

Newborn Vitamin K

What is Vitamin K and why is it important?

Vitamin K is a fat-soluble vitamin needed for blood clotting. It is named after the German word for clotting - Koagulation. We cannot make Vitamin K ourselves, and we don't store it very well in our body. We get Vitamin K1 from leafy green vegetables. We can also get Vitamin K2 from bacteria that live in our intestinal tracts. Vitamin K1 from plants makes up about 90% of our overall Vitamin K levels, while K2 from bacteria makes up only about 10%.

Vitamin K is necessary for our bodies to maintain clotting factors that help the blood to clot. The blood clotting factors are there in normal numbers at birth, but not activated fully due to low levels of Vitamin K. Babies that do not have enough Vitamin K can start to bleed suddenly, without warning. This is known as Vitamin K deficiency bleeding (VKDB). Vitamin K deficiency bleeding can be idiopathic or secondary.

- **Idiopathic VKDB** means that the cause is unknown. Virtually all cases of idiopathic VKDB happen in babies that are exclusively breastfed
- **Secondary VKDB** means that the baby has an underlying disorder such as gallbladder disease, cystic fibrosis, or medication side effects. Most babies who have secondary VKDB are also exclusively breastfed.

Vitamin K deficiency bleeding can follow one of three patterns: Early, classical, and late

- **Early VKDB happens in the first 24hrs of life.** Early VKDB is usually seen in babies born to mothers who took medicines that interfere with Vitamin K. These medications include warfarin (Coumadin), anti-seizure medications, and tuberculosis medications. The bleeding usually happens in the skin, brain, and abdomen.
- **Classical VKDB happens in days 2-7 of life,** usually during days 2-3. This is when levels of Vitamin K are lowest. Common bleeding sites include the gastrointestinal system, umbilical cord site, skin, nose, and circumcision site. The official cause of classical VKDB is listed as "unknown", but breastfeeding and poor feeding are major risk factors.
- **Late VKDB happens after the first week of life, usually during weeks 3-8.** The bleeding usually happens 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 babies who did not receive a Vitamin K shot. Some infants may also be at higher risk if they have undetected gallbladder disease, cystic fibrosis, and antibiotic use. Mortality rate for late VKDB is approximately 20%, with brain damage in nearly 40% of the surviving infants.

How common is late VKDB?

Late bleeding (after the first week of life) is the most dangerous kind of VKDB.

- When infants do not receive any Vitamin K at birth, statistics from Europe show that 4.4 to 10.5 infants out of 100,000 will develop late VKDB. Rates are higher in Asian countries (1 out of every 6000 infants)
- When infants receive oral Vitamin K at least three times during infancy (typically at birth, one week, and four weeks), anywhere from 1.4 to 6.4 infants out of 100,000 will develop late VKDB
- When infants receive the Vitamin K shot at birth, there are virtually no cases of late VKDB

The US does not track the number of cases of late VKDB, so we don't really know how frequently it would occur if we stopped giving the shot routinely.

How common is Classical VKDB?

Classical VKDB - bleeding that occurs in the first week of life - is more common than late VKDB. Information from older studies show that 0.25% to 1.5% of newborns will experience classical VKDB if they don't receive Vitamin K at birth, while more recent reviews show that the number is closer to 0% to 0.44% (0 to 440 out of 100,000). This type of VKDB is usually mild and involves bleeding at the umbilical cord or circumcision site. However, blood loss can be significant.

The mortality rate of classical VKDB is very low in developed countries. However, in Ethiopia researchers reported a mortality rate of 25%. Mortality rates from classical VKDB are probably higher in developing countries such as Ethiopia because of scarce medical resources and a delay between the start of bleeding to treatment.

What is the treatment for VKDB?

The main treatment is to give the infant Vitamin K. When an infant with VKDB receives a shot of Vitamin K1, this will usually slow or stop the bleeding within 20-30 minutes. However, if bleeding happens in the brain, the infant may already have brain damage by the time the shot is given.

