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Vitamin K Administration in the Newborn and Early Infancy

Introduction and Aim

To provide clarity for health professionals on the subject of Vitamin K for neonates.

Objectives

Prophylactic administration of Vitamin K as Konakion MM Paediatric reduces the risk of Vitamin K deficiency bleeding (VKDB).

Scope

All health professionals working in maternity and neonatal care.

Equality Health Impact Assessment	*An Equality Health Impact Assessment (EHIA) has not been completed.*
Documents to read alongside this Procedure	
Approved by	*Maternity Professional Forum*

Accountable Executive or Clinical Board Director	*Ruth Walker, Executive Nurse Director*
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Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	*June 2011*	*June 2011*	
2	June 2014	Oct 2014	Reviewed and amended by Ailsa Nonely

3	12/01/2018	15/01/2018	Reviewed and Amended by Ailsa Nonely
4	6/7/2022	07/07/2022	Reviewed and amended by Helen Lawrence

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2. Rationale

Prophylactic administration of Vitamin K reduces the risk of Vitamin K deficiency bleeding (VKDB)

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3. Antenatal Information Sharing

The administration of Vitamin K should be discussed with the expectant parent by the community midwife providing care at the 16 week and 36 week antenatal appointments. Expectant parents should be informed of the recommendation to give Vitamin K to all newborn infants. This discussion should be documented in the maternity handheld records as part of the plan for birth. The expectant parent should be provided with an information leaflet at the 16 week appointment. This leaflet can also be viewed on the Cardiff and Vale University website:

VITAMIN K (nhs.wales)

The Department of Health, Welsh Office and the Royal College of Paediatrics and Child Health recommend that all babies are given Vitamin K by intramuscular injection as soon as possible after birth. Expectant parents should be informed of this information. Early administration within the first 24 hours of birth can minimise the risk of early Vitamin K deficiency bleeding.

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4. 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 0.5mg 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 advise administration of 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 below). 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 oral Vitamin K 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.

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- 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.

5. Intramuscular Vitamin K

5.1 Administration

The administration of an intramuscular dose of Vitamin K is recommended for all babies born in Wales. It should be administered soon after birth. This is a ONCE only dose. The dose is:-

1mg of Vitamin K IM for infants 36+0 gestation or greater

A lower dose is recommended for infants < 36 weeks gestation. The dose of Vitamin K to be given will depend upon the infant's birth weight.

Weight of infant	Dose of Vitamin K at birth	Injection Volume
Under 1kg	0.4mg	0.04ml
1kg to 1.5kg	0.6mg	0.06ml
Over 1.5 to 2kg	0.8mg	0.08ml
Over 2kg	1mg	0.1ml

Phytomenadione (Vitamin K) 2mg in 0.2ml solution for injection is used in Cardiff and Vale University Health Board. For the correct dose, see above.

Intramuscular administration to premature babies weighing < 2.5kg may increase the risk for the development of kernicterus.

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 prescribed by the neonatologist via the oral route or by intravenous injection if the enteral route is contraindicated or unreliable.

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5.2 Prescription for IM Vitamin K

Intramuscular Vitamin K can be administered by the midwife as detailed in the UHB's Midwives Exemptions (Neonatal Drugs). All medication administered to neonates should be checked by two qualified members of staff. Checking and administration of IM Vitamin K should be documented on a paediatric in-patient medication administration record.

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6. Oral Vitamin K

The mother or birthing person of a healthy, mature infant who declines intramuscular Vitamin K should be offered oral Vitamin K

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6.1 Administration

Phytomendadione 2mg/0.2mg oral solution should be given as soon as possible following birth and within 24 hours of birth.

A second oral dose of Insert name of Vitamin K 2mg should be given within the first week of life (days 4 -7). A TTH should be given to the parent prior to discharge. If this is not completed then two community midwives will be required to attend the infant at home to give oral Vitamin K.

