



**Perinatal Services BC**  
An agency of the Provincial Health Services Authority

# **Routine Administration of Vitamin K<sub>1</sub> Prophylaxis to the Newborn**

**Practice Resource for  
Health Care Providers**

**July 2016**



## Practice Resource Guide: ROUTINE ADMINISTRATION OF VITAMIN K<sub>1</sub> PROPHYLAXIS TO THE NEWBORN

The information attached is the summary of the position statement and the recommendations from the recent CPS evidence-based guideline for routine intramuscular administration of Vitamin K<sub>1</sub> prophylaxis to the newborn\*:

[www.cps.ca/documents/position/administration-vitamin-K-newborns](http://www.cps.ca/documents/position/administration-vitamin-K-newborns)

### Summary

Vitamin K deficiency bleeding or VKDB (formerly known as hemorrhagic disease of the newborn or HDNB) is significant bleeding which results from the newborn's inability to sufficiently activate vitamin K-dependent coagulation factors because of a relative endogenous and exogenous deficiency of vitamin K.<sup>1</sup>

There are three types of VKDB:

1. Early onset VKDB, which appears within the first 24 hours of life, is associated with maternal medications that interfere with vitamin K metabolism. These include some anticonvulsants, cephalosporins, tuberculostatics and anticoagulants.
2. Classic VKDB appears within the first week of life, but is rarely seen after the administration of vitamin K.
3. Late VKDB appears within three to eight weeks of age and is associated with inadequate intake of vitamin K (exclusive breastfeeding without vitamin K prophylaxis) or malabsorption. The incidence of late VKDB has increased in countries that implemented oral vitamin K rather than intramuscular administration.

There are three methods of Vitamin K<sub>1</sub> administration: intramuscular, oral and intravenous. The Canadian Paediatric Society (2016)<sup>2</sup> and the American Academy of Pediatrics (2009)<sup>3</sup> recommend the intramuscular route of vitamin K administration. The intramuscular route of Vitamin K<sub>1</sub> has been the preferred method in North America due to its efficacy and high compliance rate. The incidence of late VKDB when Vitamin K<sub>1</sub> is administered orally is 1.4 to 6.4/100,000 versus 0.25 to 3.2/100,000 when intramuscularly.<sup>2,4</sup>

It is important to note that the administration of Vitamin K<sub>1</sub> by intramuscular injection does not provide complete protection, especially in breast fed infants whose oral intake of vitamin K is low.<sup>2</sup> The Canadian Paediatric Society (2016)<sup>2</sup> recommends considering additional doses of Vitamin K<sub>1</sub> to infants at high risk for VKDB, for example, infants who fail to thrive, have liver disease or have long term diarrhea.

A 1992 study<sup>5</sup> in the British Medical Journal reported a link between intramuscular Vitamin K<sub>1</sub> and childhood cancer and caused great concern, especially in Europe. This led some countries to change practice and administer Vitamin K<sub>1</sub> orally rather than the standard intramuscular route. Those countries showed an increase in late VKDB of the newborn. Since then, the CPS<sup>2</sup>, AAP<sup>3</sup> and Zipursky<sup>4</sup> reported several case-controlled studies that have found no evidence to suggest that intramuscular Vitamin K<sub>1</sub> causes childhood cancer.

\* Permission to reprint recommendations granted by the Canadian Paediatric Society on April 25, 2016.

Oral administration may be a harm-reduction alternative in cases where parents refuse intramuscular administration.<sup>1,2,6</sup> Parents may make this choice for various reasons. Some of those reasons include:

- To protect their infant from pain associated with intramuscular injection,
- They have an opinion that the injection is unnecessary,
- A desire to minimize their infant's exposure to 'toxins'.

To lessen pain associated with intramuscular injections, encourage skin to skin 10 to 15 minutes before the injection and/or breastfeeding during the injection. For infants who are unable to breastfeed, and have non-nutritive sucking (NNS) as part of their care, NNS may be used. Parents may encourage infant to suck on their clean finger.

The intravenous route for less than 1500 grams premature or ill infants is preferred by some providers in tertiary centers. This route may not fully protect against late VKDB.

## Recommendations

1. To prevent early VKDB (which occurs within the first 24 hours of life), administer Vitamin K<sub>1</sub> to expectant mothers who take drugs that impair vitamin K metabolism.
2. Administer Vitamin K<sub>1</sub> within the first 6 hours after birth following initial stabilization of the newborn and an appropriate opportunity for maternal (family) – infant interaction.
3. Administer Vitamin K<sub>1</sub> as a single intramuscular dose of:
  - 0.5 mg if birth weight is 1500 grams or less
  - 1 mg if birth weight is greater than 1500 grams
4. For infants whose parents refuse an intramuscular injection, three 2 mg oral doses of Vitamin K<sub>1</sub> are recommended at:
  - the time of the first feeding
  - repeated at 2 to 4 weeks and
  - again at 6 to 8 weeks of age

Oral prophylaxis is contraindicated in infants who are ill, on antibiotics, have cholestasis or diarrhea.