Other treatments that have been used in infants with late VKDB include blood and plasma transfusions, brain surgery to remove accumulated blood, and administration of anti-seizure medications.

Why do breastfed babies not have enough Vitamin K?

There are two main reasons why babies that are breastfed 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, breastmilk 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. When studies looked closely at infants who developed late VKDB, they found that the mothers of these babies had normal levels of Vitamin K in their breastmilk. It is thought that maybe some of these babies had a problem with absorbing the Vitamin K from their mother's milk.

Does eating a maternal Vitamin K rich diet during pregnancy and nursing help Vitamin K levels in newborns?

There is no good evidence that giving the mother extra Vitamin K during pregnancy can prevent VKDB in infants. In the largest known study looking at diets and Vitamin K deficiency, researchers followed 683 mothers before pregnancy and after giving birth. Blood was drawn from mothers during labor and from the umbilical cord after birth. Mothers were asked about food intake during pregnancy and also interviewed by a dietitian during the postpartum period. Researchers found no relationship between the Vitamin K status of mothers and that of their infants.

Some people have suggested that an alternative strategy for boosting the Vitamin K intake of breast fed babies is for the mother to take a daily supplement herself after birth. However, there is very little evidence supporting this strategy. In one small study with only 6 mothers, a 2.5 mg oral dose twice a day (one hundred times the amount that would otherwise need to be given to the baby each day) was enough to raise the vitamin content of the milk to acceptable levels. In a large Japanese study with more than 3,000 mother-infant pairs, researchers tested a maternal dose of 15 mg of Vitamin K2 by mouth once a day. They found that this dose resulted in low infant Vitamin K levels in only 0.11% of the treatment group. But so far, researchers have not tested the effects of maternal Vitamin intake on actual Vitamin K deficiency *bleeding* in infants.

If all infants are born with low Vitamin K levels, is it really a deficiency or is this the natural design of human beings?

Why are babies born with insufficient Vitamin K? Obviously, it is impossible for us to know *why* this happens. There are a couple of possibilities, and there isn't really much research to inform this...but here are a few theories:

VKDB, although catastrophic when it happens, is rare. So if you are looking at this as a case of "survival of the fittest," perhaps there is not a pressing need for newborns to be born with higher levels of Vitamin K.

When infants are born, many of their systems are not fully developed yet. For example, their nervous system and immune system are immature. It is possible that maybe an infant's clotting system also needs time to mature and come into its full strength.

Perhaps there is a reason we don't know of that leads to low transmission of Vitamin K from mom to baby before and after birth. Maybe there is an unknown beneficial mechanism that is preventing some kind of environmental toxin from reaching the baby, and this mechanism also has the side effect of keeping Vitamin K from reaching baby in sufficient quantities through the placenta and breastmilk.

You could also make the argument that it doesn't really matter *why* babies are born with low levels. The point is that they *are* born with low levels of Vitamin K, and that some babies will die from Vitamin K deficiency bleeding if they do not receive supplemental Vitamin K at the beginning of life. Most will not bleed. But some will, and some will experience brain injury or death. And these injuries and deaths are 100% preventable.

What is the evidence for the oral and injectable versions of Vitamin K? Are they effective?

In 2009, researchers published a Cochrane review combining the results of 13 studies that randomly assigned infants —almost all of whom were born at term and without complications—to either oral or injectable Vitamin K. Because late VKDB is so rare, the researchers could only look at the effects of Vitamin K on classical VKDB and laboratory results.

Most of the studies in the Cochrane review looked only at infants who were exclusively breastfed. Two of the studies were done in the 1960s, and the rest took place between 1985 and 1996.

What treatments did the researchers study?

- Seven studies compared one dose of oral Vitamin K to one dose of injectable Vitamin K. Doses ranged from 1-6 mg and were given within 12 hours of birth.
- One study compared three doses of oral Vitamin K to one dose of injectable Vitamin K.
- Four studies compared one dose of oral Vitamin K to nothing or placebo.
- Four studies compared one dose of injectable Vitamin K to nothing or placebo.

