Title: **Vitamin K for the Prevention of Vitamin K Deficiency Bleeding (VKDB) in Newborns**	**Approved Date:** June 2000	**Revised Date**: February 2014
Authorization Section Head Program Director, Women's Health		**Page** **1 OF 4**

1.0 PURPOSE:

1.1 To reduce the risk of Vitamin K deficiency bleeding in the newborns

2.0 DEFINITIONS:

2.1 **Vitamin K deficiency bleeding (VKDB) of the newborn**: previously referred to as hemorrhagic disease of the newborn. It is unexpected and potentially severe bleeding occurring within the first week of life. Late onset VKDB can also occur in infants 2-12 weeks of age with severe vitamin k deficiency. Bleeding in both types is primarily gastro-intestinal and intracranial. (See Appendix A for additional information).

2.2 **Vitamin K_1**: also known as phytonadione, an important cofactor in the synthesis of blood coagulation factors II, VII, IX and X. (See Appendix A for additional information).

3.0 PRACTICE GUIDELINES:

3.1 The infant's primary health care provider (PHCP) offers all parents the administration of vitamin K intramuscularly (IM) for their infant.

3.2 If parent(s) refuses any vitamin K administration to the infant, the infant's PHCP:

3.2.1 Discusses the risks of no vitamin K administration, regardless of route, with the parent(s). (Refer to 2.1)

3.2.2 Informs parent(s) that:

- the preferred route of administration for vitamin K is intramuscular (IM)
- intravenous (IV) route is not an acceptable option
- the oral route is not recommended. (See Appendix A).

3.2.3 Documents in the infant's medical record the discussion and parent's decision related complete refusal or alternate route of vitamin K administration.

3.3 **Administration of vitamin K (dose and route):**

3.3.1 IV administration is not an acceptable route / option – there is very little information regarding the efficacy of IV administration of vitamin K for prevention of late onset VKDB.

3.3.2 IM administration is the preferred route:

3.3.2.1 Dose for infants born with a birth weight of less than or equal to 1500 grams is **0.5mg IM as a single dose within 6 hours of birth.**

3.3.2.2 Dose for infants born with a birth weight of greater than 1500 grams is **1 mg IM as a single dose within 6 hours of age**

3.3.3 **Oral administration is not a recommended route (See appendix A). If parent(s) insist on the oral administration / route, the infant's PHCP:**

3.3.3.1 Discusses the necessity of multiple oral doses and the risks of oral doses versus IM dose administration with the parent(s) (See Appendix A)

3.3.3.2 Discusses the required oral doses of vitamin K with parents, including:

- Initial dose is 2 mg with the first feeding (within 6 hours of age)
- Repeat dose is 2 mg at **2 weeks** postnatal age
- Repeat dose is 2 mg at **4 weeks** postnatal age

3.3.3.3 Discusses with parents the importance of monitoring the infant for regurgitation of oral vitamin K. If the infant regurgitates the first or subsequent doses of vitamin K, ensure the parent(s) understand the necessity of administering another dose of vitamin K dose within 2 hours of the initial or subsequent doses of oral vitamin K.

3.3.3.4 Documents the above discussion and parent's decision in the infant's medical record.

3.3.3.5 Note: Vitamin K_1 2mg/mL injectable product may be administered orally, or Vitamin K_1 10 mg/mL injectable product may be diluted in sterile water to a concentration of 1 mg/mL. Oral preparations are available through Pharmacy.

4.0 REFERENCES:

4.1 American Academy of Pediatrics, Committee on Fetus and Newborn. Controversies concerning vitamin K and the newborn. Pediatrics 2003; 112(1): 191-2.

4.2 Canadian Pediatric Society, Fetus and Newborn Committee. Routine administration of vitamin K to newborns. Paediatric Child Health 1997; 2(6):429- 31. Reaffirmed January 30 2012 and February 1, 2014.

4.3 Health Canada. Family-Centered Maternity and Newborn Care: National Guidelines, Minister of Public Works and Government Services, Ottawa, 2000.

