

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Gastro-oesophageal reflux in children and young people: diagnosis, investigation and management of gastro-oesophageal reflux in children and young people.

Short title

Gastro-oesophageal reflux in children and young people.

2 The remit

The Department of Health has asked NICE: 'To produce a clinical guideline on the investigation and management of gastro-oesophageal reflux disease in children'.

3 Clinical need for the guideline

3.1 *Epidemiology*

- a) Gastro-oesophageal reflux (GOR) is a normal bodily process. It usually happens after eating in healthy infants, children, young people and adults. In contrast, gastro-oesophageal reflux disease (GORD) is present when GOR causes symptoms (for example, frequency of regurgitation) and/or complications (for example, oesophagitis) that have a significant effect on the person and require treatment. However, there is no exact distinction of when GOR becomes GORD, and the terms are used to cover a range of severity.
- b) All children and young people have GOR, however, the prevalence of GORD in children and young people in the UK is uncertain. Data

from the USA shows that 'problematic' regurgitation was reported in 23% of infants aged 6 months but decreased to 14% by the age of 7 months.

- c) English NHS hospital episode statistics data for 2010–11 show that there were 8943 consultant episodes for GORD with or without oesophagitis in children and young people aged 0–14 years.
- d) The prevalence of GORD is higher in children and young people with neurodevelopmental disorders, oesophageal atresia repair, cystic fibrosis, hiatal hernia, repaired achalasia or a family history of complex GORD.

3.2 Current practice

- a) Many infants and young children present in primary care with regurgitation caused by GOR/GORD. Advice may be sought from health visitors and GPs about this condition. In cases where symptoms are mild and there is no reason to suspect the presence of GORD, reassurance may be all that is given. Frequently, however, treatment is prescribed including feeding changes or drug therapy with antacids. In addition, some children are referred to a specialist for assessment and possible treatment, especially those with severe symptoms (for example, in a child with overt regurgitation the presence of blood might indicate erosive oesophagitis, or recurrent respiratory symptoms might be attributed to occult reflux) or other risk-factors, such as neurodevelopmental disorders.
- b) As well as assessing symptoms, a specialist may want to carry out diagnostic tests to demonstrate the presence of reflux or to establish its impact, such as:
 - oesophageal pH monitoring
 - combined use of multiple intraluminal impedance (MII)
 - barium meal and other forms of contrast radiography

- upper gastrointestinal endoscopy and mucosal biopsy
 - empirical trials of acid suppression.
- c) In addition to the treatments used in primary care, specialists may prescribe drugs to suppress gastric acid production, and some children may also undergo surgery.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 *Population*

4.1.1 Groups that will not be covered

- a) Children and young people under 18 years of age.
- b) Specific consideration will be given to children and young people with neurodevelopmental disorders.

4.1.2 Groups that will not be covered

- a) People aged 18 years or over.
- b) Children and young people with Barrett's oesophagus.
- c) Preterm babies in neonatal intensive care units.

4.2 *Healthcare setting*

- a) All settings where NHS healthcare is provided or commissioned.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

- a) The natural history of physiological gastro-oesophageal reflux.
- b) The distinction between physiological gastro-oesophageal reflux and gastro-oesophageal reflux disease.
- c) Indications for investigations.
- d) Indications for treatment.
- e) Effectiveness of treatments for GOR/GORD:
 - positional management
 - changes to feeds (including composition and regimens)
 - antacids (including products with alginate)
 - H₂ receptor antagonists
 - proton pump inhibitors
 - prokinetic agents
 - jejunal feeding
 - surgery.

Note that guideline recommendations 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 drug's summary of product characteristics to inform decisions made with individual patients.

4.3.2 Clinical issues that will not be covered

Clinical areas that will not be covered by the guideline are:

- a) Diagnosis and management of Barrett's oesophagus.
- b) Reflux associated with pregnancy.

- c) The management of conditions associated with GOR, for example, management of obesity.

