NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Parenteral nutrition in neonates

The Department of Health in England has asked NICE to develop a new guideline on parenteral nutrition in neonates.

The guideline will be developed using the methods and processes outlined in Developing NICE guidelines: the manual.

This guideline will also be used to develop a NICE quality standard on parenteral nutrition in neonates.

1 Why the guideline is needed

Parenteral nutrition refers to intravenous feeding, a technique for providing nutrition to those who are unable to tolerate adequate enteral nutrition (orally or through an enteral tube). It is frequently needed by preterm babies while they establish enteral feeds, critically ill babies, and babies with gastrointestinal disorders who need surgery. Inadequate nutrition, particularly in preterm babies, can have short- and long-term health effects, including an association with longer stays in the neonatal unit (for example, because of an increased need for assisted ventilation) and an increased risk of infection, and worsened developmental outcomes. There is also evidence that inappropriate nutritional management soon after birth is linked to the development of metabolic syndrome in adults.

Approximately 90,000 babies born in the UK each year need neonatal care (Bliss strategy summary 2016-2019). Parenteral nutrition is increasingly used in neonatal care. It has become common practice to start it in preterm babies within the first few hours of life, and also to support term babies who are critically ill.

Parenteral nutrition should be treated as a medicine, with safeguards on its prescription, preparation and use. Concerns have been raised about variation in practice by organisations including The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) and the Paediatric Chief Pharmacists Group (PCPG). This guideline will make recommendations on the optimal use of parenteral nutrition in neonatal care.

Key facts and figures

Parenteral nutrition is given using nutritional formulae that contain nutrients such as glucose, electrolytes, amino acids, lipids, minerals, trace elements and vitamins. It may complement enteral feeding or, in some settings, replace it.

There is wide variation across the UK in neonatal parenteral nutrition prescription, formulation and administration.

The NCEPOD enquiry into the care of hospital patients receiving parenteral nutrition (2010) reviewed 264 cases of neonatal parenteral nutrition. It found that 73% of cases represented less than 'good practice', 40% had metabolic complications, 40% did not meet nutritional needs, and in 28% the start of parenteral nutrition was delayed. In 37% the first parenteral nutrition provided was considered inadequate for the patient's needs.

Parenteral nutrition is normally formulated in an aseptic pharmacy unit. It can be in standardised or individualised forms. Prescribing is complex and open to error. Simplified, standardised regimens may reduce this risk, and may reduce costs.

Virtually all babies born before 29 weeks' gestation who weigh less than 1,200 g need parenteral nutrition for a period that depends on gestation, birthweight and other morbidities. Postnatal growth failure is common in babies born before 29 weeks' gestation. It is associated with a need for more respiratory support and increased risk of infection. It is also a potentially reversible risk factor for neurocognitive impairment.

Parenteral nutrition is expensive: for a large tertiary neonatal unit it costs approximately £175,000 a year.

Current practice

Neonatal parenteral nutrition is commonly used in:

- preterm babies who have not yet established an adequate intake of enteral milk
- babies whose feed is being withheld because necrotising enterocolitis is present or suspected
- critically ill babies
- babies with gastrointestinal disorders who need surgery.

There is no national consensus on best practice in neonatal parenteral nutrition. Its use is inconsistent both within and between neonatal units.

The use of standardised, rather than individualised, parenteral nutrition is established practice in some countries, and in some neonatal operational delivery networks in the UK.

Different versions of standardised parenteral nutrition bags are in use, with different constituent components present and their concentrations. This means that the volume of parenteral nutrition needed to achieve adequate nutrition may vary.

Parenteral nutrition services are not always available at weekends, and this has a particular impact for individualised parenteral nutrition regimes. The use of standardised regimes could avoid delays in starting parenteral nutrition, and growth outcomes are improved if it is started soon after birth.

Many babies do not receive the full amount of parenteral nutrition prescribed. This is because of concerns about correcting or maintaining their fluid and electrolyte balance, which may involve changes to the intended administration and prescription. This may result in suboptimal delivery of nutrients.

A guideline is needed to explore the evidence behind standardised concentrated parenteral nutrition regimes to see if safety, quality and cost can be improved.

Policy, legislation, regulation and commissioning

In addition to finding inadequacies in neonatal parenteral nutrition provision, the NCEPOD enquiry into the care of hospital patients receiving parenteral nutrition (2010) reported significant variation across units, and an urgent need for neonatal units across the UK to have a consensus on best practice based on current scientific evidence.

