

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

NICE guideline

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## Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The application of the recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guideline is the basis of QS112.

## Overview

This guideline covers diagnosing and managing gastro-oesophageal reflux disease in children and young people (under 18s). It aims to raise awareness of symptoms that need investigating and treating, and to reassure parents and carers that regurgitation is common in infants under 1 year.

### *Who is it for?*

- Healthcare professionals
- Children and young people with gastro-oesophageal reflux disease and their families and carers

## Introduction

Gastro-oesophageal reflux (GOR) is a normal physiological process that usually happens after eating in healthy infants, children, young people and adults. In contrast, gastro-oesophageal reflux disease (GORD) occurs when the effect of GOR leads to symptoms severe enough to merit medical treatment. GOR is more common in infants than in older children and young people, and it is noticeable by the effortless regurgitation of feeds in young babies.

In clinical practice, it is difficult to differentiate between GOR and GORD, and the terms are used interchangeably by health professionals and families alike. There is no simple, reliable and accurate diagnostic test to confirm whether the condition is GOR or GORD, and this in turn affects research and clinical decisions. Furthermore, the term GORD covers a number of specific conditions that have different effects and present in different ways. This makes it difficult to identify the person who genuinely has GORD, and to estimate the real prevalence and burden of the problem. Nevertheless, regardless of the definition used, GORD affects many children and families in the UK, who commonly seek medical advice and as a result, it constitutes a health burden for the NHS.

Generally, experts suggest that groups of children most affected by GORD are otherwise healthy infants, children with identifiable risk factors, and pubescent young people who acquire the problem in the same way as adults. The 2 other specific populations of children affected by GORD are premature infants and children with complex, severe neurodisabilities. In the latter group, the diagnosis is complicated further by a tendency to confuse vomiting with or without gut dysmotility with severe GORD. In addition, for a child with neurodisabilities, a diagnosis of GORD often fails to recognise a number of distinct problems that may coexist and combine to produce a very complicated feeding problem in an individual with already very complex health needs. For example, a child with severe cerebral palsy may be dependent on enteral tube feeding, have severe chronic vomiting, be constipated, have marked kyphoscoliosis, possess a poor swallow mechanism and be unable to safely protect their airway resulting in a risk of regular aspiration pneumonia.

This guideline focuses on signs and symptoms and interventions for GORD. Commonly observed events, such as infant regurgitation, are covered as well as much rarer but potentially more serious problems, such as apnoea. Where appropriate, clear recommendations are given as to when and how reassurance should be offered. The guideline also advises healthcare professionals about when to think about investigations, and what treatments to offer. Finally, it is emphasised that other, and on occasion more serious, conditions that need different management can be confused with some of the relatively common manifestations of GOR or GORD. These warning signs are defined under the headings of 'red flags' along with recommended initial actions.

## *Safeguarding children*

Remember that child maltreatment:

- is common
- can present anywhere
- may co-exist with other health problems, including GORD.

For more information see the NICE guideline on [child maltreatment](#).

## *Medicines*

The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

## Patient-centred care

This guideline offers best practice advice on the care of infants, children and young people with gastro-oesophageal reflux disease (GORD).

Patients and healthcare professionals have rights and responsibilities as set out in the [NHS Constitution for England](#) – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the [Department of Health's advice on consent](#). If someone does not have capacity to make decisions, healthcare professionals should follow the [code of practice that accompanies the Mental Capacity Act](#) and the supplementary [code of practice on deprivation of liberty safeguards](#).

If a young person is moving between paediatric and adult services, care should be planned and managed according to the best practice guidance described in the Department of Health's [Transition: getting it right for young people](#).

Adult and paediatric healthcare teams should work jointly to provide assessment and services to young people with GORD. Diagnosis and management should be reviewed throughout the transition process, and there should be clarity about who is the lead clinician to ensure continuity of care.



## Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in [section 1](#).