None of the studies specifically looked to see whether there were any side effects.

In two very important studies that took place in the 1960s, researchers compared injectable Vitamin K to no Vitamin K for the prevention of classic VKDB. The researchers found that Vitamin K led to a 27% decrease in the risk of bleeding between one and seven days, and an 82% decrease in the risk of bleeding after a circumcision.

In the other studies, most of the researchers found no cases of bleeding. This is because VKDB is such a rare outcome that it is hard to study in a clinical trial. Instead, researchers looked at changes in laboratory results that indicate Vitamin K deficiency.

Multiple researchers found that giving Vitamin K1—whether it was a shot or an oral dose—significantly improved the baby's lab results in the first week of life, when compared to nothing or a placebo.

In the studies that compared the Vitamin K shot to a single dose of oral Vitamin K, some researchers found no difference in lab results. However, when researchers looked specifically at Vitamin K levels, they found that the Vitamin K shot resulted in significantly higher levels of Vitamin K at one week and one month when compared to the single oral dose.

Is it possible to buy oral Vitamin K for infants?

Many research articles say that oral Vitamin K1 is not available in the U.S. That is because there is not an FDA-approved oral version for sale. However, there is an oral Vitamin K1 supplement, called **K-Quinone** (Scientific Botanicals, Inc) that you can buy online in the U.S.

K-Quinone is made up of Vitamin K1 from alfalfa, nettles, and green tea. This supplement is diluted in an olive and soy oil base. Because it is sold as a supplement without FDA approval, this medication is not required to have the stated amount of vitamin K. The amount could vary widely from vial to vial, and K-Quinone is not regulated or certified by a third party.

Pros of Vitamin K Shot: Eliminates the possibility of classic and late VKDB; Vitamin K is slowly released over time from the injection site, thus providing sufficient Vitamin K 1 until baby's Vitamin K levels reach adult levels naturally

Cons of Vitamin K Shot: Discomfort, which can be minimized by having the infant breastfeed while the shot is given; Can cause bleeding or bruising at the injection site

Pros of Oral Vitamin K: Easy to give and not invasive; lowers the risk of classic and late VKDB, but does not eliminate the risk entirely

Cons of Oral Vitamin K: Some babies may not be able to absorb it, or they may spit it up; if the baby has undetected gallbladder or liver disease, the oral Vitamin K will not protect them from VKDB; not 100% effective at preventing VKDB (although it's better than nothing); requires at least three doses and parents may forget to complete the regimen.

What are the current recommendations for giving Vitamin K?

The American Academy of Pediatrics states: "Vitamin K1 should be given to all newborns as a single, intramuscular dose of 0.5 to 1 mg." They say that it is okay to delay administration of intramuscular Vitamin K until after the first feeding is completed, but that it should be given within six hours of birth. The AAP does not recommend oral Vitamin K, because some infants may have trouble absorbing it and there is no FDA-approved version in the U.S.

*Content taken from **Evidence-Based Birth: Evidence for the Vitamin K Shot in Newborns**, found online at <http://evidencebasedbirth.com/evidence-for-the-vitamin-k-shot-in-newborns/>. Complete list of references, disclaimer, and further study information found on the link above. Copyright March 18, 2014 by Rebecca Dekker, PhD, RN, APRN, used with permission from guidelines in terms of use.*

Newborn Vitamin K

I, the undersigned parents, have received this information sheet. I have read and understand the information enclosed and choose the option indicated for administration of vitamin K to my newborn.

- Administer one dose (1mg) of injectable Vitamin K at birth.
- Waive state law requirements and decline permission to treat the baby.
- Administer Oral vitamin K, understanding that there is no currently standard accepted dosage recommendation

Electronically signed by: Sample Form

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