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Vit K, Hep B, Erythromycin IC's

Vitamin K1 Injection Informed Consent

What is Vitamin K?

Vitamin K is a fat-soluble vitamin that comes in two forms. The main type is called phylloquinone (Vitamin K1), found in green leafy vegetables like collard greens, kale, and spinach which makes up about 90% of vitamin K in our bodies (Dekker, 2014). The other type, menaquinones (Vitamin K2), are found in some animal foods and fermented foods. Menaquinones can also be produced by bacteria in the human body within the gastrointestinal (GI) tract. Vitamin K is known as the clotting vitamin. The body needs vitamin K to make certain proteins in the liver that cause blood to clot. These proteins are called clotting factors. Without vitamin K, the liver could not produce clotting factors II, VII, IX, and X, and blood would not clot causing bleeding concerns (Dekker, 2014).

Why are newborns different?

Babies don't have much vitamin K when they are born and won't have a good supply of vitamin K until they are close to six months old. This is because vitamin K does not cross the placenta and breast milk has very low levels of vitamin K. They are also born without the GI tract bacteria that can help produce vitamin K2. Without enough vitamin K, babies cannot make the substances used to form clots, called clotting factors. Unless there are genetic components their clotting abilities are assumed normal and just need to be activated with vitamin K. When bleeding happens because of low levels of vitamin K, this is called "vitamin K deficiency bleeding" or VKDB (Dekker, 2014). Newborns who are planning to be circumcised would have higher needs for vitamin K to help them clot during that procedure. It was commonly believed that traumatic births caused more likelihood for VKDB in newborns, but all newborns are at risk equally, no recent evidence supporting the theory that infants born with instrumental help, or by Cesarean, are at higher risk for Vitamin K deficiency bleeding (Dekker, 2014).

What is Vitamin K Deficiency Bleeding (VKDB)?

A baby who does not have enough Vitamin K can start to bleed suddenly, without warning and no other correlations have been found to cause this besides not receiving the vitamin K shot within 6 hours from birth and exclusive breastfeeding due to low levels passed on. Vitamin K deficiency bleeding can be *idiopathic* or *secondary*. Idiopathic VKDB means that the cause is unknown. Secondary VKDB means that the baby has an underlying disorder such as gallbladder disease, cystic fibrosis, or medication side effects (Dekker, 2014). VKDB can begin early (within the first 24 hours of life), classically (within 2-7 days of life), and late-onset (after the first week of life, usually 3-8 weeks later). Classical VKDB bleeding that occurs in the first week of life is more common than late VKDB sitting at about 440 out of 100,000 newborns (Dekker, 2014). When infants do not receive any Vitamin K at birth, statistics show that 4.4 to 7.2 infants out of 100,000 will develop late VKDB.

Statistical risks of VKDB in newborns:

When infants receive 1 mg of oral Vitamin K at least three times during infancy (typically at birth, one week, and four weeks), about 2.6 infants out of 100,000 will develop late VKDB (Dekker, 2014). When infants receive 2 mg of oral Vitamin K at least three times during infancy (at birth, 4 to 6 days, and 4 to 6 weeks) or 2 mg of oral Vitamin K after birth and 1 mg of oral Vitamin K every week for three months, somewhere between 0 to 0.9 infants out of 100,000 will develop late VKDB (Dekker, 2014). When infants receive the Vitamin K shot at birth, anywhere from 0 to 0.4 infants per 100,000 get late VKDB (Dekker, 2014). The mortality rate for late VKDB is approximately 20%. One study that looked at 131 cases around the world found an overall death rate of 14%. Of the surviving infants, about 40% had long-term brain damage (Dekker, 2014).

