

Northern Neonatal Operational Delivery Network



Clinical Guideline

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This clinical guideline has been developed to ensure appropriate evidence based standards of care throughout the Northern Neonatal Operational Delivery Network (NNODN). The appropriate use and interpretation of this guideline in providing clinical care remains the responsibility of the individual clinician. If there is any doubt please discuss with a senior colleague. It is the responsibility of all users of this guideline to ensure that the correct version is being used.	

Document History

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1.0 Introduction

1.1 Rationale for vitamin and iron supplementation

The third trimester of pregnancy is a period of rapid nutrient accretion and the time when fat-soluble vitamin stores are laid down. Premature birth interrupts this process, consequently preterm infants have lower stores of fat-soluble vitamins and potentially higher requirements for all vitamins than those born at term.

Preterm and low birth weight infants are at risk of iron deficiency due to low stores at birth, higher requirements due to rapid growth, losses caused by frequent blood sampling, the requirement for parenteral nutrition support for the smallest and sickest infants, which does not routinely contain iron and breast milk does not contain iron.

This guideline covers how to prevent fat soluble vitamin deficiency and iron deficiency in preterm infants by ensuring internationally recommended requirements are met on the neonatal unit.

2.0 Guideline Scope

2.1 Scope & Evidence

Recommendations for vitamins are based on the 'BDA/NDIG The routine supplementation of vitamins and iron and the management of zinc deficiency in preterm and small for gestational age infants: guidance for clinical practice' (1) which was produced by a combination of clinical consensus and thorough literature search, comprising three international publications (2-4) and a detailed quantitative analysis of milk, fortifier and vitamin formulations by gestation and weight (5-13).

Recommendations for iron have been agreed using a combination of review of the BDA/NDIG clinical guidance document and pragmatic discussion by the Network Nutrition Specialist Interest Group.

This guideline is to be used as an adjunct to clinical decision making. Where infants are receiving volumes of milk considered outside the "usual" range of 150 -165mL/kg/day, advice should be sought from a neonatal dietitian or unit infant feeding leads.

2.2 Supply & Alternatives

A limited range of suitable multivitamin and iron preparations are available for use in the preterm population (Appendix 1). It is widely recognised that intermittent supply issues of first line vitamin preparations bring difficulties in provision to infants. A table of alternative products suitable for use during these periods, or where peanut and soya avoidance is prudent, can be found in Appendix 2.

3.0 Recommendations for vitamin supplementation

3.1 Preterm vitamin requirements

	ESPGHAN (2022)
Thiamine (B1) (micrograms/kg/day)	140-290
Pantothenic acid (B5) (mg/kg/day)	0.6-2.2
Biotin (B7) (micrograms/kg/day)	3.5-15
Niacin (B3) (micrograms/kg/day)	1100-5700
Vitamin C (Ascorbic acid) (mg/kg/day)	17-43
Riboflavin (B2) (micrograms/kg/day)	200-430
Pyridoxine (B6) (micrograms/kg/day)	70-290
Folic acid (B9) (micrograms/kg/day)	23-100
Cobalamin (B12) (micrograms/kg/day)	0.1-0.6
Vitamin A (Retinol) (international units/kg/day)	1333-3300 (400-1000micrograms retinol ester/kg/day)
Vitamin D (Colecalciferol) (international units/kg/day)	400-700 international units/kg/day (<1000 international units/day)
Vitamin E (Alpha-tocopherol) (mg/kg/day)	2.2 – 11
Vitamin K (Phytomenadione) (micrograms/kg/day)	4.4 – 28

Recommended enteral intakes for vitamins (ESPGHAN) (2)

3.2 Who should receive vitamin supplementation?

The gestation below which additional vitamins are required is unclear, consequently supplementation practice has, in the past, varied across the UK.

Current guidelines provide recommendations for vitamin intakes in extremely low birth weight (ELBW) and very low birth weight (VLBW) infants (3) and for infants <1800g (2) but neither make any delineation by degree of prematurity.

The vitamin requirements of late and moderate preterm (LMPT) infants, defined as infants born 32+0 – 33+6 weeks gestation (moderate preterm) and 34+0 – 36+6 weeks gestation (late preterm), are likely to be higher than those for term infants, but again, there are insufficient data to inform intake levels for any except for vitamin D. Current recommendations are to provide all LMPT infants with a vitamin D supplement from birth and throughout early childhood (14, 15).

