# Administration of Neonatal Vit K1 Informed Consent

#### What is Vitamin K and Why Does My Baby Need It?

Vitamin K is a fat-soluble vitamin that our bodies need for blood clotting. The body does not store vitamin K well and our standard diets are sorely lacking in this nutrient. Foods that are rich in vitamin K include: leafy greens, broccoli, cauliflower, turnips, avocado, banana, kiwi. About 10% of our vitamin K requirement is also manufactured by gut bacteria, but there is little evidence to show that this vitamin K contributes to blood clotting. Vitamin K is also rapidly excreted from the body.

The presence of vitamin K activates clotting factors that enables our blood to clot. At birth there is a low level of vitamin K in the newborn's body, but that level can quickly decline. Since the newborn gut bacteria is not present to make vitamin K, and because there is a small amount of food (ie, breast milk) consumed in the first week of life especially, babies are at a greater risk of developing vitamin K deficiency. The level of deficiency that may cause bleeding is unique to each individual and bleeding can occur without warning. There are no preceding symptoms.

Adequate vitamin K intake for a newborn would be 1.9-3.8 mcg in 3 cups of breast milk. Studies show that breast milk contains around 1.77 mcg of vitamin K. Some small studies have shown that maternal supplementation of vitamin K can increase the level found in breast milk (4-5 mg/day).

#### What is VKDB?

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VKDB stands for Vitamin K Deficiency Bleeding. Due to a low level of vitamin K in the baby's body, bleeding can occur without warning from birth up until 8 weeks or more later. The most common types of bleeding are GI, umbilical cord site, skin, nose, and circumcision site. Rarely, bleeding can occur in the brain. Brain bleeds have been seen exclusively in breastfed babies who did not receive the vitamin K shot at birth and can occur as late as 2 or 3 months after birth.

There are three patterns to VKDB:

- Early- occurring in the first 24 hours of life. Usually these babies are born to mothers who received medication that interferes with vitamin K (Warfarin, seizure medications, tuberculosis medications)
- Classical- occurs in days 2-7. Breastfeeding is a risk factor for this since the baby is receiving small amounts colostrum. Formula is fortified with vitamin K.
- Late- this usually occurs within weeks 3-8. Bleeding in the brain is often the first sign, exclusively for breastfed babies who did not receive the vitamin K shot at birth. At an even greater risk are babies who have gallbladder disease, cystic fibrosis, chronic diarrhea, and who have receive antibiotics. There is no connection between birth trauma and late VKDB.

## What is my baby's risk of developing VKDB?

- The chance of Early and Classical VKDB occurring are 1 in 60 to 1 in 250.
- Late VKDV (with brain bleeding) is rare, occurring 1 in 14,000 to 1 in 25,000 babies.
  - Babies who do not receive vitamin K at birth are 81 times more likely to develop Late VKDB.
  - Babies receiving oral vitamin K are twice as likely to develop VKDB
    - Babies who receive the vitamin K injection after 2 hours old rate of VKDB- 0.24-3.2/100,000
    - Babies who receive oral vitamin K rate of VKDB- 1.4-6.4/100,000

Type of VKDB	Symptoms	Occurrence	Risk Factors	Treatment
Early- first 24 hours	Warning bleeds from the nose, umbilical cord stump, urethra or in bowel movements, petechial (small, bright red bumps on the skin-not to be confused with baby acne), unexplained bruising, circumcision site bleeding, abrasions or cuts that won't stop bleeding	1 in 60- 1 in 250	Mother taking medications for blood clotting, seizures, or tuberculosis No vitamin K shot at birth.	Vitamin K injection
Classical- days 2-7	Same as early	1 in 60- 1 in 250 Nearly 0 when vit K shot administered within 2 hours of birth	Breastfed, no vit K shot at birth Babies who receive the vitamin K injection <b>more than</b> <b>2 hours after birth</b> rate of VKDB- 0.24- 3.2/100,000 Babies who receive oral vitamin K rate of VKDB- 1.4- 6.4/100,000	Vitamin K injection
Late- weeks 3-8+	May not have any symptoms before GI or brain bleed becomes severe	1 in 14,000 to 1 in 25,000 *Babies who do not receive the vit K shot at birth are 81 times more likely to develop.	Only occurs in breastfeed babies with no vit K shot Babies with gallbladder disease, cystic fibrosis, chronic diarrhea, antibiotic use.	Vitamin K injection Possible blood transfusion Surgery may be necessary

