# Vitamin K/ Phytomenadione Prophylaxis in Newborn Babies

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| **Classification**: | Guideline |
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| **Authors Job Title:** | Senior Midwives |
| **Authors Division:** | Women's and Children's Health |
| **Departments/Group this Document applies to:** | Maternity |

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| **Approval Group:** Women's Health Guideline Review Group | **Date of Approval:** | Dec 2022 |
| | **Last Review:** | Aug 2022 |
| | **Review Date:** | Aug 2025 |

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| **Unique Identifier:** MIDW/GL/117 | **Status:** Approved | **Version No:** 6 |

**Guideline to be followed by (target staff):** Women and Children's Health Division

**To be read in conjunction with the following documents:**
Milton Keynes University Hospital NHS Foundation Trust. *Vitamin K for Newborn Babies.* Patient Information Leaflet. MIDW/PI/09. Version 7, 2019

**CQC Fundamental standards:**
Regulation 9 – person centered care
Regulation 11 – Need for consent
Regulation 12 – Safe care and treatment
Regulation 13 – Safeguarding service users from abuse and improper treatment
Regulation 17 – Good governance

## Disclaimer –

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.
The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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## Guideline Statement

To support staff to give Vitamin K prophylaxis to newborn babies.

## Executive Summary

This guideline is based on NICE's recommendations concerning Vitamin K for newborn babies alongside the British National Formulary (BNF) July 2022

Newborn infants have very low levels of Vitamin K which is needed for normal clotting. The aim of prophylactic treatment is to avoid Vitamin K deficiency bleeding (VKDB). Haemorrhage from this can occur in a variety of sites, including the brain.

## Definitions

ANNP – Advanced Neonatal Nurse Practitioner
IM – Intramuscular
IV – Intravenous
PCHR - Personal Child Health Record
VKDB – Vitamin K deficiency bleeding

## 1.0 Roles and Responsibilities:

Midwives – Antenatal education providing the Vitamin K leaflet, discuss the parent's wishes regarding administration at birth and gain consent. Document route of administration and follow up required. Community Midwives to ensure Vitamin K given at birth and if further doses needed.

Paediatricians – Identify high risk neonates if maternal conditions exist, ensure Vitamin K given and discuss with parents. Assist with prescribing IM Vitamin K if required. Update Baby Alert if required.

Neonatal staff – Assist with administration and documentation of Vitamin K if required to babies admitted to the neonatal unit.

## 2.0 Implementation and dissemination of document

This guideline will be available on the Trust intranet site.

## 3.0 Processes and procedures

### 3.1 The recommendations are as follows:

- "All parents should be offered vitamin K prophylaxis for their babies to prevent the rare but serious and sometimes fatal disorder of vitamin K deficiency bleeding.
- Vitamin K should be administered as a single dose of 1 mg intramuscularly as this is the most clinically and cost-effective method of administration.
- If parents decline intramuscular vitamin K for their baby, oral vitamin K should be offered as a second-line option and will require multiple doses.

### 3.2 Certain groups of babies are at high risk of early or classic VKDB:

1. Mother on anticonvulsant, anti-tuberculous drugs or anticoagulants e.g. carbamazepine, phenobarbitol, phenytoin, rifampicin or warfarin.
2. Mothers with liver disease
3. All instrumental deliveries and difficult deliveries (shoulder dystocia).
4. Delivered less than 36 weeks gestation.
5. Unable to tolerate oral feeds.
6. Babies who have experienced birth asphyxia or bleeding problems.

- For these babies the oral route is **not** recommended, and the Vitamin K should be given intramuscularly.

### 3.3 Prescribing of Vitamin K

| **Patient group** | **Initial dose of Vitamin K** Konakion MM Paediatric (2mg/0.2ml) | **Frequency** | **Who should prescribe and administer?** |
|---|---|---|---|
| Healthy Neonate of 36 weeks gestation or older,<br><br>*irrespective of birthweight* | 1mg IM at birth (0.1ml of 2mg/0.2ml Injection)<br><br>OR<br>Oral dose 2mg (0.2ml) | IM:<br>Single stat dose<br><br>Oral:<br>Two doses (At birth and days 4-7 of life)<br><br>Exclusively breast-fed babies should be given an additional dose at 1 month of age | Midwife may administer under the midwife exemptions.<br><br>Subsequent doses should be prescribed by a medical practitioner (GP or neonatologist) |
| Babies at high risk or Preterm neonate of less than 36 weeks gestation and weighing more than 2.5kg | 1mg IM at birth | IM:<br>Single stat dose | Midwife may administer under the midwife exemptions. ( This is not currently on eCare ME's) |
| Preterm neonate of less than 36 weeks gestation and weighing less than 2.5kg | 0.4mg/kg IM | IM:<br>Single stat dose | A neonatologist must prescribe; administration may be by a midwife (if IM) or neonatal nurse |

NICE's recommendations concerning Vitamin K for newborn babies alongside the British National Formulary (BNF) July 2022

### 3.4 Procedure for Administration

1. All mothers should be informed about Vitamin K prophylaxis by the Midwife in the antenatal period and given an information leaflet. The discussion should be recorded on eCare during a routine antenatal appointment.

2. The midwife caring for the mother in labour should confirm the parent's preference for the route of administration for Vitamin K and record it on eCare and the Personal Child Health Record (PCHR).

3. Information leaflet (accessible on intranet and maternity web page) to be given and all discussions should be recorded on eCare the Personal Child Health Record and in the Neonatal Discharge Summary produced for the GP.

4. **Following delivery the Midwife should administer the Vitamin K at the earliest opportunity.** (This does not need to interrupt skin to skin contact between mother and baby).