The PCPG report Improving practice and reducing risk in the provision of parenteral nutrition for neonates and children also highlighted wide variation in practice. The report's stated purpose was: 'to clarify (and where possible simplify) the complicated pathway of events that begins with a decision to feed a patient intravenously and ends with the infusion of nutrients directly into the circulation'. The report recommended that 'The Chief Pharmacist must ensure that the hospital's medicines policy mandates the use of standard parenteral nutrition solutions in preference to individualised solutions whenever it is clinically appropriate'. It also suggested that 80% of prescriptions could be met using standardised parenteral nutrition.

In 2016, the British Association for Parenteral and Enteral Nutrition highlighted issues related to commissioning of parenteral nutrition in a toolkit for commissioners and providers in England called Malnutrition matters: meeting quality standards in nutritional care.

In 2016 the British Association of Perinatal Medicine produced The provision of parenteral nutrition within neonatal services – a framework for practice. This said that standardised parenteral nutrition solutions were suitable for the vast majority of babies, and that concentrated solutions may be useful for achieving target nutrition, especially for the smallest babies.

2 Who the guideline is for

People using services, their families and carers, and the public will be able to use the guideline to find out more about what NICE recommends, and help them make decisions.

This guideline is for:

- Healthcare professionals in secondary and tertiary care who are involved in assessing neonates for parenteral nutrition and managing their care. These may include the following healthcare professionals: neonatologists, paediatricians, paediatric surgeons, paediatric pharmacists, neonatal nurses and neonatal dietitians.
- People responsible for planning services for neonatal care, including directors of public health, NHS trust managers and managers in clinical commissioning groups.
- Parents and carers of neonates who need parenteral nutrition.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive.

Equality considerations

NICE will carry out an equality impact assessment during scoping. The assessment will:

- list equality issues identified, and how they have been addressed
- explain why any groups are excluded from the scope.

The guideline will look at inequalities relating to parents and carers with communication or learning difficulties, parents and carers who do not speak English as their first language, and young mothers (aged 17 or under).

3 What the guideline will cover

3.1 Who is the focus?

- babies born preterm up to 28 days after their due birth date (preterm babies)
- babies born at term up to 28 days after their due birth date (term babies).

Specific consideration will be given to those who:

- are critically ill, **or**
- need surgery.

3.2 Settings

- Units providing NHS-funded neonatal care, including:
  - all settings that provide NHS-funded neonatal care
  - other paediatric hospital settings (such as paediatric surgical units and paediatric intensive care units).

3.3 Activities, services or aspects of care

Key areas that will be covered

We will look at evidence in the areas below when developing the guideline, but it may not be possible to make recommendations in all the areas.

1 Indications for, and approaches to, starting parenteral nutrition in preterm and term babies
2 Energy needs of preterm and term babies
3 Individual constituents in parenteral nutrition for preterm and term babies:
   - macronutrients (amino acids, carbohydrates and lipids)
   - minerals and iron
   - chloride and acetate balance.
4 Venous access for parenteral nutrition in preterm and term babies
5 Monitoring parenteral nutrition in preterm and term babies
6 Stopping parenteral nutrition in preterm and term babies

7 Service design
8 Information and support for parents and carers

Note that guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

Areas that will not be covered

1 Enteral feeding regimens
2 Individual vitamins and trace elements
3 Fluid volume and electrolyte quantity needs

Related NICE guidance

Published

- Intravenous fluid therapy in children and young people in hospital. NICE guideline NG29 (2015)
- Preterm labour and birth. NICE guideline NG25 (2015)
- Postnatal care up to 8 weeks after birth. NICE guideline CG37 (2015)
- Maternal and child nutrition. NICE public health guideline PH11 (2014)
- Neonatal infection (early onset): antibiotics for prevention and treatment. NICE guideline CG149 (2012)

In development

- Specialist neonatal care. NICE guideline. Publication expected April 2019.

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to parenteral nutrition in neonates:

- Medicines optimisation (2015) NICE guideline NG5
- Patient experience in adult NHS services (2012) NICE guideline CG138

- Medicines adherence (2009) NICE guideline CG76

3.4 Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out analyses as appropriate. The preferred unit of effectiveness will be the quality-adjusted life year (QALY), and we will usually consider the costs from an NHS and personal social services (PSS) perspective, but we may conduct further analyses to consider wider social costs associated with parenteral nutrition in neonates.

3.5 Key issues and questions

While writing this scope, we have identified the following key issues, and key questions related to them:

1 Indications for, and approaches to, starting parenteral nutrition in preterm and term infants

1.1 Which preterm and term babies benefit most from parenteral nutrition?

1.2 What is the optimal approach to starting parenteral nutrition in preterm and term babies, in relation to energy provision and daily amounts of intravenous amino acids, carbohydrates and lipids?

