



Excellent Maternity Care

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Newborn Options Informed Choice:

Vitamin K Prophylaxis:

What is Vitamin K?

Vitamin K is a fat-soluble vitamin that the body needs for blood clotting. We get about 90% of our vitamin K from green leafy vegetables and about 10% from a bacteria in our gut.

Does my baby need Vitamin K?

Normal healthy newborns are usually born with low amounts of vitamin K. The reason why newborn's levels are seemingly low is unknown, and more research needs to be done. There is some speculation that it could have to do with the newborn's clotting systems being immature, or with some sort of mechanism that lowers Vitamin K levels that protects the baby from toxins (2). What we do know is that newborn's don't receive adequate amounts of the vitamin via the placenta, the liver stores very little vitamin K, they do not eat foods containing the vitamin, and do not have enough bacteria in their gut to synthesize it (3). Vitamin K has been being administered to newborns routinely since 1961. If vitamin K levels get too low in the baby's body, the baby may start to bleed spontaneously. (2) Vitamin K levels in breast milk are low, however are readily absorbed by the baby. Some studies have shown that breastfeeding moms who supplement with Vitamin K show an increased amount of the vitamin in their breastmilk.

Vitamin K deficiency bleeding:

A condition in which the baby bleeds spontaneously due to dangerously low levels of Vitamin K. It is also called Hemorrhagic Disease of the Newborn (HDN). There are two types of the disease, the first is called idiopathic VKDB. The cause of this is unknown and usually occurs with babies that are solely breastfed. The second is called secondary VKDB. This is caused by underlying conditions such as gall bladder disease or cystic fibrosis. It can also be caused by certain medications. Most of these cases are also of babies exclusively breastfed. (2) VKDB can show up in three patterns: early, classical, and late. Early onset disease happens in the first 24 hours of life and is usually associated with moms who took medications that interfere with vitamin K such as warfarin and tuberculosis medications. Classical onset (now often considered early onset) usually occurs during days 2-3 but up to 7 days when Vitamin K levels are the lowest. Late onset occurs after 1 week, usually peaking at weeks 3-8 and happens in infants who are exclusively breastfed and who did not receive Vitamin K at birth. Late onset VKDB is the most dangerous form, usually resulting in bleeding in the infants brain. Late onset VKDB is effectively treated with a Vitamin K injection at birth. One study showed that of infants who received vitamin K injection at birth 0-6.2 per 100,000 babies developed VKDB.

How Common is Vitamin K Deficiency Bleeding?

Early VKDB is very rare. Classic VKDB is the most common and the estimated incidence is said to be between 1-3 per 200 births. Genetics and environment seem to play a role in who is more likely to suffer from VKDB. In certain areas such as Japan, Vietnam, and Thailand, instances of late VKDB may

be as high as 0.1% when vitamin K is not given at birth. Infants who didn't receive the vitamin at birth were less likely than this to develop VKDB. European countries showed instances of 4-7 per 100,000 (5). The United States doesn't track the amount of cases of late vitamin K deficiency bleeding, so it is difficult to know how commonly it occurs among Americans (2).

How Serious is it?

Although relatively rare, vitamin K deficiency bleeding can be extremely serious, leading to brain injury or death. Babies with VKDB will bleed internally, usually from the brain or stomach. Bleeding from the umbilical sight or from a circumcision sight can cause significant amounts of bleeding, although not always internal, can also be serious. It is difficult to diagnose VKDB (4) and it cannot be detected before the baby begins bleeding. Most babies who do not receive Vitamin K will not bleed, but some will, and for those it is serious. If a baby develops VKDB, treatment is available. The most common treatment is a shot of Vitamin K which usually helps stop the bleeding in 20-30 minutes. By this time, long-lasting brain damage may or may not have already occurred. Other treatments reported have been blood and plasma transplants, anti-seizure medications, and brain surgery to remove the collected blood from the brain (2).

