NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people

Short title

Gastro-oesophageal reflux disease 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 physiological 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 troublesome 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 infants, children and young people have a degree of GOR. However, the prevalence of troublesome GOR 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 certain groups – for example, in children and young people with neurodevelopmental disorders, oesophageal atresia repair, cystic fibrosis, hiatal hernia, or repaired achalasia, in preterm neonates or in people with a family history of complex GORD.

3.2 Current practice

a) Many infants and young children present in primary care with symptoms of GOR. Advice may be sought from midwives, 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 needed. Treatment is often prescribed, including feeding changes or drug therapy with alginates. In addition, some children are referred to a specialist for assessment, investigation and possible treatment. In particular, this includes 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 those who are receiving specialist care for other conditions, such as preterm neonates or children with neurodevelopmental disorders.

b) In rare situations a specialist might want to carry out diagnostic tests to demonstrate and quantify the presence of reflux or to exclude other serious problems that can present in a similar way. Tests can include:

- oesophageal pH monitoring

- combined use of multiple intraluminal impedance (MII)
- barium meal and other modalities of imaging
- upper gastrointestinal endoscopy and mucosal biopsy
- empirical trial 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, usually a fundoplication.

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 be covered

a) Infants, children and young people under 18 years.

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.

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 overt GOR.

b) The distinction between physiological GOR and GORD.

c) Risk factors associated with developing GORD.

d) Indications for investigations.

e) Indications for treatment.

f) Effectiveness of treatments for GOR/GORD:

- positional management
- changes to feeds (including composition and regimens)
- alginates and antacids
- H_2-receptor antagonists
- proton pump inhibitors
- prokinetic agents
- jejunal feeding
- fundoplication 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) Technical aspect of undertaking investigations and surgery – for example, assessing results of endoscopy.

4.4 Main outcomes

The following outcomes will be assessed where relevant:

a) Health-related quality of life.

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 is the clinical course of functional overt reflux in infancy?

b) The distinction between physiological GOR and GORD. For example, what is the association between:

- dental erosion and GOR
- back-arching and GOR
- distressed behaviour and GOR

- apnoea and GOR
- cow's milk protein intolerance and GOR?

c) What are the risk factors for GORD? For example:

- neurodevelopmental impairment
- age (for example, age of onset)
- prematurity
- family history of GORD
- obesity?

d) Which symptoms, signs and risk factors indicate the need for which investigations?

e) Which signs, symptoms and risk factors indicate the need for which treatment?

f) How effective is positional management in infants with GOR/GORD?

g) How effective are changes to feeding in infants with GOR/GORD?

h) How effective are antacids/alginates compared with placebo in the treatment of GOR/GORD?

i) How effective are H_2-receptor antagonists compared with placebo in the treatment of GOR/GORD?

j) How effective are proton pump inhibitors compared with placebo and one another in the treatment of GOR/GORD?

k) How effective are H_2-receptor antagonists compared with proton pump inhibitors in the treatment of GOR/GORD?

l) How effective are prokinetic agents compared with placebo in the treatment of GOR/GORD?

m) How effective is enteral tube feeding in the management of GOR/GORD?

n) How effective is fundoplication 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 final scope.

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 (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.