



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Policy and Procedure on the Administration of Vitamin K (Konakion MM Paediatric) Prophylaxis for Newborn Infants, HSE Home Birth Service

Document Reference Number	HB005	Document Developed By	Sub-group of the Clinical Governance Group for the HSE Home Birth Service, chaired by Ms. Michelle Waldron
Revision Number	2	Document Approved By	Clinical Governance Group for the HSE Home Birth Service, chaired by Mr Bill Ebbitt
Approval Date	January 2018	Responsibility for Implementation	National Implementation Steering Group for the HSE Home Birth Service chaired by Ms Mary Wynne
Revision Date	January 2020	Responsibility for Review and Audit	Clinical Governance Group for the HSE Home Birth Service

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1. Policy Statement

This policy mandates the Self-Employed Community Midwife (SECM) to administer Vitamin K (Konakion MM® Paediatric) to all newborn infants who have been delivered at home under the Health Service Executive (HSE) Home Birth Service, with the consent of the mother.

2. Purpose

- 2.1. To provide a policy and procedure to support the SECM in offering information, obtaining informed consent and administering Vitamin K (Konakion MM® Paediatric).
- 2.2. To support compliance with current best practice guidance and ensure safe, competent practice for all SECMs providing the administration of Vitamin K (Konakion MM® Paediatric) to prevent Vitamin K deficiency bleeding in the newborn (VKDB).
- 2.3. To support the SECM in giving advice to the mother.

3. Scope

This policy and procedure applies to all SECMs who provide home birth services on behalf of the Health Service Executive.

4. Legislation, Codes of Practice, Standards and Guidance

- 4.1. Guidance to Nurses and Midwives on Medication Management (NMBI, 2007)
- 4.2. Recording Clinical Practice (NMBI 2015)
- 4.3. Postnatal Care Clinical Guideline: Routine care for women and their babies, CG No. 37 (NICE 2006)
- 4.4. Protocol for the administration of Konakin MM Paediatric for the prophylactic treatment of Vitamin K deficiency in neonates, National Maternity Hospital Document PP-CS-DT-5
- 4.5. Vitamin K (Konakion MM® Paediatric) Prophylaxis for Newborn Infants, Our Lady of Lourdes Hospital Maternity Unit Document RCGP 22 (HSE 2013)

This list is not exhaustive and reference should be made at all times to the guideline for reference sources or the database of legislation, codes of practice, standards and guidance (Clinical Governance Group for the HSE Home Birth Service 2018).

5. Definitions

- 5.1. **Early Vitamin K Deficiency Bleeding (VKDB)** Occurs from birth to two weeks of age (formerly known as classic haemorrhagic disease of the newborn). It is rare and confined to infants of mothers who have

- received medications that interfere with Vitamin K metabolism (National Health and Medical Research Council (NHMRC 2010)).
- 5.2. **Late Vitamin K Deficiency Bleeding (VKDB)** A syndrome defined as unexpected bleeding attributable to severe Vitamin K deficiency in infants two to 12 weeks of age. This occurs primarily in exclusively breastfed infants who have received no or inadequate neonatal vitamin K prophylaxis. Approximately half of these infants will have underlying malabsorption or liver problems (NHMRC, 2010).
- 5.3. **Vitamin K** (Also known as phytomenadione or konakion MM) is a vitamin necessary for the production of blood clotting factors.

6. Roles and Responsibilities

6.1. HSE National Director of Primary Care

- 6.1.1. Shall ensure the provision of appropriate systems and structures to support the SECM to provide Vitamin K prophylaxis for all newborn infants for the HSE Home Birth Service.

