NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health and social care directorate

Quality standards and indicators

Briefing paper

Quality standard topic: Gastro-oesophageal reflux disease in children and young people.

Output: Prioritised quality improvement areas for development.

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Contents

1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for gastro-oesophageal reflux disease (GORD) in children and young people. It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

1.1 Structure

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

1.2 Development source

The key development source referenced in this briefing paper is:

Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people. NICE guideline NG1 (2015).

2 Overview

2.1 Focus of quality standard

This quality standard will cover recognition, diagnosis and management of gastro-oesophageal reflux disease in children and young people under the age of 18. This quality standard will not cover gastro-oesophageal reflux disease in adults age 18 and over as it is covered in a separate quality standard Dyspepsia and gastro-oesophageal reflux disease which is currently being developed.

2.2 Definition

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.

2.3 Incidence and prevalence

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.

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. According to the Office for National Statistics, in 2013 there were around 657,000 live births in England. If at least 40% of infants are affected by GOR during the first 6 months of their life, there could be around 262,800 infants with GOR in England each year.

English NHS hospital episode statistics for 2013-14 show that there were 10,134 consultant episodes for GORD with or without oesophagitis in children and young people aged 0–17 years. Majority of the episodes (6,940) was for infants under 1.

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.

2.4 Management

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. When symptoms indicate the presence of GORD treatment can be 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.

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.

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.

See appendix 1 for the associated care pathway and algorithms from NICE guideline NG1.

2.5 National Outcome Frameworks

Tables 1–2 show the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

Table 1 NHS Outcomes Framework 2015–16

Domain	Overarching indicators and improvement areas
2 Enhancing quality of life for people with long-term conditions	***Improvement areas*** **Reducing time spent in hospital by people with long-term conditions** 2.3i Unplanned hospitalisation for chronic ambulatory care sensitive conditions
3 Helping people to recover from episodes of ill health or following injury	***Improvement areas*** 3.1i Total health gain as assessed by patients for elective procedures
5 Treating and caring for people in a safe environment and protecting them from avoidable harm	***Improvement areas*** 5.5 Admission of full-term babies to neonatal care

Table 2 Public health outcomes framework for England, 2013–2016

Domain	Objectives and indicators
2 Health improvement	***Objective*** People are helped to live healthy lifestyles, make healthy choices and reduce health inequalities ***Indicators*** 2.5 Child development at 2 – 2 ½ years
4 Healthcare public health and preventing premature mortality	***Objective*** Reduced numbers of people living with preventable ill health and people dying prematurely, whilst reducing the gap between communities ***Indicators*** 4.2 Tooth decay in children aged 5

3 Summary of suggestions

3.1 Responses

In total 11 stakeholders responded to the 2-week engagement exercise 21/04/15 – 6/05/15.

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 3 for further consideration by the Committee.

NHS England's patient safety division did not submit any data for this topic.

Full details of all the suggestions provided are given in appendix 4 for information.

Table 3 Summary of suggested quality improvement areas

Suggested area for improvement	Stakeholders
Providing information	SCM 1, SCM 2,
Assessment • Assessment & referral • Upper GI contrast	SCM 2, SCM 3, SCM 5, SCM 6, BSPR/RCR
Stepped care approach	SCM 3, SCM 4
Dietary approach • Feeding and diet • Cow's milk free diet	SCM 2, SCM 3, SCM 4, SCM 5
Pharmacological approach • PPI & H2RA • Prokinetics	SCM 2, SCM3, SCM 6
Enteral feeding	SCM 4
Additional areas • Research • GOR & Asthma • Liquid omeprazole – price	RCOGP, SCM 4, SCM 5, BSPR/RCR
BSPR/RCR, British Society of Paediatric Radiology / The Royal College of Radiologists RCOGP, The Royal College of General Practitioners SCM, Specialist Committee Member	

4 Suggested improvement areas

4.1 Providing information

4.1.1 Summary of suggestions

Stakeholders highlighted that information on reflux and GORD should be delivered in antenatal classes as well as produced in a form of a leaflet for new parents leaving hospital. Stakeholders also highlighted the need to support parents with advice on breast feeding as well as formula feeding.

Stakeholders also highlighted the need for ongoing support for parents of children diagnosed with GORD. They suggested that after the initial contact parents of children with GORD are left alone to deal with the longer term effects of GORD such as weaning difficulties, sleep issues, faltering growth and often frequent chest and ear infections.

4.1.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 4 to help inform the Committee's discussion.