Treatment Options:

The main treatment for VKDB is to give the infant Vitamin K. When an infant with VKDB receives a shot of Vitamin K1, this will usually slow or stop the bleeding within 20-30 minutes. However, if bleeding happens in the brain, the infant may already have brain damage by the time the shot is given. Other treatments that have been used in infants with late VKDB include blood and plasma transfusions, brain surgery to remove the accumulated blood, and giving anti-seizure medicines (Dekker, 2014). There are two main options for giving your newborn vitamin K supplementation. There is the vitamin K1 injection with two options. One is preservative-free, meaning it does not contain benzyl alcohol, while the standard Vitamin K1 shot does contain it. The alternative is oral vitamin K1 supplementation with drops you can administer on your own over the course of 12 weeks. This looks like 4 drops (2 mg) on the day of birth, and then 2 drops (1 mg) once a week for 12 weeks. When infants do not receive any Vitamin K at birth, statistics show that 4.4 to 7.2 infants out of 100,000 will develop late VKDB. When newborns receive 2 mg of oral Vitamin K after birth and 1 mg of oral Vitamin K every week for three months, somewhere between 0 to 0.9 infants out of 100,000 will develop late VKDB (Dekker, 2014). When infants receive the Vitamin K shot at birth, anywhere from 0 to 0.4 infants per 100,000 get late VKDB.

Pro vs. Con to Each Treatment Method

The benefits to vitamin K1 injection are that it is a one-time very effective dose that doesn't require any more effort. The delayed-release mechanism as the vitamin is stored in the thigh muscle and released into the baby's bloodstream over the following several months, protecting against both classic AND late Vitamin K deficiency bleeding (Dekker, 2014). This method is absorbed better than oral vitamin K and all ingredients are non-toxic. When the injection is given the chances of VKDB are near zero without other underlying causes existing. The downside is any injection can lead to site irritation and redness, but this is rare and it rarely leads to any intervention. Injections can also cause pain, which can be minimized by nursing the baby during the shot (Dekker, 2014).

The benefit of oral Vitamin K1 is that there is no shot to the baby, and it can be administered by the parents themselves which some families prefer. It is more preventative of VKDB than no treatment at all even if not all doses are administered. Downsides could be that administering something orally to a newborn can be challenging and they could spit it up or doses could be forgotten or missed leading to less effective doses. This method is less effective than an injection of vitamin K1. There could be gallbladder issues underlying that are undiagnosed making this method unusable by the infant.

_____ **Please initial** stating you fully understand all risks and benefits to VKDB and all treatment options offered. You had opportunities to ask questions and do research of your own as desired prior to making this decision, and you accept full responsibility for your choices.

Vitamin K1 Informed Choices

_____ I choose the Vitamin K1 intramuscular (IM) injection to be administered to the baby after birth.

_____ I choose the preservative-free Vitamin K1 IM injection to be administered to the baby after birth and accept responsibility for paying a $25.00 out-of-pocket cost that insurance doesn't cover.

_____ I choose to self-administer the oral Vitamin K drops to the baby in the 12 week protocol and will bring these to my 36 prenatal visit to ensure the proper drops are prepared and purchased.

_____ I choose to decline all forms of Vitamin K supplementation and understand the risks of VKDB.

Client Signature: X _____Date: _____

Print Name: _____

Midwife Signature: X_____ Date: _____

Print Name: _____

Newborn Eye Infections and Sexually Transmitted Diseases Informed Consent

What is a newborn eye infection and how is it passed on?

Ophthalmia neonatorum (ON), also known as neonatal conjunctivitis or pink eye, is an infection that causes inflammation of the conjunctiva during the first four weeks of life. The *conjunctiva* is a layer of thin tissue that covers the inner part of the eyelid and the white part of the eye. When a birthing individual is positive for chlamydia or gonorrhea, something that is routinely tested for in pregnancy, their baby has a chance of exposure. In a vaginal birth, the baby travels through the vaginal birth canal and is

exposed to that STI during birth, and risks can increase to exposure the longer your water is broken, as the bag of water acts as a barrier for bacteria. This also means that cesarean birth while unlikely to have exposure compared to a vaginal birth, there is still a rare chance of exposure (Dekker, 2019).

