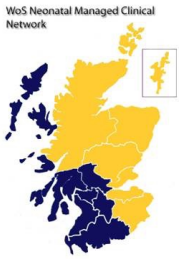
MCN for Neonatology

West of Scotland

Neonatal Guideline



Vitamin K Prophylaxis for Neonates

Introduction

This document is applicable to all medical, midwifery and nursing staff caring for the newborn in hospital or community in the West of Scotland. The guideline should be used with reference to the relevant pharmacy monographs. Nursing staff should also refer to the Patient Group Direction (PGD) which covers the administration and supply of vitamin K, by nursing and midwifery staff, for the prevention of Haemorrhagic Disease of the Newborn.

Intramuscular vitamin K – Formulary Link

The administration of an intramuscular dose of Vitamin K (phytomenadione) is recommended for all babies born in the West of Scotland. It should be administered soon after birth. This is a ONCE ONLY dose. The dose is:-

- 1mg phytomenadione (0.1ml) IM for term infants (36 weeks gestation or greater).

A lower dose is recommended for infants < 36 weeks gestation. Two dosage regimes are in use in neonatal units in the West of Scotland. The former is the recommended dose in GG&C

- 0.5mg phytomenadione(0.05ml) IM for all preterm infants less than 36weeks.

OR

- 400 micrograms/kg (0.04 ml/kg) IM.

NB - A 1ml syringe must be used due to the very small volume for injection

If intramuscular injections are contraindicated (e.g. babies with inherited disorders of coagulation or babies with very low muscle mass) then vitamin K may be given via the oral route or by intravenous injection if the enteral route is contraindicated or unreliable. See below.

Oral vitamin K

Note - The oral route is not appropriate for high risk, sick, or premature infants. In addition, the manufacturers do not recommend this route for babies born to mothers who are taking carbamazepine, phenobarbital, phenytoin, rifampicin or warfarin at the time of delivery. If a mother of a baby in any of these categories declines parenteral vitamin K or if a mother declines vitamin K by any route - see later section – *'Parents who decline vitamin K prophylaxis'.*

Mothers of healthy, mature, infants who decline intramuscular vitamin K should be offered one of the following oral Vitamin K regimen.

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Phytomenadione Paediatric – 2mg (0.2ml) orally, Three doses at 1, 7 and 28 days **– Formulary Link**

Administration –Phytomenadione Paediatric is supplied in glass ampoules. The first dose will be administered by midwifery staff. A prescription should be sent to pharmacy for the day 7 and 28 doses, these doses can be given by the community midwife/health visitor or parent /carer as appropriate.
Patient Information Leaflet

Intravenous vitamin K – Formulary Link

Phytomenadione may be administered intravenously but this is not recommended for routine treatment. Intravenous administration is not covered by the PGD and must be prescribed by a doctor.

Phytomenadione must only be diluted with 5% glucose & not mixed with other intravenous medications or infusions. The line should be flushed with IV glucose 5% before and after administration.

As intravenous administration does not provide a depot of vitamin K the manufacturers recommend administration of additional doses at 7 days and 4 weeks of age.

Patient Group Direction
Midwives Exemptions allow midwives to administer vitamin K without it having to be prescribed. The administration of phytomenadione (oral or IM) by nurses is covered by Patient Group Directions (PGDs). Administration under midwives exemption or PGD must be recorded according to local practice e.g. on Badgernet

Informed consent for the administration of vitamin K.

Parents are asked to provide verbal consent for the administration of intramuscular vitamin K. Staff should be aware of the following key points when discussing vitamin K administration, to ensure that this consent is fully informed.

- Vitamin K is required for the production of essential clotting factors in the liver. Haemorrhagic disease of the newborn (HDN) is caused by a deficiency of vitamin K. HDN may cause severe bleeding which may be fatal or cause severe brain damage. Bleeding can occur without warning.

- Vitamin K 1mg (or a lower dose for premature babies) intramuscularly gives universal protection against HDN [1].

- Whilst some studies in the early 1990's suggested a link between IM vitamin K and childhood cancers, subsequent research has not confirmed these findings. Such a link is therefore deemed to be unproven and unlikely [2]. Therefore, the possibility of a link between IM vitamin K and childhood cancer should not be raised with parents when seeking consent for the administration of Vitamin K.

- It is the agreed policy therefore to give vitamin K intramuscularly. However, if some parents object to IM administration of vitamin K then the alternative offered is oral Vitamin K (see dosage & administration information above). This however does NOT guarantee full protection, particularly if some doses are vomited or missed. Babies with liver disease are at particular risk.