A further third oral dose will be required if the infant is still being exclusively breast fed between days 21 to 28. Vitamin K 2mg should be given at this time. Infants that are receiving formula by days 21 to 28 do not required a third oral dose of Vitamin K.

If the infant vomits soon after administration of oral Vitamin K, a further dose should be given.

Any oral doses of Vitamin K administered to a neonate should be documented on a paediatric in patient medication administration record.

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 or birthing persons who are taking carbamazepine, phenobarbital, phenytoin, rifampicin or warfarin at the time of delivery.

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6.2 Prescription for oral Vitamin K

Oral Vitamin K can be administered by the midwife as detailed in the UHB's Midwives Exemptions (Neonatal Drugs). All medication administered to neonates should be checked by two qualified members of staff. Checking and administration of oral Vitamin K should be documented on the paediatric in patient medication administration record.

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6.3 Vegan oral Vitamin K

Vegan oral Vitamin K is available to order from pharmacy. This however may need to be ordered in advance and may not be available at short notice. One preparation of vegan oral vitamin K is available to order and dosing information is below:

Neokay capsules 1mg: the contents of the capsule are made with coconut oil but the capsule does contain gelatin so to avoid ingestion of this, the following should occur;

- Oral prophylaxis in healthy neonates, including healthy preterm babies: The contents of a single Neokay capsule should be administered by cutting the narrow tubular tip off the capsule and squeezing the liquid into the baby's mouth. Another dose should be given if the first dose is spat out or the baby is sick within three hours of the dose being given.
- Exclusively breast fed babies: The administration of 1mg Neokay by mouth at birth protects healthy term babies from the risk of bleeding due to vitamin K deficiency in the first week of life. Evidence to date suggests that for babies who are being exclusively breast-fed, a dose of 1mg once weekly for 12 weeks offers the best protection against late vitamin K deficiency bleeding.

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7 Supporting parents who may 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, it is important to explore the reasons why a parent may decline and to ensure that they are correctly informed of the risks of Vitamin K deficient bleeding and the potential for serious long term morbidity and mortality.

If a parent wishes to decline Vitamin K administration via any route after discussion with a midwife, a neonatologist (Tier 2 or above) should be requested to attend to support information sharing and exploration of any issues with the parents.

See Appendix 1 – Supporting parents who may decline Vitamin K prophylaxis

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7.1 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. Bleeding may also occur later than this over the following few months. This is known as ‘Late’ VKBD. Both Classical and Late VKDB are preventable by giving the baby vitamin K.
- 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 every Welsh maternity unit recommends this treatment for all babies.
- 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.

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8 Auditable Standards

- Antenatal information sharing regarding Vitamin K administration should occur at the 16 and 36 week appointments and be clearly documented in the antenatal handheld notes. (Standard 100%)
- Correct documentation of administration of Vitamin K on the paediatric in-patient medication administration chart. (Standard 100%)
- Any mother or birthing person who declines intramuscular Vitamin K should be offered oral vitamin K for their baby. This should be clearly documented in the patient notes. (Standard 100%)

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9 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

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Appendix 1

Vitamin K Antenatal Information Leaflet

Information for parents

This leaflet explains what vitamin K is, and its importance in preventing bleeding problems in newborn babies. If you would like further information to support your decision making, please contact your named midwife.

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. All babies are born with low levels of vitamin K. As babies mature and feed well, they begin to produce their own supply of vitamin K from natural bacteria found in their bowel. They can also get a small amount of vitamin K from their mother's breast milk and it is added to formula milk.

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 VKBD) for short. A classical form of VKBD usually happens around the first week of life. The baby may bleed from the mouth or nose or from the stump around 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 Department of Health, the Welsh Government, NICE and the Royal College of Paediatrics and Child Health recommend 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 in the first month of life. Vitamin K by mouth is not advised for high risk, sick or premature babies. Vegan vitamin K is also available to give your baby by mouth. For a small number of babies, vitamin K may not be effective when given by mouth. This may because

the baby has difficulty absorbing the vitamin or if the baby vomits after the baby has been given vitamin K.

