



Department of Health

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February 19, 2020

DHDTC DAL: 20-03
Re: Vitamin K

Dear Center Colleague/Hospital Chief Executive Officer:

This letter is to clarify the requirements regarding certain newborn treatments – eye prophylaxis and vitamin K – and to provide guidance regarding the provision of these medications in a manner supportive of breastfeeding. Resources that providers can use to educate parents about the importance of vitamin K administration are provided and should be shared as appropriate.

Eye Prophylaxis

Under Section 12.2 of Title 10 of the Compilation of the Rules and Regulations of the State of New York (NYCRR) (10 NYCRR § 12.2), it shall be the duty of the attending physician, licensed midwife, licensed nurse or other authorized provider in attendance at delivery to place into the eyes of the infant, on delivery, an agent effective for preventing purulent conjunctivitis of the newborn, such as erythromycin eye ointment.

Eye prophylaxis is given to prevent gonococcal infection of the eyes. This infection was once a common cause of blindness and has now been almost entirely eradicated using prophylactic medications. Eye prophylaxis is a universal requirement because the treatment is effective and safe. Moreover, targeted prophylaxis, treating only infants of mothers known to be infected with gonorrhea, is not an effective approach to prevention. This infection is found among women of childbearing age and the organism can be difficult to culture. Targeted prophylaxis would miss many infants and lead to many cases of preventable blindness. Erythromycin eye ointment has minimal side-effects and is highly effective.

Vitamin K

Under 10 NYCRR § 12.3, it shall be the duty of the attending physician, licensed midwife, registered professional nurse or other licensed medical professional attending the newborn to assure administration of a single intramuscular dose of 0.5-1.0 mg of vitamin K1 oxide (phytonadione) within six hours of birth.

Vitamin K is given by injection within six hours of birth to prevent vitamin K deficiency bleeding (VKDB), a potentially fatal condition. Oral vitamin K is not as effective as vitamin K by injection and is not approved by the U.S. Food and Drug Administration (FDA) for use in newborns. Vitamin K prophylaxis is mandated for all newborns because the condition it prevents is life-threatening and intervention is very safe.

There is anecdotal evidence that some parents may have reservations about the shot. The Department of Health has developed the attached two resources to providers related to vitamin K prophylaxis: "Vitamin K Shot Hesitancy – Information for Providers", and "Vitamin K Shot: Why does my newborn need it?", to use to support parent education about vitamin K prophylaxis. These resources have been developed to aid in the discussions with parents who have questions, are hesitant or refuse the vitamin K shot. It supports evidence-based education when a parent is concerned and needs more information.

Breastfeeding

Breastfeeding has a significant impact on improving the health of infants and mothers. Breastfeeding has been associated with a reduction in the risk of acute otitis media, asthma in young children and chronic diseases, including obesity and diabetes, later in life. Breastfeeding also has significant health benefits to the mother such as reducing postpartum bleeding and may lower the risk of breast and ovarian cancers. Breastfeeding contributes economic benefits to the family.

One of the keys to successful breastfeeding is to ensure that newborn babies are placed in their mother's arms or on the mother's chest, skin-to-skin, within the first half-hour after birth, and held there for at least 30 minutes. Eye prophylaxis should be given within one hour of birth. To promote breastfeeding, vitamin K administration may be delayed up to 6 hours to allow for uninterrupted mother-infant skin-to-skin contact and breastfeeding. Unless contraindicated due to the health of the mother or newborn, mothers should be supported to initiate breastfeeding within one hour of birth. Please review your hospital's policies and procedures to ensure they are in conformance with this practice and be sure your staff understands the importance of supporting new mothers to breastfeed within 1 hour of delivery, as well as throughout their stays in the hospital.

Health care personnel should explain to any objecting parent that the administration by health care personnel, of eye prophylaxis and vitamin K are mandated by 10 NYCRR §§ 12.2 and 12.3. It may also be helpful to have an attending obstetrician or pediatrician explain the purpose and need for the procedures. These treatments represent the standard of care recommended by the American Academy of Pediatrics^{1,2} and the American College of Obstetricians and Gynecologists².

