Vitamin K Administration Neonatal Clinical Guideline

V2.0

March 2019
Summary

Antenatal identification of high risk mothers – need for antenatal Vit K supplementation

Antenatal discussion about postnatal Vit K and route of administration

Healthy infants ≥ 34 weeks should receive 1mg im

Infants < 34 weeks should receive 0.5mg im (IV in special circumstances)

IM Vit K is the gold standard. If declined oral Vit 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. **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 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 can’t rely on Opt out, it must be Opt in.

The DPA18 covers how the Trust obtains, hold, record, use and store all personal and special category (e.g. Health) information in a secure and confidential manner. This Act covers all data and information whether held electronically or on paper and extends to databases, videos and other automated media about living individuals including but not limited to Human Resources and payroll records, medical records, other manual files, microfilm/fiche, pathology results, images and other sensitive data.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the ‘information use framework policy’, or contact the Information Governance Team rch-tr.infogov@nhs.net

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. (Appendix 3).

2.2. **Antenatally**

Parents should be made aware antenatally of the evidence supporting the administration of Vitamin K to new-born 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 to their infant

2.2.2. Parents’ wishes should be reaffirmed when the mother goes into labour. The advice of a Paediatrician can be sought if required.

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.

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. This is in compliance with NICE guidance on postnatal care.

2.3.2. Preterm Infants (34 weeks or ≤):
All infants under 34 weeks gestation should receive 0.5mg (0.05ml via a special syringe from pharmacy) Vitamin K (Konakion MM Paediatric) intramuscularly (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.

2.3.4. All neonates with medical concerns (illness, severe jaundice, surgical conditions) will need to be discussed with a senior member of the medical team prior to the administration of Vitamin K.

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. 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).

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

2.4.4. Responsibility for Administration of Oral Vitamin K

2.4.4.1. 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.

2.4.4.2. 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. At 1 month.
- Administration will be determined locally by the GP, who may administer the vitamin K, or delegate to the health visitor or district nurse.
3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Key Changes to practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Dr. Paul Munyard</td>
</tr>
<tr>
<td>Tool</td>
<td>Audit</td>
</tr>
<tr>
<td>Frequency</td>
<td>As dictated by audit findings</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>Child Health Directorate Audit and Neonatal Clinical Guidelines Group</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>Dr. Paul Munyard. Consultant Paediatrician and Neonatologist.</td>
</tr>
</tbody>
</table>

| 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, Inclusion & Human Rights 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

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Vitamin K Administration Clinical Guideline V2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>26th February 2019</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>February 2019</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>February 2022</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Dr Paul Munyard, Consultant Paediatrician and Neonatologist</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252667</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>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.</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Vitamin K. Neonatal. Phytomenodium</td>
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<tr>
<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>February 2019</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>Administration of Vitamin K – Neonatal Clinical Guideline V1.0</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Consultant approval. Child Health Directorate Audit. Neonatal Clinical Guidelines Group</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes</td>
<td>Debra Shields, Care Group General Manager</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>Not required</td>
</tr>
<tr>
<td>Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Name: Caroline Amukusana</td>
<td></td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet</td>
</tr>
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</table>
Related Documents:

7. www.nice.org.uk/guidance/CG37
8. Vitamin K for newborn babies. PL/CMO/98/3 PL/CNO/98/4

Training Need Identified? No

Version Control Table

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry. This document is only valid on the day of printing

Controlled Document
This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.
Appendix 2. Initial Equality Impact Assessment Form

This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed</th>
<th>Vitamin K Administration Neonatal Clinical Guideline V2.0</th>
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</thead>
<tbody>
<tr>
<td>Directorate and service area:</td>
<td>Women’s Children’s and Sexual Health, Neonatal</td>
</tr>
<tr>
<td>Is this a new or existing Policy:</td>
<td>Existing</td>
</tr>
<tr>
<td>Name of individual completing assessment:</td>
<td>Dr. Paul Munyard</td>
</tr>
<tr>
<td>Telephone:</td>
<td>01872 252667</td>
</tr>
</tbody>
</table>

1. **Policy Aim***

   *Who is the strategy / policy / proposal / service function aimed at?*
   
   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.