Table 4 Specific areas for quality improvement

Suggested quality improvement area	Suggested source guidance recommendations
Providing information	**Diagnosing and investigating GORD** NICE NG1 Recommendation 1.1.3 (KPI) NICE NG1 Recommendation 1.1.4

Diagnosing and investigating GORD

NICE NG1 Recommendation 1.1.3 (key priority for implementation)

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.

NICE NG1 Recommendation 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.

4.1.3 Current UK practice

Information and advice

The Infant Feeding Survey (2010) found that nearly seven in ten mothers breastfeeding in the hospital, birth centre or unit (69%) had been shown how to put their baby to the breast in the first few days (84% of first-time mothers and 50% of mothers of second or later babies).

Just under half of mothers breastfeeding in the hospital, birth centre or unit (48%) were informed about how to recognise that their baby was getting enough milk and nearly two in five (37%) felt they were confident enough to recognise whether or not their baby was getting enough milk.

Nearly seven in ten mothers (69%) had been given the contact details of a voluntary organisation or community group which helps new mothers with infant feeding. Nearly two-thirds of mothers (64%) were aware of the National Breastfeeding Helpline, with four per cent saying they had used it in the UK.[1]

Midwives responding to the survey carried out by the Royal College of Midwives (2013) said that they had enough time and resources to support the women with:

- normal infant behaviour - 35%
- breastfeeding - 70%

[1] Infant Feeding Survey (2010). Health and Social Care information Centre.

- artificial feeding - 33%

The midwives found making referrals to other professionals with infant feeding problem

- very easy – 34%
- quite easy – 51%
- no option – 3%
- quite difficult – 11%
- very difficult – 1%

Support with feeding was the main reason for extra visits from midwives. 57% of midwives also said that they would like to provide more or a lot more of this type of support.[2]

A small study (60 patients) assessing current practice and adherence to ESPGHAN guidelines regarding the diagnosis and management of infants presenting with a diagnosis of GOR or GORD in a UK hospital found that all parents were provided with education and guidance[3].

[2] Audit of practice in postnatal care. The Royal College of Midwives.
[3] ST Belitsi et al. Management of gastroesophageal reflux in infants: current practice of diagnosis and treatment in a UK district general hospital

4.2 Assessment

4.2.1 Summary of suggestions

Assessment and referral

Stakeholders highlighted the need for infants, children and young people with symptoms of gastro-oesophageal reflux to have a detailed assessment including history, feeding review and examination looking for red flags. They acknowledged that vast majority of infants will have functional reflux and would improve with simple advice regarding feeding, and reassurance may be all that is required.

Stakeholders highlighted that the diagnosis of GORD is not made early enough and that there needs to be a better understanding of the condition during the hospital post-natal period. They suggested that early diagnosis would reduce number of doctors and/or health visitor appointments. They also suggested that from a parent's point of view it would reduce anxiety and allow access to a defined support network.

Stakeholders highlighted the need for referral in case of gastrointestinal or systemic symptoms and signs as per Table 1 'Red flag' symptoms within NG1.

Upper GI contrast

Stakeholders suggested that infants and children with symptoms of GOR should not have an upper GI contrast to diagnose or assess the severity of GOR. They highlighted that upper GI contrast studies have a radiation burden, are time-consuming, can be disruptive for the patient, and are neither sensitive nor specific for diagnosing GOR.

4.2.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. These are presented in full after table 4 to help inform the Committee's discussion.

Table 4 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Assessment and referral	**Diagnosing and investigating GORD** NICE NG1 Recommendation 1.1.5 (KPI) NICE NG1 Recommendation 1.1.6 (KPI) NICE NG1 Recommendation 1.1.12 NICE NG1 Recommendation 1.1.20 (KPI)
Upper GI contrast	**Diagnosing and investigating GORD** NICE NG1 Recommendation 1.1.15 (KPI)

Diagnosing and investigating GORD

NICE NG1 Recommendation 1.1.5 (key priority for implementation)

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.

NICE NG1 Recommendation 1.1.6 (key priority for implementation)

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.

NICE NG1 Recommendation 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.

NICE NG1 Recommendation 1.1.15 (key priority for implementation)

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

NICE NG1 Recommendation 1.1.20 (key priority for implementation)

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.

4.2.3 Current UK practice

A small study of 60 patients with a diagnosis of GOR or GORD in a UK hospital found that 100% of patients included in this study were diagnosed with GOR, rather than GORD despite the presence of what could be considered as “troublesome

symptoms”. The two most frequently reported symptoms were poor weight gain n = 6 (10%) and irritability n = 40 (66%).