- Give advice about gastro-oesophageal reflux (GOR) and reassure parents and carers that in well infants, effortless regurgitation of feeds:
  - is very common (it affects at least 40% of infants)
  - usually begins before the infant is 8 weeks old
  - may be frequent (5% of those affected have 6 or more episodes each day)
  - usually becomes less frequent with time (it resolves in 90% of affected infants before they are 1 year old)
  - does not usually need further investigation or treatment.
- In infants, children and young people with vomiting or regurgitation, look out for the 'red flags' in [table 1](#), which may suggest disorders other than GOR. Investigate or refer using clinical judgement.
- Do not routinely investigate or treat for GOR if an infant or child without overt regurgitation presents with only 1 of the following:
  - unexplained feeding difficulties (for example, refusing to feed, gagging or choking)
  - distressed behaviour
  - faltering growth
  - chronic cough
  - hoarseness
  - a single episode of pneumonia.
- Do not offer an upper gastrointestinal (GI) contrast study to diagnose or assess the severity of gastrointestinal reflux disease (GORD) in infants, children and young people.
- Arrange a specialist hospital assessment for infants, children and young people for a possible upper GI endoscopy with biopsies if there is:

- haematemesis (blood-stained vomit) not caused by swallowed blood (assessment to take place on the same day if clinically indicated; also see [table 1](#))
  - melaena (black, foul-smelling stool; assessment to take place on the same day if clinically indicated; also see [table 1](#))
  - dysphagia (assessment to take place on the same day if clinically indicated)
  - no improvement in regurgitation after 1 year old
  - persistent, faltering growth associated with overt regurgitation
  - unexplained distress in children and young people with communication difficulties
  - retrosternal, epigastric or upper abdominal pain that needs ongoing medical therapy or is refractory to medical therapy
  - feeding aversion and a history of regurgitation
  - unexplained iron-deficiency anaemia
  - a suspected diagnosis of Sandifer's syndrome.
- In formula-fed infants with frequent regurgitation associated with marked distress, use the following stepped-care approach:
    - review the feeding history, then
    - reduce the feed volumes only if excessive for the infant's weight, then
    - offer a trial of smaller, more frequent feeds (while maintaining an appropriate total daily amount of milk) unless the feeds are already small and frequent, then
    - offer a trial of thickened formula (for example, containing rice starch, cornstarch, locust bean gum or carob bean gum).
  - In formula-fed infants, if the stepped-care approach is unsuccessful (see [recommendation 1.2.3](#)), stop the thickened formula and offer alginate therapy for a trial period of 1–2 weeks. If the alginate therapy is successful continue with it, but try stopping it at intervals to see if the infant has recovered.
  - Do not offer acid-suppressing drugs, such as proton pump inhibitors (PPIs) or H<sub>2</sub> receptor antagonists (H<sub>2</sub>RAs), to treat overt regurgitation in infants and children occurring as an isolated symptom.

- Do not offer metoclopramide, domperidone or erythromycin to treat GOR or GORD without seeking specialist advice and taking into account their potential to cause adverse events.

## 1 Recommendations

The following guidance is based on the best available evidence. The [full guideline](#) gives details of the methods and the evidence used to develop the guidance.

The wording used in the recommendations in this guideline (for example, words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation). See [about this guideline](#) for details.

### *Terms used in this guideline*

Infants, children and young people are defined as follows:

- infants: under 1 year
- children: 1 to under 12 years
- young people: 12 to under 18 years.

**Gastro-oesophageal reflux (GOR)** is the passage of gastric contents into the oesophagus. It is a common physiological event that can happen at all ages from infancy to old age, and is often asymptomatic. It occurs more frequently after feeds/meals. In many infants, GOR is associated with a tendency to 'overt regurgitation' – the visible regurgitation of feeds.

**Gastro-oesophageal reflux disease (GORD)** refers to gastro-oesophageal reflux that causes symptoms (for example, discomfort or pain) severe enough to merit medical treatment, or to gastro-oesophageal reflux-associated complications (such as oesophagitis or pulmonary aspiration). In adults, the term GORD is often used more narrowly, referring specifically to reflux oesophagitis.

