

National Institute for Health and Clinical Excellence

**Gastro-oesophageal reflux disease in children and young people
Scope Consultation Table
21 December – 25 January 2013**

Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
British Medical Association	3	4.1.1	We believe that the heading for this section is incorrect and should read 'Groups that will be covered' rather than 'Groups that will not be covered'.	Thank you for this comment. We have amended this error.
British Medical Association	1	General	We think the population considered by the guideline should be split into two groups: the first, infants; and the second, older children and children with disabilities. Infants possetting take up large amounts of GP and health visitor time although only a very small number have GORD. In older children and those with medical problems, the chances of GORD are much higher.	Thank you for your comment. We agree that diagnosis, investigation and management will vary by age. The exact divisions to be used in the guideline will be determined by the guideline development group.
British Medical Association	2	General	We believe that the increased numbers of infants now being investigated for GORD could better be dealt with by increased advice and support from health visitors on feeding, including positioning the infant during feeding. This should be covered by the guideline.	Thank you for your comment. The recommendations may include advice and support for parents, but until the

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				<p>evidence has been reviewed this cannot be confirmed.</p> <p>A review question on positioning is outlined.</p>

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British Society for Paediatric Radiology	5	1	Delete first 6 words –‘Gastro-oesophageal reflux in children and young people’(Repetition of the short title)	Thank you for your comment. This is the standard format for titles of NICE guidelines. Therefore, no change will be made.
British Society for Paediatric Radiology	1	3 and 3.1	Definition of Gastro Oesophageal Reflux	Thank you for your comment. One of the main aims of the guideline will be to provide a working definition of GOR that can be used across healthcare settings.
British Society for Paediatric Radiology	2	3.1b	barium meal and other modalities of imaging (instead of ‘other forms of contrast radiography’)	Thank you for your comment. This change has been made.
British Society for Paediatric Radiology	3	4.1.1	Delete <u>not</u> in the first line	Thank you for this comment. We have amended this error.
British Society for Paediatric Radiology	4	4.5	Between b) and c) please insert What are the clinical indications for Radiological investigations? a)Barium meal b)Ultrasound of stomach and gastro oesophageal junction c) Nuclear medicine –	Thank you for your comment. We will be reviewing which symptoms, signs and risk

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			scintigraphic evaluation of gastro-oesophageal reflux and gastric emptying	<p>factors may require which investigations.</p> <p>We will not be carrying out a detailed evidence based comparison of tests occasionally used by tertiary practitioners in the field.</p> <p>We will offer advice as to when practitioners should arrange specific tests like a contrast meal or U/S of the pylorus to exclude other conditions that can present like GOR/GORD.</p>

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British Society of Allergy and Clinical Immunology	1	3.1d	The prevalence of GORD is also higher in children with Non IgE mediated gastrointestinal dysmotility disorder and allergy	<p>Thank you for your comment.</p> <p>The co-existing conditions were only meant to be examples rather than an exhaustive list. Therefore, we have amended the sentence to read '...The prevalence of GORD is higher in certain group, for example, in children and young people with neurodevelopmental disorders, oesophageal atresia repair, cystic fibrosis, hiatal hernia, repaired achalasia or a family history of complex GORD.'</p>
British Society of Allergy and Clinical Immunology	2	3.2a	<p>Some children may be referred to allergy specialists (as outlined in the RCPCH NICE guidelines) for GORD associated with (1) multiple allergic disease and poor weight gain (2) atopic eczema (3) eosinophilic oesophagitis (4) eosinophilic enteropathy and (5) other dysmotility symptoms</p> <p>It is important to appreciate that cow's milk protein intolerance is a frequent, but under-</p>	<p>Thank you for your comment.</p> <p>The focus of this guideline is the diagnosis, investigation and treatment of GOR</p> <p>We agree that cow's milk protein intolerance may</p>

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			recognised underlying cause of GORD. The treatment for this condition is simple, cost-effective and successful.	<p>exacerbate GOR, and a review question on this is planned for the guideline.</p> <p>This guideline will not be extended to a more detailed coverage of allergic conditions.</p> <p>The guideline will suggest symptoms and signs which may suggest other diagnosis including eosinophilic oesophagitis (EO) but will not be offering a specific review question on EO.</p>