Are some babies at a higher risk of Vitamin K Deficient Bleeding?

Babies who are thought to be at a higher risk include those who:

- are premature
- had a complicated birth requiring the use of forceps or ventouse, where bruising has taken place
- have liver disease
- cannot absorb fat-soluble vitamins due to diarrhoea, coeliac disease or cystic fibrosis
- are babies of mothers taking anti-convulsant medications
- are babies of mothers with significant liver disease

It is impossible to identify all babies who will definitely be high risk. 1 in every 4 babies who develop VKBD have none of the problems above.

What is the risk?

VKBD 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 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 five babies would die of this condition.

Can vitamin K be harmful?

A concern was expressed in the early 1990s that there was a link between vitamin K supplements and leukaemia or other cancers. A careful review of the data from the UK Children's Cancer Study Group in 2003 found no evidence to support this.

When do I need to start thinking about this?

During your pregnancy you should 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. If you would like your baby to have vegan vitamin K by mouth, please let your midwife know in your pregnancy so the vitamin K can be ordered ready for your baby.

What if I say no to vitamin K for my baby?

Parents of healthy term babies have the option to decline to give their baby Vitamin K. Following birth, a midwife and a neonatologist (baby doctor) will offer to explore with you the reasons why you may wish to decline to give your baby vitamin K. They will support you to ensure that you have the correct information for your decision making.

Further information

If you would like further information to support your decision making, please contact your named midwife

Appendix 2

Information for Parents who are Considering Declining Vitamin K for their Baby

This information leaflet has been provided to help you to make a decision about whether to give your baby vitamin K.

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 need it as it helps our blood to clot and to prevent bleeding problems. All babies are born with low levels of vitamin K.

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

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 Deficiency Bleeding (VKBD), previously known as Haemorrhagic Disease of the Newborn (HDN).

Bleeding most commonly occurs between day 2 and day 7 of life. This is known as 'Classical' VKBD. Bleeding may also occur later than this over the following few months. This is known as 'Late' VKBD. Both Classical and Late VKBD are preventable by giving the baby vitamin K.

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

The excessive bleeding seen in VKBD may appear as sever 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.

How can Vitamin K Deficient Bleeding be prevented?

The Department of Health, the Welsh Government, NICE and the Royal College of Paediatrics and Child Health recommend 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.

Alternatively vitamin K can be given in a liquid form into your baby's mouth and your baby will need to have a number of doses in the first month of life. Vitamin K given by mouth can be almost as effective as the intramuscular injection if all doses required are given.

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 the injection of vitamin K as the safest option. However, if you do not want the intramuscular injection then oral vitamin K can be given to your baby.

Vegan Vitamin K

Vegan Vitamin K can be given orally to your baby. This may not be immediately available from the pharmacy. Please ask your midwife for more information about vegan vitamin K.

Are some babies at a higher risk of Vitamin K Deficient Bleeding?

Babies who are thought to be at a higher risk include those who:

- are premature
- had a complicated birth requiring the use of forceps or ventouse, where bruising has taken place
- have liver disease
- cannot absorb fat-soluble vitamins due to diarrhoea, coeliac disease or cystic fibrosis
- are babies of mothers taking anti-convulsant medications
- are babies of mothers with significant liver disease

It is impossible to identify all babies who will definitely be high risk. 1 in every 4 babies who develop VKBD have none of the problems above.

What is the risk?

VKBD occurs in one in every 8,500 full term babies if no vitamin K supplement is given. The risk for exclusively breastfed babies is higher – around one in every 1,200 babies. In the whole of the UK, if no vitamin K 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 five babies would die of this condition.

Can vitamin K be harmful?

A concern was expressed in the early 1990s that there was a link between vitamin K supplements and leukaemia or other cancers. A careful review of the data from the UK Children's Cancer Study Group in 2003 found no evidence to support this.

What if I say no to vitamin K for my baby?

If you decide against vitamin K 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

Appendix 3

Supporting parents who may decline Vitamin K prophylaxis