5. The route and dose should be clearly recorded in the Baby's eCare records, the PCHR and subsequently on the Community Discharge Form.

6. Babies who have received the oral route of Vitamin K and are noted to vomit within an hour of the administration should have a further dosage of the same amount (2 mg). Babies who continue to vomit and are unable to tolerate the oral route, should be given Vitamin K intramuscularly with the parents' consent.

7. The person (Midwife/Paediatrician/ANNP) undertaking the neonatal examination should check that the Vitamin K was given. If it is not recorded, enquiries should be made as to whether Vitamin K was not given or not recorded. If not given, and the parents are agreeable for the baby to receive it, then it should be administered promptly.

8. Babies who receive Vitamin K orally need further doses, as follows: -
   - 2 mg /0.2 mls orally Phytomenadione/Vitamin K at 4-7 days of age (irrespective of type of feed).
   - 2 mg/ 0.2 mls orally Phytomenadione/Vitamin K at 1 month of age, if exclusively breast fed at the time. This is prescribed by the GP.

9. For babies who have received the Vitamin K orally and are exclusively breastfed on transferring care the Midwife should inform the Health Visitor of the probability of the baby requiring further doses of Vitamin K.

10. The Health Visitor should assess the need for a further supplement at 1 month of age.

11. The subsequent dose (at 1 month) where necessary should be prescribed by the GP. The administration of this is by the Health Visitor or Practice Nurse and the information recorded on the PCHR.

## 4.0 Statement of evidence/references

The Human Medicines Regulations 2012 (SI 2012/1916). [Online]. Available from: http://www.legislation.gov.uk/uksi/2012/1916/contents/made [Accessed 18/08/2022]

Paediatric Formulary Committee. Phytomenadione. *BNF for Children* [Online]. Available from: https://bnfc.nice.org.uk/drug/phytomenadione.html [Accessed 18/08/2022]

# 5.0 Governance

## 5.1 Document review history

| Version number | Review date | Reviewed by | Changes made |
|---|---|---|---|
| **1** | | | **Descroption of roles and responsibilities** |
| **3.2** | | | Formatting and moving section 3.2 to above prescribing table |
| **3.3** | | | Documentation to be made on eCare |
| **4** | | | Change of reference list |
| **5** | | | Reviewed |
| **6** | Aug 2022 | Donna James, Katrina Caen | Reviewed and updated. |

## 5.2 Consultation History

| Stakeholders Name/Board | Area of Expertise | Date Sent | Date Received | Comments | Endorsed Yes/No |
|---|---|---|---|---|---|
| Julie Cooper | Head of Midwifery | 29/08/2019 | 30/08/2019 and 02/12/2019 | Formatting, changes to wording regarding eCare. | Yes |
| Jayne Plant | Library | 21/10/2019 | 18/11/2019 | Formatting and references changed or updated | Yes |
| Niamh Kelly | Clinical Governance | 21/10/2019 | 22/10/2019 | New Trust template, comments given | Yes |
| All staff in Women's Health | | 18/11/2019 | | See individual comments | |
| Fran Mngola | Pharmacist | 18/11/2019 | 20/11/2019 | Comments received | Yes |
| Karen Rice | NNU | 18/11/2019 | | Nil comments received | |
| Indranil Misra | NNU | 18/11/2019 | | Nil comments received | |
| Zuzanna Gawlowski | NNU | 18/11/2019 | | Nil comments received | |
| Denise Campbell | Paediatrics | 18/11/2019 | 18/11/2019 | Comments received | Yes |
| Janice Styles | Consultant Midwife | 25/8/22 | 25/8/22 | Confirming format of dosages. | Yes |
| Ruth Nyarko | Community Midwife | 19/8/22 | 23/8/22 | Clarification of use of information leaflet | Responded |
| Marion Forster | Practice Educator | 19/8/22 | 19/8/22 | Wording change | Yes |

## 5.3 Audit and monitoring

| Audit/Monitoring Criteria | Tool | Audit Lead | Frequency of Audit | Responsible Committee/Board |
|---|---|---|---|---|
| a) Consent is gained for the administration of Vitamin K.<br>b) Numbers of parents declining Vitamin K and reasons.<br>c) That babies receiving oral Vitamin K received subsequent doses. | Audit | Audit Midwife | 3 yearly | Women's Health |

### 5.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible, remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

| Equality Impact Assessment | | | |
|---|---|---|---|
| Division | Women & Children's Health | Department | Maternity |
| Person completing the EqIA | Katrina Caen and Donna James | Contact No. | |
| Others involved: | | Date of assessment: | 18/08/2022 |
| Existing policy/service | Yes | New policy/service | No |

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| Will patients, carers, the public or staff be affected by the policy/service? | Yes |
| If staff, how many/which groups will be affected? | All Midwives, Neonatal staff |

| Protected characteristic | Any impact? | Comments |
|---|---|---|
| Age | NO | Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff |
| Disability | NO | |
| Gender reassignment | NO | |
| Marriage and civil partnership | NO | |
| Pregnancy and maternity | YES | |
| Race | NO | |
| Religion or belief | NO | |
| Sex | NO | |
| Sexual orientation | NO | |

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| What consultation method(s) have you carried out? |
| Sent via email for consultation to all staff, discussed at guideline review group. |
| How are the changes/amendments to the policies/services communicated? |
| Email minutes, guideline monthly memo. |
| What future actions need to be taken to overcome any barriers or discrimination? |

| What? | Who will lead this? | Date of completion | Resources needed |
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| Review date of EqIA | Aug 2025 | | |