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British Society of Allergy and Clinical Immunology	3	3.2b	The prevalence of cow's milk protein intolerance in GORD needs to be defined here	Thank you for your comment. We agree that cow's milk intolerance may be important and a review question on this is planned for the guideline, as outlined in section 4.3.
British Society of Allergy and Clinical Immunology	4	3.2b	Additional treatments may also include dietary elimination, antihistamines and mast cell stabilisers for children with allergy associated GORD?	Thank you for your comment. The remit of this guideline is the diagnosis, investigation and treatment of GOR, not allergy. Therefore, whilst Cow's milk protein will be examined, more specific allergy treatment will not.
British Society of Allergy and Clinical Immunology	5	4.1.1	Should the title read "groups that will be covered"?	Thank you for this comment. We have amended this error.
British Society of Allergy and Clinical Immunology	6	4.3.1d	Would a section " Indications for specialist referral be recommended (as shown in our NICE allergy RCPCH guidelines)?	Thank you for your comment. The guideline will address indications for referral and these will be driven by the

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				indications for investigation and treatment. For example, a child requiring an endoscopy will need a referral to a specialist.
British Society of Allergy and Clinical Immunology	7	4.3.1e	To perhaps include antihistamines, anti-mast cell stabilisers, allergen-exclusion diets?	<p>Thank you for your comment.</p> <p>The focus of the guideline is the diagnosis, investigation and management of GOR up to the point of specialist tertiary care.</p> <p>We agree that cow's milk protein intolerance may be important and a review question on this is planned for the guideline. However, we will not be offering detailed analysis of anti-allergy treatments apart from the exclusion of cow's milk protein.</p>
British Society of Allergy and Clinical Immunology	8	4.4c	To include healing of eosinophilic oesophagitis and lympho-nodular hyperplasia?	<p>Thank you for your comment.</p> <p>The focus of this guideline is</p>

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				<p>the diagnosis, investigation and treatment of GOR. Other conditions including eosinophilic oesophagitis are not being specifically reviewed.</p> <p>The guideline is likely to advise practitioners which symptoms and signs should suggest alternative diagnosis and the need for tests.</p>
British Society of Allergy and Clinical Immunology	12	4.5	In general to include in this section “How effect are antihistamines, mast cell stabilisers?” What are the clinical indications for offering an allergen- elimination test and then an allergen-elimination diet if the test is positive i.e. soya, Extensively hydrolysed milk formula or amino acid formula? “How effective is an allergen-elimination diet in the treatment of GORD?”	<p>Thank you for your comment.</p> <p>The focus of this guideline is the diagnosis, investigation and treatment of GOR, not allergy. Therefore, whilst Cow’s milk protein will be examined, more specific allergy treatment will not.</p>
British Society of Allergy and Clinical Immunology	9	4.5a	To include failure to thrive at the end?	<p>Thank you for your comment.</p> <p>The list provided is for illustrative purposes. The</p>

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				final list of symptoms and signs will be determined by the available evidence and the clinical opinion of the GDG, and this may include failure to thrive.
British Society of Allergy and Clinical Immunology	10	4.5b	Is there an association between GORD and atopic dermatitis; GORD and food allergy	<p>Thank you for your comment.</p> <p>The focus of the guideline is the diagnosis, investigation and management of GOR up to the point of specialist tertiary care.</p> <p>We agree that cow's milk protein intolerance may be important and a review question on this is planned for the guideline.</p> <p>We are not intending to investigate other symptoms or signs of allergic conditions or devise a guideline on food allergy in general.</p>
British Society of Allergy	11	4.5e	To include "What are the clinical indications for	Thank you for your

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and Clinical Immunology			allergy testing?"	<p>comment.</p> <p>The focus of the guideline is the diagnosis, investigation and management of GOR up to the point of specialist tertiary care.</p> <p>We agree that cow's milk protein intolerance (type 4 / cell mediated) may be important and a review question on this is planned for the guideline</p> <p>However, we will not be offering detailed analysis of various allergy tests in common practice.</p>
British Society of Gastroenterology	1	General	The draft scope does not consider endoscopic treatments for reflux – does this have a role in the paediatric reflux population? (It doesn't at present outside research in adult GORD)	<p>Thank you for your comment.</p> <p>NICE guidelines do not include treatments that are not used outside research settings. Therefore, based on your comment, they</p>

