PEDIATRIC NEWBORN MEDICINE CLINICAL PRACTICE GUIDELINE

Vitamin K Administration In Newborns

Clinical Guideline Name	Vitamin K Administration in Newborns
Effective Date	
Approved By	Department of Pediatric Newborn Medicine Clinical Practice Council 6/13/19 CWN PPG _____ BWH SPP Steering _____ Nurse Executive Board/CNO_____

Purpose

a. To provide guidelines for Vitamin K administration to newborn infants throughout the Center for Women and Newborns at Brigham and Women's Hospital
b. To provide guidelines for management of situations in which parents refuse administration of IM Vitamin K and/or oral Vitamin K for their newborn.

All CPGs will rely on the NICU Nursing Standards of Care. All relevant nursing PPGs are listed below:

Points of emphasis/Primary changes in practice:

- There is strong evidence to support the practice of administration of IM Vitamin K for the prevention of hemorrhagic disease of the newborn.
- Every effort should be made to have a thorough discussion with parents regarding the superior efficacy of IM Vitamin K administration prior to initiating the discussion of administration of oral Vitamin K.

Background and Summary of the Evidence

- Vitamin K administration is for the prevention of hemorrhagic disease of the newborn, also known as vitamin K dependent bleeding (VKDB).
- The baseline incidence of VKDB is 4.4-8.6 per 100,000 infants.
- Intramuscular (IM) Therapy:
  A single-dose of intramuscular vitamin K reduces this risk to approximately 1 per 1,000,000 infants (81 fold)[1,2]
  The American Academy of Pediatrics guideline recommends 0.5 – 1.0 mg IM at birth.[7] Costakos, et al. compare 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.[3]
- Oral Therapy:
  Oral Vitamin K therapy has been reviewed by Ipema in the Annals of Pharmacotherapy in 2012.[4] Oral regimens range from daily to weekly for 3 months.

The most practical regimen is outlined below.[5] 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.[6] These data highlight the utility of oral therapy as well as its 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.[7]

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 hours 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.

Intramuscular Administration:

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

Oral Administration (ONLY for use when IM form is refused):

2 mg PO x 3 doses:

- As soon as possible after birth
- At 4 days of age
- At 4 weeks of age

For more information, see Vitamin K Drug Administration Guideline:

BWH NICU Drug Administration Guidelines

Refusal of IM Vitamin K

- When parents refuse administration of intramuscular vitamin K for their newborn, the Birth and Transition Service will be consulted. A Birth and Transition provider will meet with the family, provide the CDC patient handout for the family to review (Appendix B), and discuss the risks of VKDB. If the family still opts to refuse administration of IM vitamin K, they will be asked to sign the IM Vitamin K refusal form (Appendix C). Although a resident may be involved in the discussion, a NICU fellow, advanced practice provider (NP or PA), or attending neonatologist will oversee this counseling and the signing of 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 refused IM administration of Vitamin K, consultation with risk management may occur at the physician's discretion.
- Parental refusal will be documented on the IM Vitamin K Refusal form. This form will then be included in the infant's medical record along with other consents. In the event of oral administration of Vitamin K, the Oral Administration consent form (Appendix D) will be also be signed and included in the infant's medical record.
- **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, only one signature is required on each form.

Administration of Oral Vitamin K

- Following the provider's (NICU fellow, advanced practice provider, or attending neonatologist) 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 (Appendix D) will be signed by the parent(s) 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 in the Birth and Transition Service consult note. The SmartPhrases .VITAMINKREFUSALCONSULT and .VITAMINKIMREFUSALANDORALCONSENTCONSULT are available to facilitate this documentation.
- **Second and Third Doses of Oral Vitamin K**: An outpatient prescription can be provided to the parents for the second and third doses of oral vitamin K. Ordering instructions are readily available in Epic. It is recommended to ensure the desired outpatient pharmacy carries or compounds the oral solution. BWH carries a commercially-available 5mg/mL (3 mL) oral syringe with a 90 day expiration that can be stored at room temperature; compounded oral vitamin K commonly comes as a 1mg/mL oral solution with a 3 day expiration that requires refrigeration. If the family desires, the prescription can be filled by the BWH outpatient pharmacy. Of note, babies who are still hospitalized at 4 days of age (e.g. babies born by cesarean section) and 4 weeks of age should be given their second and third doses of oral vitamin K, respectively, as inpatients. Appendix E provides instructions for placing an order for bedside delivery of outpatient prescriptions.

References

1. CDC. Notes from the field: late vitamin K deficiency bleeding in infants whose parents declined vitamin K prophylaxis--Tennessee, 2013 MMWR 2013; 62: 901-2.
2. Van Winckel M et al. Vitamin K, an update for the paediatrician. Eur J Pediatr 2009; 168: 127-34
3. Costakos DT, et al. Vitamin K prophylaxis for premature infants: 1 mg versus 0.5 mg. Am J Perinatol 2003; 20: 485-90
4. Ipema HJ. Use of oral vitamin K for prevention of late vitamin k deficiency bleeding in neonates when injectable vitamin K is not available.Ann Pharmacother 2012; 46: 879-83
5. Laubscher B et al. Prevention of vitamin K deficiency bleeding with three oral mixed micellar phylloquinone doses: results of a 6-year (2005-2011) surveillance in Switzerland. Eur J Pediatr 2013; 172: 357-60
6. McNinch AW et al. Haemorrhagic disease of the newborn in the British Isles: two year prospective study. BMJ 1991; 303: 1105-9.
7. American Academy of Pediatrics Committee on Fetus and Newborn. Controversies concerning vitamin K and the newborn. Pediatrics. 2003 Jul;112(1 Pt 1):191-2.
8. Loyal Jet al. Factors Associated With Refusal of Intramuscular Vitamin K in Normal Newborns. Pediatrics. 2018 Aug;142(2).

