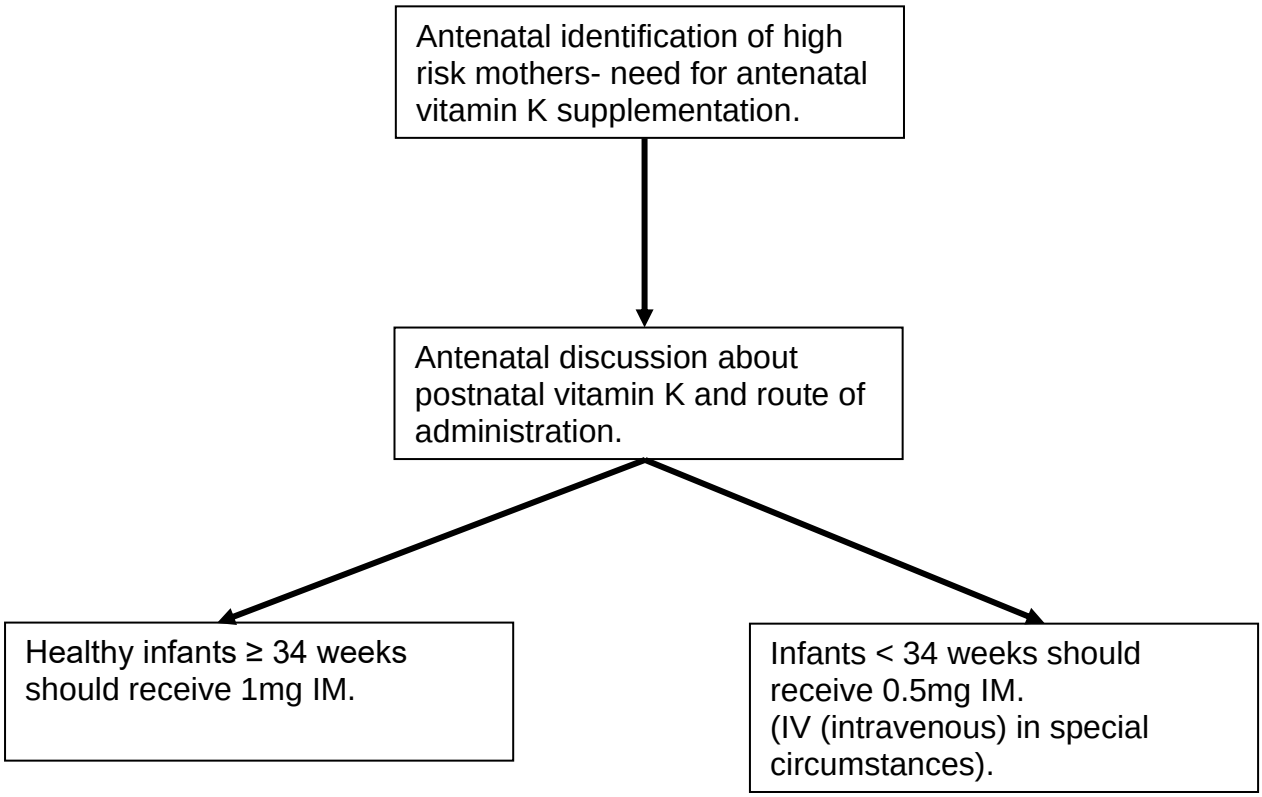
Royal Cornwall Hospitals
NHS Trust

Vitamin K Administration
Neonatal Clinical Guideline

V4.0

May 2025

Summary



IM (intramuscular) vitamin K is the gold standard.
If declined oral vitamin K can be given in repeated doses, see schedule below.

1. Aim/ Purpose of this Guideline

1.1. This guideline applies to all staff responsible for the administration of Vitamin K (Phytomenodium) to newborn babies.

1.2. This version supersedes any previous versions of this document.

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

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2. The Guidance

2.1. The administration of Intramuscular Vitamin K helps can prevent Vitamin K Deficiency Bleeding (VKDB) or Haemorrhagic Disease of the Newborn (HDN) developing.

Vitamin K deficiency occurs because of poor placental transfer, the absence of Vitamin K_2 producing bacteria in the sterile fetal (and early neonatal) gut and due to liver immaturity.

Breast milk has particularly low levels of vitamin K. Formula feeds are supplemented.

If left untreated VKDB can cause significant internal bleeding which can result in brain damage or death.