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				would not be included.
British Society of Gastroenterology	2	General	The draft scope should consider management of Barrett's oesophagus in children, its surveillance and the use of translational clinics (when the child as a teenager requires continuing specialist care as an adult).	<p>Thank you for your comment.</p> <p>The inclusion of children with Barrett's oesophagus has been discussed. Given that Barrett's oesophagus is extremely rare in children it has been decided not to cover it in the guideline.</p> <p>Furthermore it was felt that young people can be treated like adults with this condition and as such we will refer to existing NICE guidance for Barrett's oesophagus.</p>
British Society of Gastroenterology	3	General	For children the frequency of misdiagnosis is common. The commonest alternative cause of symptoms is eosinophilic oesophagitis and this has not been mentioned anywhere in the document. The diagnosis of eosinophilic oesophagitis should be considered in all patients whose reflux management is either troublesome, or in whom standard medical therapy with acid suppression is not fully effective. Any unit performing antireflux surgery in children must	<p>Thank you for this comment.</p> <p>This guideline will concentrate on the assessment of GOR/GORD in the primary and secondary setting.</p> <p>We will offer advice as to which symptoms and signs may suggest an alternative</p>

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			have the facilities and pathways to diagnose eosinophilic oesophagitis.	<p>diagnosis and may benefit from referral to a tertiary specialist.</p> <p>The diagnosis of eosinophilic oesophagitis (EO) requires an endoscopy which for infants, children and young people by definition usually involves a tertiary specialist.</p> <p>A detailed review of the presentation, investigation and treatment of EO is beyond the scope of this particular guideline.</p>

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British Society Of Paediatric Gastroenteology, Hepatology & Nutrition	3	4.5	<p>REVIEW QUESTIONS</p> <p>The scope is asking important review questions. We suggest further questions as follow: _</p>	Thank you for your comment.
British Society Of Paediatric Gastroenteology, Hepatology & Nutrition	4	4.5	<p>1. Review questions should be asked about evidence for managing patients with neurodisability</p>	<p>Thank you for your comment.</p> <p>The management of GOR in children and young people with neurodisability is included in the guideline. However, the wider management of these conditions is not.</p>
British Society Of Paediatric Gastroenteology, Hepatology & Nutrition	5	4.5	<p>2. The evidence for using gastroplication and bulking in children (if this was not done in the relevant published guidelines)</p>	<p>Thank you for your comment.</p> <p>The guideline will examine the indications for fundoplication surgery, as this is the most commonly used procedure in the UK.</p> <p>We are aware that other procedures are occasionally used but are not frequently</p>

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				or routinely undertaken in this population within the NHS and as such will not be covered by the guideline.
British Society Of Paediatric Gastroenteology, Hepatology & Nutrition	6	4.5	3. There should be a section offering guidance on patient pathways with indications for specialist referral (ie from a paediatrician to a paediatric gastroenterologist) in light of new commissioning arrangements	<p>Thank you for your comment.</p> <p>The guideline will address indications for referral and these will be driven by the indications for investigation and treatment.</p> <p>For example, if a patient needs an endoscopy then they will be referred to a specialist.</p>
British Society Of Paediatric Gastroenteology, Hepatology & Nutrition	7	4.5	4. The indications and evidence for barium radiology should be considered	<p>Thank you for your comment.</p> <p>The indications for undertaking a barium meal have been added to the scope. However, evidence</p>

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				on diagnostic value of barium meals will not be included.
British Society Of Paediatric Gastroenteology, Hepatology & Nutrition	8	4.5	5. There needs to be a section on multi disciplinary working - gastroenterology/surgical joint decisions around surgery including multidisciplinary team (ie medical, surgical, SALT etc involvement/local child developmental team) involvement	Thank you for your comment. The focus of the guideline is the diagnosis, investigation and management of GOR up to the point of specialist tertiary care.
British Society Of Paediatric Gastroenteology, Hepatology & Nutrition	9	4.5	The section on feeding in infants 4:5 should cover evidence to inform clinical decisions to deal with the diagnosis and management of possible milk allergy (and when change from Cow's milk to alternative milk formulae in an infant with GORD)	Thank you for your comment. We agree that cow's milk protein intolerance may be important and a review question on this is already planned for the guideline
British Society Of Paediatric Gastroenteology, Hepatology & Nutrition	10	4.5	A review question about other less common surgical procedures eg oesophageal dissociation, creation of roux en y jejunostomy should be included	Thank you for your comment. The focus of this guideline is on diagnosis, investigation and treatment of GOR up to the point of tertiary care.