What causes ON?

Pink eye or ON can be caused by viruses like herpes, bacteria, chemicals, and blocked tear ducts. Today, the most common cause of ON is chlamydia (a sexually transmitted infection) responsible for 2% to 40% of reported cases of ON in the U.S (Dekker, 2019). The sexually transmitted disease gonorrhea now accounts for less than 1% of cases. There is a variety of other bacteria that can contribute to ON, but a majority of non-gonorrheal and non-chlamydial bacteria are not dangerous and do not progress to blindness (Dekker, 2019).

What are the chances of ON happening?

Among U.S. women, chlamydial infection is about six times more common than gonorrheal infection. In 2015, the rate of chlamydia was 646 per 100,000 females in the U.S., and the rate of gonorrhea was 107 cases per 100,000 females in the U.S. (CDC, 2015). Although chlamydia is the most *common* cause of ON, gonorrhea results in the most *serious* type of ON. Other types of bacteria from the mother, hospital, or home environment are thought to cause 30% to 50% of cases, and the herpes virus causes less than 1% (AAP, 2015). Of newborns born to mothers with untreated gonorrhea, between 1 in 2 to 1 in 3 of them risk developing gonorrheal ON, which carries with it a high risk of blindness. Left untreated, gonorrheal ON can begin to cause vision loss in as little as 24 hours. The risk of a newborn getting chlamydia from an infected mother ranges from 8% to 44%, with the best estimate around 15%. Chlamydia has a low risk of blindness but can still cause eye damage and, rarely, loss of vision if not treated (Kapoor et al., 2016).

Why is treatment recommended, and what is the treatment?

Erythromycin is a topical antibiotic eye ointment that is recommended for preventing ON by giving it to all newborns within 24 hours of birth. The eye ointment is intended to kill or weaken bacteria in the eye–particularly gonorrhea–to protect the infant from getting pink eye, since pink eye from gonorrhea can cause serious eye damage and blindness if left untreated. This looks like a medical provider with gloved hands gently pressing on the bottom of your baby's eye to pull the lower lid down and placing a 1cm line of erythromycin in each of their eyes. It doesn't need to be wiped off or anything and is usually absorbed pretty quickly (Dekker, 2019). Adverse effects can include chemical pink eye or eye irritation. If chemical pink eye is mistaken for bacterial pink eye, it could lead to treatment with more antibiotics while waiting for test results. Blurred vision could potentially interfere with bonding by disrupting early eye gazing between the newborn and the parents. Erythromycin is not 100% effective at preventing gonorrheal ON. It had a 20% failure rate in the past and might be less effective now due to growing antibiotic resistance. Erythromycin may not be effective at preventing chlamydial ON or ON from other non-gonorrheal bacteria (Dekker, 2019).

Alternative Treatments

One option is for the mother to be screened for sexually transmitted infections during pregnancy and receive antibiotic treatment, along with her sexual partner(s), if needed. If the mother is treated, then she would need follow-up testing to make sure the treatment is effective. If a mother is not infected with

gonorrhea and is in a monogamous relationship with an uninfected partner, then newborn eye ointment may be reasonably declined but could not rule out all bacteria (Dekker, 2019).

There is a wait-and-see method that is essentially the medical staff being aware of risks, watching the baby closely for signs of symptoms developing such as pus-containing discharge, and then the baby immediately being admitted to the hospital in the event they do develop an issue. They then run testing on it and provide injectable antibiotic treatment while waiting for results. This method relies on access to quick treatment (Dekker, 2019).