2 What are the energy needs of preterm and term babies receiving parenteral nutrition?

3 Individual constituents in parenteral nutrition for preterm and term babies

3.1 What quantity of intravenous amino acids should be provided?

3.2 What quantity of intravenous carbohydrates should be provided?

3.3 What quantity of intravenous lipids should be provided?

3.4 What is the comparative efficacy and safety of lipid formulations from different sources (for example, soya, fish oil, or mixed sources)?

3.5 What quantity of intravenous minerals (calcium, phosphorus and magnesium) should be provided?

3.6 What quantity of intravenous iron should be provided?

3.7 What is the most effective balance between intravenous chloride and acetate?

3.8 What is the efficacy and safety of standardised parenteral nutrition bags compared with individualised bags?

4 What positioning of parenteral nutrition venous lines is effective and safe?

5 What parameters should be monitored, and how frequently, to ensure that parenteral nutrition in preterm and term babies is effective and safe?

6 What strategies are best for stopping parenteral nutrition?

7 What approaches to prescribing and providing parenteral nutrition in preterm and term babies (for example, nutrition care teams) are effective and safe?

8 What information and support do parents and carers need?

The key questions may be used to develop more detailed review questions, which guide the systematic review of the literature.

3.6 Main outcomes

The main outcomes that will be considered when searching for and assessing the evidence are:

1 Anthropometric measurements (for example, weight, length, head circumference).

2 Nutritional intake.

3 Duration of hospital stay.

4 Sepsis.

5 Adverse effects of parenteral nutrition, for example:

- central venous catheter related complications, including catheter displacement leading to loss of access or cardiac tamponade, obstruction, or thrombosis
- parenteral nutrition related liver disease

- hyperglycaemia
- hypertriglyceridaemia.

6 Parent or carer health-related quality of life.

4 NICE quality standards and NICE Pathways

4.1 NICE quality standards

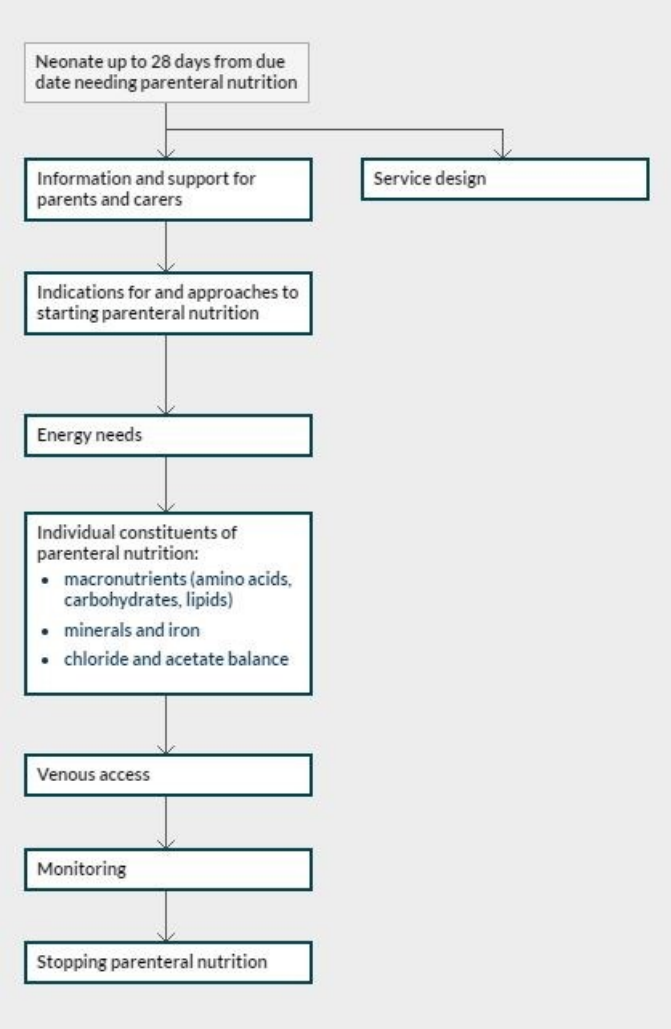
NICE quality standards that may use this guideline as an evidence source when they are being developed

- Parenteral nutrition in neonates. NICE quality standard. Publication date to be confirmed

4.2 NICE Pathways

NICE Pathways bring together all related NICE guidance and associated products on a topic in an interactive topic-based flowchart. When this guideline is published, the recommendations will be added to NICE Pathways.

A draft outline for parenteral nutrition in neonates, based on the draft scope, is included below. It will be adapted and more detail added as the recommendations are written during guideline development.



5 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 27 April to 25 May 2017.

The guideline is expected to be published in August 2019.

You can follow progress of the guideline.

Our website has information about how NICE guidelines are developed.