NICE National Institute for Health and Care Excellence

NICE guideline

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

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All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

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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

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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,

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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.

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Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in the recommendations section.

- 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 in the section on diagnosing and investigating GORD, 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 gastro-oesophageal reflux disease (GORD) in infants, children and young people.

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- 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 in the section on diagnosing and investigating GORD)
  - melaena (black, foul-smelling stool; assessment to take place on the same day if clinically indicated; also see table 1 in the section on diagnosing and investigating GORD)
  - 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 the recommendation on stepped-care approach for formula-fed infants with frequent regurgitation associated with marked distress), stop the thickened formula and offer

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alginate therapy for a trial period of 1 to 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_2 receptor antagonists (H_2RAs), 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 unless all of the following conditions are met:
  - the potential benefits outweigh the risk of adverse events
  - other interventions have been tried
  - there is specialist paediatric healthcare professional agreement for its use.

    Metoclopramide, domperidone and erythromycin are not licensed for use in children. Metoclopramide is contraindicated in infants, and should only be prescribed for short-term use (up to 5 days). For licensing and prescribing information, see the individual SPCs and BNF for children. MHRA drug safety updates have been issued covering risk of cardiac side effects with domperidone and:
    - risk of neurological adverse events with metoclopramide
    - risk of infantile hypertrophic pyloric stenosis with erythromycin
    - cardiac risks (QT interval prolongation) with erythromycin and potential drug interaction of erythromycin with rivaroxaban.

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Using this guideline

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information about shared decision making.

Healthcare professionals should follow our general guidelines for people delivering care:

- Babies, children and young people's experience of healthcare
- Decision making and mental capacity
- Medicines adherence
- Medicines optimisation
- Multimorbidity
- Shared decision making
- Transition from children's to adults' services

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

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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.

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,

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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 tothe 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)

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- 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

Gastrointestinal symptoms and signs

Gastrointestinal symptoms and signs	Possible diagnostic implications	Suggested actions
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

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Gastrointestinal symptoms and signs	Possible diagnostic implications	Suggested actions
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 urinary tract infection in under 16s) 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 food allergy in under 19s) 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 food allergy in under 19s)	Specialist referral

Systemic symptoms and signs

Systemic symptoms and signs	Possible diagnostic implications	Suggested actions
Appearing unwell Fever	May suggest infection (also see the NICE guideline on fever in under 5s)	Clinical assessment and urine microbiology investigation Specialist referral

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Systemic symptoms and signs	Possible diagnostic implications	Suggested actions
Dysuria	May suggest urinary tract infection (also see the NICE guideline on urinary tract infection in under 16s)	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 bacterial meningitis and meningococcal disease)	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 bacterial meningitis and meningococcal disease)	Specialist referral
Infants and children with, or at high risk of, atopy	May suggest cows' milk protein allergy (also see the NICE guideline on food allergy in under 19s)	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

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- 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 under 19s.

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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 overweight and obesity management).

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.

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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

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- dental erosion associated with a neurodisability
- frequent otitis media
- a possible need for fundoplication (see the recommendations in the section on surgery for GORD)
- 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 on sudden infant death syndrome (SIDS), 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**

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- 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 to 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 the recommendation on stepped-care approach for formula-fed infants with frequent regurgitation associated with marked distress), stop the thickened formula and offer alginate therapy for a trial period of 1 to 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

Not all PPIs and H2RAs are licensed for use in children and those that are licensed vary in the age that they are licensed from. For licensing and prescribing information, see the individual SPCs and BNF for children. MHRA drug safety updates have been issued for PPIs, covering hypomagnesaemia, the increased risk of fracture with long-term use and very low risk of subacute cutaneous lupus erythematosus.

1.3.1 Do not offer acid-suppressing drugs, such as proton pump inhibitors (PPIs) or H_2 receptor antagonists (H_2RAs), 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_2RA 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:

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- 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_2RA 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_2RA, 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_2RAs, 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_2RA 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 unless all the following conditions are met:

- the potential benefits outweigh the risk of adverse events
- other interventions have been tried
- there is specialist paediatric healthcare professional agreement for its use.

  Metoclopramide, domperidone and erythromycin are not licensed for use in children. Metoclopramide is contraindicated in infants, and should only be

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prescribed for short-term use (up to 5 days). For licensing and prescribing information, see the individual SPCs and BNF for children. MHRA drug safety updates have been issued covering risk of cardiac side effects with domperidone and:

- risk of neurological adverse events with metoclopramide
- risk of infantile hypertrophic pyloric stenosis with erythromycin
- cardiac risks (QT interval prolongation) with erythromycin and potential drug interaction of erythromycin with rivaroxaban.

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.

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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.

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Recommendations for research

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.

1 Symptoms of 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 the recommendation for research was made

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 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?

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Why the recommendation for research was made

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).

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 the recommendation for research was made

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.

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Finding more information and resources

To find NICE guidance on related topics, including guidance in development, see the NICE topic page on gastro-oesophageal reflux, including Barrett's oesophagus.

For full details of the evidence and the guideline committee's discussions, see the full guideline. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

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Update information

October 2019: Information has been added to recommendations in section 1.3 on PPI and H_2RA licensing for use in children. Recommendation 1.3.7 has been amended to clarify when metoclopramide, domperidone or erythromycin can be offered.

Minor changes since publication

March 2025: We updated links following publication of NICE's guideline on overweight and obesity management.

March 2024: We updated links to our guidance on bacterial meningitis and meningococcal disease following the launch of NICE's guideline on meningitis (bacterial) and meningococcal disease: recognition, diagnosis and management.

May 2021: In recommendation 1.3.7, we highlighted the MHRA drug safety updates about the risk of infantile hypertrophic pyloric stenosis with erythromycin, cardiac risks with erythromycin and potential drug interaction of erythromycin with rivaroxaban.

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