4.3 Stepped care approach

4.3.1 Summary of suggestions

Stakeholders highlighted that most infants with gastro-oesophageal reflux do not require pharmacological intervention and parents or carers should be reassured and given advice on the natural history of this. They also suggested that there had been an apparent increase in treating overt regurgitation as an isolated symptom with acid suppression therapy where a stepped care approach recommended by NG1 is both more appropriate, avoids adverse effects and is cost effective.

4.3.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. These are presented in full after table 5 to help inform the Committee's discussion.

Table 5 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Stepped care approach	**Initial management of GOR and GORD** NICE NG1 Recommendation 1.2.3 (KPI) NICE NG1 Recommendation 1.2.5 (KPI)

Initial management of GOR and GORD

NICE NG1 Recommendation 1.2.3 (key priority for implementation)

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).

NICE NG1 Recommendation 1.2.5 (key priority for implementation)

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.

4.3.3 Current UK practice

No published studies on current practice were highlighted for this suggested area for quality improvement. This area is based on stakeholder's knowledge and experience.

4.4 Dietary approach

4.4.1 Summary of suggestions

Feeding and diet

Stakeholders highlighted the need to carry out feeding review and making required adjustments to feeding volumes and frequencies before other steps were taken. They also suggested an approach of weaning onto solid food from 4 months onwards.

Stakeholders suggested that children and young people (and their parents or carers) who are obese and have heartburn should be advised that losing weight may improve their symptoms.

Cow's milk free diet

Stakeholders suggested early institution of a cow's milk-free diet or a trial of extensively hydrolysed non - cow's milk formula for 2-4 weeks followed by a re-challenge of cow's milk formula.

4.4.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. These are presented in full after table 6 to help inform the Committee's discussion.

Table 6 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Feeding and diet	**Initial management of GOR and GORD** NICE NG1 Recommendation 1.1.14 NICE NG1 Recommendation 1.2.3 (KPI)
Cow's milk free diet	**Initial management of GOR and GORD** NICE NG1 Recommendation 1.1.11

Initial management of GOR and GORD

NICE NG1 Recommendation 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).

NICE NG1 Recommendation 1.2.3 (Key Priorities for Implementation)

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).

NICE NG1 Recommendation 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.

4.4.3 Current UK practice

No published studies on current practice were highlighted for this suggested area for quality improvement. This area is based on stakeholder’s knowledge and experience.

4.5 Pharmacological approach

4.5.1 Summary of suggestions

Proton pump inhibitor (PPI) & H2 receptor antagonist (H2RA)

Stakeholders highlighted that there is a considerable overprescription of PPIs/H2RAs in primary and secondary care. They suggested that infants and children with isolated regurgitation and no risk factors should not be offered PPI/H2RA treatment. However some stakeholders suggested considering a 4 week trial of a proton pump inhibitor (PPI) or H2 receptor antagonist (H2RA) in those unable to communicate their symptoms. They suggested that the patient should be reassessed at 4 weeks and referred for possible endoscopy if there is no improvement or if recurrence on stopping treatment.

Prokinetics

Stakeholders suggested that children with GOR should not be offered prokinetics without specific advice regarding potential side-effects.

4.5.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. These are presented in full after table 7 to help inform the Committee's discussion.

Table 7 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
PPI & H2RA	**Pharmacological treatment of GORD** NICE NG1 Recommendation 1.3.1 (KPI) NICE NG1 Recommendation 1.3.2 NICE NG1 Recommendation 1.3.4
Prokinetics	NICE NG1 Recommendation 1.3.7 (KPI)

Pharmacological treatment of GORD

NICE NG1 Recommendation 1.3.1 (key priority for implementation)

Do not offer acid‑suppressing drugs, such as proton pump inhibitors (PPIs) or H2 receptor antagonists (H2RAs), to treat overt regurgitation in infants and children occurring as an isolated symptom.

NICE NG1 Recommendation 1.3.2

Consider a 4‑week trial of a PPI or H2RA 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.

NICE NG1 Recommendation 1.3.4

Assess the response to the 4‑week trial of the PPI or H2RA, and consider referral to a specialist for possible endoscopy if the symptoms:

- do not resolve or
- recur after stopping the treatment.

NICE NG1 Recommendation 1.3.7 (key priority for implementation)

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.