**Marked distress** There is very limited evidence, and no objective or widely accepted clinical definition, for what constitutes 'marked distress' in infants and children who are unable to adequately communicate (expressively) their sensory emotions. In this guideline, 'marked distress' refers to an outward demonstration of pain or unhappiness that is outside what is considered to be the normal range by an appropriately trained, competent healthcare professional, based on a thorough assessment. This assessment should include a careful analysis of the description offered by the parents or carers in the clinical context of the individual child.

**Occult reflux** refers to the movement of part or all of the stomach contents up the oesophagus, but not to the extent that it enters the mouth or is obvious to the child, parents or carers, or observing healthcare professional. There is no obvious, visible regurgitation or vomiting. It is sometimes referred to as silent reflux.

**Overt regurgitation** refers to the voluntary or involuntary movement of part or all of the stomach contents up the oesophagus at least to the mouth, and often emerging from the mouth. Regurgitation is in principle clinically observable, so is an overt phenomenon, although lesser degrees of regurgitation into the mouth might be overlooked.

**Specialist** refers to a paediatrician with the skills, experience and competency necessary to deal with the particular clinical concern that has been identified by the referring healthcare professional. In this guideline this is most likely to be a consultant general paediatrician. Depending on the clinical circumstances, 'specialist' may also refer to a paediatric surgeon, paediatric gastroenterologist or a doctor with the equivalent skills and competency.

## 1.1 *Diagnosing and investigating GORD*

1.1.1 Recognise regurgitation of feeds as a common and normal occurrence in infants that:

- is due to gastro-oesophageal reflux (GOR) – a normal physiological process in infancy
- does not usually need any investigation or treatment
- is managed by advising and reassuring parents and carers.

1.1.2 Be aware that in a small proportion of infants, GOR may be associated with signs of distress or may lead to certain recognised complications that need clinical management. This is known as gastro-oesophageal reflux disease (GORD).

1.1.3 Give advice about GOR and reassure parents and carers that in well infants, effortless regurgitation of feeds:

- is very common (it affects at least 40% of infants)
- usually begins before the infant is 8 weeks old
- may be frequent (5% of those affected have 6 or more episodes each day)

- usually becomes less frequent with time (it resolves in 90% of affected infants before they are 1 year old)
- does not usually need further investigation or treatment.

1.1.4 When reassuring parents and carers about regurgitation, advise them that they should return for review if any of the following occur:

- the regurgitation becomes persistently projectile
- there is bile-stained (green or yellow-green) vomiting or haematemesis (blood in vomit)
- there are new concerns, such as signs of marked distress, feeding difficulties or faltering growth
- there is persistent, frequent regurgitation beyond the first year of life.

1.1.5 In infants, children and young people with vomiting or regurgitation, look out for the 'red flags' in [table 1](#), which may suggest disorders other than GOR. Investigate or refer using clinical judgement.

**Table 1 'Red flag' symptoms suggesting disorders other than GOR**

Symptoms and signs	Possible diagnostic implications	Suggested actions
<b>Gastrointestinal</b>		
Frequent, forceful (projectile) vomiting	May suggest hypertrophic pyloric stenosis in infants up to 2 months old	Paediatric surgery referral
Bile-stained (green or yellow-green) vomit	May suggest intestinal obstruction	Paediatric surgery referral

Haematemesis (blood in vomit) with the exception of swallowed blood, for example, following a nose bleed or ingested blood from a cracked nipple in some breast-fed infants	May suggest an important and potentially serious bleed from the oesophagus, stomach or upper gut	Specialist referral
Onset of regurgitation and/or vomiting after 6 months old or persisting after 1 year old	Late onset suggests a cause other than reflux, for example a urinary tract infection (also see the NICE guideline on <a href="#">urinary tract infection in children</a> ) Persistence suggests an alternative diagnosis	Urine microbiology investigation Specialist referral
Blood in stool	May suggest a variety of conditions, including bacterial gastroenteritis, infant cows' milk protein allergy (also see the NICE guideline on <a href="#">food allergy in children and young people</a> ) or an acute surgical condition	Stool microbiology investigation Specialist referral
Abdominal distension, tenderness or palpable mass	May suggest intestinal obstruction or another acute surgical condition	Paediatric surgery referral
Chronic diarrhoea	May suggest cows' milk protein allergy (also see the NICE guideline on <a href="#">food allergy in children and young people</a> )	Specialist referral
<b>Systemic</b>		
Appearing unwell Fever	May suggest infection (also see the NICE guideline on <a href="#">feverish illness in children</a> )	Clinical assessment and urine microbiology investigation Specialist referral

