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### Decision Aid: Vitamin K for the Newborn

The decision to administer Vitamin K should begin with the material received from the midwife and also includes but is not limited to discussion, research, knowledge and your personal opinion of the risks and benefits. This informed consent contains information that has already been provided to you and is a reiteration for you to make a *signed* and documented choice. You may withdraw your consent at any time prior to the procedure.

- A. Purpose of Procedure
- **B.** Description of Procedure
- C. Risks, benefits, and uncertainties of the procedure
- D. Reasonable alternative procedures
- E. Consequences of not accepting the proposed procedure

# A. Purpose of Procedure

Vitamin K is essential for the synthesis of blood-clotting factors. Vitamin K is stored poorly and babies are born with very minimal amounts. It is suggested that by 2 weeks of age, healthy term infants will be producing enough Vitamin K to clot their blood efficiently although full levels aren't reached until about nine months of age. For babies that undergo trauma (seen or unseen), there is a greater risk for Vitamin K Deficiency Bleeding (formerly Hemorrhagic Disease of the Newborn). Vitamin K Deficiency

Bleeding (VKDB) can cause internal bleeding that leads to cognitive disability or death. The babies who are more susceptible to developing classical VKDB are those with birth trauma, asphyxia, postnatal hypoxia and those who are preterm, or if low birthweight (Myles) although it is impossible to identify which babies could potentially suffer from VKDB.

The incidence of VKDB with no additional risk factors is 1 per 10,000 (Myles). This risk is reduced to 1 in 400,000 if the injectable Vitamin K is given. Unfortunately, there are no reliable studies that have been performed with oral vitamin K. Research indicates that the levels of injectable vitamin k and oral vitamin k can be equal if oral vitamin k is given in several doses, therefore creating the assumption that it would be effective in preventing VKDB.

In babies that develop VKDB, the overall death rate in effected babies is 14-19%, and 21-40% of the survivors have long-term neurological handicaps.

#### **B.** Description of Procedure

If the client opts to have the midwife provide the vitamin K injection, it is given to the infant intramuscularly into the thigh before the midwife leaves during the immediately postpartum period. If a client opts to have the oral vitamin K for her newborn, it must be obtained and administered by the client. There are different dose regimens depending on which is purchased.

### C. Risks, benefits, and uncertainties of the procedure

*Risks:* General side effects of Vitamin K include jaundice, hemolytic anemia, flushing, rash urticaria, or a mild local reaction at the injection site. In addition any foreign entity given by injection can cause an anaphylactic reaction. There have been two or more studies that found a link between Vitamin K injection given at birth and childhood cancer, although several subsequent studies found **no** correlation.

Benefits: Potential decreased risk of classical VKDB.

*Uncertainties*: There are always uncertainties or unforeseeable risks with any procedure. The purpose of this procedure is to prevent classical VKDB but there are other forms of VKDB which can occur during the first 12



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months of life. It is unknown what risk there is in exposing the newborn to high concentrations of vitamin K. The concentration of Vitamin K (0.5mg) is 500 times the recommended daily allowance for an adult. Vitamin K is a fat soluble Vitamin so the purpose of such a high amount is so that it slowly releases from fat over time. There is also a preservative in injectable vitamin K, which is typically aluminum and may produce unknown side effects.

## D. Reasonable alternative procedures

- Increased maternal dietary Vitamin K 34+ weeks. Vitamin K is poorly absorbed across the placenta but in mega-
- doses, studies show that it does increase the fetus' vitamin K storage.
- In addition to the above, the mother can strive for a 5-15mg Vitamin K DAILY intake and this will increase what crosses through breast milk.
- Oral vitamin K is considered an alternative procedure. Studies have shown that with a scheduled administration of oral vitamin K, the risk of VKDB is 1.2 to 1.8 per 100,000 infants.
- Formula fed babies do receive adequate amounts of Vitamin K.

## E. Consequences of not accepting the proposed procedure

Potentially increased risk of classical VKDB. I understand that the CDC, AAP, ACOG guidelines are that a vitamin K injection is given to all neonates within the first hour of birth. I understand that VKDB can occur up to 12 months of age and the vitamin K administration is to help prevent classical VKDB which typically occurs between 1-7 days of life. I understand that VKDB can lead to cognitive disability and death. I have read and understood the description of VKDB and options that have been provided to me to help reduce risk to the newborn. I have had my questions answered to my satisfaction and can make an informed choice regarding vitamin K administration. I accept full responsibility for my decision.

I have chosen to have an immediate postpartum period.	Statement of Choice n injection of Vitamin K administered to m	y infant by the midwife during the
I have chosen to administer oral vitamin K for my infant. I will follow the recommended administration schedule. I understand I can purchase my own Vitamin K or purchase it directly from my midwife. I have chosen to not have any vitamin K in any form administered to my newborn.		
Client's Signature	Printed Name	Date
Partner's	s Signature N	Aidwife's Signature