6.2. The Chief Officer

- 6.2.1. Shall ensure the implementation of systems and structures to provide Vitamin K prophylaxis for all newborn infants for the HSE Home Birth Service

6.3. The Designated Midwifery Officer (DMO)

shall ensure:

- 6.3.1. That the appropriate systems and structures are in place to implement this policy.
- 6.3.2. That a copy of this policy and procedure is made available to all SECMs, and record same.
- 6.3.3. That appropriate professional support is provided as required to the SECM.
- 6.3.4. That monitoring and audit of this policy and procedure are undertaken on a regular basis

6.4. The SECM

shall:

- 6.4.1. Comply with this policy and procedure.
- 6.4.2. Communicate to the woman the importance of Vitamin K prophylaxis for the newborn and provide information to support this.
- 6.4.3. Obtain written consent to undertake the administration of Vitamin K prophylaxis to the newborn.
- 6.4.4. Document appropriately if the mother declines administration.

7. Procedure for Vitamin K Prophylaxis for Newborn Infants

7.1. Background: Current national and international guidelines recommend that all newborn infants receive a single dose of 0.5-1mg of Vitamin K intramuscularly at birth as this is the most clinical and cost-effective method of administration (Dermott et al, 2009). Vitamin K prophylaxis protects almost all babies if given intramuscularly or by multi-dose oral regimes (Busfield et al, 2012). Administration of Vitamin K requires informed consent. Explanation and education regarding Vitamin K deficiency bleeding signs and symptoms should be offered to the woman (NICE, 2006).

7.2. Procedure for the intramuscular injection of Vitamin K

- 7.2.1. The SECM should inform the woman during the antenatal period of the importance of Vitamin K prophylaxis for their newborn infant. The SECM should provide the woman with a Vitamin K administration information leaflet (Appendix I).
- 7.2.2. Vitamin K should be prescribed by the doctor and obtained by the woman.
- 7.2.3. The woman should be advised to store the Vitamin K at home as per the pharmaceutical instructions.
- 7.2.4. The SECM should seek informed consent from the mother prior to the administration of Vitamin K.
- 7.2.5. Vitamin K should be administered as soon as possible after birth. The SECM is responsible for both the administration and documentation of the Vitamin K.
- 7.2.6. The second midwife should check the prescription, drug, and dose and expiry date with the midwife following delivery.
- 7.2.7. A single intramuscular injection of Vitamin K Konakion MM Paediatric ampoules (Phytomenadione/Vit K 2mg/0.2ml) is recommended.
- 7.2.8. Dosage is according to birth weight (adapted from the National Maternity Hospital Protocol).

Weight of infant	Dose of Vitamin K	Injection volume
2 kg-2.29kg	0.8mg	0.08ml
2.3kg-2.49kg	0.9mg	0.09ml
2.5kg or more	1mg	0.1ml

- 7.2.9. Konakion MM Paediatric should be prepared in a 1ml syringe and administered using a 25g (orange) needle.
- 7.2.10. The injection should be administered at a 45-degree angle into the quadriceps muscle (vastus lateralis) in the lateral mid-third of the thigh.
- 7.2.11. If the mother declines intramuscular Vitamin K a multi-dose oral regime using Konakion MM Paediatric should be offered.

7.3. Procedure for oral Vitamin K administration.

- 7.3.1 The SECM should ascertain that the drug is prescribed.
- 7.3.2 The SECM must receive and document consent from the mother.
- 7.3.3 When gaining consent, the SECM should ensure that the mother is aware of the need for multiple oral doses of Vitamin K.

7.3.4 2mg (0.2mls) of Konakion MM Paediatric should be prepared using the oral syringe supplied in the pharmaceutical supplier's box.

Method of infant feeding	Oral dose of Vitamin K	Frequency
Formula	2mg	At birth Second dose between day 4 and 7
Exclusively Breastfed	2mg	At birth Second dose between day 4 and 7 Third dose at one month old administered by mother or (sometimes) PHN

7.3.5 Document in baby's notes that a prescription for oral Vitamin K has been received and the mother has consented to give it to her baby.

7.3.6 The syringe should be placed into the baby's mouth towards the cheek; the drug should be administered into the mouth and the baby's swallow should be observed.