4.4 Winnipeg Regional Health Authority (WRHA) (2006). Pediatric Parenteral Drug Monograph Vitamin K. Authorized by WRHA Child Health Pharmacotherapy by sub-committee.

5.0 RESOURCES:

5.1 Clinical Educator – Postpartum and Normal Newborn Units, Women's Hospital, Women's Health Program, WRHA.

5.2 Clinical Nurse Specialist – Women's Hospital, Women's Health Program, WRHA.

5.3 Clinical Resource Pharmacist, Pediatrics/Neonatology & Women's Health, Children's Hospital, Child Health Program, WRHA.

5.4 Assistant Medical Director Intermediate Care Nursery, Women's Hospital, Child Health Program, WRHA

Appendix A

Vitamin K Information

1. Vitamin K_1 (Phytonadione) compounds are fat-soluble naphthoquinones. Phytonadione (Vitamin K_1) occurs in a variety of natural materials and is synthesized by certain bacteria in the gastrointestinal tract. Commercially prepared Phytonadione is synthetically produced and essentially possesses the same type and degree of activity as naturally occurring Vitamin K_1.
2. Vitamin K is an essential cofactor for the function of blood coagulation factors (factors II, VII, IX and X).
3. Vitamin K dependent factors are low in all neonates. The deficiency may be prolonged in preterm neonates and exclusively breast-fed infants.

Vitamin K Deficiency Bleeding Information

1. Vitamin K deficiency causes vitamin K deficiency bleeding (VKDB), previously known as hemorrhagic disease of the newborn (HDNB].
2. All neonates are at risk for VKDB although some are at greater risk. Risk is increased by use of antibiotics, exclusive breast-feeding and fat malabsorption.
3. Vitamin K should be administered to all neonates at birth or immediately after to reduce or prevent complications of VKDB which can be devastating e.g. (profound hemorrhage, intracranial hemorrhage)
4. Vitamin K deficiency bleeding (VKDB) occurs in three forms – early, classic and late
   - 4.1 **Early VKDB**
     - is often severe (cephalhematoma, intracranial & intra-abdominal hemorrhage) occurring during the first 24 hours of life.
     - Likelihood of occurrence increases by exposure of the fetus to drugs e.g. oral anticoagulants and drugs that act on hepatic metabolism (e.g. anticonvulsants, antituberculosis drugs)
   - 4.2 **Classic VKDB**
     - presents mainly as gastrointestinal hemorrhage
     - occurs in the first week of life (between 24 hours and 7 days of life)
   - 4.3 **Late VKDB**
     - presents between 7 days and 3 months of life
     - occurs typically in infants who are exclusively breastfed and have not received vitamin K at birth [4.3]
   - 4.4 **Incidence:**
     - Early and classic VKDB (first week of life): 0.4 to 1.7 %; disabling or fatal hemorrhage: 2.2 per 100,000 births
     - Late VKDB (weeks 2-12 of life):4.4 to 10.5 per 100,000 births [4.4]

Vitamin K Administration Information

1. Routes that Vitamin K_1 can be given include:
   - 1.1 **Intramuscular (IM)** administration is the preferred and most effective route of Vitamin K administration for the prevention of all forms of VKDB. (CPS and AAP recommended route)
   - 1.2 Oral **(PO)** - is not the preferred route and is only considered when parents decline intramuscular (IM) Vitamin K_1.

     Note: Due to the reduced efficacy of the oral administration versus IM

administration, as well as the risk of loss to follow-up and failure to administer all doses, reserve oral vitamin K for infant whose parent(s) is refusing the IM route. Families should be adequately informed about the greater risk of VKDB in populations receiving oral vitamin K, particularly the increased risk of intracranial hemorrhage; close follow up is necessary. A single oral dose of vitamin K provides less protection against late onset VKDB than IM route with a relative risk of VKDB of 13.8 [2.9-66.2].

2. **Vitamin K should not be given intravenously (IV)** as there is very little evidence available as to its efficacy, particularly with prevention of late VKDB. There is much more evidence that the IM route is the most effective route of administration for the prevention of all forms of VKDB.