Dysuria	May suggest urinary tract infection (also see the NICE guideline on <a href="#">urinary tract infection in children</a> )	Clinical assessment and urine microbiology investigation Specialist referral
Bulging fontanelle	May suggest raised intracranial pressure, for example, due to meningitis (also see the NICE guideline on <a href="#">bacterial meningitis and meningococcal septicaemia</a> )	Specialist referral
Rapidly increasing head circumference (more than 1 cm per week) Persistent morning headache, and vomiting worse in the morning	May suggest raised intracranial pressure, for example, due to hydrocephalus or a brain tumour	Specialist referral
Altered responsiveness, for example, lethargy or irritability	May suggest an illness such as meningitis (also see the NICE guideline on <a href="#">bacterial meningitis and meningococcal septicaemia</a> )	Specialist referral
Infants and children with, or at high risk of, atopy	May suggest cows' milk protein allergy (also see the NICE guideline on <a href="#">food allergy in children and young people</a> )	Specialist referral

1.1.6 Do not routinely investigate or treat for GOR if an infant or child without overt regurgitation presents with only 1 of the following:

- unexplained feeding difficulties (for example, refusing to feed, gagging or choking)
- distressed behaviour
- faltering growth
- chronic cough
- hoarseness



- a single episode of pneumonia.
- 1.1.7 Consider referring infants and children with persistent back arching or features of Sandifer's syndrome (episodic torticollis with neck extension and rotation) for specialist assessment.
- 1.1.8 Recognise the following as possible complications of GOR in infants, children and young people:
- reflux oesophagitis
  - recurrent aspiration pneumonia
  - frequent otitis media (for example, more than 3 episodes in 6 months)
  - dental erosion in a child or young person with a neurodisability, in particular cerebral palsy.
- 1.1.9 Recognise the following as possible symptoms of GOR in children and young people:
- heartburn
  - retrosternal pain
  - epigastric pain.
- 1.1.10 Be aware that GOR is more common in children and young people with asthma, but it has not been shown to cause or worsen it.
- 1.1.11 Be aware that some symptoms of a non-IgE-mediated cows' milk protein allergy can be similar to the symptoms of GORD, especially in infants with atopic symptoms, signs and/or a family history. If a non-IgE-mediated cows' milk protein allergy is suspected, see the NICE guideline on [food allergy in children and young people](#).
- 1.1.12 When deciding whether to investigate or treat, take into account that the following are associated with an increased prevalence of GORD:
- premature birth

- parental history of heartburn or acid regurgitation
- obesity
- hiatus hernia
- history of congenital diaphragmatic hernia (repaired)
- history of congenital oesophageal atresia (repaired)
- a neurodisability.

1.1.13 GOR only rarely causes episodes of apnoea or apparent life-threatening events (ALTEs), but consider referral for specialist investigations if it is suspected as a possible factor following a general paediatric assessment.

1.1.14 For children and young people who are obese and have heartburn or acid regurgitation, advise them and their parents or carers (as appropriate) that losing weight may improve their symptoms (also see the NICE guideline on [obesity](#)).

1.1.15 Do not offer an upper gastrointestinal (GI) contrast study to diagnose or assess the severity of GORD in infants, children and young people.

1.1.16 Perform an urgent (same day) upper GI contrast study for infants with unexplained bile-stained vomiting. Explain to the parents and carers that this is needed to rule out serious disorders such as intestinal obstruction due to mid-gut volvulus.

