

## Prophylaxis against Vitamin K deficiency bleeding in Newborns - Full Neonatal Clinical Guideline

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### Introduction

All new-born infants are deficient in Vitamin K and Vitamin K dependent coagulation factors. Vitamin K prevents haemorrhagic disease of the new-born which may be fatal or cause brain damage.

### Aim and Purpose

This guideline provides advice for medical and nursing staff to ensure all babies receive the appropriate prophylaxis Vitamin K dose at birth.

### Background information

Intramuscular Vitamin K gives virtually 100% protection and it has been the policy in South Derbyshire to give this to all babies born in our unit for the past twenty years. There now have been many well controlled studies that have refuted the links between intramuscular Vitamin K and childhood cancer previously reported in Golding *et al* in 1992.

Cochrane Review 2020 has stated

“A single dose (1.0 mg) of intramuscular vitamin K after birth is effective in the prevention of classic Haemorrhagic Disease of the Newborn (HDN). Either intramuscular or oral (1.0 mg) vitamin K prophylaxis improves biochemical indices of coagulation status at 1-7 days. Neither intramuscular nor oral vitamin K has been tested in randomized trials with respect to effect on late HDN. Oral vitamin K, either single or multiple doses, has not been tested in randomized trials for its effect on either classic or late HDN. Different methods of prophylaxis have been tested in randomized trials for their effect on coagulation status and vitamin K levels, but these outcomes are of uncertain clinical importance. When single doses of oral and intramuscular vitamin K are compared, the only difference found is lower plasma vitamin K levels in the oral group at two weeks. Despite this, there is no evidence of a difference in indices of coagulation status. When three doses of oral vitamin K (Konakion MM) are compared to a single dose of intramuscular vitamin K, the plasma vitamin K levels are higher in the oral group at two weeks and two months, but, again, there is no evidence of a difference in coagulation status”

Three types of vitamin K deficiency bleeding (VKDB) have been classified:

1. Early onset - occurring in the first 24 hours post-birth
2. Classic - occurring at days 2 to 7
3. Late onset – occurring at 2 to 12 weeks and up to 6 months of age

Early VKDB is commonly associated with maternal medications that inhibit vitamin K activity, such as antiepileptics. Classic VKDB is associated with low intake of vitamin K, and late VKDB with chronic malabsorption and low vitamin K intake

## Doses

Table 1: The recommended intramuscular doses are as follows:

Konakion MM Paediatric Phytomenadione 2 mg/0.2 ml solution for injection	Weight of the baby	Dose of vitamin K at birth	Injection volume
	<1.5 kg	0.5 mg	0.05 ml
	≥1.5 kg	1 mg	0.1 ml

Important note: All babies whose parents do not wish intramuscular Vitamin K to be given should be offered the oral preparation in the Delivery Suite as below. If still in hospital when subsequent doses are due, these will be prescribed and administered as an in-patient. If parents wish to exercise their right to choose and decline intramuscular vitamin K for their baby, oral vitamin K should be offered as a second-line option. Parents should be advised that oral vitamin K must be given according to the manufacturer's instructions for clinical efficacy and will require multiple doses.

Table 2: Oral option for vitamin K, where IM Phytomenadione has been declined

RDH ONLY:	QHB ONLY:	
Neokay (Phytomenadione) 1mg capsules	Oral option:	Konakion MM Paediatric Phytomenadione 2 mg/0.2 ml solution for injection
The contents of ONE capsule (1mg) to be administered at birth or soon after.  *If to be exclusively breast fed, the contents of ONE capsule (1mg) to be administered WEEKLY, for an additional 11 weeks.	<b>Dose 1:</b> At birth or soon after	2mg (= 0.2mL)
	<b>Dose 2:</b> Day 4 - 7	2mg (= 0.2mL)
	<b>Dose 3:</b> 1 month of age (unless exclusively formula fed*)	2mg (= 0.2mL)

*\*Breast fed infants are at particular risk of late onset haemorrhagic disease of the newborn and require repeated doses. If breastfeeding mother chooses to switch to formula feeding then oral doses can be discontinued.*

Parents who choose not to take up the offer of prophylaxis against Vitamin K deficiency take responsibility of that decision. The Paediatrician must be notified and the decision recorded in the notes.

## Discharge

If vitamin K is being administered orally as per table 2 above, remaining doses must be provided by the ward the baby is being discharged from.

## References

- a) The Cochrane Library, 2020 available online:  
[https://www.cochrane.org/CD002776/NEONATAL\\_prophylactic-vitamin-k-for-vitamin-k-deficiency-bleeding-in-neonates](https://www.cochrane.org/CD002776/NEONATAL_prophylactic-vitamin-k-for-vitamin-k-deficiency-bleeding-in-neonates) Last accessed 20.10.2020
- b) Konakion MM Paediatric, Roche Products Ltd., Summary of Product Characteristics, 2020 available online: [www.medicines.org.uk/emc/product/9754/smpc](http://www.medicines.org.uk/emc/product/9754/smpc) last accessed 23.10.20
- c) Neokay, Neoceuticals Ltd., Summary of Product Characteristics, 2017, available online: [www.medicines.org.uk/emc/product/2677/smpc](http://www.medicines.org.uk/emc/product/2677/smpc) last accessed 23.10.20
- d) Canadian Paediatric Society, Guidelines for vitamin K prophylaxis in newborns, 2018 available online: [www.cps.ca/en/documents/position/vitamin-k-prophylaxis-in-newborns](http://www.cps.ca/en/documents/position/vitamin-k-prophylaxis-in-newborns) last accessed 23.10.20

## Documentation Controls

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