Vitamin K Prophylaxis in the Newborn

A consensus statement.
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

The Fetus and Newborn Committee of the Paediatric Society of New Zealand issued a statement on vitamin K prophylaxis for haemorrhagic disease of the newborn (now preferably called vitamin K deficiency bleeding: VKDB) in 1995[1]. In 1992 a British report had suggested a possible association between intramuscular vitamin K and an increased risk of childhood cancer. By 1995 several large epidemiological studies from North America and Europe had been published, none of which supported such an association. Evidence also suggested that the alternative oral route for vitamin K administration was not as successful at preventing the late form of VKDB. The 1995 statement, therefore, recommended that "all newborn infants should have vitamin K prophylaxis and that the preferred route of administration is intramuscular".

Since 1995 there has been continuing debate on this issue, a number of further studies published and, importantly, ongoing surveillance of cases of VKDB in several countries. In addition, the launch of a new vitamin K product (Konakion MM®, which will replace Konakion®) in New Zealand demands a review of previous recommendations.

As with earlier studies of a possible link between intramuscular vitamin K prophylaxis and childhood cancer, the most recent have been of variable design and not without methodological problems. Whilst most reviewers[2] have interpreted these studies as not demonstrating any such link at least one editorial[3] concluded a small risk of leukaemia (but not other cancers) could not be excluded, although "the potential risk ... seems more hypothetical than real". The risk of leukaemia may be small but does nevertheless influence the decision making of some families.

Neonatal bleeding is not always due to vitamin K deficiency and vitamin K deficiency often occurs after the four week neonatal period, hence the specific term, vitamin K deficiency bleeding has been adopted internationally[4]. VKDB is bleeding due to inadequate activity of vitamin K dependant coagulation factors (II, VII, IX, X). In a bleeding infant a prolonged prothombin time (PT) together with normal fibrinogen level and platelet count is almost diagnostic and rapid correction of the PT and/or cessation of bleeding after vitamin K administration are confirmation[5].

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, 20 mg/day, for 2 weeks prior to delivery.

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

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.

Recent surveillance in Australia and Europe gives the risk of late VKDG per 100,000 babies as being:

	Australia	Europe
No Vitamin K	34.4[a]	
1 dose oral Konakion®	20	
2 doses oral Konakion MM®		5
3 doses oral Konakion®	4.1	2.6
I.M. Konakion® at birth	0.2	0

[a] "344" appears in reference but this was an estimate and "34.4" is likely to be more accurate and is closer to that in other studies (Dr P. Loughman).

Konakion ®, the only form of vitamin K available in New Zealand for many years, has not been licensed for oral uses (although practitioners may still prescribe it by that route). It contains phytomenadione (vitamin K1) as the active ingredient but also polyethoxylated castor oil, propylene glycol and phenol, which some practitioners consider are mucosal irritants for the infant. The new Konakion MM® is designed specifically for oral, as well as intramuscular, use and contains phytomenadione and the naturally occurring products, glycocholic acid and lecithin. The advent of this form of vitamin K should allay any concerns about oral administration related to the phenol content of the former preparation.

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.

Recommendations

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 (of Konakion MM®, 2mg/0.2ml) being given at birth. Preterm infants may receive 0.5mg.
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 of the cases of late VKDB occur when there is a 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.

References

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Mission statement

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