1.1.17 Consider an upper GI contrast study for children and young people with a history of bile-stained vomiting, particularly if it is persistent or recurrent.

1.1.18 Offer an upper GI contrast study for children and young people with a history of GORD presenting with dysphagia.

1.1.19 Arrange an urgent specialist hospital assessment to take place on the same day for infants younger than 2 months with progressively worsening or forceful vomiting of feeds, to assess them for possible hypertrophic pyloric stenosis.

1.1.20 Arrange a specialist hospital assessment for infants, children and young people for a possible upper GI endoscopy with biopsies if there is:

- haematemesis (blood-stained vomit) not caused by swallowed blood (assessment to take place on the same day if clinically indicated; also see [table 1](#))
- melaena (black, foul-smelling stool; assessment to take place on the same day if clinically indicated; also see [table 1](#))
- dysphagia (assessment to take place on the same day if clinically indicated)
- no improvement in regurgitation after 1 year old
- persistent, faltering growth associated with overt regurgitation
- unexplained distress in children and young people with communication difficulties
- retrosternal, epigastric or upper abdominal pain that needs ongoing medical therapy or is refractory to medical therapy
- feeding aversion and a history of regurgitation
- unexplained iron-deficiency anaemia
- a suspected diagnosis of Sandifer's syndrome.

1.1.21 Consider performing an oesophageal pH study (or combined oesophageal pH and impedance monitoring if available) in infants, children and young people with:

- suspected recurrent aspiration pneumonia
- unexplained apnoeas
- unexplained non-epileptic seizure-like events
- unexplained upper airway inflammation
- dental erosion associated with a neurodisability
- frequent otitis media
- a possible need for fundoplication (see [section 1.5](#))

- a suspected diagnosis of Sandifer's syndrome.

1.1.22 Consider performing an oesophageal pH study without impedance monitoring in infants, children and young people if, using clinical judgement, it is thought necessary to ensure effective acid suppression.

1.1.23 Investigate the possibility of a urinary tract infection in infants with regurgitation if there is:

- faltering growth
- late onset (after the infant is 8 weeks old)
- frequent regurgitation and marked distress.

## 1.2 *Initial management of GOR and GORD*

1.2.1 Do not use positional management to treat GOR in sleeping infants. In line with [NHS advice](#), infants should be placed on their back when sleeping.

1.2.2 In breast-fed infants with frequent regurgitation associated with marked distress, ensure that a person with appropriate expertise and training carries out a breastfeeding assessment.

1.2.3 In formula-fed infants with frequent regurgitation associated with marked distress, use the following stepped-care approach:

- review the feeding history, then
- reduce the feed volumes only if excessive for the infant's weight, then
- offer a trial of smaller, more frequent feeds (while maintaining an appropriate total daily amount of milk) unless the feeds are already small and frequent, then
- offer a trial of thickened formula (for example, containing rice starch, cornstarch, locust bean gum or carob bean gum).

1.2.4 In breast-fed infants with frequent regurgitation associated with marked distress that continues despite a breastfeeding assessment and advice, consider alginate therapy for a trial period of 1–2 weeks. If the alginate therapy is

successful continue with it, but try stopping it at intervals to see if the infant has recovered.

- 1.2.5 In formula-fed infants, if the stepped-care approach is unsuccessful (see recommendation 1.2.3), stop the thickened formula and offer alginate therapy for a trial period of 1–2 weeks. If the alginate therapy is successful continue with it, but try stopping it at intervals to see if the infant has recovered.