Listed below are some important factors.

- Breast milk contains LESS Vitamin K than formula milks and breast fed babies have a reduced intake in the first few days. As a result of this haemorrhagic disease of the newborn has the greatest incidence amongst breast fed babies. This is not a reason not to breast feed but a reason for Vitamin K prophylaxis.

- Vitamin K is a fat soluble Vitamin and is poorly absorbed from the gut when there is liver disease. Many liver diseases are not apparent for days or weeks after birth, therefore, these babies cannot be identified when prophylaxis is first given. Small, repeated doses of oral Vitamin K will reduce the risk. Midwives should be alert to the possibility of liver disease signified by prolonged jaundice after 14 days.

- Babies of mothers who are taking some enzyme-inducing drugs - carbamazepine, phenobarbital, phenytoin or rifampicin, or who are taking warfarin must have prophylactic Vitamin K given parenterally. These drugs antagonise Vitamin K in the baby.

Parents who decline vitamin K prophylaxis

Parents of healthy term babies have the right to refuse consent for vitamin K prophylaxis by any or all routes. However, we have a duty to explore the reasons for complete refusal and ensure that they are correctly informed of the risks of Vitamin K deficient bleeding and the potential for serious long term morbidity or mortality. If, having explored the reasons for refusal and having ensured that they are correctly informed of the risks, they continue to refuse prophylactic vitamin K then this conversation and their decision should be clearly documented in the baby notes. It is not appropriate to get the parents to sign a medical 'disclaimer'. This discussion should be with a Middle Grade or Consultant Paediatrician.

Where a baby is clearly at high risk of bleeding however, vitamin K is required as treatment rather than prophylaxis and should always be administered in the best interests of the baby.

Such cases would include:

- Prematurity
- Sepsis
- Liver disease
- Maternal treatment with enzyme inducing drugs including e.g. Anticonvulsants and Rifampicin
- Prolonged Prothrombin time

Information to be given to parents if vitamin K prophylaxis is declined

- Vitamin K is an essential vitamin required by the liver to make 'clotting factors'. Clotting factors are natural chemicals produced by the liver which circulate in the blood and respond to bleeding by helping blood clots to form.

- Babies who do not get enough vitamin K are at risk of bleeding excessively over the first few days and weeks of life. This is called vitamin K deficient bleeding (VKDB) or Haemorrhagic Disease of the Newborn (HDN).

- Bleeding most commonly occurs between day 2 and day 7 of life. This is known as 'Classical' VKDB. Classical VKBD is almost entirely preventable by giving the baby vitamin K. Bleeding may also occur later than this over the following few months. This is known as 'Late' VKBD. This may also be reduced by giving the baby Vitamin K although there is insufficient research to confirm this.

- Rarely, bleeding can occur on day 1 of life. This is called 'Early' VKDB.

- The excessive bleeding seen in VKDB may appear as severe or unexplained bruising, oozing of blood from the umbilical stump or from injection sites, nose bleeds or bleeding from the stomach or bowel. These types of bleeding serve as a warning that the baby's blood is not clotting but seldom cause severe illness.

- The main concern however, is bleeding within the brain which can occur without any warning and may lead to permanent brain damage or death.

- Breast milk, whilst being the healthiest way to feed your baby, contains very little vitamin K and the majority of bleeds reported in the UK occur in babies who have been fed exclusively with breast milk [3]. Most of the other bleeds were seen in babies fed with soya based formula milk or who are absorbing vitamin K poorly due to liver disease [3].

- Severe bleeding can be almost completely prevented by giving Vitamin K at the time of birth by an intramuscular injection. And this is the reason that West of Scotland maternity units recommend this treatment for all babies. This recommendation is supported by all major health agencies [8].

- Vitamin K given by mouth, according to the schedules above, is almost as effective as the intramuscular injection. However a number of babies each year are reported to have had bleeds

because some doses were missed or because the baby vomited shortly after the dose was given or because the Vitamin K did not get absorbed due to liver disease in the baby. Because of this we recommend intramuscular vitamin K as the safest option. However, if parents do not want the intramuscular injection then oral treatment can be offered.

- If no Vitamin K is given at birth the risk of spontaneous bleeding for all babies is around 1:8500 [4]. The risk for exclusively breastfed babies is higher - around 1:1200 [6]. Many more of these babies - up to 1:80, may show excess bleeding following minor surgical procedures such as circumcision [7].

- Babies with specific risk factors including liver disease, prematurity or those born to mothers who are on medicines for epilepsy are at a much higher risk and treatment of these babies with Vitamin K is essential.