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				The surgical technique mentioned here are highly specialist and not widely used in the NHS therefore they will not be covered by the guideline.
British Society Of Paediatric Gastroenterology, Hepatology & Nutrition	11	4.5	A review question about assessment pathways for evaluating possible GORD in patients having insertion of a gastrostomy should be considered (with neurodisability)	<p>Thank you for your comment.</p> <p>We will be looking at enteral tube feeding.</p> <p>We have also identified children with complex neurodevelopmental problems as a group that deserves specific attention.</p> <p>We will be suggesting referral pathways for the investigation of GORD.</p> <p>However, this guideline is not intended to offer detailed enteral feeding advice or devise pathways for the insertion of permanent enteral feeding devices.</p>

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British Society Of Paediatric Gastroenterology, Hepatology & Nutrition	1	4.1.1 Population	Groups that <u>will</u> be covered first. We suggest that you might consider also "neonates and Infants" as well as children and young people in the consultation? The scope population should include neonates and infants. The scope should include patients with neurodevelopmental /neurodisability disorders.	Thank you for this comment. We have amended this error. Furthermore, neonates have now been removed from the excluded populations and will be in the guideline.
British Society Of Paediatric Gastroenterology, Hepatology & Nutrition	2	General	The scope does identify key areas of practice apart from one area- a clearly defined section on GOR in infants and how to approach cow's milk allergy is required in this document.	Thank you for your comment. The guideline will examine the association between GOR and Cow's milk protein allergy.
Department of Health	1	General	No comment	Thank you for taking the time to read the draft scope.
Neonatal and Paediatric Pharmacists Group (NPPG)	1	4.1.1	Our comments are as follows We wish to confirm that this section should read that these are populations which WILL be covered by the Guideline.	Thank you for this comment. We have amended this error.
Neonatal and Paediatric Pharmacists Group (NPPG)	2	4.1.2	Our comments are as follows If section 4.1.1 includes the populations which WILL be covered by the Guideline - we are disappointed	Thank you for this comment. We have amended this error.

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			that it is proposed that the Guideline will NOT cover pre-term babies in neonatal intensive care units. We request that this decision is given further consideration since this is an area where treatment for GORD is often initiated. We understand that this was raised at the scoping meeting and those present agreed that premature babies should be included in the proposed population to be covered. We suggest that pre-terms babies should be included in the Guideline.	Neonates have been removed from the list of excluded groups and will now be included in the guideline's population.
Neonatal and Paediatric Pharmacists Group (NPPG)	3	4.3.1	Our comments are as follows We are happy that the proposed treatments for GOR/GORD include the groups of medications listed. However in view of the fact that many of the drugs used to treat GOR/GORD in children are used "off-label" or may even be unlicensed – we consider that using the manufacturers Summary of Product Characteristics is not the most appropriate source from which to obtain information about the drugs. We suggest that as well as reviewing the literature, the BNF for Children should be consulted as a standard prescribing text for decision making on medicines in children across the UK.	Thank you for your comment. We agree that many of these medications may be unsuitable in certain age-groups. The aim of the guideline will be to determine which medications should or should not be used in children and young people with GOR up to the age of 18. The standard source of information for use of

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				medications is the manufacturer's Summary of Product Characteristics. Please refer to section 9.3.6.3 of the guidelines manual for further information on off label use in guidelines
Neonatal and Paediatric Pharmacists Group (NPPG)	4	4.5	Our comments are as follows We note the draft review questions as listed which includes items h)-l) looking at the efficacy of various medicines. Whilst accepting that these questions are draft and will be finalised by the Guideline Development Group (GDG) – we suggest that the Group may also wish to look at the safety profile of the medications listed as well as their efficacy against placebo.	Thank you for your comment. Adverse events of interventions and treatments are part of this guideline. The commonly used medications will be assessed in detail in review questions.
Neonatal and Paediatric Pharmacists Group (NPPG)	5	General	Our comments are as follows We are disappointed that the recent call for members of the GDG did not include a request for a paediatric pharmacist. We hope that the suggestion of appointing a paediatric pharmacist as a specialist expert advisor on this topic will not be overlooked in the light of the fact that GOR/GORD is a condition encountered frequently by Paediatric pharmacists in their daily practice. It is also one with many	Thank you for your comment. A paediatric pharmacist will be included as an expert advisor to the guideline development group.