### 1.3 *Pharmacological treatment of GORD*

- 1.3.1 Do not offer acid-suppressing drugs, such as proton pump inhibitors (PPIs) or H<sub>2</sub> receptor antagonists (H<sub>2</sub>RAs), to treat overt regurgitation in infants and children occurring as an isolated symptom.
- 1.3.2 Consider a 4-week trial of a PPI or H<sub>2</sub>RA for those who are unable to tell you about their symptoms (for example, infants and young children, and those with a neurodisability associated with expressive communication difficulties) who have overt regurgitation with 1 or more of the following:
- unexplained feeding difficulties (for example, refusing feeds, gagging or choking)
  - distressed behaviour
  - faltering growth.
- 1.3.3 Consider a 4-week trial of a PPI or H<sub>2</sub>RA for children and young people with persistent heartburn, retrosternal or epigastric pain.
- 1.3.4 Assess the response to the 4-week trial of the PPI or H<sub>2</sub>RA, and consider referral to a specialist for possible endoscopy if the symptoms:
- do not resolve or
  - recur after stopping the treatment.
- 1.3.5 When choosing between PPIs and H<sub>2</sub>RAs, take into account:
- the availability of age-appropriate preparations
  - the preference of the parent (or carer), child or young person (as appropriate)

- local procurement costs.

1.3.6 Offer PPI or H<sub>2</sub>RA treatment to infants, children and young people with endoscopy-proven reflux oesophagitis, and consider repeat endoscopic examinations as necessary to guide subsequent treatment.

1.3.7 Do not offer metoclopramide, domperidone or erythromycin to treat GOR or GORD without seeking specialist advice and taking into account their potential to cause adverse events.

## 1.4 *Enteral tube feeding for GORD*

1.4.1 Only consider enteral tube feeding to promote weight gain in infants and children with overt regurgitation and faltering growth if:

- other explanations for poor weight gain have been explored **and/or**
- recommended feeding and medical management of overt regurgitation is unsuccessful.

1.4.2 Before starting enteral tube feeding for infants and children with faltering growth associated with overt regurgitation, agree in advance:

- a specific, individualised nutrition plan
- a strategy to reduce it as soon as possible
- an exit strategy, if appropriate, to stop it as soon as possible.

1.4.3 In infants and children receiving enteral tube feeding for faltering growth associated with overt regurgitation:

- provide oral stimulation, continuing oral feeding as tolerated
- follow the nutrition plan, ensuring that the intended target weight is achieved and that appropriate weight gain is sustained
- reduce and stop enteral tube feeding as soon as possible.

1.4.4 Consider jejunal feeding for infants, children and young people:

- who need enteral tube feeding but who cannot tolerate intragastric feeds because of regurgitation or
- if reflux-related pulmonary aspiration is a concern.

## 1.5 *Surgery for GORD*

- 1.5.1 Offer an upper GI endoscopy with oesophageal biopsies for infants, children and young people before deciding whether to offer fundoplication for presumed GORD.
- 1.5.2 Consider performing other investigations such as an oesophageal pH study (or combined oesophageal pH and impedance monitoring if available) and an upper GI contrast study for infants, children and young people before deciding whether to offer fundoplication.
- 1.5.3 Consider fundoplication in infants, children and young people with severe, intractable GORD if:
- appropriate medical treatment has been unsuccessful or
  - feeding regimens to manage GORD prove impractical, for example, in the case of long-term, continuous, thickened enteral tube feeding.

## 2 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

### 2.1 *Symptoms of gastro-oesophageal reflux gastro-oesophageal reflux disease (GORD) in infants, children and young people with a neurodisability*

What are the symptoms of GORD in infants, children and young people with a neurodisability?

#### **Why this is important**

The evidence reviewed on the symptoms associated with GORD in children and young people with a neurodisability was limited to 3 studies and graded as low- to very low-quality. The lack of a set of clearly defined features makes GORD difficult to recognise and differentiate from other vomiting problems. The proposed study would use objective measures of reflux (such as oesophageal pH monitoring) to assess GORD symptoms in infants, children and young people with a neurodisability.

### 2.2 *Cows' milk protein elimination in formula-fed infants*

What is the effectiveness and cost effectiveness of a trial of hydrolysed formula in formula-fed infants with frequent regurgitation associated with marked distress?