Due to the lack of detailed guidance, a pragmatic approach needs to be taken as to the population this guideline applies to however, available evidence would suggest vitamin supplementation (in particular, vitamin D) is required for all infants born <37 weeks gestation.

3.3 Single Dosing Pragmatic Approach

Born <34weeks and/or <1.8kg	
Fortified breastmilk (Gold Prem® or Nutriprem® fortifier) OR Nutriprem® 1/Gold Prem® 1	Abidec® 0.6mL/day
Unfortified breastmilk (not recommended *)	Abidec® 0.6mL/day and Colecalciferol 300 international Units/day
On reaching 1.8kg - 2kg ** or discharge ** dependent upon local policy for change to nutrient enriched post discharge formulas	
Fortified breastmilk (Gold Prem® or Nutriprem® fortifier) (including fortified breastmilk feeding post discharge) OR Gold Prem® 2/Nutriprem® 2 OR Term/Specialist/High Calorie Term Formula	Abidec® 0.6mL/day
Unfortified breastmilk and/or breastfeeding	Abidec® 0.6mL/day. 50 micrograms vitamin K once daily on discharge & continued for 3 months (Appendix 3)
Born 34-36 ⁺⁶ weeks and ≥1.8kg	
Breastmilk	Abidec® 0.6mL/day. 50 micrograms vitamin K once daily on discharge & continued for 3 months (Appendix 3)
Term Formula	Abidec® 0.6mL/day

* ESPGHAN supports the routine use of breast/human milk in infants born <1.8kg.

Without breast milk fortifier full nutritional requirements for all electrolytes, vitamins, calcium, phosphate, other minerals and trace elements will not be met.

Consider continuing prescribed supplements for at least 6 months corrected (up to maximum of 1 year actual age), at which point national public health policy on childhood vitamin supplementation should be employed (16, 17). Where vitamin K prescribed on discharge, vitamin K should be continued for a minimum of 3 months (18).

Consider measuring serum 25 (OH) D at 3-4 weeks of life and then every month until discharge (2).

3.4 Recommendations for vitamin supplementation

DaliVit® is not recommended as a first line preparation as it has a much higher vitamin A content than other preparations. Therefore, it is not a directly interchangeable product with others on the market (see Appendix 1).

3.5 Managing vitamin D deficiency

If a 25-hydroxy-vitamin D of less than 50nmol/L is identified on blood results, then additional cholecalciferol supplementation should be considered (18). The trust pharmacy service should be consulted regarding available and appropriate cholecalciferol formulations as per the childrens BNF, the ESPGHAN 2022 maximum recommended dose of 1000 international units/day (from multivitamin, feed and additional supplementation) considered (2) and vitamin D level monitored (to determine when it is appropriate to discontinue additional vitamin D supplementation).

3.6 Vitamin K1

Vitamin K is a group of lipophilic, hydrophobic vitamins necessary for the synthesis of coagulation factors (factors II (prothrombin), VII, IX, and X, and the anticoagulation proteins C and S in the liver, as well as many other important functional proteins such as osteocalcin. Insufficient levels of vitamin K may lead to haematological complications, resulting in the impaired production of these active coagulation molecules (19, 20) and a subsequent increased risk of vitamin K deficiency bleeding (VKDB), which may be devastating.

Vitamin K deficiency is far more common in neonates compared to adults due to immaturity of the coagulation system, inadequate colonisation with Vitamin K-producing bacteria in the intestines, limited maternal transfer of vitamin K across the placenta, and low concentrations of the vitamin in breast milk (21). Exclusive human milk feeding is a risk factor for VKDB in otherwise-healthy preterm and term infants (22-24, 19-20), with a significant proportion of term infants showing evidence of subclinical Vitamin K deficiency at age 2-5 months related to breastfeeding duration (25-27, 28).

All preterm infants are offered prophylactic Vitamin K at birth, and those exclusively fed human milk receive sufficient extra Vitamin K from multi-nutrient milk fortifiers if given during the NICU stay. However, a preterm infant on full exclusive unfortified breastmilk feeds (150 mL/kg/day) receives only a minimal proportion of their currently recommended Vitamin K intake of 4.4-28 micrograms/kg/day (2). A recent prospective observational study in exclusively breastfed preterm infants who all received intramuscular prophylaxis at birth showed that some already had undetectable Vitamin K levels prior to discharge, and that the majority who remained exclusively breastfed post-discharge had developed biochemical evidence of functional subclinical Vitamin K deficiency by 2-3 months corrected age for both haematological and bone Vitamin K-dependent proteins (28).