4.4 Main outcomes

The following outcomes will be assessed where relevant:

- a) Health-related quality of life (measured using EQ-5D and/or disease-specific tools, if available).
- b) Change in symptoms and signs, for example:
- cessation or reduction (volume or frequency) of regurgitation
 - reduction in crying and distress
 - improved feeding
 - improved nutritional status.
- c) Improvement in investigative findings, including:
- healing of erosive oesophagitis.
- d) Adverse events of interventions (diagnostic or treatment).
- e) Resource use and cost.

4.5 Review questions

Review questions guide a systematic review of the literature. They address only the key clinical issues covered in the scope, and usually relate to interventions, diagnosis, prognosis, service delivery or patient experience. Please note that these review questions are draft versions and will be finalised with the Guideline Development Group.

- a) What clinical features indicate or suggest the presence of GORD?
For example:
- duration of persisting overt reflux
 - excessive crying or distressed behaviour ('infant colic')

- feeding difficulties or feed refusal.
- b) Is there an association between GOR and:
- apnoeic episodes
 - respiratory disease
 - dental erosion
 - sinusitis
 - asthma.
- c) What are the clinical indications for endoscopy?
- d) What are the clinical indications for pH monitoring?
- e) What are the clinical indications for impedance monitoring?
- f) How effective is positional management in infants with GOR/GORD?
- g) How effective are changes to feeding (including composition and regimens) in infants with GOR/GORD?
- h) How effective are antacids compared to placebo in the treatment of GOR/GORD?
- i) How effective are H₂-receptor antagonists compared to placebo in the treatment of GOR/GORD?
- j) How effective are proton pump inhibitors compared to placebo and one another in the treatment of GOR/GORD?
- k) How effective are H₂-receptor antagonists compared to proton pump inhibitors in the treatment of GOR/GORD?
- l) How effective are prokinetic agents compared to placebo in the treatment of GOR/GORD?

- m) Which, if any, combinations of treatments should be used to alleviate symptoms in children and young people with GOR/GORD?
- n) How effective are naso-gastric, gastrostomy and jejunal feeding in the management of GOR/GORD?
- o) What are the clinical indications for offering surgery?
- p) How effective is surgery in the treatment of GOR/GORD?

4.6 *Economic aspects*

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

4.7 *Status*

4.7.1 *Scope*

This is the consultation draft of the scope. The consultation dates are 21 December 2012 to 25 January 2013.

4.7.2 *Timing*

The development of the guideline recommendations will begin in April 2013.

5 Related NICE guidance

5.1 *Published guidance*

5.1.1 NICE guidance to be updated

This is a new guideline and will not replace any existing guidance.

5.1.2 NICE guidance to be incorporated

None.

5.1.3 Other related NICE guidance

- [Patient experience in adult NHS services](#). NICE clinical guideline 138 (2011).
- [Endoluminal gastroplication for gastro-oesophageal reflux disease](#). NICE interventional procedure guidance 404 (2011).
- [Barrett's oesophagus](#). NICE clinical guideline 106 (2010).
- [Medicines adherence](#). NICE clinical guideline 76 (2009).
- [Catheterless oesophageal pH monitoring](#). NICE interventional procedure guidance 187 (2006).
- [Endoscopic injection of bulking agents for gastro-oesophageal reflux disease](#). NICE interventional procedure guidance 55 (2004).
- [Dyspepsia](#). NICE clinical guideline 17 (2004).
- [Obesity](#). NICE clinical guideline 43 (2006)

5.2 *Guidance under development*

NICE is currently developing the following related guidance (details available from the NICE website):

- Dyspepsia and gastro-oesophageal reflux disease: investigation and management of dyspepsia, symptoms suggestive of GORD, or both (update). NICE clinical guideline. Publication to be confirmed.

6 Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

- [‘How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS’](#)
- [‘The guidelines manual’](#).

Information on the progress of the guideline will also be available from the [NICE website](#).