7.3.7 The SECM should observe the baby for signs of aspiration.

7.3.8 Administration of oral Vitamin K must be documented by the SECM in the mother's clinical record.

7.3.9 The SECM should inform the mother that the oral treatment regimen determines that all babies (bottle and breastfed) are administered a repeat oral dose of 2mg Konakion MM Paediatric between days four and seven of life.

7.3.10 The SECM should inform the mother that exclusively breastfed babies should receive a further dose at one month of age. Standard infant milk formulae are supplemented with Vitamin K. Mothers should be reassured that breastfeeding remains the optimum method of infant nutrition.

7.3.11 Mothers should be given a reminder letter by the SECM for the Public Health Nurse to administer oral Vitamin K at one month old (Appendix II) if the PHN in the area provides this service or the mother can administer the third dose herself.

7.3.12 The SECM should be aware that oral Vitamin K is unsuitable for babies of mothers who were on medication for epilepsy, blood clotting disorders or tuberculosis during the pregnancy. Research suggests that the baby may not be able to absorb oral Vitamin K and may require Vitamin K intramuscularly (reference from information leaflet).

7.4. Contraindications to intramuscular Vitamin K

7.4.1 Family history of a bleeding disorder e.g. haemophilia

7.4.2 Neonatal alloimmune thrombocytopenia

7.5. Parental decline of Vitamin K

7.5.1 If a mother declines the administration of any form of Vitamin K to the newborn baby the SECM should offer the opportunity for further discussion between the mother and the paediatrician or doctor (Appendix III).

7.5.2 If a mother declines the administration of any form of Vitamin K to their newborn baby, then the SECM shall request that they

- sign an opt-out form indicating that they have read and understand the importance of Vitamin K prophylaxis and have made an informed decision to decline it (Appendix III).
- 7.5.3 The SECM should inform the DMO, DPHN and GP and furnish each of them with copies of the signed opt-out form.

8. Monitoring and Audit

- 8.1. Monitoring of compliance with this policy and procedure shall be undertaken by the DMO.
- 8.2. Audit of compliance with this policy and procedure shall be undertaken by the SECM, DMO or other nominated HSE professionals.

9. Training

The SECM shall ensure that she/he has sourced appropriate education and training to support the implementation of this policy and procedure.

10. Implementation Plan

The Clinical Governance Group for the HSE Home Birth Service developed this document, which has been approved for implementation by the National Implementation Steering Group for the HSE Home Birth Service. This document will be piloted for a year from the approval date. It will be disseminated by the Designated Midwifery Officers to relevant healthcare personnel and to all Self-Employed Community Midwives who provide home birth services on behalf of the HSE.

11. Appendix I

Vitamin K Parent Information Leaflet

VITAMIN K should be given to all babies at birth.

WHAT IS VITAMIN K?

Vitamin K is a vitamin that occurs naturally in food. We all need Vitamin K; it helps to make blood clot in order to prevent bleeding.

WHY IS VITAMIN K GIVEN TO NEWBORN BABIES?

Newborn babies have very little Vitamin K, which can lead to a condition known as Vitamin K Deficiency Bleeding (VKDB). This is a serious but rare condition that can lead to internal bleeding and can result in brain damage or death. By giving newborn babies a Vitamin K supplement the condition can be almost completely prevented. All newborn babies are given Vitamin K with their parents' permission.

WHICH BABIES ARE AT A GREATER RISK OF BLEEDING?

Premature babies (babies born before 36 weeks)

Babies delivered by forceps or vacuum

Babies delivered by caesarean section

Babies who are ill, have difficulty absorbing feeds or have prolonged jaundice.

Babies whose mother took certain drugs in pregnancy (e.g. drugs for epilepsy, anti-coagulants, anti-tuberculosis drugs).

HOW IS VITAMIN K GIVEN?

There are two ways of giving Vitamin K to your baby:

- by injection
- by mouth

It is currently recommended that a single injection of Vitamin K is given into a muscle shortly after birth to prevent Vitamin K Deficient Bleeding. The National Institute of Clinical Excellence (NICE) guidelines clearly recommend that one injection into a muscle is the best treatment (NICE, 2006).