Nutritional guidelines for preterm infants do not offer recommendations for Vitamin K supplementation after discharge, however more recent publications suggest a daily supplement of 50micrograms/day (not per kg) for all preterm infants born <37 weeks gestation being discharged exclusively on unfortified human milk feeds, for at least the first 3 months at home, in order to improve intakes in early infancy and guard against subsequent deficiency (29). The Northern Neonatal Network recommend vitamin K supplementation for infants on breast milk as an exclusive feed to commence upon discharge from the neonatal unit and to be continued for 3 months.

3.7 Prophylactic vitamin K1 at birth

ESPGHAN recommend all parents should be offered vitamin K prophylaxis for their babies (30). A single 1 milligram intramuscular dose (or 0.5mg for premature babies <34 weeks) provides almost complete protection against Vitamin K Deficiency bleeding (30). ESPGHAN state vitamin K prophylaxis and the mode of administration should be documented (30). Preterm infants (<32/40) who received i.m vitamin K at birth but are >50% breast milk fed should still receive ongoing oral vitamin K at discharge.

Verbal consent should be sought for the administration of intramuscular vitamin K. Parents of healthy term babies have the right to decline vitamin K prophylaxis by any or all routes. Staff have a duty to explore the reasons for complete refusal and ensure they are correctly informed of the risks of VKDB and the potential for serious long-term morbidity and mortality. This conversation should take place with a member of suitably informed member of the medical or midwifery staff. If, having ensured parents are correctly informed of the risks, parents continue to decline, this conversation should be clearly documented in the patient notes (30).

Those parents who decline intramuscular vitamin K should be offered an oral vitamin K regime and advised that all (daily) doses must be given to ensure adequate prophylaxis against both early and late onset haemorrhagic disease. Oral vitamin K at birth is not recommended for high risk, sick or premature infants (30). Manufacturers do not recommend oral vitamin K at birth for babies born to mothers taking carbamazepine, phenobarbital, phenytoin, rifampicin or warfarin at the time of delivery (as these drugs antagonise vitamin K in the baby).

Healthy, mature infants whose parents decline intramuscular vitamin K but accept oral prophylaxis should receive 1mg vitamin K orally shortly after birth and if the maternal intent is to breast feed, the baby then requires a daily 50 microgram dose vitamin K, commencing the next day. This should be continued for 14 weeks. If the infant vomits or regurgitates the formulation within 1 hour of administration, repeating the oral dose may be appropriate (30). Babies who are receiving mixed breast and formula feeds should receive daily vitamin K supplements until or unless the formula feeds reliably comprise >50% of the total volume.

4.0 Recommendations for iron supplementation

A summary of guidance from the international guidelines and studies (2-4, 31) focusing on iron supplementation is detailed the table below:

Guideline	Weight (kg)	Amount (expressed as elemental iron)	Start	End
ESPGHAN 2022 (2)	<1.8	2-3mg/kg	2 weeks	6-12 months
	≥1.8	Not specified	Not specified	Not specified
Koletzko 2021 (3)	<1.5	2-3mg/kg	2 weeks	6-12 months
	1.5 - 2	2mg/kg	2-4 weeks	6-12 months
	2 - 2.5	1-2mg/kg	4-6 weeks	6 months
ESPGHAN 2023 – Late to moderate preterm infants (31)	<2	2-3mg/kg	Not specified	At least 6 months
	<2.5	1-2mg/kg		
WHO 2022 – term infants (4)	<2.5	2-4mg/kg	When enteral feeds are well established	Until baby receives iron from another source

Current guidelines provide recommendations for iron intakes for any infants born <1.8kg (2), preterm infants born <1.5kg, 1.5-2kg, 2-2.5kg (3, 31) and term infants born <2.5kg (4).

To meet these requirements exactly using sodium feredetate 27.5mg of iron per 5mL oral solution would involve multiple different doses based on gestation and weight. Multiple doses and different ages at which supplementation commenced could lead to non-compliance so a pragmatic approach to dosing is recommended.

It should be noted that the two breast milk fortifiers in the UK differ in terms of their iron content. Gold prem® fortifier contains iron while Nutriprem® fortifier does not.