## Symptoms of VKDB

If you decline the vitamin K shot at birth, you will need to watch your baby for symptoms of bleeding. Internal bleeding will not be obvious at first. Remember that there may be no warning signs for Late VKDB, which is rare. Otherwise, warning signs can include:

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- Warning bleeds from the nose, umbilical cord stump, urethra or in bowel movements, petechial (small, bright red bumps on the skin-not to be confused with baby acne), unexplained bruising, circumcision site bleeding, abrasions or cuts that won't stop bleeding
- Jandice beyond 2 weeks of age with dark urine, light colored stool. This is particularly a warning sign for babies who are receiving oral vitamin K.

The treatment for this is to administer vitamin K and a blood transfusion may be necessary.

#### Can I prevent VKDB?

The vitamin K shot is the prevention for VKDB with a 0% failure rate when it is administered within 2 hours of birth and the baby does not have an underlying health condition.

#### What is in the vitamin K shot and are there risks?

There have been a great deal of myths going around about the vitamin K shot. Understandably, it does feel unnatural to give your baby a shot of anything at birth. Please be informed that the vitamin K shots are a neonatal dosage, contrary to popular myth that it is an adult dose.

The vitamin K that we carry to births at no cost to you is manufactured by Hospira and contains:

- phytonadione 2 mg (vit K)
- polyoxyethylated fatty acid derivative 70 mg (castor oil)
- hydrous dextrose 37.5 mg
- benzyl alcohol 9mg (preservative)
- May contain hydrochloric acid for pH adjustment

You can order a preservative- free vitamin K injection with your birth kit that will cost you an additional \$37. It contains:

- 1 mg vitamin K
- **10 mg Polysorbate 80,** made from natural sorbitol and plant-based oleic acid, is used in a wide variety of foods, medicines, and vitamin supplements
- 10.4 mg propylene glycol, recognized as safe by the FDA for use in food products
- **0.7 mg sodium acetate anhydrous,** a mixture of salt and bicarbonate, that is used to adjust the pH of the injection
- 0.00002 mg glacial acetic acid (Vinegar)

There has only been one report of 1 baby having an anaphylactoid reaction to the vitamin K injection, worldwide. It is known to be very safe.

Concern about pain at the injection site is important to us. The vitamin K shot can be administered while you breastfeed your baby or hold their hand, and we use the tiniest needle possible and give the injection as gently as we can.

#### Are there alternatives to the vitamin K shot?

Oral vitamin K is an alternative to the vitamin K shot, but is not as effective. With oral administration the risk of VKDB is twice that of a vitamin K injection given more than 2 hours after birth. Multiple doses will be necessary. It is also important to note that no studies have been done on the oral vit K available in the US. All studies available have been performed on the type of vitamin K available in other countries, which is formulated differently than what we have here.

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Your baby is not a good candidate for oral vitamin K if they were born prematurely, circumcised, required resuscitation at birth, born via c-section, or had a traumatic birth.

An evidence based protocol for giving your baby oral vitamin K is:

- 2 mg at birth
- 2 mg in the first week of life
- 2 mg at one month
- 1 mg/wk from weeks 5-13

(Check the dosage according to manufacturer. The popular blue and white bottle variety contains 2 mg in 4 drops.

#### **Additional Resources**

You may also find the information at Evidence Based Birth helpful in guiding your decision:

https://evidencebasedbirth.com/evidence-for-the-vitamin-k-shot-in-newborns/

https://www.cdc.gov/ncbddd/vitamink/facts.html

# References

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