2.2. **Antenatally**

Parents should be made aware antenatally of the evidence supporting the administration of Vitamin K to newborn infants, together with the Trust guideline regarding Vitamin K administration.

2.2.1. The Antenatal discussion should be documented in maternal obstetric notes and should contain:

- Whether parental consent has been given.
- The dose and route of administration of Vitamin K.
- An account of a full discussion with parents if they decline Vitamin K administration or choose oral administration.

2.2.2. Parents' wishes should be reaffirmed when the mother goes into labour.

2.2.3. High risk infants, see below (2.3), should be identified so that mothers can receive oral Vitamin K supplementation prior to their infant's birth.

2.3. **Dose**

A single intramuscular injection of vitamin K remains the gold standard in the prevention of classic and late VKDB. The most recent evidence continues to show an advantage of IM vitamin K even over repeat oral doses. Doses should be appropriately prescribed and documented administration.

2.3.1. Term Infants (34 weeks or ≥):

All healthy infants of 34 weeks and above should receive 1mg (0.1ml) Vitamin K (Konakion MM Paediatric) as soon as is practical after birth.

2.3.2. Preterm Infants (34 weeks or ≤):

All infants under 34 weeks gestation should receive 0.5mg (0.05ml via the included special syringe) Vitamin K (Konakion MM Paediatric) intramuscular (or intravenously on medical advice).

2.3.3. At Risk Infants:

Mothers at high risk (taking potentially hepatic enzyme inducing drugs during pregnancy, i.e., phenytoin, phenobarbitone, carbamazepine, primidone, topiramate, rifampicin, isoniazid, and warfarin) should be identified, so that oral Vitamin K 20mg is given daily for 4 weeks prior to delivery.

2.4. Oral Vitamin K

2.4.1. If parents have opted for oral administration, Vitamin K is given by mouth as soon as possible after birth as Konakion MM Paediatric 2 mg (0.2 mls). This should be repeated in all babies as a single extra dose at 4 - 7 days.

2.4.2. RCH only stock the Konakion MM brand of phytomenadione which contains glycholic acid derived from beef. Vegetarians and vegans may not feel comfortable giving this to their baby. Please see below for alternatives.

Vegan alternatives to Konakion MM Paediatric are limited, if parents are unhappy using Konakion MM Paediatric due to the beef content, they have the option of purchasing an alternative over the counter as vitamin K supplements are classed as a food supplement. One such alternative is Neokay oral drops (not the capsules as these contain gelatin), but availability is often limited. Ideally the decision to use an alternative should be made prior to birth to allow the parents to obtain supplies. Please be aware that food supplements may require different dosing regimens to prescribed vitamin K.

2.4.3. In those exclusively breast fed, all babies should have a further dose as Konakion MM Paediatric 2 mg should be given at 1 month of age (BNFc (British National Formulary for Children)).

2.4.4. The BNFc suggests an alternative regime of phytomenadione (Neokay capsules) 1mg at birth then 1mg weekly for 12 weeks in exclusively breast-fed infants.

2.4.5. Unless there are any clinical concerns which puts the baby at higher risk, there is no indication to discuss declining vitamin K or choice for oral vitamin K with the Neonatal team if discussions have already been held ante and perinatally.

2.4.6. Responsibility for Administration of Oral Vitamin K

2.4.6.1. In Hospital:

- At Birth: The hospital midwife will administer vitamin K orally.
- At 4-7 days: The hospital midwife will administer vitamin K orally. Details of these doses will be documented at discharge.