Iron supplementation should be considered at 12 months actual age. Clinical judgement should be exercised where there is developmental delay or feeding difficulties. The dose of iron given in mixed feeding regimens should be informed by the predominant feed (that is the feed which comprises over 50% of intake).

4.1 Recommendations for iron supplementation summary

Dosing preterm infant gestation born < 34 weeks and/or birthweight < 1.8 kg (aim 2-3 mg/kg/day) from 2 weeks of age			
Feed	Working Weight (kg)	Sodium feredetate (27.5 mg/5mL) dose (mL/ day)	Ferrous fumarate * (45mg/5mL) dose (mL/day)
Breast milk or fortified breast milk with Nutriprem [®] fortifier	< 1.8	0.5	0.3
	≥ 1.8	1	0.6
Standard or specialist formula designed for term infants	≥ 1	0.5	0.3
Continue supplementation until 12 months actual age**			
The following feeds do not require iron supplementation:			
Nutriprem 1 [®] , Nutriprem 2 [®] , Gold Prem 1 [®] , Gold Prem 2 [®] , Fortified breast milk with Gold prem [®] fortifier			
Infant gestation born 34-36 ⁺⁶ weeks or >37weeks with a birthweight ≥1.8kg -2.5kg (aim 1-2 mg/kg/day) from 2 weeks of age			
Feed	Sodium feredetate (27.5 mg/5 mL) dose (mL/day)		Ferrous fumarate* (45 mg/5 mL) dose (mL/day)
Breast milk or predominantly breast milk in combination feeding	1		0.6
Continue supplementation until 6 months actual age**			
The following feeds do not require iron supplementation:			
Standard or specialist formula designed for term infants			

* The Galfer[®] brand of ferrous fumarate has dosing recommendations for preterm neonates from 4 weeks of age. If using other ferrous fumarate products, assess the excipient content prior to use (31).

** Clinical judgement should be exercised when discontinuing iron supplementation. Some infants may require iron supplementation beyond timeframe stated such as ELBW infants and LMPT infants with birth weight ≤ 2 kilograms.

5. Guideline - Summary of Recommendations

Multivitamin supplementation

All infants born less than 36+6 weeks gestation to receive Abidec® 0.6 mL/day.

All infants born less than 34 weeks gestation and consuming only unfortified breast milk feeds* to receive 300 International Units /day cholecalciferol and Abidec® 0.6 mL/day.

Commence Abidec® or Abidec® & cholecalciferol at 100ml/kg/day feed. Prescribe to at least 6 months corrected age at which point national public health policy should be followed.

Iron Supplementation (Sodium feredetate dose based on 27.5 mg/5 mL solution)

Infants born less than 34 weeks gestation and/or less than 1.8kg should receive iron supplementation if consuming only unfortified breast milk feeds*, breast milk and Nutriprem® fortifier or a formula designed for term infants e.g. standard newborn or specialist such as amino acid based or hydrolysed formulas. Dose depends on weight see below:

- Infants less than 1.8kg should be given 0.5 mL/day Sodium feredetate
- Infants over 1.8kg infants should be given 1 mL/day Sodium feredetate

Infants born 34-36+6 weeks gestation and over 1.8kg on exclusive breast milk feeds should receive 1 mL/day Sodium feredetate

Vitamin K

All parents should be offered vitamin K prophylaxis for their babies. Vitamin K prophylaxis and the mode of administration should be documented.

All infants born less than 36+6 weeks gestation who received i.m vitamin K at birth & are consuming greater than 50% of feeds as breast milk should receive ongoing oral vitamin K at discharge. Commence 50 micrograms Vitamin K once daily to be continued for 3 months.

*For infants born < 34 weeks and/or < 1.8kg, unfortified breast milk will not meet nutritional recommendations for a variety of nutrients that are required in higher amounts due to preterm birth. Please discuss the feeding plan with a dietitian with neonatal training.