4.5.3 Current UK practice

PPI & H2RA

A small study (60 patients) assessing current practice and adherence to ESPGHAN guidelines regarding the diagnosis and management of infants presenting with a diagnosis of GOR or GORD in a UK hospital found that despite being “officially” diagnosed with GOR, 55 out of 60 children (91%) were commenced on anti-reflux medication (i.e. proton pump inhibitors or the H2 receptor blocker Ranitidine).[4]

Prokinetics

[4] ST Belitsi et al. Management of gastroesophageal reflux in infants: current practice of diagnosis and treatment in a uk district general hospital

Data analysis carried out using data from the General Practice Research Database between 1990 and 2006 for children <18 years revealed that the proportion of children <2 years old being prescribed one of the medications doubled during the study period. Prescriptions of domperidone increased 10-fold, mainly following the withdrawal of cisapride in 2000. Prescriptions of metoclopramide did not change significantly. Medicines and Healthcare Products Regulatory Agency issued safety warnings for domperidone in May 2012 and restricted its indications. Despite the increase in prescriptions of domperidone, no new safety signals were identified since[5].

[5] Shahrul Mt-Isa et al. Prokinetics Prescribing in Paediatrics: Evidence on Cisapride, Domperidone and Metoclopramide

4.6 Enteral tube feeding

4.6.1 Summary of suggestions

Stakeholders suggested that children started on enteral feeding should have an individualised nutritional plan and an exit strategy in place. This would ensure that the enteral feeding processes are stopped as soon as appropriate.

4.6.2 Selected recommendations from development source

Table 8 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. These are presented in full after table 8 to help inform the Committee's discussion.

Table 8 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Enteral tube feeding	**Enteral tube feeding for GORD** NICE NG1 Recommendation 1.4.2

Enteral tube feeding for GORD

NICE NG1 Recommendation 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.

4.6.3 Current UK practice

No published studies on current practice were highlighted for this suggested area for quality improvement. This area is based on stakeholder's knowledge and experience.

4.7 Additional areas

Summary of suggestions

The improvement areas below were suggested as part of the stakeholder engagement exercise. However they were felt to be either unsuitable for development as quality statements, outside the remit of this particular quality standard referral or require further discussion by the Committee to establish potential for statement development.

There will be an opportunity for the QSAC to discuss these areas at the end of the session on 17th June 2015.

Research

Stakeholders suggested that more research is needed to derive a safe and effective pro-motility agent fundamental in the treatment of respiratory related events with GORD. They have also highlighted the need for research into day 1 cow's milk protein exposure and subsequent development of cow's milk protein (CMP) allergy. Need for research into specific approaches is not usually addressed within NICE quality standards which focus on evidence based actions that lead to improving quality of services received by patients.

GOR and asthma

Stakeholders highlighted the need to look for GOR in refractory asthma and suggested that there may be merit for gastro-oesophageal reflux treatment for prolonged non-specific cough in children and adults. This area is outside the scope of this quality standard because it focuses on asthma as an underlying medical condition.

Liquid omeprazole – price

Stakeholders suggested that the price of liquid omeprazole in the UK is too high and addressing that issue would transform the treatment of infants with GORD by enabling appropriate treatment and dose management. They also highlighted that liquid omeprazole is the only reliable way of administering a PPI in infancy. NICE quality standards would not normally address pricing as an area for quality improvement.

Appendix 1: Additional information

Box A - Gastro-oesophageal reflux disease – recognition and diagnosis

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.

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).
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.

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.

In infants, children and young people with vomiting or regurgitation, look out for the 'red flags' in Table R1, 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.

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.

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.

Recognise the following as possible symptoms of GOR in children and young people:

- heartburn
- retrosternal pain
- epigastric pain

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.

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.

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)
- neurodisability.

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.

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.

Box B – Investigation

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

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.

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.

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

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 R1)
- melaena (black, foul-smelling stool; assessment to take place on the same day if clinically indicated; also see Table R1)
- 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.

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 epileptic seizure-like events
- unexplained upper airway inflammation
- dental erosion associated with a neurodisability
- frequent otitis media
- a possible need for fundoplication
- a suspected diagnosis of Sandifer's syndrome

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.

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.

Box C - Management of overt regurgitation in infants and children

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.

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. 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.

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

- review the feeding history, the
- 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 26), 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 H2 receptor antagonists (H2RAs), to treat overt regurgitation in infants and children occurring as an isolated symptom.

Consider a 4-week trial of PPI or H2RA 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.

When choosing between PPIs and H2RAs,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.

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.

Box D - Management of heartburn, retrosternal or epigastric pain

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)

Consider a 4-week trial of a PPI or H2RA for those 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.

Consider a 4-week trial of a PPI for children and young people with persistent heartburn, retrosternal or epigastric pain.