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			challenges in terms of provision of suitable drug regimens and products. The correct choice of medication with the right dose regimen and a suitable formulation can be key to management of this condition and pharmacists are ideally placed to advise on this. We would be grateful if you could ensure that Paediatric Pharmacy expertise is obtained in development of the guideline.	
NHS Direct	1	General	No comment	Thank you for taking the time to read the draft scope.
Nutrition and diet resources UK (NDR UK)	1	General	This is a much needed consultation for a condition which can seriously impact on children's nutritional intake and subsequent growth and development. We would recommend that all aspects of enteral feeding - oral nutrition , tube feeding including gastrostomy and jejunostomy, feeding pre and post surgery and optimising nutritional status should be included in the scope.	Thank you for your comment. We will be reviewing enteral tube feeding but will not be preparing a detailed or comprehensive feeding guideline.
Nutrition and diet resources UK (NDR UK)	2	General	A further recommendation would be to recruit a specialist paediatric dietitian to the guideline development group in order to contribute to the nutritional aspects of the guideline.	Thank you for your comment. A paediatric dietician will be included as a member on the guideline development group.

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Reckitt Benckiser healthcare UK Ltd	1	3.2a	<p>It is inaccurate to solely include drug treatment with antacids as the current standard of therapy for gastroesophageal reflux (GOR) in infants and young children.</p> <p>Alginates therapies, such as Gaviscon Infant, are licensed, efficacious pharmaceutical options for the treatment of gastric regurgitation, GOR and GOR associated with hiatus hernia in infants and young children.</p> <p>For example, Gaviscon Infant is composed of sodium alginate and magnesium alginate. Neither of these active ingredients possess acid neutralisation ('antacid') properties and it is therefore incorrect to group antacid and alginate treatments together within this guideline.</p>	<p>Thank you for your comment.</p> <p>We have amended the wording in this introductory section.</p>
Reckitt Benckiser healthcare UK Ltd	2	4.3.1e	<p>It is inaccurate to group antacid and alginate treatments together. Antacid and alginate products have distinctly different therapeutic modes of action.</p> <p>As previously stated, Gaviscon Infant contains sodium alginate and magnesium alginate. The product has a physical mode of action; on contact with acidic stomach contents it thickens to form a viscous gel, stabilising the stomach</p>	<p>Thank you for your comment.</p> <p>We have amended the text to include and separate antacids and alginates.</p>

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			<p>contents and reducing the incidence of reflux or regurgitation into the vulnerable oesophagus, which can cause distress.</p> <p>Unlike antacids, the product does not possess any acid neutralisation capacity and does not significantly alter the pH of the stomach contents.</p> <p>It is therefore critical that alginate reflux suppressants such as Gaviscon Infant are captured under a separate and distinct heading within the guideline in order to prevent confusion of the mode of action of these specialised products and their therapeutic value in treating infants or young children with GOR or regurgitation.</p>	
Royal College of Nursing	2	4.1.1	The heading should read "groups that will be covered"	Thank you for this comment. We have amended this error.
Royal College of Nursing	3	4.3.1	Consider adding sleeping pattern as this is affected in GORD infants	<p>Thank you for your comment.</p> <p>The list provided is for illustrative purposes. The final list of symptoms and signs will be determined by</p>

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				the available evidence and the clinical opinion of the GDG, and this may include sleeping patterns.
Royal College of Nursing	4	4.3.1	Development is also affected especially crawling	<p>Thank you for your comment.</p> <p>The list provided is for illustrative purposes. The final list of symptoms and signs will be determined by the available evidence and the clinical opinion of the GDG, and this may include developmental delay.</p>
Royal College of Nursing	5	4.3.1e	Could / should a management of crying baby be included?	<p>Thank you for your comment.</p> <p>The list provided is for illustrative purposes. The final list of symptoms and signs will be determined by the available evidence and the clinical opinion of the GDG, and this may include crying babies.</p> <p>However, the management</p>