What if my baby is full-term, healthy, and has a gentle birth?

Evidence doesn't show a difference in the incidence of VKDB with male, female, small, large, pre-term, or late-term babies. Neither does evidence support that having a traumatic birth, either via cesarean, forceps, or otherwise traumatic has any impact on whether or not a baby will bleed. In fact, in 2013, 6 infants developed VKDB, and none of them had traumatic births (2.)

The babies at greatest risk are those who do not get Vitamin K and who exclusively breastfeed.

Other less common factors are listed below:

- Exclusively Breastfeeding
- Not Getting Vitamin K Shot
- Certain Medications
- Poor Feedings/Low transfer of milk (<100mL milk/day)
- Antibiotic use
- Diarrhea
- Cystic Fibrosis
- Gall Bladder Disease (1 in 60,000) (2)
- Liver Disease (1 in 60,000) (2)

Signs of Vitamin K Deficiency Bleeding:

- Difficulty feeding
- Low temperature
- Lethargy or 'failure to thrive'
- Low weight for age or slow gain
- Excessive bruising
- Blood in stool
- Blood in mouth or nose
- Excessive bleeding at injection sight or small scratches or injuries
- Bleeding at cord site
- Bleeding at circumcision
- Fluid-filled lump on the skull appearing later on after birth (not immediately after)

Treatment:

There are two types of Vitamin K available for newborns. The standard of care is one intramuscular injection that is given shortly after birth. This reduces the incidence of late bleeding to 1 in 400,000 births. The other is an oral vitamin K that is given repeatedly after birth and throughout early infancy and if done properly may be as effective as the injection. The American Academy of Pediatrics recommends that Vitamin K should be administered to all newborns to prevent Vitamin K deficiency bleeding. They state that oral vitamin K or the injection are acceptable ways to prevent early bleeding up to 2 weeks. However, they do not recognize that oral vitamin K is as effective at preventing late onset bleeding from 2-12 weeks, and so recommend the injection at birth to prevent both early and late VKDB (4). Because vitamin K does not easily cross the placenta, delayed cord clamping is not effective at raising vitamin K levels in the baby.

Intramuscular Injection:

The American Association of Pediatrics recommends an intramuscular injection of vitamin K as prophylactic (preventative) treatment for bleeding (4). A small needle is used to inject the Vitamin K (phytonadione) into one of the baby's thigh muscle within a couple hours after birth. 1mg of the vitamin is injected. This is a very high amount of vitamin K, much more than the baby needs. In fact, the injection contains 2,000 times the newborn's natural levels at birth and is approximately 100 times greater than the recommended daily adult dose. The thought is that the vitamin is stored in the leg muscle and then slowly released into the body over two months, providing long term protection from bleeding(9). While there is no obvious risk of babies having such high concentrations in their bodies it is unknown whether these unnaturally high levels of vitamin K pose any risk to the baby or it's body systems. The use of Vitamin K injection has been shown to be extremely effective and nearly wipe out all cases of late VKDB (2, 5). Your midwife can do this injection at your bedside while you or your partner holds your baby. There is a form of vitamin K known as "Preservative Free;" this formula contains less chemicals than the standard formula. The ingredients of this injection include: Vitamin K1 (fat soluble and absorbed from plants), polysorbate-80, propylene glycol, sodium acetate anhydrous (salt and bicarbonate to adjust the pH), and glacial acetic acid (vinegar, also to adjust the pH.) There is some concern from parents about the chemicals in the shot, particularly propylene glycol. The FDA approves this chemical derived from petroleum, and says that it is safe in small amounts such as the vitamin K shot (8).

