**Newborn Guideline 12**

# VITAMIN $K_1$ PROPHYLAXIS

## *INTRODUCTION*

Vitamin K Deficiency Bleeding or VKDB (also known as Hemorrhagic Disease of the Newborn or HDN) is bleeding due to inadequate activity of Vitamin K-dependent coagulation factors.[1] There is considerable evidence that infants at birth present with low levels of Vitamin K which places them at a higher risk for VKDB and that the risk for VKDB is increased for those infants exclusively breastfed.[2-6] Prophylactic Vitamin K administration to newborns has been utilized since the 1950's as a therapy to decrease the incidence of VKDB.[7]

## *CAUSES, RISK FACTORS, AND FREQUENCY*

Table 1 describes the three types of VKDB, their causes, risk factors, frequency and preventive measures.[8]

**Table 1** Sutor, A. et al., (1999). Vitamin K deficiency bleeding in infancy. Thrombosis and haemostasis, 81, p.457.

| | Early VKDB | Classical VKDB | Late VKDB |
|---|---|---|---|
| **Age** | Less than 24 hours | Days 1-7 (mostly 3-5) | Week 2 to 6 months (mostly weeks 2-8) |
| **Causes & Risk Factors** | Drugs taken during pregnancy (some anticonvulsants, oral anticoagulants, tuberculostatics, and antibiotics). | Marginal Vitamin K content in breast milk. Inadequate milk intake for any reason, including late onset of feeding. | Marginal Vitamin K content of breast milk (idiopathic). Malabsorption of Vitamin K (liver or bowel disease). Increased incidence in males and in summer months. |
| **Location in order of Frequency** | Cephalhematoma, umbilicus, intracranial, intra-abdominal, intrathoracic, gastrointestinal. | Gastrointestinal tract, umbilicus, nose, needle-prick sites, circumcision, intracranial. | Intracranial (30-60%), skin, nose, gastrointestinal tract, needle-prick sites, umbilicus, urogenital tract, intrathoracic. |
| **Frequency without VitaminK Prophylaxis** | Less than 5% in high-risk groups (see causes and risk factors). | 0.01% - 1.5%; wide variations due to different feeding patterns and risk factors. | 4-10 per 100,000 births (more common in South East Asia). |
| **Preventative Measures** | Stop or replace offending drugs. Give VitaminK prophylaxis to the mother during pregnancy. | Adequate Vitamin K supply by early and adequate breast-feeding. Vitamin K prophylaxis to newborn. | Vitamin K prophylaxis. Early recognition of predisposing conditions (prolonged jaundice, failure to thrive) and prompt investigation of "warning bleeds". |

## *VITAMIN $K_1$ ADMINISTRATION & STORAGE*

### I. ADMINISTRATION

There are two methods of Vitamin $K_1$ administration: intramuscularly (IM) and orally (PO). Intramuscular injection is the recommended route of administration.

### A) Intramuscular

The American Academy of Pediatrics (1993) and the Canadian Paediatric Society (1997) recommend the intramuscular route of Vitamin K administration. The intramuscular route of Vitamin K administration has been the preferred method in North American due to its high efficacy rate and high compliance rate.

A well publicized study[9] reporting a link between IM Vitamin K and childhood cancer created great concern, especially in Europe, and led some countries to adopt oral Vitamin K rather than the standard IM. Those countries showed a great increase in late VKDB of the newborn. Zipursky[10] reported several case-controlled studies that have found no evidence to suggest that IM Vitamin K causes childhood cancer.

### B) Oral

Oral administration may be an alternative in cases where parents refuse intramuscular administration to protect their infant from pain associated with intramuscular injection. Intramuscular administration of Vitamin K however, is preffered for the following reasons:[11-18]

- Oral Vitamin K is not absorbed as well as IM Vitamin K
- Several doses of oral Vitamin K are needed over several weeks. Consequently, compliance may be an issue.
- There may be unreliable intake of oral Vitamin K e.g. variable absorption or regurgitation.
- An appropriate oral form of Vitamin K has not been licensed in North America
- The efficacy of oral Vitamin K has not been fully established

## *RECOMMENDATIONS[19]*

1. Vitamin $K_1$ should be given within the first 6 hours after birth following initial stabilization of the baby and an appropriate opportunity for maternal (family) – baby interaction.

2. Vitamin $K_1$ should be given as a single intramuscular dose of:

   - 0.5 mg for birth weight 1500 g or less
   - 1.0 mg for birth weight greater than 1500 g

3. For newborn infants whose parents refuse an intramuscular injection, the following is recommended:

    - an oral dose of 2.0 mg of vitamin $K_1$ at the time of the first feeding
    - this dose should be repeated at 2-4 weeks and 6-8 weeks of age
    - the parenteral form of vitamin K for oral administration is all that is currently available
    - parents should be advised of the importance of baby receiving follow-up doses and be cautioned that their infants remain at an increased risk of late VKDB

4. The IM route should be used for preterm and sick infants. The IV route may be necessary for extremely low birth weight (ELBW) babies.

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