If you choose to give the Vitamin K to your baby by mouth, then your baby will need **two** or **three** doses to get the same result as the injection.

- The first dose is given soon after birth
- The second dose is given when the baby is between four and seven days old.
- Exclusively breast milk-fed babies should receive a third dose of Vitamin K orally at one month old.

You will have to get a Vitamin K prescription from your doctor and collect it at your local pharmacy. You will have to give written consent to give/not give Vitamin K to your baby.

Your Public Health Nurse will be informed in writing regarding the need to give any additional doses of Vitamin K to your baby.

IS VITAMIN K SAFE FOR MY BABY?

In 1990 and 1992 concerns were raised following studies in Bristol in the UK over the possible association between childhood cancer and Vitamin K injection to newborn

babies. A careful review of data from the UK Children's Cancer Study Group found no evidence that neonatal Vitamin K administration, irrespective of route, influences the risk of children developing leukaemia or any cancer (Fear et al, 2003).

POSSIBLE SIDE EFFECTS

Local irritation may occur where the injection was given. Rarely this may be severe. Signs include redness, swelling, pain, and it may cause a scar.

If you need any further information please ask your midwife or doctor, who will be happy to help.

References

Fear et al (2003), Vitamin K and Childhood Cancer: A Report from the United Kingdom Childhood Cancer Study. British Journal of Cancer 89(7):1228-1231

National Institute of Clinical Excellence (NICE) (2006), Routine Care of Women and Their Babies. www.nice.org.uk/nicemedia/pdf/CG37NICEguideline.pdf

12. Appendix II

Letter to the Public Health Nurse for babies who require administration of oral Vitamin K



**Feidhmeannas Seirbhíse Sláinte
Health Service Executive**

SECM

Infant of

Mother's name and address

Baby's Date of Birth _____

Breastfeeding

Date

Dear Public Health Nurse,

Please note that this baby has received 2mg oral Vitamin K at birth and on day four, and is due another 2mg oral dose of Vitamin K when this baby is one month old.

Yours sincerely

.....
SECM Name and Contact details

13. Appendix III

Opt-Out of Vitamin K Prophylaxis Form

Date: _____

Woman's name and

address: _____

I have been given written information on Vitamin K prophylaxis to prevent early and late onset Vitamin K deficiency bleeding in newborn babies.

Yes no

I have been informed that national and international guidelines recommend that all newborn infants receive Vitamin K prophylaxis either by a single intramuscular injection after birth or by an oral regime.

Yes no

I wish to discuss this further with my GP/consultant paediatrician or Public Health Nurse.

Yes no

I am making an informed decision not to give my baby prophylaxis Vitamin K.