Assess the response to the 4-week trial of the PPI or H2RA, and consider referral to a specialist for possible endoscopy if the symptoms:

- do not resolve or
- recur after stopping the treatment

When choosing between PPIs and H2RAs, 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.

Offer PPI or H2RA treatment to infants, children and young people with endoscopy-proven reflux oesophagitis, and consider repeat endoscopic examinations as necessary to guide subsequent treatment.

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.

Box E - Management of endoscopy-proven reflux oesophagitis

Offer PPI or H2RA treatment to infants, children and young people with endoscopy-proven reflux oesophagitis, and consider repeat endoscopic examinations as necessary to guide subsequent treatment.

When choosing between PPIs and H2RAs, 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.

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.

Box F - Enteral feeding

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

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.

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.

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.

Box G – Fundoplication

Offer an upper GI endoscopy with oesophageal biopsies for infants, children and young people before deciding whether to offer fundoplication for presumed GORD.

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. 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.

Appendix 2: Key priorities for implementation (NG1)

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

Diagnosing and investigating GORD

- 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.

[Recommendation 1.1.3]

- 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.

[Recommendation 1.1.5]

- 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.

[Recommendation 1.1.6]

- 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.

[Recommendation 1.1.15]

- 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).

[Recommendation 1.1.20]

Initial management of GOR and GORD

- 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.

[Recommendation 1.2.5]

Pharmacological treatment of GORD

- Do not offer acid-suppressing drugs, such as proton pump inhibitors (PPIs) or H2 receptor antagonists (H2RAs), to treat overt regurgitation in infants and children occurring as an isolated symptom.

[Recommendation 1.3.1]

- 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.

[Recommendation 1.3.7]

Appendix 3: Suggestions from stakeholder engagement exercise – registered stakeholders

ID	Section number	Stakeholder	Key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
1	4.1	SCM 1	Introduction of information on GORD and reflux into anti-natal classes.	I am not sure if this information is current provided in the hospital pack and ante natal class information as my last child was born in 2010.	Regurgitation is known to occur in over 90% of infants but GORD is a condition that many parents are unaware of. Production of a leaflet showing information from Section 1.1 Diagnosing and Investigating GORD in the recently published NICE guidance on Gastro-oesophageal reflux disease: Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people would make parents more aware of the condition. In my opinion this would: a) Reassure parents of “normal” infants that some regurgitation is normal b) Advise parents what symptoms may be linked to GORD and when to seek help. c) Make more people aware of the condition before the infant is born and provide information on who to contact for help and guidance.	

2	4.1	SCM 2	Advice and Reassurance. Give advice about gastro-oesophageal reflux (GOR) and reassure parents and carers. Ensure adequate support networks.	In well infants, effortless regurgitation of feeds does not usually require investigation or treatment.	Medications can have side effects and are not always needed. Despite the new NICE guidance, medications are still being prescribed when not indicated	
3	4.1	SCM 1	Breast feeding support and advice for parents of GOR(D) infants.	Parents are always informed that breast feeding is the best choice for both mother and infants. Breast feeding does not come naturally to all mothers or infants due to issues with latching on, tongue tie, failure to thrive, mastitis, low milk supply and general anxiety about not producing enough milk for an infant. GOR (D) is often present from birth and I feel that there is a lack of support for new and experienced parents who wish to breast feed. I myself switched to formula feeding a GORD baby and know other parents who have done the same. In my opinion the main issues and anxieties felt by a breast feeding parent of a GORD infant are:	Supporting parents of GORD infants who wish to breast feed their baby may reduce costs for prescription formula which is expensive and there's some evidence that breast feeding may reduce the severity of GORD symptoms.	The La Leche League International produce a document entitled "Breast Feeding the baby with Reflux". It can be downloaded from the reflux.org. website. It discusses the benefits and issues of breast feeding a baby with GORD.

				a). Is my baby receiving enough breast milk? The may infant may feed, regurgitate the feed and then begin feeding again. b) How do I give feed thickening agents to a breast fed baby? c) Is it easier to administer medication and monitor feeding in a formula fed infant? d) Are there any advantages or disadvantages to FF or BF a GORD infant?		

