



Prophylactic Vitamin K Informed Consent/Refusal

What is Vitamin K?

Vitamin K is a vital nutrient that our body needs for blood clotting. We get vitamin K from foods such as leafy greens, fruits, whole grains, safflower, poly-saturated oils, and dairy. Some vitamin K is also made by the good bacteria that live in our intestines. Babies have very little vitamin K in their bodies at birth.

Why does my baby need Vitamin K?

Vitamin K is not easily shared with the developing baby during the pregnancy. The intestine of the newborn baby has no bacteria so they are not making sufficient vitamin K. If there is a lack of Vitamin K in the blood of newborns it can take too long for their blood to clot. Therefore, some babies may develop Vitamin K Deficiency Bleeding during the first few weeks or even months of life. This can cause a range of problems, including life threatening bleeding.

What is Vitamin K deficiency bleeding?

Vitamin K Deficiency Bleeding (VKDB) occurs when the baby does not have enough vitamin K. Babies are born with low reserves of Vitamin K and research shows that they may produce insufficient amounts until 4-6 months of age. Breast milk is low in Vitamin K (colostrum carries more vitamin K than mature milk). Babies that are breastfed or fed soy formula are at higher risk for developing problems.

There are Kinds of Vitamin K Deficiency Bleeding:

- **Early Onset:** Occurs in babies less than 24 hours old. Most often related to maternal drug intake (specifically seizure medications and or blood thinners) during pregnancy.
- **Classical:** Occurs between 2-7 days of life, with most cases obvious on days 3-5. This is when Vitamin K levels are lowest. Risk factors are breastfeeding and/or poor feeding with inadequate intake. Common bleeding sites include the gastrointestinal system, umbilical cord site, skin, nose, and circumcision site.
- **Late Onset:** 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 infants who did not receive a Vitamin K shot. Some infants may also be at higher risk if they have undetected gallbladder disease, cystic fibrosis, chronic diarrhea, and antibiotic use.

How common is late Vitamin K deficiency bleeding (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 6,000 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, anywhere from 0 to 0.62 infants per 100,000 have VKDB. In an 18 year period in the United Kingdom, only two babies who received the shot had late VKDB brain bleeds, out of 64 million births." -Evidence Based Birth

Possible warning signs of VKDB:

- Mild bruises
- Nose bleeds
- Umbilical oozing
- Irritability, seizures
- Excessive sleepiness
- Increased vomiting
- Paler than normal skin coloring
- Pale appearing gums
- Yellow eyes after baby is 3 weeks old
- Easy bruising especially around the baby's head and face.
- Blood in the stool, black tarry stool, vomiting blood

Complication of VKDB:

- Life-threatening intracranial bleeding
- Bleeding in the gastro-intestinal tract, umbilicus, ears, nose, throat, and/or brain

Risks of Vitamin K injection:

In 1990 there was a study conducted by British researchers who published data that concluded an association between vitamin K injections in newborns and childhood leukemia. Since this research many scientists have looked at the same data as well as additional research and have been unable to duplicate the results. Many scientists now discredit this study. There are no known long-term risks to giving the preservative free vitamin k injection currently. Possible side effects at the time of injection include pain, swelling, tenderness at the injection site, redness to injection site and rash.

What is in the Vitamin K shot?

The Vitamin K shot is a synthetic version of the natural Vitamin K produced in the body. Phytonadione is the active ingredient along with Polysorbate 80 which acts as a stabilizer and Propylene Glycol a second active ingredient that is used as a solvent. A single dose of Vitamin K injected into the newborn's thigh contains .5 to 1 milligram of Vitamin K.

What about oral Vitamin K administration?

Unfortunately, there is no FDA-approved oral version available in the US. Most oral vitamin K offered in the US is made up of Vitamin K1 from alfalfa, nettles, and green tea and diluted in an olive and soy oil base. Because it is sold as a supplement without FDA approval, it does not usually have the stated amount of vitamin K, the amount can vary widely from vial to vial, and it is not regulated by a third party. This makes it difficult for parents to know whether their newborn is being administered enough vitamin K, even if they follow the proper schedule. Studies show that even when oral Vitamin K from outside the US is used following the proper schedule, it is not 100% effective and does not prevent Vitamin K Deficiency Bleeding at the same rate as injected vitamin K.

For more information on administration of Vitamin K to prevent deficiency bleeding please see evidencedbasedbirth.com

I, _____, have been fully informed of the reasons why prophylactic Vitamin K injection is considered the standard of care for all newborns. I have been fully informed of the catastrophic consequences that can occur to my newborn by refusing prophylactic Vitamin K at birth.

- I CONSENT to the Vitamin K injection being administered after birth to my child.
- I refuse prophylactic Vitamin K injection supplementation for my newborn. I have been informed of the signs and symptoms of Vitamin K Deficiency Bleeding (VKDB), and I understand that not all babies who develop VKDB develop any warning signs or symptoms. I am aware that the consequences of my actions may result in injury or even my child's death, but I take full responsibility for my decision and action. I hereby release, waive, and discharge Shanna Hinrichs LM, CPM dba Natural Born Midwifery Care, its midwives, apprentices, and staff from any responsibility resulting in the personal injury, accidents, or illnesses including, but not limited to death, arising from the refusal of this treatment.
- I have decided to consult my child's health care provider regarding this matter and choose to allow that provider to provide supplementation that may be required.

Parent's Signature

Printed Name

Date

Midwife's Signature

Printed Name

Date