Vitamin K Prophylaxis in Newborn Babies

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Departments/Group this Document applies to:	Maternity

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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 centred 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 – For clinical Guideline only

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 in their guideline on postnatal care (CG37, 2006, updated 2015)

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:

Obstetricians – Assist with identifying the high-risk neonates in pregnancy, discuss with parents and document. Complete a baby alert referral to inform Paediatricians.

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 IV 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.

Health Visitors – Identify at first initial visit that Vitamin K has been administered, route given and if further doses required.

General Practitioners – Provide postnatal care to neonate, prescribe the 1-month dose if oral route chosen and exclusively breastfeeding.

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. **[2006]**

- 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. **[2006]**

- 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. **[2006]"** (NICE, CG37, 2006, updated 2015, Sections 1.4.42-44)

3.2 Certain groups of babies are at high risk

(a) 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.

  For preterm babies Vitamin K may be given 400 micrograms/kg (max. 1mg). (BNFC, 2019)

(b) Of late onset VKDB:
1. Babies with liver disease or other bleeding disorders.

- These babies may present with prolonged jaundice with pale stools/dark urine or with minor bleeds from the skin, nose or mouth. At any time in the first 6 months of life, minor bleeds should be investigated, especially in the breast-fed babies.

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, *irrespective of*	1mg IM at birth (0.1ml of 2mg/0.2ml Injection)	IM: Single stat dose	Midwife may administer under the midwife exemptions. Midwife may administer under the exemptions as

birthweight	**or** Oral dose 2mg (0.2ml)	Oral: Two doses (At birth and days 4-7 of life) Exclusively breast-fed babies should be given an additional dose at 1 month of age	laid out in Schedule 17 of the Human Medicines Regulations 2012 (as amended) This should be documented on eCare. 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 or IV at birth (0.1ml of 2mg/0.2ml injection)	IM: Single stat dose IV: Any babies receiving IV vitamin k should receive subsequent oral dosing	Midwife may administer under the midwife exemptions. This should be documented on eCare. IV: A neonatologist must prescribe; administration may be by a neonatal nurse
Preterm neonate of less than 36 weeks gestation and weighing less than 2.5kg	0.4mg/kg IM or IV at birth Dose will be evaluated by a neonatologist	IM: Single stat dose IV: Any babies receiving IV vitamin k should receive subsequent oral dosing	A neonatologist must prescribe; administration may be by a midwife (if IM) or neonatal nurse

(Based on BNFC entry for phytomenadione (2019), and eMC Summary of Product Characteristics for Konakion MM Paediatric (2019)

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. Where consent is withheld the midwife should discuss with the paediatric registrar who should then speak with the parents. Information leaflet to be given and all discussions should be recorded in the electronic maternal records. If consent continues to be

withheld this fact should be recorded in the baby's electronic records, 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 KONAKION MM Paediatric (0.2 mls orally) at 4-7 days of age (irrespective of type of feed).
   - 2 mg KONAKION MM Paediatric (0.2 mls orally) at 1 month of age, if exclusively breast fed at the time.

9. Babies who are having oral Vitamin K require a second dose on days 4-7 of birth. If they are an inpatient this should be administered by the midwives on the ward or nurses on NNU.
   If the baby is at home, Community Midwives will visit on Day 5 and administer the 2nd dose as part of the routine Day 5 visit. This is then documented in the PCHR.

10. 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.

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

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

13. Mothers will be strongly advised to remind the Midwife/Health Visitor of the need for this to be given.

4.0 Statement of evidence/references

Ardell, S., et al. (2018) Prophylactic vitamin K for the prevention of vitamin K deficiency bleeding in preterm neonates. *Cochrane Database of Systematic Reviews* 2018, Issue 2. Art. No.: CD008342. DOI: 10. 1002/14651858.CD008342.pub2. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008342.pub2/full [Accessed 15 November 2019]

Department of Health (1998) *Vitamin K for newborn babies*. PL/CMO/98/3; PL/CNO/98/4. [Online]. Available from: https://webarchive.nationalarchives.gov.uk/20000815094022/http://www.doh.gov.uk:80/cmo/cmo98_3.htm [Accessed 15 November 2019] *Note that this document has been archived*.

Electronic Medicines Compendium (emc). *Konakion MM Paediatric 2 mg/0.2ml*. Patient information leafet. Last updated February 2019. [Online]. Available from: https://www.medicines.org.uk/emc/product/9754/pil [Accessed 15 November 2019]

Electronic Medicines Compendium (emc*). Konakion MM Paediatric 2 mg/0.2ml*. Summary of Product Characteristics. Last updated 22 February 2019. [Online]. Available from: https://www.medicines.org.uk/emc/product/9754/smpc [Accessed 15 November 2019]

The Human Medicines Regulations 2012 (SI 2012/1916). [Online]. Available from: http://www.legislation.gov.uk/uksi/2012/1916/contents/made [Accessed 15 November 2019] *Note that this link is to the regulations as originally made – please check for amendments to the legislation, which are listed here*: http://www.legislation.gov.uk/changes/affected/uksi/2012/1916

National Institute for Health and Care Excellence (2006, updated 2015) *Postnatal care up to 8 weeks after birth*. Clinical guideline [CG37] [Online]. Available from: https://www.nice.org.uk/guidance/cg37 [Accessed 15 November 2019]

Paediatric Formulary Committee. Phytomenadione. *BNF for Children* [Online]. Available from: https://bnfc.nice.org.uk/drug/phytomenadione.html [Accessed 15 November 2019]

Puckett, R.M. and Offringa, M. (2000) Prophylactic vitamin K for vitamin K deficiency bleeding in neonates. *Cochrane Database of Systematic Reviews 2000*, Issue 4. Art. No.: CD002776. DOI: 10.1002/14651858.CD002776. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD002776/full [Accessed 15 November 2019]

5.0 Governance

5.1 Document review history

Version number: 5			**Date:** 11/2019	
Section Number	**Amendment**	**Deletion**	**Addition**	**Reason**
1.0			Description of roles and responsibilities	
3.2			Formatting and moving section 3.2 to above prescribing table	
3.3		Documentation on drug charts	Documentation to be made on eCare	**Change in process**
4.0	Change of reference list	Previous references removed and replaced correctly.		

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

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. b) Numbers of parents declining Vitamin K and reasons. c) That babies receiving oral Vitamin K received subsequent doses.	Audit	Audit Midwife	2 yearly	Women's Health CIG

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	Laura Andrews	Contact No.	
Others involved:		Date of assessment:	20/11/2019
Existing policy/service	Yes	New policy/service	No

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	NO	
Race	NO	
Religion or belief	NO	
Sex	NO	
Sexual orientation	NO	

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
What future actions need to be taken to overcome any barriers or discrimination?

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