5	4.1	SCM 1	Ongoing support for parents of children diagnosed with GORD.	Currently many parents of children diagnosed with GOR(D) are given feed thickening agents or thickened formula and are then advised to return for a review a few weeks later to access if the medication is working. I've discussed this with other parents of GORD children and they strongly feel that they are not told how long the GORD will last and what the longer term implications can be. After the initial contact period the parents are often left alone to deal with the longer term effects of GORD such as weaning difficulties, sleep issues, faltering growth and often frequent chest and ear infections. Support could be given by midwife, health visitors or GP's.	Lack of support for parents of GORD infants has cost implications for the NHS: Increased number of doctors and/or health visitor appointments Increased number of prescription medications issued if the child's medication is not reviewed regularly.	Please see the Section 1.1 Diagnosing and Investigating GORD in the recently published NICE guidance on Gastro-oesophageal reflux disease: Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people

	4.2	SCM 1	Early diagnosis/reassurance to parent from birth	As a lay person and parent of a GORD infant I feel that the diagnosis of GORD is not made early enough and that there needs to be a better understanding of the condition during the hospital post-natal period. The condition is often present from birth and it's often noticed by the parents that the infant is regurgitating significant amounts of feeds after every meal.	Diagnosis of GORD is often delayed by the parent's assumption that the volumes and frequency of feed regurgitation is normal. The frequency and severity of GORD symptoms can vary significantly amongst infants. Early reassurance or diagnosis of the condition where this applies would reduce number of doctors and/or health visitor appointments. From a parents point of view it would reduce anxiety and allow access to a defined support network.	Please see the Section 1.1 Diagnosing and Investigating GORD in the recently published NICE guidance on Gastro-oesophageal reflux disease: Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people
6	4.2	SCM 6	Infants and children with symptoms of GOR should not have a upper GI contrast to diagnose GOR	Contrast swallows have a radiation burden, and are time-consuming, and can be disruptive for the patient, and are neither sensitive nor specific for diagnosing GOR.	There are uses for a contrast swallow, such as food sticking, or concerns about malrotation, or before fundoplications, but a large proportion are done for GOR.	Studies have supported the lack of sensitivity/specificity of a contrast swallow.

7	4.2	British Society of Paediatric Radiology (BSPR) / The Royal College of Radiologists (RCR)	Recommends not offering an upper gastro intestinal (GI) contrast study to diagnose or assess the severity of Gastro _Oesophageal Reflux Disease (GORD) in infants, children and young adults.	This is likely to reduce the number of Upper GI contrast studies performed particularly for referrals such as suspected aspiration pneumonias, unexplained apnoeas, suspected diagnosis of Sandifer's syndrome	It is known that upper GI contrast study is not sensitive diagnose and assess the severity of reflux. Some of the previous referrals for upper GI contrast studies will now be referred with stricter criteria for more sensitive but invasive examinations such as pH monitoring and paediatric gastroenterology referral for upper GI endoscopy.	Pediatric gastroesophageal reflux clinical practice guidelines: joint recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) J Pediatr Gastroenterol Nutr. 2009 Oct;49(4):498-547
8	4.2	SCM 6	Infants, children and young people with symptoms of gastro-oesophageal reflux have a detailed assessment including history and examination looking for red flags.	This vast majority of infants will have functional reflux and will improve with simple advice regarding feeding, and reassurance may be all that is required.	Many well infants are referred to secondary care due to parental anxiety.	This is the main focus of NICE guidance as half of all infants under 3m of age have GOR.

9	4.2	SCM 3		Consider possible UTI in infants with regurgitation if there is faltering growth, late onset (after the infant is eight weeks old or onset after 6 months),or increasing regurgitation with distress.	It is important to exclude any other underlying treatable disease process that may contribute to or cause this presentation. Assessment of urine is a simple procedure and can be undertaken in primary and secondary care, and treatment of UTI may avoid unnecessary and potentially harmful investigations and treatment.	See NICE urinary tract infection in children 2007 CG54
10	4.2	SCM 6	Refer all babies and children with bile-stained vomiting for same day paediatric assessment.	To avoid babies and children with surgical diagnoses being misdiagnosed as GORD	To avoid babies being mismanaged and misdiagnosed.	This is easily achievable, and safe practice. One recent study suggested that over 40% of babies with bilious vomiting have a surgical diagnosis such as malrotation, and 40% had another treatable cause such as sepsis.

11	4.2	SCM 3		Red flags - referral expectations. Assess and refer for same day specialist review if there is any of 1. frequent, projectile or forceful vomiting (refer if 8 weeks or less to exclude pyloric stenosis); 2. haematemesis (not explained by nosebleed or ingested blood from a cracked nipped in breastfeeding infants);3. Malaena or other blood in stool; 4 . Abdominal distension, tenderness or palpable mass;5. Bile stained vomiting 6 . Dysphagia and other symptoms and signs noted in table R1 , page 20 of NICE Gastro-oesophageal reflux disease in children and young people (2015) .	It is important to highlight and differentiate potentially serious and life threatening diagnoses and parents or carers should be advised to present acutely if there are specific red flags	See NICE Gastro-oesophageal reflux disease in children and young people (2015) and table R1
12	4.2	SCM 5		Earlier referral of infants with GORD to a paediatrician or paediatric gastroenterologist.	Correct and appropriate treatment of this phenomenon.	Research that indicates an estimate of 9 GP visits as an infant before a diagnosis of GOR/GORD is arrived at.