#### **Why this is important**

There is a widespread belief that GOR and/or GORD in formula-fed infants is often caused by intolerance to cows' milk. As a result, health professionals often prescribe a trial of hydrolysed formula as a substitute for cows' milk formula. This has resource implications because hydrolysed formula is more expensive than cows' milk formula. Additionally, there is no evidence on the clinical or cost effectiveness of this approach. Therefore, it is proposed that a randomised controlled trial is undertaken to explore this question. It is important to consider 2 population subgroups:

- infants with a personal or family history of atopic conditions
- infants whose GOR and/or GORD has not responded to the initial management outlined in this guideline (up to and including alginates).



## 2.3 *Fundoplication and oesophageal pH monitoring*

In infants, children and young people with overt or occult reflux, is fundoplication effective in reducing acid reflux as determined by oesophageal pH monitoring?

### **Why this is important**

Fundoplication is used to manage severe GORD. At present, there is limited evidence that overt regurgitation is reduced after surgery. However, this has not been objectively measured. In addition, the effect of surgery on occult reflux has not been assessed. This is important because surgery may be masking a continuing problem. The proposed study would monitor regurgitation before and after fundoplication using oesophageal pH monitoring. This may help health professionals identify which infants, children and young people will benefit from surgery.

## 3 Other information

### 3.1 *Scope and how this guideline was developed*

NICE guidelines are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

#### How this guideline was developed

NICE commissioned the National Collaborating Centre for Women's and Children's Health to develop this guideline. The Centre established a Guideline Development Group (see [section 4](#)), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in [the guidelines manual](#).

### 3.2 *Related NICE guidance*

Further information is available on the [NICE website](#).

#### Published

##### *General*

- [Medicines adherence](#) (2009) NICE guideline CG76

##### *Condition-specific*

- [Obesity](#) (2014) NICE guideline CG189
- [Dyspepsia and gastro-oesophageal reflux disease](#) (2014) NICE guideline CG184
- [Autism – management of autism in children and young people](#) (2013) NICE guideline CG170
- [Feverish illness in children](#) (2013) NICE guideline CG160
- [Postnatal care](#) (2013) NICE guideline CG37
- [Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease](#) (2013) NICE interventional procedure guidance 461

- [Laparoscopic insertion of a magnetic bead band for gastro-oesophageal reflux disease \(2012\) NICE interventional procedure guidance 431](#)
- [Spasticity in children and young people \(2012\) NICE guideline CG145](#)
- [Endoluminal gastroplication for gastro-oesophageal reflux disease \(2011\) NICE interventional procedure guidance 404](#)
- [Food allergy in children and young people \(2011\) NICE guideline CG116](#)
- [Barrett's oesophagus – ablative therapy \(2010\) NICE guideline CG106](#)
- [Constipation in children and young people \(2010\) NICE guideline CG99](#)
- [Diarrhoea and vomiting in children under 5 \(2009\) NICE guideline CG84](#)
- [Surgical management of otitis media with effusion in children \(2008\) NICE guideline CG60](#)
- [Maternal and child nutrition \(2008\) NICE guideline PH11](#)
- [Urinary tract infection in children \(2007\) NICE guideline CG54](#)
- [Endoscopic augmentation of the lower oesophageal sphincter using hydrogel implants for the treatments of gastro-oesophageal reflux disease \(2007\) NICE interventional procedure guideline 222](#)
- [Catheterless oesophageal pH monitoring \(2006\) NICE interventional procedure guidance 187](#)
- [Endoscopic injection of bulking agents for gastro-oesophageal reflux disease \(2004\) NICE interventional procedure guidance 55](#)

## **4 The Guideline Development Group, National Collaborating Centre and NICE project team, and declarations of interests**

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**Paul Jacklin**  
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**Stephen Murphy**  
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#### **4.4** *NICE project team*

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#### 4.5 *Declarations of interests*

The following members of the Guideline Development Group made declarations of interests. All other members of the Group stated that they had no interests to declare.