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				of crying babies in general will not be covered by the guideline.
Royal College of Nursing	6	4.4a	Will this include quality of life for parents of small babies?	Thank you for your comment. The focus of the guideline is the person with the condition. Therefore, the quality of life of parents will not be included, as there are multiple variables that will affect this.
Royal College of Nursing	7	4.4b	Would be helpful to include clarity on measurement of nutritional status	Thank you for your comment. The exact outcomes used will be clarified by the guideline development group.
Royal College of Nursing	8	4.5b	Include association with post natal depression?	Thank you for your comment. The list provided is for illustrative purposes. The final list of risk factors will be determined by the available evidence and the clinical

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				opinion of the GDG. However, the focus of the guideline is the diagnosis, investigation and treatment of GOR. It will not cover the management of post natal depression.
Royal College of Nursing	1	General	The Royal College of Nursing welcomes proposals to develop this guideline. It is timely.	Thank you for your comment and taking the time to read the draft scope.
Royal College of paediatrics and child health	20	1	Delete first 6 words –‘Gastro-oesophageal reflux in children and young people’(Repetition of the short title)	Thank you for your comment. This is the standard format for titles of NICE guidelines. Therefore, no change will be made.
Royal College of paediatrics and child health	21	3 and 3.1	Definition of gastro oesophageal reflux	Thank you for your comment. One of the main aims of the guideline will be to provide a working definition of GOR that can be used across healthcare settings.
Royal College of paediatrics and child health	16	3.1	We need to start with a better distinction between GOR and GORD, and a statement	Thank you for your comment.

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			whether GOR may need treatment. It is being both over- and under-treated	One of the main aims of the guideline will be to provide a working definition of GOR/GORD that can be used across healthcare settings.
Royal College of paediatrics and child health	22	3.1b	Barium meal and other modalities of imaging (instead of 'other forms of contrast radiography')	Thank you for your comment. This change has been made.
Royal College of paediatrics and child health	9	3.2a	Although infants and children may be referred by primary healthcare professionals because of troublesome GORD, sometimes this diagnosis isn't recognised and the patient may be referred instead for associated problems such as apnoea or asthma. Hopefully, this will be addressed as outlined in section 4.5b. It should be made clear that in infants and children with neurodisabilities, GORD may be overlooked amongst all their other difficulties and so this diagnosis needs to be considered if addressing one of the problems that can be associated with GORD.	Thank you for your comment. One of the main aims of the guideline will be to provide a working definition of GOR that can be used across health care settings. Furthermore, children with neurodevelopmental requirements have been highlighted (see section 4.1.1) as a group that need particular attention.
Royal College of paediatrics	34	3.2c	Targeted abdominal sonography (with	Thank you for this comment.

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and child health			provocation test is also an option).	We will limit the review of diagnostic tests to those in common use with an evidence base that can be assessed. Tests like this are more likely to be requested in specific circumstances by tertiary specialists.
Royal College of paediatrics and child health	10	4.1.1	Presumably, there is a typing error and this section refers to groups that will be considered (not, as stated, that will NOT be considered since this is addressed in 4.1.2). It is very encouraging that infants and children with neurodisabilities will be specifically considered since GORD is more common in this patient group and is often more resistant to treatment yet, because these patients often have multiple other problems, GORD can be overlooked.	Thank you for this comment. We have amended this error.
Royal College of paediatrics and child health	23	4.1.1	Delete <u>not</u> in the first line	Thank you for this comment. We have amended this error.
Royal College of paediatrics and child health	1	4.1.2c	Why are preterm babies in NICUs excluded? GOR/D is more common in preterm babies and the medications are widely used (rightly or wrongly) in NICUs for these babies and this guideline is a great opportunity for clinicians and babies. What about full term babies in NICUs, are they	Thank you for this comment. We have amended this error. Neonates have been removed from the list of excluded groups and will