If the infant vomits or regurgitates the dose within one hour of administration, the oral dose should be repeated.<sup>7</sup>

An appropriate oral form of Vitamin K<sub>1</sub> has not been licensed in North America. The injectable form of Vitamin K<sub>1</sub> is currently being used for oral administration.

Family education is imperative. Promote awareness among families of the risks of late VKDB (including the 50% chance of an intracranial hemorrhage with late VKDB) associated with inadequate vitamin K prophylaxis with the current oral dosage regimens, particularly for newborns who are breastfed. Inform parents of the importance of the follow-up doses. (Refer to Appendix for sample family handout).

5. Consider the possibility of vitamin K deficiency for any bleeding that occurs during the first six months of life. Consider consultation or referral as appropriate. Institute appropriate therapy with Vitamin K<sub>1</sub> when required.
6. Consider administering further doses of Vitamin K<sub>1</sub> to infants at high risk of VKDB, identified as those who fail to thrive, have liver disease or have long term diarrhea.

## References

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## Protect Your Baby from Bleeds – Talk to Your Healthcare Provider about Vitamin K



Without enough vitamin K, your baby has a chance of bleeding into his or her intestines, and brain, which can lead to brain damage and even death. Infants who do not receive the vitamin K shot at birth can develop VKDB up to 6 months of age.

### How can I prevent VKDB?

The good news is that VKDB is easily prevented. The easiest and most reliable way to give babies vitamin K is by a shot into a muscle in the leg. One shot given after birth will protect your baby from VKDB.

### Protect Your Baby from Vitamin K Deficiency Bleeding

Before having a baby, most parents don't give much thought to the vitamin K injection (shot) for their newborn. It's just not something that is talked about during prenatal checkups, even though babies have been routinely given this important shot at birth since the practice was first recommended by the American Academy of Pediatrics in 1961.

Vitamin K is needed for blood to clot normally. Babies are born with very small amounts of vitamin K in their bodies which can lead to serious bleeding problems. Research shows that a single vitamin K shot at birth protects your baby from developing dangerous bleeding which can lead to brain damage and even death. Ask your healthcare provider about the benefits of Vitamin K before your delivery. Protect your newborn by making sure he or she gets the shot after birth.

### What is vitamin K deficiency bleeding (VKDB)?

Vitamin K deficiency bleeding or VKDB, is a condition that occurs when the baby does not have enough Vitamin K.

### What is vitamin K?

Vitamin K is a vital nutrient that our body needs for blood to clot and stop bleeding. We get vitamin K from the food we eat. 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 because:

### Why does my baby need a vitamin K shot?

1. Vitamin K from the mom is not easily shared with the developing baby during the pregnancy
2. The intestine of the newborn baby has very little bacteria so they do not make enough vitamin K on their own.

Without enough vitamin K, blood cannot clot well. As a result, bleeding can occur anywhere in the body. This means not only that bleeding from a cut or bruise may continue for a long time, but that uncontrolled bleeding into the brain and other organs may occur.



### What are the warning signs of VKDB?

In the majority of cases of VKDB, there are NO WARNING SIGNS at all before a life-threatening bleed starts. Babies who do not get a vitamin K shot at birth might develop any of these signs of VKDB:

- Easy bruising especially around the baby's head and face
- Bleeding from the nose or umbilical cord
- Paler than usual skin color or, for dark skinned babies, pale appearing gums
- Yellow eyes after the baby is 3 weeks old
- Blood in the stool, black tarry stool, or vomiting blood
- Irritability, seizures, excessive sleepiness, or a lot of vomiting may all be signs of bleeding in the brain

#### Did You Know?

About half of all babies who develop VKDB bleed into their brains.

### Is Vitamin K safe?

A study from the early 1990's found a possible link between getting vitamin K and developing childhood cancer. Pediatricians became very concerned about this and have done many studies since then, in many different ways, trying to see if this link was true. None of the studies found this link again, even though doctors and scientists looked very hard for it.

### Does my baby get vitamin K from breast milk?

Yes, but not enough to prevent VKDB. There is only a little vitamin K in breast milk. Breastfed babies are low in vitamin K for several weeks until they start eating regular foods, usually at 4-6 months, and until the normal intestinal bacteria start making vitamin K.

### Should all babies get a vitamin K shot at birth?

Yes. Babies do not have enough vitamin K at birth and are, therefore, at risk for having serious bleeding. Thus, it is very important that all babies get a vitamin K shot to prevent VKDB.

### Where can I get more information?

For more information, please visit our website at:

<http://www.cdc.gov/ncbddd/blooddisorders/index.html>