13	4.3	SCM 3		Formula fed well infants less than 6 months with frequent regurgitation and associated distress should have, after previous assessment and advice on positioning and reassurance, a review of feeding history, then reduced feed volumes if excessive for the infant's weight, then a trial of smaller more frequent feeds (maintaining the total daily volume), then a trial thickened formula. If this is unsuccessful, a 1-2 week trial of alginate followed by review and only continuing this if helpful should be undertaken. Breast fed infants who have frequent regurgitation with distress should be referred to a person with appropriate expertise and training to carry out a breastfeeding assessment.	Most infants with gastro-oesophageal reflux do not require pharmacological intervention and parents or carers should be reassured and given advice on the natural history of this. Where there is associated distress and possible GORD, there has been an apparent increase in treating overt regurgitation as an isolated symptom with acid suppression therapy (with H receptor antagonists and proton pump inhibitors) where a stepwise approach is both more appropriate, avoids adverse effects and is cost effective. Similarly, there has been routine (investigations and) treatment in infants or children without overt regurgitation and only one symptom of : unexplained feeding difficulties, distressed behaviour, faltering growth, chronic cough, hoarseness or a single episode of pneumonia. There is a lack of evidence for this and risk of potential adverse effects.	See published guidelines from NICE, Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN). There is a need for greater quality of evidence in this area
14	4.3	SCM 4		There is good evidence that a thickened feed should be offered as a first line treatment for babies who are formula fed.	This is a simple non-medical intervention that is cost effective as parents/carers can buy the milk at a similar cost to the babies' usual formula.	

15	4.3	SCM 4		There is good evidence that if a thickened feed is not effective for babies who are formula fed. The thickened feed should be stopped and a trial of alginate therapy given for two weeks.	This ensures that infants are re-assessed and alternative treatment initiated if not beneficial improving quality	
16	4.4	SCM 2	In formula-fed infants with frequent regurgitation associated with marked distress, review the feeding history.	Feeding volumes may be excessive for the infant's weight. Smaller more frequent feeds may be all that is required	Reviewing feeding history and making required adjustments may reduce further input and avoid medication being prescribed.	
17	4.4	SCM 4		There is good evidence to support the need for a feeding assessment in breast and formula fed babies and infants presenting with GOR	This would ensure identification of excessive feeds and simple corrective measures made (involving no cost) A lot of babies are currently started on treatment without a feeding assessment being completed.	http://www.nct.org.uk/parenting/what-reflux
18	4.4	SCM 3		Advise children and young people (and their parents or carers) who are obese who have heartburn that losing weight may improve their symptoms.	There is an association between obesity and Gastro-oesophageal reflux which causes heartburn, but obesity is also associated with Barrett's oesophagus and oesophageal adenocarcinoma. Weight loss has been found to improve GORD	See the NICE guideline on obesity 2014 CG189 and Gastro-oesophageal reflux disease in children and young people(2015). Obesity volume 21, issue 2, pp284-290, February 2013.
19	4.4	SCM 5		Disseminate the approach of weaning onto solid food from 4 months onwards.	Less likely to cause significant GOR with solid food than milk.	Personal experience.

20	4.4	SCM 3		Consider a trial of extensively hydrolysed non - cow's milk formula for 2-4 weeks followed by a re-challenge of cow's milk formula, especially if there is a history or family history of atopy in formula fed infants presenting with non bilious regurgitation before considering prescribed medication such as H2RAs and PPIs.	It is known that some symptoms of non-IgE mediated cow's milk protein allergy can be similar to the symptoms of GORD, especially if there are symptoms and/or signs of atopy or a family history. It is important to identify those who might benefit from a milk free formula and to avoid the development of complications (such as enteropathy) without adding to costs of trialling cow's milk free formulae.	See the NICE guideline on food allergy in children and young people (2011)CG116. There is a lack of evidence in this specific area and more research is needed to assess cost - effectiveness of this diagnostic intervention.
21	4.4	SCM 5		Early institution of a cow's milk-free dietary approach in infants with reflux and an atopic background.	Generally not implemented at a primary care level.	General knowledge that this is the case.
22	4.5	SCM 2	1.3.2 Consider a 4-week trial of a PPI or H2RA . Review patient after the 4 week trial.	To stop long term use of these drugs if they are proving ineffective	So that drugs that are ineffective are not continued to be prescribed and administered when unnecessary	