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			included?	now be included in the guideline's population.
Royal College of paediatrics and child health	25	4.3.1 management and 4:5 review questions	The scope does identify key areas of practice apart from one area- a clearly defined section on GOR in infants and how to approach cow's milk allergy is required in this document.	Thank you for your comment. We agree that cow's milk protein intolerance may be important and a review question on this is planned for the guideline.
Royal College of paediatrics and child health	2	4.3.1d and (e)	What about the effectiveness of various investigations?	Thank you for your comment. The focus of the guideline is the diagnosis, investigation and management of GOR up to the point of specialist tertiary care. We will be reviewing which symptoms, signs and risk factors may require which investigations. We will not be carrying out a detailed evidence based comparison of tests used by tertiary practitioners in the

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				field.
Royal College of paediatrics and child health	3	4.3.1e	Under the bullet point "surgery", will the guideline look at different operations separately?	<p>Thank you for your comment.</p> <p>The guideline will examine the indications for fundoplication surgery, as this is the most commonly used procedure used in this population in the UK. We are aware that other procedures are occasionally used but are not frequently or routinely undertaken within the NHS and as such will not be covered by the guideline.</p>
Royal College of paediatrics and child health	7	4.3.1e	There is widespread use of unlicensed medicines (Specials) and off-label use of medicines in the management of GORD in infants and children. Whilst NICE guidelines are usually restricted to commenting on use of medicines within their licensed indications and doses, some comment on the unlicensed formulations and doses should be included in	<p>Thank you for your comment.</p> <p>We agree that many of these medications may be unsuitable in certain age-groups. The aim of the guideline will be to</p>

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			this guideline.	determine which medications should or should not be used in children and young people with GOR up to the age of 18. Please refer to section 9.3.6.3 of the guidelines manual for further information on off label use in NICE clinical guidelines.
Royal College of paediatrics and child health	11	4.4	In children with neurodisabilities, GORD may impair general developmental progress (hopefully this may be covered in health related quality of life assessments.	Thank you for your comment. This is an important issue and will be taken into account if evidence is found that reports on health-related quality of life for children with neurodisabilities.
Royal College of paediatrics and child health	4	4.4b	What about the change in severe symptoms and complications, e.g. aspiration and respiratory morbidities?	Thank you for your comment. The exact outcomes used will be clarified by the guideline development group.

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Royal College of paediatrics and child health	8	4.5	In the section considering the value of nasogastric feeding tubes, comment should be made about the appropriate method of assessing placement in GORD patients, who may have altered gastric pH due to the drug treatments they receive.	Thank you for your comment However, this guideline is not intended to offer detailed enteral feeding advice or devise pathways for the insertion of temporary or permanent enteral feeding devices.
Royal College of paediatrics and child health	24	4.5	Between b) and c) please insert What are the clinical indications for radiological investigations? a) Barium meal b) Ultrasound of stomach and gastro oesophageal junction c) Nuclear medicine – scintigraphic evaluation of gastro-oesophageal reflux and gastric emptying	Thank you for your comment. We will include indications for use of barium meals. However, ultrasound and nuclear medicine will not be examined as they are infrequently used.
Royal College of paediatrics and child health	26	4.5 review questions	The scope is asking important review questions. We suggest further questions as follow: 1. Review questions should be asked about patients with neurodisability 2. The evidence for decision making in a child with possible GORD who is listed for gastrostomy insertion should be considered 3. The evidence for using gastroplication and bulking, oesophageal dissociation and roux en y Jejunostomy insertion should be considered	Thank you for your comment. Please see our previous responses to these questions.

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			<p>4. There should be a section on patient indications for specialist referral (ie from a paediatrician to a paediatric gastroenterologist)</p> <p>5. The indications for barium radiology should be considered</p> <p>6. There needs to be a section on - gastroenterology/surgical joint decisions around things like surgery including multidisciplinary team (medical, surgical, SALT etc involvement/local child developmental team involvement</p>	
Royal College of paediatrics and child health	33	4.5	The section on feeding in infants should cover evidence to inform clinical decisions to deal with possible allergy and when change from Cow's milk to alternative milk formulae.	<p>Thank you for your comment.</p> <p>We agree that cow's milk protein intolerance may be important and a review question on this is planned for the guideline.</p>
Royal College of paediatrics and child health	12	4.5a and b	As mentioned in 4.5a, infant distress (colic) can be a sign of GORD, but pain may also be a feature in some older children with GORD and so could be considered in 4.5b.	<p>Thank you for your comment.</p> <p>The list provided is for illustrative purposes. The final list of symptoms and signs will be determined by the available evidence and the clinical opinion of the</p>