Appendix A

Vitamin K Quick Reference

ROUTINE ADMINISTRATION OF IM VITAMIN K

Intramuscular Administration:

Neonates ≥ 1500 grams, give 1 mg IM x 1 at birth
Neonates < 1500 grams, give 0.5 mg IM x 1 at birth
May be delayed up to 6 hours after birth

PARENTAL REFUSAL OF IM VITAMIN K

1. Consult Birth and Transition team
2. Provide CDC handout:
   https://www.cdc.gov/ncbddd/blooddisorders/documents/vitamin-k-p.pdf
   https://www.cdc.gov/ncbddd/vitamink/documents/consumer-vitamink-span-p.pdf
3. Parent to sign refusal form: DR resident may provide counseling but NICU fellow, advanced practice provider (NP or PA), or attending neonatologist will oversee this counseling and the signing of the refusal form (Appendix C)
   SmartPhrases:
   .VITAMINKREFUSALCONSULT
   .VITAMINKIMREFUSALANDORALCONSENTCONSULT

ORAL VITAMIN K

1. Parents sign oral consent form (Appendix D)
2. Oral Administration: (**ONLY for use when IM form is refused**)

   2 mg PO x 3 doses:
   - As soon as possible after birth
   - At 4 days of age
   - At 4 weeks of age
3. Outpatient prescription:
   Write Outpatient Rx
   IP Pharmacy Consult to Pharmacy Bedside Delivery Program (Appendix E)

Appendix B

CDC Vitamin K Parent Information in English and Spanish

Appendix C

Newborn Nursery Vitamin K Shot Refusal

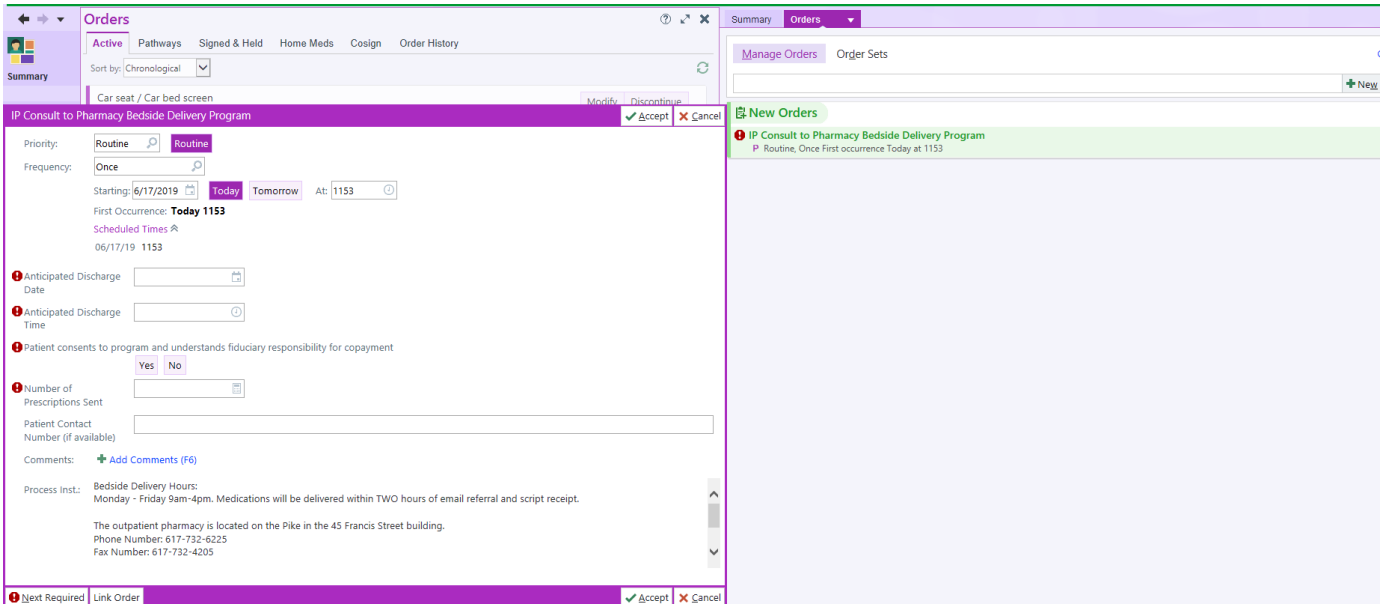
Appendix D

Newborn Nursery Vitamin K Consent

Appendix E

How to order IP Consult to Pharmacy Bedside Delivery Program

1. **Go to Orders**
2. **Type "IP Consult to Pharmacy Bedside Delivery Program"**
3. **Complete required fields**




BWH