Oral:

Because VKDB is so rare, it is difficult to have effective studies around the topic. The Cochrane review was a set of clinical trials to study oral vitamin K. However, the studies were too small to produce significant evidence (2). When looking at the incident of VKDB over time in different countries who used oral vitamin K, the statistics show that oral Vitamin K has been effective at reducing VKDB, but does not eliminate it(2). The American Association of Pediatrics approves oral vitamin K as a preventative treatment for early-onset only (4). However, the oral vitamin K is not as long-lasting and levels remain in the body for only up to 3-4 weeks (9). Because of this, it has shown to be less effective at preventing late-onset VKDB. In Demark, between 1992 and 2000, 396000 of 507850 babies received oral vitamin k prophylaxis, the rest got an injection. The regimen for the oral was as follows: 2mg vitamin K at birth, and 1mg weekly until 3 months of age. No cases of VKDB were reported, and the conclusion was "Weekly oral vitamin K supplementation during the first 3 mo of life was an efficient prophylaxis against VKBD. Parental compliance with the regimen was good" (11). New, more bio-available oral vitamins are now available, one brand is called Bio-K-Mulsion. In the U.S., another brand is K-Quinone and it is made up of Vitamin K1 from alfalfa, nettles, and green tea in olive and soy oils. Oral vitamin K supplements are not FDA approved and so not all supplements will state the amount of vitamin K per serving or dose. The amount could vary widely from vial to vial, and many supplements are not regulated or certified by a third party. If used, a minimum of three doses must be given; at birth, one month, and two-three months. If any of these doses are missing, the treatment is significantly less effective (2). Other possible problems with oral vitamin K is that baby's can spit it up before it is absorbed, and oral vitamin K is likely to be *ineffective* for babies with undiagnosed gallbladder or liver problems (2). In order for oral treatment to be effective, they must have a fully functioning gallbladder, liver, and intestinal system. Because oral vitamin K is not the standard of care in the U.S., if you choose this route you, the parents, are solely responsible for researching which vitamin K to buy, when to administer it, and what does to administer it in. You are also solely responsible to administer this to your baby.

Risks of Treatment:

The injection has relatively low risks associated with it. Pain or irritation at the injection sight is most likely. Skin irritations have been reported in 7 infants (10). In the mid 1950's, higher doses of vitamin K were given in extremely high doses and in a different form than used today. These injections were associated with jaundice in the newborn. This method is no longer used, and vitamin K1 at low doses of 0.5-1mg pose a very low risk to no risk of causing jaundice (10). Anaphylaxis (allergic reaction leading to shock) has also been reported, but is extremely rare with the kind of injections babies get at birth. Rebecca Dekker, a nurse researcher with a PhD and founder of evidenced based birth states that there has only ever been one case world-wide of a child who had a severe allergic reaction to the shot and went into shock in Turkey in 2014, he fully recovered and the cause for his anaphylaxis is "unknown". (2, 10). There are some theoretical and potential risks or side effects associated with the chemicals in the injection. At this time, there is no research supporting that these risks are significant, or that they outweigh the risk of VKDB.

What about the link between Vitamin K and childhood cancer?

One study done in 1990 and published in a British journal claimed a connection between vitamin K injections and childhood Leukemia. They stated a possible doubled increase of cancers among babies who had the injection. Almost immediately, there was a switch from injectable vitamin K to oral in Britain, followed by dozens of studies on the topic. Many of the studies indicated that there was no direct link between the two, however one study showed an increased risk in all types of childhood cancer (2,10). However, the general consensus among experts is that there is no solid evidence supporting that Vitamin K injections cause or increase the risk of childhood cancer. The World Health Organization reviewed several of the studies in 1999 and released a statement that there was not enough evidence to link the two. Here's a quote from another study: "We found no association between exposure to vitamin K and an increased risk of any childhood cancer or of all childhood cancers combined, although a slightly increased risk could not be ruled out. The benefits of neonatal vitamin K prophylaxis against hemorrhagic disease have been well described. Unless other evidence supporting an association between vitamin K and cancer appears, there is no reason to abandon the routine administration of vitamin K to newborns. (6). Another study published in 2002 pooled data from 6 case-control studies in Great Britain and Germany to investigate the possible connection. One of the groups showed a very slight increase in cancers. There were elements to the study such as hospital records that made it difficult to determine how many babies did or did not receive vitamin K. Because of the possible large error margin in the study, they concluded "that small effects cannot be entirely ruled out, our analysis provides no convincing evidence that intramuscular vitamin K is associated with childhood leukemia" (7).