3. **Policy Objectives***

   As above

3. **Policy – intended Outcomes***

   Audit

4. *How will you measure the outcome?*

   Audit

5. **Who is intended to benefit from the policy?***

   Patients

6a Who did you consult with

<table>
<thead>
<tr>
<th>Workforce</th>
<th>Patients</th>
<th>Local groups</th>
<th>External organisations</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

b). Please identify the groups who have been consulted about this procedure.

Consultant led Neonatal Guidelines Group
7. The Impact

Please complete the following table. **If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.**

Are there concerns that the policy could have differential impact on:  

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race / Ethnic communities /groups</td>
<td>x</td>
<td></td>
<td></td>
<td>Information provided should be in an accessible format for the parent’s/ carer’s needs – i.e available in different languages if required/access to an interpreter if required</td>
</tr>
<tr>
<td>Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.</td>
<td>x</td>
<td></td>
<td></td>
<td>Those parent’s/ carer’s 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</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
<td>x</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Marriage and Civil partnership</td>
<td>x</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Pregnancy and maternity</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**You will need to continue to a full Equality Impact Assessment if the following have been highlighted:**

- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation- this excludes any policies which have been identified as not requiring consultation. or
- Major this relates to service redesign or development
8. Please indicate if a full equality analysis is recommended.  

| Yes | No | ✓ |

9. If you are **not** recommending a Full Impact assessment please explain why.

No areas indicated

**Signature of policy developer / lead manager / director**  
Dr. Paul Munyard

**Date of completion and submission**  
26/02/19

**Names and signatures of members carrying out the Screening Assessment**

1. Dr. P. Munyard  
2. Human Rights, Equality & Inclusion Lead

**Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead**  
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa,  
Truro, Cornwall, TR1 3HD

**This EIA will not be uploaded to the Trust website without the signature of the**  
**Human Rights, Equality & Inclusion Lead.**

A summary of the results will be published on the Trust’s web site.

Signed ___P. Munyard___________

Date ___26/02/19___________
Appendix 3. Vitamin K Medical Factsheet

Low levels of Vitamin K are associated with potentially lethal Vitamin K deficiency bleeding (VKDB). Vitamin K deficiency occurs because of poor placental transfer, the absence of Vitamin K₂ 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.

Can be divided by time of presentation

**Early VKDB (<24 hours):** rare, more likely in infants of mothers on anticonvulsants or anti-TB therapy. Bleeds occur from the skin, umbilicus, GI tract or intracranial, and can be life threatening. Identify mothers at risk antenatally, treat them with Vitamin K in the last 4 weeks of pregnancy, as well as intramuscular or intravenous Vitamin K to the infant at birth.

**Classic VKDB (2-7 days):** occurs in up to 1.7% of unsupplemented breast fed infants. May present with skin, GI tract or nasal bleeding. Prolonged bleeding may occur after venepuncture or circumcision.

**Late VKDB (8 days - 6 months):** Presents with skin, GI tract or intracranial bleeds. Carries a 20% mortality and risk of neurological sequelae.

It must be emphasised that many serious bleeds are proceeded by minor episodes, and therefore any concerns regarding abnormal bleeding in infants < 6months old should be investigated urgently.

A single intramuscular injection of vitamin K remains the gold standard in the prevention of classic and late VKDB¹. The most recent evidence continues to show an advantage of IM vitamin K even over repeat oral doses.²,³,⁴,⁵.

This policy is supported by The National Institute of Clinical Excellence, in its guidance on Post Natal Care⁶, which states that all parents should be offered vitamin K prophylaxis for their babies and that vitamin K should be administered as a single dose of 1 mg intramuscularly.

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.

If the oral route is selected a single repeat dose at 4 – 7 days is recommended for all babies. If exclusively breast fed then a further dose at 1 month is required.

Other risk factors include certain maternal drugs, anticonvulsants, warfarin and anti-TB therapy, which interfere with vitamin K metabolism. Liver disease, fat malabsorption (eg cystic fibrosis) or chronic diarrhoea will also put the infant at increased risk.
**Safety of Intramuscular Vitamin K**

In the early 1990’s there were reports of a possible association between IM Vitamin K and childhood cancers, at least 10 subsequent studies have not found this association.

A communication from the Chief Medical and Nursing Officers\(^7\) concluded that there was no increase in leukaemia or solid tumours in childhood.

**Newer findings.**

The incidence of VKDB has not changed since 2006, with changes in vitamin K preparations, IM prophylaxis does not prevent all cases (eg. those with liver disease), and the incidence could be halved if all parents consented to prophylaxis\(^8\).