2.4.6.2. Not In Hospital:

- At birth: The community Midwife will administer vitamin K orally.
- At 4 -7 days: the community midwife will administer the Vitamin K orally. The parents can be shown how to administer the Konokian. The vitamin K vial can be given to parents if it is anticipated parents will administer at one month.
- At 1 month (only if exclusively breast fed): The community midwife will administer the dose, unless the parents are happy to do so.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Key Changes to practice.
Lead	Dr. Chris Bell.
Tool	Audit, recorded on either Excel or Word document.
Frequency	As dictated by audit findings.
Reporting arrangements	Child Health Directorate Audit and Neonatal Clinical Guidelines Group.
Acting on recommendations and Lead(s)	Dr. Chris Bell. Consultant Paediatrician and Neonatologist.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 3 months. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Vitamin K Administration Neonatal Clinical Guideline V4.0.
This document replaces (exact title of previous version):	Vitamin K Administration Neonatal Clinical Guideline V3.1.
Date Issued/Approved:	May 2025.
Date Valid From:	May 2025.
Date Valid To:	May 2028.
Directorate / Department responsible (author/owner):	Dr. Chris Bell; Neonatal Consultant.
Contact details:	01872 252667.
Brief summary of contents:	This guideline outlines the management of an infant regarding the administration of Vitamin K. It also considers the information that needs to be provided to, and management of mothers, antenatally.
Suggested Keywords:	Vitamin K. Neonatal. Phytomenodium.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer.
Approval route for consultation and ratification:	Neonatal Audit and Guidelines Meeting.
Manager confirming approval processes:	Caroline Chappell.
Name of Governance Lead confirming consultation and ratification:	Michael Cross.
Links to key external standards:	None required.
Related Documents:	1. Haemorrhagic disease of the newborn in the British Isles: Two year prospective study. McNinch AW, Tripp JH. BMJ 1991;303:1105-1109. 2. Cornelissen E.A.M. Effects of Oral and

Information Category	Detailed Information
	Intramuscular Vitamin K Prophylaxis on vitamin K1. PIVKA - II and clotting factors in breast fed infants. Arch. Dis. Child. 1992;67:1250 - 1254. 3. Von Kries and Goble. Lancet 1994;343;352. 4. Baenzigro, Lancet 1996;348;1456. 5. Cornelissen M. Prevention of vitamin K deficiency bleeding: Efficacy of different multiple oral dose schedules of vitamin K. European Journal of Paediatrics 1997;156;126 – 30. 6. Alison Busfield, Andrew McNinch, John Tripp Neonatal vitamin K prophylaxis in Great Britain and Ireland:the impact of perceived risk and product licensing on effectiveness Arch Dis Child 2007;92:754–758. doi: 10.1136/adc.2006.105304. 7. Vitamin K for newborn babies. PL/CMO/98/3 PL/CNO/98/4. 8. Busfield A, et al. Arch Dis Child 2013;98:41–47. doi:10.1136/archdischild- 2011-301029.
Training Need Identified?	No.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet.
Document Library Folder/Sub Folder:	Clinical/ Newborn Care.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
February 2015	V1.0	Initial Issue and Formatting.	Author: Paul Munyard. Consultant Paediatrician and Neonatologist. Formatter: Kim Smith. Staff Nurse.

Date	Version Number	Summary of Changes	Changes Made by
February 2019	V2.0	Minor change of document title. Flow chart added. Minor change in dosing schedule.	Author: Paul Munyard. Consultant Paediatrician and Neonatologist.
January 2022	V3.0	Minor updates to formatting.	Chris Bell; Neonatal Consultant.
July 2023	V3.1	Formatting update. Section 2.4.5.2. updated.	Chris Warren; Paediatric Consultant.
February 2025	V4.0	Patient Information Leaflet added as appendix. Reference to NICE guidance removed. Section 2.4.5 added.	Jenna Julian; Advanced Neonatal Nurse Practitioner.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Vitamin K Administration Neonatal Clinical Guideline V4.0
Directorate and service area:	Neonatal
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Neonatal Audit and Guidelines Group
Contact details:	01872 252667

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	This guideline is aimed at clinical staff responsible for the administration of neonatal Vitamin K to infants both in the acute hospital setting and also in the community.
2. Policy Objectives	As above.
3. Policy Intended Outcomes	As above.
4. How will you measure each outcome?	Audit.
5. Who is intended to benefit from the policy?	Patients.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Neonatal Audit and Guidelines group
6c. What was the outcome of the consultation?	Approved.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No.

7. The Impact
Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	Any information provided should be in an accessible format for the parent/ carer needs- i.e., available in different languages if required/ access to an interpreter if required.

Protected Characteristic	(Yes or No)	Rationale
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	Those parent/ carer with any identified additional needs will be referred for additional support as appropriate- i.e., to the Liaison Team or for specialised equipment. Written information will be provided in a format to meet the family's needs e.g., easy read, audio etc.
Religion or belief	No	All staff should be aware of any beliefs that may impact on the decision to treat and should respond accordingly.
Marriage and civil partnership	No	All staff should be aware of any marital arrangements that may have an impact on care (for example: separated parents).
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Neonatal Audit and Guidelines Group.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Vitamin K Patient Information Leaflet

Vitamin K Patient Information Leaflet RCHT 3034.