

# Vitamin K Waiver of Liability



Excerpt from AAP Policy Statement, Controversies Concerning Vitamin K and the Newborn, July 2003 – Reaffirmed, May 2006 and May 2009.

*Please read the entire two page statement included in your new client packet before signing this waiver.*

## Abstract

Prevention of early Vitamin K deficiency bleeding (VKDB – a clotting disorder that causes spontaneous, uncontrolled bleeding – often internal bleeding – which can cause death or permanent brain damage) of the newborn, with onset at birth to 2 weeks of age (formerly known as hemorrhagic disease of the newborn), by oral or intramuscular (IM) administration of Vitamin K is accepted practice. In contrast, late VKDB, with onset from 2 to 12 weeks of age, is most effectively prevented by IM administration of Vitamin K. Concern regarding a possible causal association between IM Vitamin K and childhood cancer has not been substantiated.

## Recommendations from the American Academy of Pediatrics

Because IM Vitamin K has been shown to prevent VKDB of the newborn and young infant and the risks of cancer have been unproven, the AAP recommends the following: 1) Vitamin K should be given to all newborns as a single, intramuscular dose. 2) Parents should be aware of the risks of late VKDB associated with inadequate Vitamin K prophylaxis from current oral dosage regimens, particularly for newborns who are breastfed exclusively.

## Background

Adults produce vitamin K by the synthesis of bacterial flora in the large intestine and by eating foods that are rich in vitamin K. But the vitamin K produced in the sterile newborn's gut does not appear to be usable by the baby until he or she is 4-6 months old, and does not prevent VKDB<sup>(1)</sup>. VKDB is prevented in nearly all formula fed babies who ingest vitamin K on a daily basis and those babies who receive an IM injection of vitamin K<sup>(1,4)</sup>.

Although the majority of babies will do fine without receiving supplemental vitamin K, it is impossible to predict which healthy baby will later be stricken with VKDB, and this is the basis for injecting all babies. There are several different estimates of the risk of the healthy, breast fed infant developing early VKDB ranging from 2.5:1,000 to 17:1,000<sup>(AAP)</sup> or 1:10,000 to 1:25,000<sup>(6)</sup> and for late VKDB from 1:14,000 to 1:20,000<sup>(3-4)</sup> or 4.4 – 7.2 in 100,000<sup>(6,7,8)</sup>. In one German study of late VKDB, the overall death rate in affected babies was 19%, and 21% of the survivors had long-term neurological handicaps<sup>(9)</sup>.

## Are there more natural ways to prevent VKDB?

Not that we are currently aware of. During pregnancy, very little vitamin K crosses the placenta and even if you take huge quantities of a supplement, vitamin K will only be found in small quantities in breastmilk<sup>(5)</sup>.

## What about oral vitamin K?

Some studies have found that in order for oral vitamin K to be potentially as effective as IM vitamin K, babies must receive 2 mg orally at birth, and 1 mg orally each week for the first three months VKDB<sup>(10,11)</sup>. This is an accepted method of receiving Vitamin K in a number of countries, however, prophylactic oral Vitamin K is not recommended for newborns in this country at this time. A disadvantage of using oral vitamin K is that some babies who have liver or other problems, may not absorb it into their systems well. Because of its bitter taste, many babies spit up the oral vitamin K, which makes it difficult to properly dose the baby. Logistically, it may be difficult to obtain the correct formulation of newborn oral vitamin K because it is not readily available in this country. Your child's pediatrician may not be familiar with the effectiveness or the dosage. For these reasons, we do not recommend oral vitamin K.

## What if I choose to decline IM vitamin K?

Although symptoms may come on quickly or not show until damage has already been done, if you choose not to inject Vitamin K, get care for your baby immediately if any symptoms develop and remind your baby's health care provider that the baby was not given a vitamin K injection. Some of the most common signs are:

- Bruises. Normal newborns should not have unexplained bruises.
- Bleeding from the mouth, nose, ears, umbilicus, or other sites. Normal newborns do not bleed easily.
- Blood in the urine, stool, or vomit. Blood in the stool may appear as a faint red "halo" around wet parts of the diaper.
- Poor appetite, difficulty breathing, unusual sleepiness, vomiting
- Prolonged bleeding from puncture sites (heel prick or injections) or circumcision.
- Irritability, agitation, screaming, touch sensitivity, spasms.
- Fontanel (soft spot) is bulging or tight.
- Unusual posture, seizures.

## References

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- 4 Cornelissen M, von Kries R, Loughnan P, Schubiger G. Prevention of vitamin K deficiency bleeding: efficacy of different multiple oral dose schedules of vitamin K. *Eur J Pediatr* 1997;156:126-30.
- 5 Shearer MJ. Vitamin K metabolism and nutrition. *Blood Rev* 1992;6:92-104.
- 6 von Kries R and Hanawa Y, Neonatal vitamin K prophylaxis, Report of scientific and standardization subcommittee on perinatal haemostasis, *Thrombosis and Haemostasis*, 1993: 69: 293-95.
- 7 Motohara K, Endo F, Matsuda I. Screening for late neonatal vitamin K deficiency by acarboxyprothrombin in dried blood spots. *Arch Dis Child*. 1987;62:370 –375
- 8 Shearer MJ Vitamin K deficiency bleeding (VKDB) in early infancy Volume 23, Issue 2, Pages 49-59 (March 2009)
- 9 Sutor AH. Late form of vitamin K deficiency bleeding in Germany. *Klin Padiatr*. 1995 May-Jun;207(3):89-97.
- 10 van Hasselt PM. Prevention of Vitamin K Deficiency Bleeding in Breastfed Infants: Lessons From the Dutch and Danish Biliary Atresia Registries *Pediatrics* 2008;121:e857-e863
- 11 Hansen KN. Weekly oral vitamin K prophylaxis in Denmark. *Acta Paediatr*. 2003 Jul;92(7):802-5.

## Please indicate which option you choose for your baby and sign:

<p>Vitamin K injection:</p> <p>I would like my baby to have the vitamin K injection. I understand that there may be as yet unknown risks with the vitamin K injection, and I release and hold harmless my midwife from any complications that may occur.</p> <p>_____</p> <p>Signature</p> <p>_____</p> <p>Date</p> <p>_____</p> <p>Witness</p>	<p>Oral vitamin K:</p> <p>I would like my baby to have oral vitamin K. I understand that it is my responsibility to inform my pediatrician and to obtain the vitamin K. I understand that my baby must receive 2 mg orally at birth, and 1 mg orally each week for the first three months in order for it to be as effective as the vitamin K injection. I understand that a midwife will give my baby the first dose soon after birth, but that I am responsible for administering subsequent doses. I understand that there may be unknown risks to high oral vitamin K concentrations, and I release and hold harmless my midwife from any complications that may occur.</p> <p>_____</p> <p>Signature</p> <p>_____</p> <p>Date</p> <p>_____</p> <p>Witness</p>	<p>Refusal of Vitamin K:</p> <p>I do not want my baby to have vitamin K. I accept the risks and I release and hold harmless my midwife from any complications that may occur.</p> <p>_____</p> <p>Signature</p> <p>_____</p> <p>Date</p> <p>_____</p> <p>Witness</p>
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