Povidone-iodine eye drops are becoming popular in some countries because they are less expensive than erythromycin. This disinfectant does not increase the risk of antibiotic resistance, and it is just as effective as erythromycin and silver nitrate at preventing gonorrheal ON. Povidone-iodine is also considered more effective than silver nitrate and equally effective as erythromycin at preventing chlamydial ON. Another advantage is that the newborn's eye turns temporarily brown after putting in the drops, which helps the provider know whether full coverage was achieved. Newborn eye drops made out of povidone-iodine are not yet available in the U.S (Dekker, 2019).

Some individuals would prefer to use their first milk or colostrum in the baby's eye to help prevent infections. Newborns were broken into two groups one for breastmilk application over 10 days (327 newborns) and the other for erythromycin prophylaxis (238 newborns). Pink eye occurred in 9% of the babies receiving breast milk drops and 26% receiving antibiotics. The most common cause of ON in both groups was Staphylococcus bacteria (Pishva et al. 1998). While this study looks good for breastmilk, there is another one that they found that ON from staph bacteria was most common in the infants that did not receive any prophylactic treatment (33%), followed by the group receiving colostrum drops (24%) and the group receiving erythromycin (16%). So the evidence is conflicting and inconclusive, supporting this method as adequate prevention. It relies on the birther having enough colostrum to provide treatment to the baby and remembering to do so before each feed for 10 days (Dekker, 2019).

Eye prophylaxis Informed Choice

Patient Name _____ Date _____

I choose (Please initial choice):

<u>Treatment Options</u>

_____I desire routine eye ointment prophylaxis within 24 hours from birth for my newborn.

_____ I decline treatment for my infant for routine eye prophylaxis and had ample time to have questions answered. I fully accept responsibility for any outcome.

<u>Initial Visit and 36-Week Gestation STI Screening</u>

_____ I choose to be screened at both visits for Chlamydia and Gonorrhea.

_____ I choose to only be screened at my initial visit for Chlamydia and Gonorrhea.

_____ I choose to only be screened at my 36-week visit for Chlamydia and Gonorrhea.

_____ I decline all screenings and accept full responsibility for any outcomes.

Patient Signature X _____ Date _____

Print Name _____

Midwife Signature X _____ Date _____

Midwife Name _____

Hepatitis B Vaccine in the Newborn Informed Consent

What is Hepatitis B and why is the Vaccine recommended at birth?
Hepatitis means inflammation of the liver. Hepatitis B is a liver infection caused by the hepatitis B virus. Some people are able to recover from their infection. For others, the virus remains in their bodies and becomes a chronic, or lifelong, infection. Approximately 1000 US infants are perinatally infected with the hepatitis B virus (HBV) each year (AAP).

Many women do not know they are infected and people with hepatitis B often have no symptoms. As a result, all pregnant women should get a blood test for hepatitis B as part of their prenatal care. The test is usually performed during the first prenatal visit. The hepatitis B virus is spread when someone comes in contact with blood, semen, or other body fluids from an infected person.When a pregnant woman has hepatitis B, it can be easily spread to her baby at birth. This can happen during a vaginal delivery or a c-section. Babies and young children can also get hepatitis B from close contact with family members or others who might be infected by direct contact with an infected person, where blood is passed through breaks in the skin or soft tissues, such as the nose, mouth and eyes (CDC, 2019). Additional ways a birther may contract Hepatitis B would be unprotected intercourse with someone who has Hepatitis B. Unconventional ways to possibly contract it could be sharing care products such as toothbrushes, razors, or nail clippers, sharing illegal drug needle usage, or tattoos with unsterile equipment.

Treatment and Procedure
Whether or not a birther is positive for Hepatitis B or negative it is recommended for all stable babies weighing ≥2000g to get the hepatitis B surface antigen (HBsAg) within the first 24 hours of birth. Timing of the hepatitis B birth dose is critical because the vaccine is 75% effective (94% effective when given with hepatitis B immune globulin) in preventing perinatal hepatitis B transmission when given within 24 hours of birth (Chabra & Hofstetter, 2020). This is typically done as a shot in the newborns thigh.

