

Clinical Practice Policy:

Vitamin K Administration in Newborn Infants

Effective Date:

10/13/2015

1. Purpose

To provide guidelines for Vitamin K administration to newborn infants throughout the Center for Women and Newborns at Brigham and Women’s Hospital

2. Background and Summary of the Evidence

- Vitamin K administration is for the prevention of hemorrhagic disease of the newborn.
- The baseline incidence of late vitamin K dependent bleeding (VKDB) is 4.4-8.6 per 100,000 infants.
- Intramuscular Therapy:
 - A single-dose of intramuscular vitamin K reduces this risk to approximately 1 per 1,000,000 infants (81 fold).(CDC. MMWR Morb Mortal Wkly Rep 2013; 62: 901-2. For review, see van Winckel, et al. Eur J Pediatr 2009; 168: 127-34).
 - The American Academy of Pediatrics guideline recommends 0.5 – 1.0 mg IM at birth. Costakos, et al. (Am J Perinatol 2003; 20: 485-90) compares 1 mg vs. 0.5 mg for prevention of hemorrhagic disease in 27 breastfed premature infants (< 32 weeks GA). They conclude on the basis of vitamin K levels that 0.5 mg is adequate for this population.
- Oral Therapy:
 - Oral Vitamin K therapy has been reviewed by Ipema in Ann Pharmacother 2012; 46: 879-83.
 - Oral regimens range from daily to weekly for 3 months. The most practical regimen is outlined below (Laubscher et al. Eur J Pediatr 2013; 172: 357-60.). Infants treated with this regimen had an incidence of late vitamin K dependent bleeding of 0.87 per 100,000 (95% confidence interval 0.24-2.24) in a 6-year cohort study in Switzerland. This mirrors the 13 fold reduction in late VKDB compared to no therapy observed in other cohorts.(McNinch et al. BMJ 1991; 303: 1105-9.). These data highlight the utility of oral therapy as well as its dramatic inferiority to the recommended intramuscular route. Therefore, oral therapy will only be offered after signed refusal of intramuscular vitamin K and signed consent form for oral therapy.

For additional information, see the summary of AAP guidelines available in Pediatrics 2003; 112: 191-2.

3. Drug Administration

Vitamin K will be administered in the CLB per the obstetrical care provider order and per the drug administration guideline (doses below). Vitamin K administration may be delayed up to 6 hrs after birth. In the event that Vitamin K is not administered in the CLB (e.g., parent refusal, transfer to NICU, etc.), it will be documented and verbally communicated during transfer of care. Refusal will be documented on the IM refusal form, which is stocked in Labor and Birth, the NICU, and the Well-Baby Nursery, and can be found electronically on the Department of Pediatric Newborn Intranet site (https://www.bwhpikenotes.org/Departments_Centers/NewbornMedicine_NICU/policiesandguidelines.aspx), as an appendix to this clinical practice guideline, and from a link within the Drug Administration Guideline. This form will then be included in the infant’s chart along with other consents. In the event of oral administration of Vitamin K, the oral administration consent form, which can be found in the same locations as the IM refusal form, will be signed and included in the infant’s chart.

- **Please note:** Two lines are included on both the refusal of IM vitamin K administration form and consent to oral vitamin K administration form. These two lines are provided to help ensure that both parents, if applicable, are present and part of the conversations regarding vitamin K administration. However, it should be noted that only one signature is required on each form.

Intramuscular Administration:

Neonates \geq 1500 grams, give 1 mg IM x 1 at birth

Neonates < 1500 grams, give 0.5 mg IM x 1 at birth

Oral Administration:

2 mg PO as soon as possible after birth, on day 4 of life, and in week 4 of life

[dose is not weight dependent]

For more information, see Drug Administration Guideline, section V: Vitamin K (phytonadione)
http://www.bwhpikenotes.org/policies/departments/NICU/drug_admin/DAGs/Vitamin%20K.pdf

4. Refusal of IM Vitamin K Administration

- When administration of intramuscular (IM) vitamin K is refused, a referral will be made to the attending pediatrician caring for the infant. For infants in the well newborn nursery born during daytime hours, the referral will be made to pediatrician covering the newborn nursery service. For infants who require Vitamin K on the overnight shift (5pm – 7am), a referral will be made to the Neonatology Birth and Transition Team. This referral will be generated by labor and birth as part of the Neonatology Consultation Order Set.
- The attending physician will meet with the family and discuss the risks of VKDB. If the family still opts to refuse administration of IM vitamin K, the attending physician will have the family sign the refusal form.
- **Please note:** Circumcision cannot be done without administration of IM Vitamin K. There is also an increased risk of bleeding in the event of emergency or non elective surgical procedures.
- **Please note:** If a patient is at high risk of bleeding (i.e. is born premature, has a familial history of hemorrhagic disease) and the family refuses IM administration of Vitamin K, consultation with risk management may occur at the physician's discretion.

5. Administration of Oral Vitamin K

- Following the attending physician's discussion with the family regarding refusal of IM Vitamin K administration, oral administration of the drug will be offered to the family.
- If oral administration is agreed to by the family, the Oral Vitamin K Consent Form will be signed by the parents of the infant.
- Both the refusal of IM Vitamin K and oral administration of Vitamin K consent forms will be documented in the infant's medical record.

6. Points of Emphasis

Every effort should be made to have a thorough discussion with the parents regarding the superior efficacy of IM Vitamin K administration prior to initiating the discussion of administration of oral Vitamin K.

7. References

- CDC. MMWR Morb Mortal Wkly Rep 2013; 62: 901-2.
van Winckel, et al. Eur J Pediatr 2009; 168: 127-34
Costakos, et al. (Am J Perinatol 2003; 20: 485-90
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