Efforts to provide education to parents objecting to the administration of eye prophylaxis and vitamin K must be documented. In addition to the information sheets attached, there are many useful resources that hospitals can use to educate parents. A list of resources is appended to this letter. The Centers for Disease Control and Prevention (CDC) website has testimonies from two families that refused vitamin K injection whose infants went on to have vitamin K deficiency bleeding (VKDB). These may be particularly effective as they are written from the perspective of families who have had first-hand experience. It is important to note that some resources offer oral vitamin K as an alternative to intramuscular (IM) injection. As previously stated, oral vitamin K does not meet the regulation's requirements.

If efforts to provide education and guidance are not successful and the family continues to object to these procedures, the care provider should document refusal and consult with their legal counsel or risk management. Previous guidance circulated in 1999 advised providers to report a family's refusal to Child Protective Services. This is no longer correct. The New York State Office of Children and Family Services (OCFS) has taken the position that the refusal of preventative medical procedures such as eye prophylaxis and vitamin K does not meet the definition of a maltreatment of a child and a report to the Statewide Central Registry (SCR) will not be accepted in these circumstances. The SCR will, however, accept a report when a parent

who has a relevant pre-existing condition (e.g., vitamin K deficiency, gonorrhea, chlamydia) and refuses to allow medical treatment (e.g., eye prophylaxis, or vitamin K injection) for the newborn which harms the newborn or places the newborn at imminent risk of harm.

We recognize that refusal of these procedures can be a difficult situation to manage but the consequences of not administering these medications can be catastrophic. Hospitals and healthcare providers must make every effort to engage parents and provide the necessary education to allow them to make an informed decision. Should you have any questions please contact Christopher Kus, M.D., M.P.H. at 518-473-9883.

Sincerely,

Marilyn A. Kacica, M.D., M.P.H.
Medical Director
Division of Family Health

Deirdre Astin, M.S.
Director
Division of Hospitals & Diagnostic & Treatment
Centers

1. American Academy of Pediatrics, Committee on Fetus and Newborn. Controversies concerning Vitamin K and the newborn. *Pediatrics*. 2003; 112:191-192
2. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. *Guidelines for Prenatal Care*. 8th Edition. 2017

Attachments (2)

- Vitamin K Shot Hesitancy – Information for Providers
- Vitamin K Shot: Why does my newborn need it?

Resources

<https://www.cdc.gov/ncbddd/vitamink/freematerials.html>

<https://www.cdc.gov/ncbddd/vitamink/olive-story.html>

<https://www.cdc.gov/ncbddd/vitamink/judah-stories.html>



Vitamin K shot hesitancy – Information for providers

What is the current NYS requirement for newborn vitamin K prophylaxis?

New York State regulations (10 NYCRR 12.3) state that “[it] shall be the duty of the attending physician, licensed midwife, registered professional nurse or other licensed medical professional attending the newborn to assure administration of a single intramuscular dose of 0.5 - 1.0 mg of vitamin K1 oxide (phyonadione) within six hours of birth in accordance with current standards of medical care”. Since 1961, the American Academy of Pediatrics (AAP) has recommended an intramuscular (IM) dose of vitamin K to prevent vitamin K deficiency bleeding (VKDB).

Is oral vitamin K an acceptable substitute for the injection?

No. Oral vitamin K for newborns does not meet the requirements of NYS regulation and is not recommended by the New York State Department of Health or the American Academy of Pediatrics.¹

What are the risks and benefits of the vitamin K shot, and why is it important?

The intramuscular injection of vitamin K is safe. The risks associated with the vitamin K shot are similar to the risks associated with any other shot: pain, bruising or swelling at the injection site.² However, it effectively prevents vitamin K deficiency bleeding (VKDB).

Where do parents get information about vitamin K?