Typically, women of childbearing age are not candidates for antiviral therapy owing to early stage of the HBV disease. However, such patients with high viremia may benefit from antiviral therapy when planning to become pregnant since it reduces the risk of perinatal transmission. This may look like Pegylated-interferon treatment course available for chronic hepatitis B infection. This may be a good option for women who wish to conceive and who are willing to wait 18 months (consisting of 12 months of therapy followed by 6 months to assess the response) prior to conceiving. During pregnnacy, an HBV DNA level greater than 200,000 IU/mL or 1 million cp/ml indicates a level where the combination of the birth dose of the hepatitis B vaccine (and HBIG) will fail. First-line, antiviral therapy with tenofovir (TDF/viread) is recommended starting from week 28 of pregnancy until delivery but may continue 3 months postpartum. Please talk to your doctor about your own test results (Ayoub & Cohen, 2016).

After the first shot is given after birth, the next shot of the hepatitis B vaccine is usually given at 1 to 2 months of age. The last shot is given between 6 months and 18 months of age for full coverage. There is no additional risk of HBV transmission through breastfeeding, even in the absence of immunization. However, breastfeeding should be avoided in the presence of cracked or bleeding nipples as this would cause mixing of serous exudates with breast milk and can potentially lead to transmission of hepatitis B (Ayoub & Cohen, 2016).

Risks and Benefits

Reasons parents may delay this of decline this vaccine are they may perceive their infant to be low risk, may have specific or general vaccine concerns, or may prefer to receive the vaccine in the outpatient setting on a delayed schedule. The maternal to child transmition risk was reduced from 90% to 5–10% following universal vaccination. However, it remains a concern for 8–15% of infants in high-risk groups who are born to highly viremic mothers, for instance, women who are positive for hepatitis B e antigen and/or have high HBV DNA levels(Safadi et al., 2021). Risks of the vaccine are fever, tiredness, loss of appetite, nausea, vomiting, yellow skin and eyes, aching muscles, abdominal pain or joints arthritis, rarely anaphylactic shock, or another rare side effect is the hypotonic-hyporesponsive episode (HHE) (Department of health and human services, n.d.). Risks to not getting the vaccine would be When babies become infected with hepatitis B, they have about a 90% chance of developing a lifelong, chronic infection. Left untreated, about 1 in 4 children who have chronic hepatitis B will eventually die of health problems related to their infection, such as liver damage, liver disease, or liver cancer (CDC, 2019).

Alternative Treatments

There are no alternative treatments for Hepatitis B besides the vaccine and antiviral treatments in some cases. There are ways to naturally reduce levels of the viral load in a person body such as eating a healthy well balanced diet, avoid inflammatory foods/drinks, stay hydrated, reduce stress, milk thistle, and boosting glutathione levels in your body (Dr. Axe, 2020). These are not substitutions for treatment but more of mainanence measures to be considered and discussed with a provider.

Hepatitis B Informed Choice

Patient Name _____ Date _____

I choose (Please initial choice):

Screening Options

_____ I desire to be screened during my pregnancy usually with the initial labs at the beginning of care for Hepatitis B.

_____ I decline Hepatitis B screening and understand this is a requirement for Sweet Miracles LLC and that you will need to find a new care provider if declining and that you fully accept the responsibility for any outcome.

Treatment Options

_____I desire routine Hepatitis B vaccine administration within 24 hours from birth for my newborn.

_____ I decline treatment for my infant for routine Hepatitis B vaccine and had ample time to have questions answered. I fully accept responsibility for any outcome.

_____ If positive, I would like antiviral therapy beginning at 28 weeks if my HBV DNA level greater than 200,000 IU/mL or 1 million cp/ml.

_____ If positive, I decline all treatment and antivirals and have had ample time for my questions to be answered and accept full responsibility for any outcome.

Patient Signature X _____ Date _____

Print Name _____

Midwife Signature X _____ Date _____

Midwife Name _____

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