempt to find a practitioner who will do a tongue tie revision without Vitamin K, but this may need to be a private practitioner[2].

What are the risks of Vitamin K supplementation?

Injections are painful for babies. Considering that most babies have never before felt pain, being given the vitamin K by injection is likely to be a deeply unpleasant experience for them. It is often given very soon after birth, during the time where the baby and mother are just starting to get to know one another, and the pain of the injection can impact on this important bonding period. There is no reason to give the injection until mother and baby are ready – you don't need to be rushed into it just for the convenience of the medical staff. If you make the decision to allow your baby to have the VK injection, you can decide when it's given. We do know that babies can feel less pain when they are breastfeeding, so you might decide to wait until your baby is feeding well, which may be a few hours after birth, before allowing them to have the injection – or longer if you wish.

It is not uncommon for babies to get a bruise at the site of the injection.

Like all medications, it is possible, although very unlikely, that the wrong medication or the wrong dose may be given. The UK has robust protocols to avoid this but you are entitled to see the bottle of medication before it's used to ensure that you are happy that it is the correct product.

There is one known case of an allergic reaction to Vitamin K supplementation[3]. There are three known cases of pneumonia caused by aspiration of the oral Vitamin K[4].

The Vitamin K dose is much higher than babies would ever have naturally in their body and we do not know if this may have a negative effect on them when they are given the dose, or later in life. One research paper[5] showed that preterm babies given 0.5-1mg of VK (1mg, if injected, is the norm for term babies) still had levels which were 1900-2600 times higher than babies who were not given the Vitamin K two days after the injection, and 550-600 times 10 days after. Although babies who are premature (less than 36 weeks' gestation) should be given a dose which relates to their birthweight, we have had reports of babies being given the full dose for a term baby. There is also some concern[6] that formula fed

premature babies may have excessively high levels of Vitamin K in their bodies as the formula's added Vitamin K is an extra supplement.

There was a study in 1992[7] which appeared to show an increase in childhood cancer for babies who are given Vitamin K by injection, but not orally. Further research[8] studies did not find an increase in cancer rates and concerns about the way the 1992 study was carried out have been raised. No randomised controlled trials have ever been done to look at this possible risk. It is very unlikely that this will ever happen and we will probably never know for certain whether this link exists or not.

I've heard that as many as 1/60 babies may experience Vitamin K Deficiency Bleeding. Is this true?

Much of the research that we have on Vitamin K is of poor quality and cannot be relied upon to give us accurate information.

For instance, one study, Sutherland et al[9] (1967) looked at whether there was a difference between the amount of bleeding seen in breastfed babies compared to babies fed on formula, and how Vitamin K affected this. This is an important study to mention because it is frequently referred to, even now, and references which state that VKDB can be as high as 1 in 60 babies refer back to this study. Even The Guardian newspaper published an article in 2019 which gave this statistic.
https://www.theguardian.com/news/2019/feb/21/anti-vaxxers-delivery-ward-doctor-mother-newborn

In this study there were four groups:

1. Babies who were breastfed and given Vitamin K
2. Babies who were breastfed and not given Vitamin K
3. Babies who were formula fed and given Vitamin K
4. Babies who were formula fed and not given Vitamin K

Babies were not put to the breast until 8-12 hours after birth, and formula fed babies were given sterile water for 1 -3 feeds FROM 12 hours old (it appears they were starved before this) and thereafter an artificial milk made from evaporated milk mixed with carbohydrate. The results actually showed that the breastfed babies who were given Vitamin K had fewer incidents of bleeding than any other group – possibly because the formula did not have added Vitamin K (this is not stated in the paper) or maybe because the breastfed babies were able to take in nutrients sooner than their formula fed counterparts. By contrast, babies who were breastfed but did not have Vitamin K were most likely to show signs of bleeding. There is very little of value to be taken from this study given that the babies were not fed appropriately, and in addition many were circumcised, with the amount of bleeding from the penis being one marker for problematic bleeding. It is possible that the removal of the attached foreskin from the glans of the baby's penis (which is similar to removing a fingernail), done without pain relief on an awake and immobilised infant, could change other physiological processes which may affect blood clotting.

The Tennessee Cluster

In addition to this research, in June 2014 Schulte et al[10] released a paper looking at five babies in Tennessee, USA, who experienced VKDB, plus a further two who had blood tests and were found to have what was considered to be dangerously low levels of blood clotting factors but had no symptoms. We are not able to evaluate how many babies this is, compared to babies who did not experience VKDB in this region, as this information is not included in this paper, so we do not know if it was an unusual number of babies. Every baby was older than 2 weeks (the youngest was 6 weeks) and therefore all of the babies who had bleeds were experiencing Late Onset VKDB which may mean that there was an underlying illness in these babies. This is not a research paper or a trial, and there is not enough information in it to draw the conclusion that VKDB is more common than the above studies have reported.

Does artificial Vitamin K contain any animal products?

Some versions of the Vitamin K supplement do contain animal products. A vegan version is available and you can ask your midwife to source this for you if you wish.

References:

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3. Koklu et al, Anaphylactic shock due to vitamin K in a newborn and review of literature: www.ncbi.nlm.nih.gov/pubmed/24059412
4. Bhandari et al, Aspiration pneumonia in association with oral vitamin K: www.ncbi.nlm.nih.gov/pmc/articles/PMC1721474/
5. Costakos et al, Vitamin K prophylaxis for premature infants: 1mg versus 0.5mg: www.ncbi.nlm.nih.gov/pubmed/14703597
6. Pediatrics Journal: Did "Controversies Concerning Vitamin K and the Newborn" Cover All the Controversies? Controversies Concerning Vitamin K and the Newborn | Pediatrics | American Academy of Pediatrics
7. Golding et al, Childhood cancer, intramuscular vitamin k, and pethadine given during labour: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1883000/
8. Zipersky, Vitamin K at birth: www.ncbi.nlm.nih.gov/pmc/articles/PMC2351614/?page=1
9. Sunderland et al, Hemorrhagic disease of the newborn. Breast feeding as a necessary factor in the pathogenesis: www.ncbi.nlm.nih.gov/pubmed/6071586
10. Schulte et al, Rise in late onset vitamin K deficiency bleeding in young infants because of omission or refusal of prophylaxis at birth: www.ncbi.nlm.nih.gov/pubmed/24842255

Further reading:

Cochrane, Pre-term babies and vitamin k: www.cochrane.org/CD008342/NEONATAL_prophylactic-vitamin-k-prevention-vitamin-k-deficiency-bleeding-preterm-neonates

Evidence Based Birth on vitamin k: https://evidencebasedbirth.com/evidence-for-the-vitamin-k-shot-in-newborns

Circumcision and vitamin k : www.yourwholebaby.org/vitamink