Member	Interest declared	Type of interest	Decision taken
Ieuan Davies	Member of the council of the British Society of Paediatric Gastroenterology, Hepatology and Nutrition.	Personal non-pecuniary	Declare and participate
Ieuan Davies	Chair of the endoscopy working group for the British Society of Paediatric Gastroenterology, Hepatology and Nutrition.	Personal non-pecuniary	Declare and participate
Ieuan Davies	Member of JAG through other work with the British Society of Paediatric Gastroenterology, Hepatology and Nutrition.	Personal non-pecuniary	Declare and participate
Charlie Fairhurst	Department participated in therapeutic trial on pain/spasticity funded by GW Pharma for Sativex.	Non-personal pecuniary	Declare and participate
Rebecca Harmston	Member of the family is employed by Pharmaceutical Product Development (PPDI).	Personal family interest	Declare and participate
Rebecca Harmston	Lay Member of Research Ethics Committee Cambridgeshire East (Health Research Authority).	Personal non-pecuniary	Declare and participate
Bruce Jaffray	Published research on the subject of survival after fundoplication surgery.	Personal non-pecuniary	Declare and participate
Bruce Jaffray	Provided a lecture at the British Society of Paediatric Gastroenterology Hepatology and Nutrition (BSPGHAN) Annual Meeting	Personal non-pecuniary	Declare and participate

Russell Peek	Member of the Royal College of Paediatrics and Child Health	Personal non-pecuniary	Declare and participate
Russell Peek	Member of the British Association of Perinatal Medicine	Personal non-pecuniary	Declare and participate
Mike Thomson	Speaker expenses from Janssen to attend the Australian Gastroenterology week.	Personal pecuniary interest	Declare and participate
Mike Thomson	Reasonable expenses paid by Nestle to attend the ESPGHAN conference in Jerusalem.	Personal pecuniary interest	Declare and participate
Mike Thomson	Speaker and chairman for Scientific committee. Attending the World Congress of Paediatric Gastroenterology. Reasonable expenses paid.	Personal pecuniary interest	Declare and participate
Mike Thomson	Author of a study that was discussed in the evidence summary during a GDG meeting.	Personal non-pecuniary	Declare and participate
Mike Thomson	Provided a lecture at The British Society of Paediatric Gastroenterology Hepatology and Nutrition (BSPGHAN) Annual Meeting.	Personal non-pecuniary	Declare and participate
Mike Thomson	Member of advisory board for a producer of endoscopic diagnostic equipment – Sandhill Scientific.	Personal non-pecuniary	Declare and participate
Mike Thomson	Member of medical advisory board for a charity supporting families with babies and children with reflux – 'Living with Reflux'	Personal non-pecuniary	Declare and participate
Mike Thomson	Medical Advisor to a charity providing support to families and individuals with reflux – FORT (Fighting Oesophageal Reflux Together)	Personal non-pecuniary	Declare and participate
Mike Thomson	Runs endoscopy training courses that benefits department and employer –Sheffield Children's hospital.	Non-personal pecuniary	Declare and participate



Mike Thomson	Ran peer reviewed and ethics approved multicentre and unicentre pharma-funded trials of medication including prucalopride for constipation. Funding provided by Novartis.	Non-personal pecuniary	Declare and participate
Mark Tighe	Lead on the Cochrane review on gastro-oesophageal reflux in children.	Personal non-pecuniary	Declare and participate

## About this guideline

NICE guideline recommendations are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

This guideline was developed by the National Collaborating Centre for Women's and Children's Health, which is based at the Royal College of Obstetricians and Gynaecologists. The Collaborating Centre worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

## *Strength of recommendations*

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also [patient-centred care](#)).

## **Interventions that must (or must not) be used**

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

## **Interventions that should (or should not) be used – a 'strong' recommendation**

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer...') when we are confident that an intervention will not be of benefit for most patients.

## **Interventions that could be used**

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

## *Other versions of this guideline*

The full guideline, [gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people](#) contains details of the methods and evidence used to develop the guideline. It is published by the National Collaborating Centre for Women's and Children's Health.

The recommendations from this guideline have been incorporated into a [NICE pathway](#).

We have produced [information for the public](#) about this guideline.

## *Implementation*

[Implementation tools and resources](#) to help you put the guideline into practice are also available.

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## Accreditation

