SCOPE: **Maternity and Neonatal Unit**

GUIDELINE: **Vitamin K administration to the newborn baby**

AUTHOR: NNU Quality Coordinator

PURPOSE: To ensure that the current evidence and recommendations is given to parents and that Vitamin K when administered is given in a safe manner with informed parental consent

DEFINITIONS: Vitamin K is necessary for the production of clotting factors by the liver.

GUIDELINE:

Vitamin K deficiency bleeding (VKDB) is due to inadequate activity of vitamin K dependent coagulation factors.

Neonatal bleeding is not always due to Vitamin K deficiency.

Current evidence supports the administration of vitamin K to all babies, to prevent vitamin K deficiency bleeding (VKDB).

Early studies showed a possible link between intramuscular vitamin K prophylaxis and childhood cancer. The most recent studies have been of variable design and not without methodological problems. Whilst most reviewers have interpreted these studies as not demonstrating any such link, at least one editorial (von Kries 1998) concluded a small risk of leukaemia (but not other cancers) could not be excluded, although "the potential risk…seems more hypothetical than real." The potential risk of leukaemia may be small but does nevertheless influence the decision making of some families.

Factors which can predispose an infant to haemorrhagic disease of the newborn:

- maternal use of anticoagulants
- maternal anti convulsant medication (e.g. phenytoin and phenobarbitone)
- maternal tuberculostatic medication (rifampicin and isoniazid)
- maternal ingestion of some antibiotics eg cephalosporins
- birth asphyxia
- prolonged labour
- prematurity
- other conditions which delay oral feeding.

<u>Breast feeding</u>

Breast feeding has been cited as a risk factor for VKDB.

Breast milk has lower vitamin K content to infant formula. Studies have shown that VKDB has occurred more frequently in breast fed babies compared to infant formula fed babies.

There are three forms of VKDB

VKDB is an uncommon but potentially fatal disorder which presents with spontaneous bleeding, or bruising. Internal haemorrhage, including intracranial bleeding, may occur. There are three recognised forms:

Early: This is very rare, and occurs on the first day of life in infants whose mothers are taking anticonvulsants (particularly phenobarbitone or phenytoin), anti-tuberculous therapy or vitamin K antagonist anticoagulants. Consideration should be given to treating such mothers with oral vitamin K, 20mg/day, for 2 weeks prior to delivery. (Zipursky 1998)

Classic: Bleeding occurs from the 2nd to 7th day of life. Older data suggest the incidence in babies who do not receive vitamin K prophylaxis is in the order of 400 to 1700 per 100,000 births. (Zipursky 1998)

Late: This occurs between one week and six months of age, almost exclusively in breast fed babies, and often in association with unrecognised liver disease or malabsorption syndrome.

A consensus statement from the following organisations is printed below:
Fetus and Newborn Committee of the Paediatric Society of New Zealand
The New Zealand College of Midwives (Inc.)
The New Zealand Nurses Organisation
The Royal New Zealand College of General Practitioners
The Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

Current evidence supports the administration of vitamin K to all babies, to prevent vitamin K deficiency bleeding (VKDB). A new formulation of vitamin K is available, which can be given either intramuscularly (the preferred route) or orally.

Current recommendations

The international debate and uncertainties in the last decade over the safety of vitamin K administration to newborns requires maternity providers to ensure that patients have access to discussion and information that recognises the complexity around their decision making in newborn care. The following recommendations are based on current evidence, which supports the administration of vitamin K to prevent VKDB in susceptible babies.

1. It is the responsibility of the lead maternity carer (LMC) to discuss vitamin K prophylaxis and ensure that parents are aware of the recommendation that **all babies should receive vitamin K prophylaxis.**

2. The recommended route of administration is intramuscular; 1mg (0.1ml) (of Konakion MM®, 2mg/0.2ml) being given at birth. Infants who weigh less than 1500 gms at birth should receive 0.5mg. (0.05ml).

3. If parents do not agree to an intramuscular injection, the alternative is for the infant to receive Konakion MM®, 2mg orally at birth. These infants should then receive a repeat oral dose (2mg) at 3-5 days and at 4-6 weeks of age. If the infant vomits or regurgitates within 1 hour of an oral dose, this dose should be repeated.

4. The oral regime is not recommended in "high risk" situations, such as maternal anticonvulsant or anticoagulant therapy (warfarin or phenindione), tuberculostatic drugs (such as rifampicin and isoniazid), prematurity, birth asphyxia or other conditions which will delay oral feeding.

5. If the parents opt for repeat oral doses of vitamin K, both the LMC and the parents themselves carry responsibility to see that the infant receives these doses.

6. Most cases of severe VKDB are preceded by "warning bleeds" and it is important for practitioners and parents to be aware that spontaneous bleeding in the first six months of life may be caused by haemorrhagic disease. Examples of "warning bleeds" include bleeding from the nose or umbilicus, spontaneous bruising and black bowel motions. Parents who have opted for no vitamin K prophylaxis should particularly be made aware of these signs.

7. Many cases of late VKDB occur when there is liver dysfunction. Prolonged jaundice in the newborn needs to be investigated. In the event that the infant has conjugated hyperbilirubinaemia, the need for vitamin K administration should be considered and discussed with parents.

8. Infants who are suspected of having VKDB should normally be admitted to hospital for investigation. Consideration should be given to intravenous vitamin K administration and fresh frozen plasma or other source of clotting factors.

9. A written record of the date, dose and method of administration of vitamin K should be kept in the Child Health Record Book

   (MEDSAFE Prescriber Update No. 21:36-40 January 2001)

If parents decline to have either IM or oral vitamin K for their baby(s), LMC/core staff should refer them for a consultation with the paediatrician for further discussion.

Vitamin K (Phytomenadione 2mg in 0.2ml) must be prescribed on the baby's drug chart and signed for appropriately

ASSOCIATED DOCUMENTS

TDH Policy Informed Consent
TDH Safe Administration of Medicine

REFERENCES

National Women's hospital Newborn clinical guideline
www.adhbt.govt.nz/newborn/Guidelines/Blood

MEDSAFE Prescriber Update No. 21:36-40 January 2001

NHMRC Joint statement and recommendations on Vitamin K administration to newborn infants to prevent vitamin K deficiency bleeding in infancy

Overview of Vitamin K (last literature review February 2015) www.uptodate.com

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