23	4.5	SCM 3		Consider a 4 week trial of a proton pump inhibitor (PPI) or H2 receptor antagonist (H2RA) in those unable to communicate their symptoms (eg infants and young children, and those with a neuro disability and associated communication difficulty who have overt regurgitation and one or more of unexplained feeding difficulties, distressed behaviour and/or faltering growth. Reassess at 4 weeks and refer for possible endoscopy if there is no improvement or if recurrence on stopping treatment.	PPIs and H2RAs should not be used to treat overt regurgitation as an isolated symptom in infants and children due to the current paucity of evidence and potential risk of adverse effects. Despite the lack of available evidence, it is a reasonable strategy to consider when overt regurgitation is associated with a cluster of symptoms (which might suggest reflux oesophagitis), as long as there is review with a view to appropriate investigation if symptoms and signs persist. (In children and young people complaining of heartburn, a 4 week trial of PPI with review and consideration of endoscopy for recurrent symptoms or treatment failure is a more easily identified group)	Two RCTs suggest H2RAs (Simeone et al, 1997; Cucchiara et al, 1989) and PPIs (Omari et al, 2007; Moore et al, 2003) showed improvement in oesophagitis compared with placebo. ESPGHAN suggest PPI is superior to H2RAs (no significant difference was noted in NICE guideline 1 (Gastro-oesophageal reflux disease in children and young people) , but there is a need to consider accessibility, palatability and local cost. More high quality evidence is required in this area.
24	4.5	SCM 6	Do not offer PPI/H2RA treatment for infants and children with isolated regurgitation and no risk factors.	There is a considerable overprescription of PPIs/H2RAs in primary/secondary care.	These medications don't work for isolated regurgitation, and again NHS BSA data suggest a considerable cost to the NHS.	See NICE evidence appraisal

25	4.5	SCM 6	Do not offer treatment with prokinetics (domperidone, erythromycin and metoclopramide) for children with GOR without specific advice regarding potential side-effects	Previously many infants and children are offered prokinetics, without an evidence-base	NHS BSA figures in 2014 estimated that £300,000 was spent per month on domperidone	This was a particular focus given the lack of evidence and recent MHRA alert.
26	4.6	SCM 4		Children where enteral feeding has been initiated should have an individualised nutritional plan and an exit strategy in place	This ensures that the enteral feeding processes are stopped as soon as appropriate.	
27	4.7	SCM 5		More research to derive a safe and effective pro-motility agent	Fundamental in the treatment of respiratory related events with GORD.	Unfortunately cisapride which was the best motility agent was removed from the marketplace without proper consideration. No subsequent drugs have yet been identified to replace it.
28	4.7	SCM 5	Additional developmental areas of emergent practice	Research into day 1 cow's milk protein exposure and subsequent development of CMP allergy.		

29	4.7	British Society of Paediatric Radiology (BSPR) / The Royal College of Radiologists (RCR)	Looking for Gastro Oesophageal reflux in refractory asthma	Investigating GOR is unlikely to alter the management of asthma.	Gastro-oesophageal reflux treatment for prolonged non-specific cough in children and adults. Cochrane Database Syst Rev. 2011 Jan 19;(1).	
30	4.7	SCM 5		Price of liquid omeprazole. Private pharmacies make this preparation at great cost to the consumer and virtually no cost to themselves e.g. £300-£400 pcm when the same preparation costs approx. £10 pcm in the USA. It is the only reliable way of administering a PPI in infancy.	This would transform the treatment of infants with GORD and enable appropriate treatment and dose management in infants.	Personal experience.
31	4.7	The Royal College of General Practitioners	Quality Standard Title	Can it be made explicit that this includes neonates and infants as this is the group with the high prevalence in general practice.		
32	N/A	NHS England		Thank you for the opportunity to comment on the above quality standard. I wish to confirm that NHS England has no substantive comments to make regarding this consultation.		

33	N/A	The Royal College of Pathologists		The Royal College of Pathologists does not have any comments at this stage.		
34	N/A	The Royal College of Paediatrics and Child Health		Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the NICE quality standard topic engagement exercise for GORD in children and young people. We have not received any responses for this consultation.		
35	N/A	SCM 5	Additional evidence sources for consideration	NASPGHAN and ESPGHAN Conjoint Recommendations 2009 JPGN.		