There are relatively few resources for parents that are produced by reputable clinical, academic or government organizations. Some of the resources include information about oral vitamin K, because it is used in parts of Europe, and some states allow its use. As stated above, oral vitamin K does not meet NYS regulation requirements.

Also, there are many sources of incorrect information or misinformation. Parents may use social networks and peer groups, forums, and unregulated websites to access information. But some parents report that they consulted a medical provider.³

Why are parents hesitant about the vitamin K shot?

Parents are in fear of adverse side effects. However, vitamin K is safe, and has been safely administered since 1961. Also, parents may not understand what VKDB is, or why vitamin K is needed to protect their babies from VKDB, or how dangerous VKDB can be.

Why are parents concerned about the vitamin K shot?

Some of the concerns that can make a parent hesitant about the vitamin K shot at birth are: pain, exposure to preservatives, an excessive dose, and potential side effects.⁴

When parents are worried about pain, it might be helpful to suggest holding or breastfeeding their baby during or immediately after the shot is given.⁵

Some parents want to limit the early exposure to preservatives. One of the ingredients found in the vitamin K shot is benzyl alcohol, a preservative. However, benzyl alcohol is a common ingredient in many medications.² Benzyl alcohol is proven to be harmless in small doses, such as what is found in the vitamin K shot.

Similarly, some are concerned about potential excessive dosage. The amount of vitamin K in the IM dose is in fact higher than the daily requirement of vitamin K. However, it is important to justify the reason for the higher dose. Babies have low levels of vitamin K at birth, and the current IM dose will supply their need for vitamin K until they have another source from his or her diet.²

Some parents are concerned by a previously reported link between the vitamin K shot at birth and childhood leukemia. This study has since been disproved by numerous studies across different countries.⁶

A comprehensive evidence-based Questions and Answers document for the most common misconceptions and myths about vitamin K prophylaxis has been published by the University of Michigan C.S Mott's Children's Hospital, and is listed as additional educational resources for parents.

What are some effective strategies when working with parents who are reluctant or nervous about vitamin K?

Parents want what they believe is best for their baby. In order to provide them with the most effective and comprehensive information, it is important to assess the parent's individual knowledge about the vitamin K shot. Providers should provide factual information about the risks and benefits of receiving the shot. A provider should respectfully inquire and address their medical concerns by providing individualized parental education, while giving scientific evidence to address myths and misinformation. Studies report an increase in the acceptance of the vitamin K shot after receiving education about VKDB.⁷

Why is it important to address parental vitamin K hesitancy?

While VKBD is rare in the United States, it can be fatal. Also, there is a known association between vitamin K refusal and subsequent hesitancy and refusal to immunize.^{3,8} Hesitancy during the newborn stage offers the provider an opportunity to learn about the parent's concerns. It is important to take the time to provide adequate information about IM vitamin K, and provide additional education around vaccinations to increase likelihood of future immunization adherence.⁹

Additional educational resources for parents

The New York State Department of Health has developed a fact sheet for expecting parents. This document answers some of the most frequent questions that have been identified by researchers.

- https://health.ny.gov/community/infants_children/vitamin_k/index.htm

In addition, the University of Michigan has developed a Questions and Answers document that provides additional information on frequently asked questions, and addresses misinformation that is often shared through social media and social networks.

- www.med.umich.edu/1libr/Pediatrics/vitaminKQuestionsAndAnswers.pdf

¹ <https://pediatrics.aappublications.org/content/112/1/191> (full position reaffirmed February 2015)

² www.cdc.gov/ncbddd/vitamink/faqs.html

³ www.ncbi.nlm.nih.gov/pmc/articles/PMC5526450/pdf/nihms882898.pdf

⁴ www.ncbi.nlm.nih.gov/pubmed/26371205

⁵ www.womenshealth.gov/pregnancy/childbirth-and-beyond/your-babys-first-hours-life

⁶ www.med.umich.edu/1libr/Pediatrics/vitaminKQuestionsAndAnswers.pdf

⁷ www.ncbi.nlm.nih.gov/pubmed/26711469

⁸ www.ncbi.nlm.nih.gov/pubmed/25873083

⁹ www.aappublications.org/news/2018/07/27/vitamin-k-in-the-newborn-period-how-important-is-it-pediatrics-7-27-18



Vitamin K shot: Why does my newborn need it?