Resources for Families

Families can be directed to the leaflet attached to the end of this document

References

1. Puckett RM, Offringa M. Prophylactic vitamin K for vitamin K deficiency bleeding in neonates. The Cochrane Database of Systematic Reviews 2000, Issue 4. Art. No.: CD002776. DOI: 10.1002/14651858.CD002776

2. American Academy of Pediatrics. Policy Statement - Controversies Concerning Vitamin K and the Newborn (RE9302). Vitamin K Ad Hoc Task Force. Pediatrics May 1993 91 (5), 1001-1003

3. McNinch A et al. Vitamin K deficiency bleeding in Great Britain and Ireland: British Paediatric Surveillance Unit Surveys, 1993-94 and 2001-02. Arch Dis Child 2007; 92;759-766

4. Busfield A et al. Neonatal Vitamin K prophylaxis in Great Britain and Ireland; The impact of perceived risk and product licensing on effectiveness Arch Dis Child 2007; 92; 754-75

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7. Sutherland JM et al. Haemorrhagic Disease of the Newborn: breastfeeding as a necessary factor in the pathogenesis 1967;113:524-533

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Vitamin K for Newborn Babies

Information for parents

This leaflet explains what vitamin K is, and its importance in preventing bleeding problems in newborn babies. We hope it gives you enough information to help you make an informed choice about this part of your baby's care.

What is vitamin K?

Vitamin K occurs naturally in food (especially red meat and some green vegetables). It is also produced by friendly bacteria in our gut. We all need it as it helps to make our blood clot and to prevent bleeding problems. Newborn babies and young infants have very little vitamin K.

How do low levels of Vitamin K affect a newborn baby?

A very small number of babies suffer bleeding problems due to a shortage of vitamin K.

This is called Vitamin K Deficiency Bleeding (or VKDB for short). The classical form usually happens in the first week of life. The baby may bleed from the mouth or nose or from the stump of the umbilical cord.

Late onset VKDB is a more serious problem which happens after the baby is about three weeks old. The bleeding is sometimes into the gut or the brain and in some cases it can cause brain damage or even death.

How can Vitamin K Deficient Bleeding be prevented?

The Scottish Government recommends that all newborn babies are given vitamin K to reduce the chances of dangerous internal bleeding. The most effective treatment is a single dose of vitamin K injected into the thigh muscle shortly after birth. Vitamin K by mouth is also effective in most cases but your baby will need to have a number of doses through the first 1-3 months of life. Vitamin K by mouth may not work in a small number of babies.

Does my baby get vitamin K from their milk?

Whilst breastfeeding is recommended due to its many benefits for baby and mother, it contains very little vitamin K, and therefore breast feeding does not prevent VKDB. Most cases of VKDB in the UK occur in breastfed babies who have not any vitamin K supplements or in babies who have not completed a full course of vitamin K given by mouth (if some doses are missed or vomited) [1].

Formula milk has vitamin K added (except Soya Formula) but some formula fed babies, who have not had an injection of vitamin K, do get VKDB if they have problems with their liver [1]. Babies with liver disease do not absorb vitamin K very well from their milk.

When do I need to start thinking about this?

During your pregnancy you must consider whether your baby should receive vitamin K, and if so, how it should be given. Vitamin K for your baby should be given as soon as possible after birth.

What is the risk?

VKDB occurs in one in every 8,500 full term babies if no vitamin K supplement is given. In the whole of the UK, if no vitamin K supplement was given, 10 to 20 of the 800,000 babies born each

year might be brain damaged as a result of a bleed into the brain, and about five babies would die of this condition.

Final thoughts

If you decide against vitamin K supplements for your baby it is extremely important to be aware of the risk of VKDB. **Remember that in most cases there are no warning signs**.

You should seek medical help at once if there is any of the following

- Easy bruising especially around the baby's head and face.
- Bleeding from the nose or umbilical cord
- Jaundice (yellow eyes and skin) after the first 3 weeks
- Blood in the stool, black tarry stool or vomiting blood
- Paler than usual skin colour
- Irritability, seizures, excessive sleepiness, or repeated vomiting

This leaflet has been written to help you understand the importance of giving your baby vitamin K, but do not be alarmed. VKDB is uncommon and, although serious, the condition is preventable.

Further information

[1]McNinch A, Busfield A, Tripp J Vitamin K deficiency bleeding in Great Britain and Ireland: British Paediatric Surveillance Unit Surveys, 1993–94 and 2001–02 Archives of Disease in Childhood 2007;92:759-766.