

# Kona Birth & Midwifery Services

## INFORMED CONSENT VITAMIN K

Vitamin K is a fat-soluble vitamin needed for blood coagulate. We cannot make Vitamin K ourselves, and it does not store well in the body. Newborns have little to no stores of vitamin K when born. Vitamin K1 comes from leafy green vegetable sources while Vitamin K2 is produced through bacteria in our intestinal tracts. Plant based sources produce 90% of our overall stores of Vitamin K.

Newborns are at risk for vitamin K deficiency bleeding (VKDB) due to these low stores and inability to produce Vitamin K. If birth is difficult, newborns are at greater risk for VKDB.

### **What is Vitamin K Deficiency Bleeding (VKDB)?**

Vitamin K is necessary for our bodies to coagulate our blood flow. Without adequate levels of Vitamin K, our bodies are unable to stop bleeding once it starts. Generally this is not a problem and our bodies work just fine. However, in a newborn, spontaneous and uncontrolled bleeding can be very dangerous. A newborn who does not have enough Vitamin K can start bleeding suddenly and without warning.

There are three patterns of VKDB:

- **Early** which occurs within the first 24 hours of life. This is usually seen in newborns where the mother has been on medication including certain antibiotics and anticoagulants.
- **Classical** occurs within the first 2-7 hours of life and more commonly in the first 2-3 days. Vitamin K levels are lowest on day 2 and 3. Common bleeding sites include: the umbilical cord stump, gastrointestinal system, skin, nose and the circumcision site. When breastfeeding is poor risk is increased.
- **Late** occurs after the first week but before the 8<sup>th</sup> week. The bleeding usually occurs in the brain, skin, and gastrointestinal tract. Bleeding in the brain is often the first sign of late VKDB. Late VKDB happens in exclusively breastfed infants who did not receive a Vitamin K shot.
- When infants **do not receive any Vitamin K at birth**, statistics show an increase in late VKDB (4.4 to 10.5 infants out of 100,000). Rates are higher in Asian countries (1 out of every 6,000 infants).

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## Why do breastfed babies not have enough Vitamin K?

There are two main reasons why babies do not have enough Vitamin K in their system.

First, babies are born with very limited amounts of Vitamin K. Their levels are lowest at days 2-3 and do not reach adult levels until about 6 months of age. The levels are low because:

- Very little Vitamin K1 transfers from the mother to the baby through the placenta
- Babies do not have enough bacteria in their intestines to make Vitamin K2

Second, breast milk has very tiny amounts of Vitamin K. Colostrum has about 2 micrograms of Vitamin K per Liter, while mature milk has 1 microgram per Liter (von Kries et al, 1987).

Virtually all babies with late VKDB are exclusively breastfed. When studies looked closely at infants who develop late VKDB, they found that mothers of these babies had normal levels of Vitamin K in their milk supply. It is thought that maybe some of these babies had a problem with absorbing the Vitamin K from their mother's milk due to lack of intestinal bacteria. (Shearer 2009).

## What are the risks to having the Vitamin K Injection?

As with any injection there are risks. Most parents are concerned about the ingredients in the shot. One way to alleviate this concern is to ask your hospital if they have the preservative-free version of Vitamin K.

The ingredients in a shot with NO preservatives include:

- 1 mg of Vitamin K1, a fat-soluble vitamin derived from plants
- 10 mg of Polysorbate 80, which helps Vitamin K1 (a fat-soluble Vitamin) dissolve in liquid for the injection. Polysorbate 80 is made from natural sorbitol and plant-based oleic acid, is used in a wide variety of foods, medicines, and vitamin supplements, and is included in the *Handbook of Green Chemicals*.
- 10.4 mg of Propylene glycol, which helps absorb extra water and maintain moisture in certain medicines. Propylene glycol has been recognized as safe by the FDA for use in food products.
- 0.17 mg of Sodium acetate anhydrous, a mixture of salt and bicarbonate, that is used to adjust the pH of the injection
- 0.00002 mL of Glacial acetic acid, also known as vinegar, that is used to adjust the pH of the injection

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Are there any side effects from these ingredients?

Some parents have concerns about use of the **propylene glycol**. Propylene glycol is used in many medications (oral, topical, and injections) because it is very good at helping medications absorb into liquid. Any cases about severe side effects from propylene glycol are from decades ago and were related to very high doses.

For example, in one case, infants were given a multivitamin that had 300mg of propylene glycol daily (Macdonald et al., 1987). This dose, which was 30 times higher than the one used in the Vitamin K shot, led to seizures in the infant.

As far as allergic reactions to the Vitamin K shot, almost all of the cases in history occurred with the intravenous (IV) form, something that is never used in the newborn period unless an infant comes in to a hospital with Vitamin K deficiency bleeding.

Side effects from Vitamin K injections given at birth are incredibly rare and if they are seen, they end up being case reports due to rarity.

## Supplemental Vitamin K

To establish an optimal level of Vitamin K for the newborn the mother can increase her stores through Vitamin K supplementation in pregnancy. This will lower, but not prevent, the newborn risk of VKDB.

Vitamin K levels can be increased prenatally with a supplement of 4,000 mcg alfalfa tablets daily, beginning at 32 weeks gestation. Alfalfa can be continued through lactation to support milk supply and has shown to also reduce maternal PPH.

## Injection vs. Drops

There is less likelihood of VKDB after intramuscular injection of Vitamin K, although is not completely effective for eliminating hemorrhagic episodes. The incidence of VKDB after 1 mg Vitamin K injection is 0.25 per 100,000. The Vitamin K1 injection, given as a shot in the muscle (IM = intramuscular) is the preferred method for several reasons (Puckett and Offringa 2000; Shearer 2009):

- There is no proven oral version of Vitamin K available for infants in the U.S.
- The shot is absorbed more easily than the oral version.
- The shot has a delayed release effect that protects against both classical and late bleeding.

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- When the shot is used, the chance of late VKDB is near zero (does not completely eliminate the risk in cases of underlying liver or gallbladder disorders)
- In contrast, the typical 3-dose regimen of oral Vitamin K1 lowers the chance of VKDB but does not eliminate it entirely. Also, infants with underlying (and sometimes undetected) gallbladder or liver disorders may not be able to absorb the oral Vitamin K when it is given in a 3-dose regimen. To learn more about a more effective weekly dose of Vitamin K, see the section on “Weekly and Daily Dosing of Oral Vitamin K” below.

**One reason that other countries may use the oral version of Vitamin K is because mothers and infants usually receive home visits from nurses. Home care does not routinely occur in the U.S.,** and if the oral version is used, the parents need a reminder to administer the follow-up doses, and someone needs to monitor that the infant does not spit it up. When oral Vitamin K is used it requires at least 3 doses (birth, 1 week, and 6 weeks), and the breakthrough cases of Vitamin K deficiency bleeding are often related to missing the final dose (Busfield, Samuel et al. 2013).

When seen by a midwife, oral Vitamin K should be considered and can be administered during the postpartum visits.

## Vitamin K and Circumcision

If circumcision is planned, consider waiting until the eighth day to offer the greatest protection from VKDB. Physiologically, the newborn's Vitamin K levels will have increased from their lowest on day 2 and 3 to an optimal level by day 8.

I have read and understand this information. I have had the opportunity to ask questions. I am aware of the risks of Vitamin K and benefits of Vitamin K.

- I have chosen to have Vitamin K administered to my newborn via injection.
- I have chosen to have Vitamin K administered to my newborn via drops
- I decline Vitamin K administration.

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Mother's signature

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Date

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