Yes no

Signed by

Mother: _____

Partner: _____

Witnessed By: _____ **SECM**

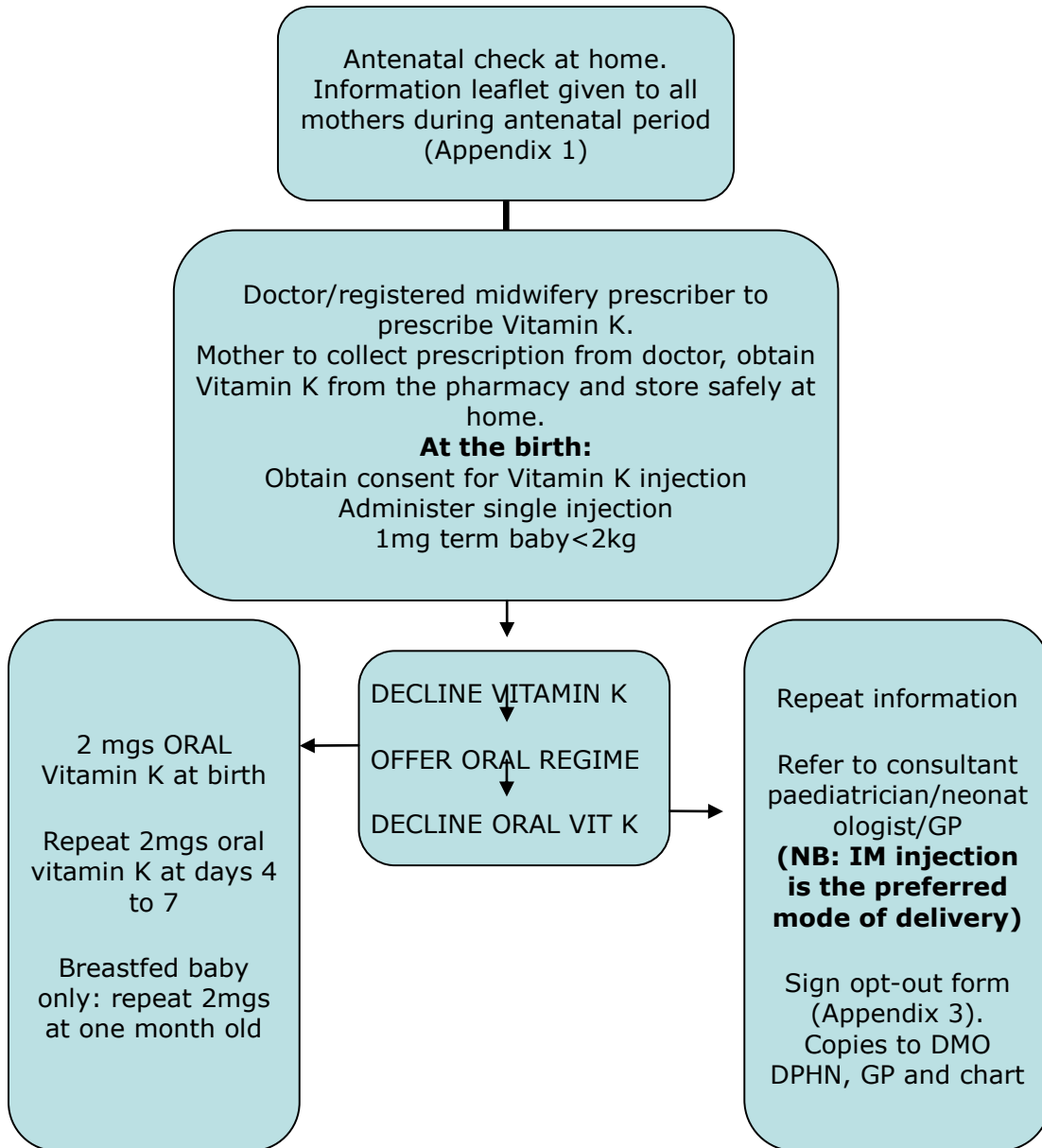
Date _____

Copies as appropriate to:

DMO, DPHN, GP, consultant paediatrician, copy filed in notes

14. Appendix IV

Flowchart for Vitamin K prophylaxis



15. Membership of Working Group

The Clinical Governance Group (CGG) for the HSE Home Birth Service commissioned a Sub-Group (members below) to develop this document which was then reviewed by the Quality Assurance Sub Group (members below). A final draft was produced by the CGG members and recommended for approval to the National Implementation Steering Group for Home Births (NISG). Following a 12 month pilot of this document, the NISG have approved its revision and implementation.

Sub-Group Members:

Ms Michelle Waldron, Designated Midwifery Officer HSE DNE (Sub-group chair)

Ms Sue Ryan Designated Midwifery Officer HSE South

Mr Bill Ebbitt Primary Care Manager, HSE

Dr John Bermingham, Consultant Obstetrician, WRH

Quality Assurance Sub-Group:

Dr Karen Robinson, Risk Advisor Clinical Indemnity Scheme (CIS) (Sub-group chair)

Ms Brigid Doherty, Patient Focus

Ms Virginia Pye, National Lead for Public Health Nursing (ONMSD)

Dr Edwina Dunne, Assistant National Director, Quality & Patient Safety (QPS)