What is vitamin K?

Vitamin K is an important nutrient. It is used by the body to help blood clot and to stop bleeding.

Where do we naturally get vitamin K from?

Adults get vitamin K from the food we eat, and from bacteria living in our guts. Babies are born with low levels of vitamin K, and do not have enough bacteria to produce vitamin K on their own.¹ The vitamin K shot increases their low vitamin K levels at birth.

Why do babies need vitamin K?

All babies are born with low levels of Vitamin K.² That amount is not enough to prevent a bleeding disorder called “Vitamin K Deficiency Bleeding”, also called VKDB.

What is Vitamin K Deficiency Bleeding (VKDB)?

VKDB is a bleeding disorder in babies. It can be prevented by a single shot of vitamin K shortly after birth. Without this shot, VKDB can be fatal for a baby even if there is no physical injury to the baby. VKDB happens when babies cannot stop bleeding because their blood does not have enough vitamin K to form a clot. The bleeding can happen inside or outside the body. When the bleeding is inside the body, it can be hard to notice. A baby with VKDB can bleed into their internal organs, or into the brain, which can lead to brain damage and even death. Most cases of VKDB happen within the first two weeks of life, but babies who do not get the vitamin K shot can be at risk for VKDB up to six months of age.³

Are all babies in New York required to receive vitamin K?

Yes. New York State requires your baby’s medical provider to give vitamin K within six hours of birth to prevent VKDB. The American Academy of Pediatrics (AAP) recommends that the vitamin K shot should be given to newborns as an intramuscular dose.⁴ Vitamin K shots have been used since they were first recommended by the AAP in 1961.

Will breastfeeding increase my baby’s vitamin K?

Breastmilk is the most nutritious food for your baby, but it does not have enough vitamin K. Even if a parent eats more vitamin K-rich foods or takes vitamin K supplements during pregnancy or while breastfeeding, babies still won’t have enough vitamin K to prevent VKDB.⁵ The AAP recommends that all newborns, breastfed or formula fed, should receive the vitamin K shot.⁶

What about oral vitamin K?

Oral vitamin K for newborns does not work as well at protecting your baby.⁷ A vitamin K shot given at birth is the best way to prevent Vitamin K Deficiency Bleeding.

Are there any potential risks associated with the vitamin K shot?

No. Vitamin K has been safely used to prevent the risk of newborn bleeding since 1961. The vitamin K shot is safe and necessary for your baby.

Will the vitamin K shot hurt?

Parents do not like to see their newborns in pain. Babies have a little discomfort after getting the vitamin K shot.⁸ If you want to soothe your baby after the vitamin K shot, you can breastfeed, hold your baby skin-to-skin or swaddle your baby.⁷ All of these are great ways to comfort babies.

¹ www.cdc.gov/ncbddd/vitamink/faqs.html

² www.mountsinai.org/health-library/diseases-conditions/vitamin-k-deficiency-bleeding-of-the-newborn

³ www.cdc.gov/ncbddd/vitamink/faqs.html

⁴ www.healthychildren.org/English/ages-stages/prenatal/delivery-beyond/Pages/Where-We-Stand-Administration-of-Vitamin-K.aspx

⁵ <https://health.ucsd.edu/specialties/obgyn/maternity/resources/Documents/Vit%20K%20fact%20sheet.pdf>

⁶ www.cdc.gov/breastfeeding/breastfeeding-special-circumstances/diet-and-micronutrients/vitamin-k.html

7 www.med.umich.edu/1libr/Pediatrics/VitaminKQuestionsAndAnswers.pdf8 www.womenshealth.gov/pregnancy/childbirth-and-beyond/your-babys-first-hours-life