Sources:

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9.) Loughnan, P. M. and P. N. McDougall (1996). "Does intramuscular vitamin K₁ act as an unintended depot preparation?" *J Paediatr Child Health* 32(3): 251-254. <http://www.ncbi.nlm.nih.gov/pubmed/8827545>

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Eye Prophylaxis:

What is it?

Newborn eye prophylaxis refers to the treatment of placing antibiotic ointment into newborns eyes after birth to prevent bacterial infections causing blindness. Erythromycin is the antibiotic usually used and is effective at preventing infections from bacteria associated with chlamydia and gonorrhea. Erythromycin DOES NOT PREVENT BLINDNESS OR INFECTION FROM ANY OTHER CAUSE besides gonorrhea and chlamydial bacterial infections.

Does my baby need antibiotics?

If a baby born to a woman infected with gonorrhea or chlamydia is untreated, he or she may develop an infection in their eyes called ophthalmia neonatorum (ON). Gonorrhea and chlamydia are sexually transmitted infections that may or may not have any symptoms. When a mom has a vaginal birth, the baby can become infected with the bacteria that causes these STI's. The infection is like a conjunctivitis or pink eye occurring only in the first month of life and can lead to blindness. Antibiotic treatment is done before infection and helps to prevent blindness due to these infections. Most moms are tested for these infections in pregnancy, but it is possible that she could have contracted it unknowingly since she was last tested. Because of this, it is recommended by multiple health organizations including the U.S. Preventive Services Task Force, the American Association of Family Physicians, and the American Academy of Pediatrics that all newborns receive this treatment in case the mother has an unknown infection. Babies who are born to mothers via cesarean section and whose bag of waters never broke before birth are very unlikely to contract these infections. In many states in the U.S. this treatment is required by law, and healthcare workers are required to administer it to babies whether or not the mother has gonorrhea or chlamydia. In other countries such as the United Kingdom, Australia, Norway, and Sweden, it is not automatically given to every baby.

Risks and Benefits of Treatment:

The antibiotic cream can cause blurred vision in the newborn and much evidence shows that this may interfere with infant and mother bonding. Also worth considering are the negative effects that antibiotics can have on the microbiome and the gut health of the infant. There is a lot of new and excellent research on the long-term negative effects of antibiotic use in young children, I encourage you to research this topic before using antibiotics. Antibiotic resistance to these bacteria is also a real problem caused by unnecessary and overuse of antibiotics. For example, it is recommended that all babies be treated with antibiotic eye prophylaxis at birth, however, the majority of babies are born to mothers without infections, and so the treatment is unnecessary and the baby is exposed to unneeded antibiotics. There is also a slight risk that the treatment would be ineffective at preventing infection or blindness; (one study showed up to 20% of infants treated were infected anyway) (2). All things

considered, the risks associated with prophylactic antibiotic treatment are significantly less than the risk of blindness and infection if a baby is born to a mother with one of these infections. According to the CDC, 18-44% of women with active chlamydia infections will pass on eye infections to their infants (5). The treatment is near 100% effective at preventing newborn blindness due to gonorrhea. Sometimes, however, infections due to chlamydia can occur up to two weeks after birth. In this case, oral antibiotics will be necessary to cure the infant(3). If choosing to decline treatment, a woman infected with either of these STI's unknowingly, or knowingly, may pass on the infection to her infant, causing irreversible eye damage or blindness.