6.0 Monitoring & Audit

Annual Network Level Audit

Standard	Monitor/audit			
	Method	By	Group/committee	Frequency
Every neonatal unit in the Northern region has a policy/guideline (that is in date and ratified by the Trust) detailing vitamin and mineral supplementation for preterm infants, that meets current international nutritional recommendations, based on products used on the unit/within trust.	Audit	ODN dietitian	NNN Nutrition SIG	Annually
Every neonatal unit in the Northern region has a policy/guideline (compliant with ESPGHAN recommendations, in date and ratified by the Trust) regarding vitamin K prophylaxis in preterm infants, documentation of prophylaxis and process in the event of parental refusal.	Audit	ODN dietitian	NNN Nutrition SIG	Annually

Recommended Neonatal Unit Level Audit

Standard	Monitor/audit			
	Method	By	Group/committee	Frequency
Trust policy/guideline for vitamin and mineral supplementation (that ensures preterm infants meet current international nutritional recommendations based on products used on the unit/within trust) is followed.	Audit	Unit staff	Trust	Every 2 years
Trust policy/guideline (compliant with ESPGHAN recommendations) for vitamin K prophylaxis in preterm infants, documentation of prophylaxis and process in the event of parental refusal is followed.	Audit	Unit staff	Trust	Every 2 years

Appendix

Appendix 1: Available Multivitamin Preparations

Vitamin	Abidec® 0.3 mL*	Abidec® 0.6 mL*	DaliVit® 0.3 mL	DaliVit® 0.6 mL	Healthy Start 5 drops	Units
A	667 (200)	1333 (400)	2500 (750)	5000 (1500)	777 (233)	international units (microgram)
D	200 (5)	400 (10)	200 (5)	400 (10)	400 (10)	international units (microgram)
B1 (thiamine)	0.2	0.4	0.5	1	0	milligram
B2 (riboflavin)	400	800	200	400	0	micrograms
B3 (nicotinamide/niacin)	4	8	2.5	5	0	milligram
B6 (pyridoxine)	400	800	250	500	0	micrograms
C (ascorbic acid)	20	40	25	50	20	milligram

*Manufacturers guidance regarding Abidec® “Vitamin A palmitate contains refined peanut oil (Arachis oil) and should not be taken by patients known to be allergic to peanut. Patients with soya allergy should also avoid Abidec® Multivitamin Drops.”

Appendix 2: Alternative Vitamin Supplementation when shortage of first line products

Born <34weeks and/or <1.8kg	
Fortified breastmilk (Gold Prem® or Nutriprem® fortifier) (including fortified breastmilk feeding post discharge) OR Nutriprem® 1/ Gold Prem® 1	Colecalciferol (400 international units/day)
Unfortified breastmilk (not recommended*)	DaliVit® 0.3mL/day and Colecalciferol (400 international units/day)
On reaching 1.8kg – 2kg or at discharge ** dependent upon local policy for change to nutrient enriched post discharge formulas	
Fortified breastmilk (Gold Prem® or Nutriprem® fortifier) (including fortified breastmilk feeding post discharge) OR Gold Prem® 2/ Nutriprem® 2 OR Term/Specialist/High Calorie Term Formula	Healthy Start (5 drops) OR Colecalciferol (400 international units/day)
Unfortified breastmilk and/or breastfeeding	DaliVit® 0.6mL/day 50 micrograms vitamin K once daily on discharge & continued for 3 months (Appendix 3)
Born 34-36⁺⁶ weeks and ≥1.8kg	
Breast milk	Healthy Start (5 drops) OR 400 international units/day Colecalciferol 50 micrograms vitamin K once daily on discharge & continued for 3 months (Appendix 3)
Term Formula	Healthy Start (5 drops) OR 400 international units/day Colecalciferol

Appendix 3: Options for Vitamin K supplementation

Current multivitamin preparations used for preterm infants do not contain vitamin K, though there are a range of acceptable options for supplementation that can be implemented in line with unit preference and Integrated Care Board product availability (29). Options that would effectively deliver the equivalent of at least the minimum daily requirement of 50 micrograms could include:

i) Konakion MM Paediatric® (phytomenadione 2mg /0.2 mL solution for injection; Neon Healthcare Ltd); 2mg **given orally** once monthly.

ii) A single further Konakion MM Paediatric® 1mg intramuscular injection at discharge - this should last for up to 3 months and would avoid compliance issues but maybe far less acceptable to parents and babies (29).

iii) NeoKay oral drops® (Neoceuticals Ltd; 200microgram/mL VK₁): Give 50microgram (0.25mL via dropper) once daily to provide daily VK₁ intake comparable to that from formula milks which are supplemented to meet current recommendations (VK₁ content typically 60-80microgram/L); this product is a food supplement

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