Alternative Treatments:

Silver Nitrate: Discovered as effective treatment in the 1800's,t, silver nitrate has been used to prevent this blinding infection. Studies showed it to be as effective as Erythromycin at preventing infection due to gonorrhea, but about 30% effective at preventing infection caused by chlamydia (2). Silver nitrate can cause pain in the newborn's eyes and temporary blindness on occasion. It is not used in the U.S. anymore and cannot be administered by a provider. Some parents may choose to do this on their own, however, it is not recommended.

Povidone iodone: This is a popular method of treatment in developing countries. It is less expensive than antibiotics and does not contribute to antibiotic resistance. This treatment is as effective as erythromycin at preventing gonorrheal infections and more effective than silver nitrate at preventing chlamydial ones. These are not yet available in the United States.(

A reasonable alternative to treating every infant is to accurately rule out mothers who are not infected, giving them the opportunity to decline the treatment. Most women who are in the U.S. are screened for chlamydia at least once in pregnancy. Women who are treated for either of these STI's should be retested before birth. Women who are in a mutually monogamous relationship with an unaffected partner are at very low risk for these STI's and can safely decline the treatment. There is always a slight risk that the mother could have been unknowingly infected by an unfaithful partner, this something each woman must take into consideration and decide for herself. Your midwife can offer you testing for both of these STI's at any point in pregnancy in office or in your home.

Another option, used in the United Kingdom is to wait and see if the baby develops an infection. If the eyes become infected, system antibiotic treatment is used. The risk of this is that the infection may not be caught soon enough to prevent damage to the eyes, and mom's in rural areas may experience a delay in treatment.

Sources:

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- 3.) Source Dad to Dad: Parenting Like a Pro (Copyright © American Academy of Pediatrics 2012, <https://www.healthychildren.org/English/ages-stages/prenatal/delivery-beyond/Pages/Erythromycin-Ointment.aspx>
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- 5.) CDC on Chlamydia: <http://www.cdc.gov/std/chlamydia/stdfact-chlamydia.htm>, <http://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm>

Vitamin K and Eye Prophylaxis Informed Choice:

I, _____ have read in full the documents provide to me regarding Vitman K and Eye Prophylaxis treatment options by my midwives at Legacy Midwifery LLC I have had an opportunity to conduct any further research that I feel necessary and speak with my pediatrician, doctor, medical professional, friends, and my family about these topics. I am satisfied with the information given to me both verbally and in written form. I have discussed my views and thoughts on the topic with my midwives and understand the risks and benefits of accepting or declining both prophylactic vitamin K treatment and newborn eye prophylaxis. I understand that vitamin K deficiency bleeding is a rare and unpredictable condition that can cause bleeding in the brain, neurological damage, and death. I understand that newborns infected by bacteria associated with chlamydia and gonorrhea at birth may be blinded by the infection. I understand that an intramuscular injection of vitamin K and erythromycin ointment prophylactic treatments along with hepatitis B vaccination are the standard of care and are recommended for all newborns in the U.S. by the AAP and the CDC. I understand that my midwives does not administer the hepatitis B vaccine and if I desire this for my newborn I will need to see another provider for that service. I release Kelsey Wright, CPM, LDM, Tiffany Seiders, CPM, LDM, and Legacy Midwifery LLC from all responsibility regarding newborn options and I take full responsibility for my choices regarding the explained newborn options. I choose to:

_____ Accept Vitamin K prophylactic intramuscular injection for my newborn
_____ Decline Vitamin K prophylactic intramuscular injection for my newborn

AND

_____ Accept Erythromycin prophylactic treatment for my newborn
_____ Decline Erythromycin prophylactic treatment for my newborn

OR

_____ I Decline Vitamin K prophylactic injection and choose to administer oral vitamin K to my newborn. I understand that this is not a service my midwife provides and I agree to do my own research, purchase the supplement in time for my birth, and write and implement a dosage plan for oral vitamin k supplementation for my baby.

Mother's signature: _____ Date: _____

Father's signature: _____ Date: _____

Midwives signature: _____ Date: _____

_____ Initial