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				GDG, and this may include pain.
Royal College of paediatrics and child health	13	4.5b	The possible association between GORD and ear infections could also be explored. Megale SR et al, Gastroesophageal reflux disease: its importance in ear, nose, and throat practice. International Journal of Pediatric Otorhinolaryngology. 2006 Jan;70(1):81-8.	Thank you for your comment. The list provided is for illustrative purposes. The final list of symptoms and signs will be determined by the available evidence and the clinical opinion of the GDG, and this may include ear infections.
Royal College of paediatrics and child health	5	4.5e	What about the clinical indications for contrast radiological studies?	Thank you for your question. There will be a review question on the indications for investigations. There will also be guidance on which tests (like contrast radiology) may be indicated to exclude other conditions whose symptoms, signs and presentation may be similar to GOR/GORD.
Royal College of paediatrics and child health	18	4.5h and I	It is worth considering the efficacy of these therapies in infants/older children separately.	Thank you for your comment.

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				We agree that diagnosis, investigations and treatment will vary by age.
Royal College of paediatrics and child health	19	4.5l	Some units use more than one prokinetic agent in combination (eg domperidone with erythromycin). It is worth considering whether the following should included: "How effective is the use of multiple prokinetic agents compared with placebo/single agent in the treatment of GORD". We appreciate this may be a part of the response to 4.5m.	Thank you for your comment. The GDG will finalise a review question on the effectiveness of pro-kinetic agents in the treatment of GORD.
Royal College of paediatrics and child health	6	4.5n	There should be comparison between NG & jejunal feeding, NG and gastrostomy and jejunal and gastrostomy.	Thank you for this comment. The GDG will develop and finalise a review question regarding the enteral feeding tubes in the condition. It is recognised by the GDG that increasingly jejunal feeding is being used as both an empirical test and treatment for GORD particularly in infants and children with complex neurodevelopmental

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				problems.
Royal College of paediatrics and child health	14	General	Ensure that the 'changes in feed composition' addresses the questions 'is there is an association with CMPI?' and 'is a trial of CMP free milk is an appropriate intervention?'	Thank you for your comment. The guideline will examine the association between GOR and Cow's milk protein allergy as this is an established issue.
Royal College of paediatrics and child health	15	General	This is such an important topic that it merits very careful consideration of the scope of the guideline. As it is currently drawn I feel that it will ignore important information in relation to parental expectations of normality and thresholds for parental presentation with infants who vomit. Thus we feel strongly that the scope of the guideline needs to be widened to include parental coping strategies, prevalence of parental anxiety, depression and expectations of normality. There is evidence that the perceived level of infant distress and vomiting frequency is strongly mediated by parental, especially maternal mood. Much of the professional response is titrated against reported symptoms that are hard to clarify in objective ways. Thus this guideline is at risk of suggesting	Thank you for your comment. The guideline will examine risk-factors for children presenting with GOR. The guideline development group will determine which risk-factors are included. This may include parental mood. The subjective assessment of symptom severity is always a concern in research and guidelines. The guideline development group will select a number

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			<p>medical management of symptoms taken at face value when it could offer helpful suggestions about suitable and sensitive exploration of parental mood and coping strategies if the broader aspects of GOR and its presentation in all health care settings is included.</p> <p>Long-term Outcomes of Infant Behavioral Dysregulation Hyde, et al. Pediatrics peds.2010-3517 Pediatrics. 2005 Feb;115(2):306-14. Maternal depressive symptoms and children's receipt of health care in the first 3 years of life. Minkovitz CS, Strobino D, Scharfstein D, Hou W, Miller T, Mistry KB, Swartz K. BMJ 15 Dec 2011 Douglas & Hill Excessive crying in infants</p>	<p>of outcomes, and this should include both subjective (parent reported) and objective measures that can be assessed by professionals by targeted history taking, observation and examination.</p>
Royal College of paediatrics and child health	17	General	<p>Does GORD have an effect on growth, to what extent; does treatment of GORD improve growth parameters, to what extent.</p>	<p>Thank you for your comment.</p> <p>Symptoms and signs associated with GORD will be examined. The GDG will determine which are examined, and this may include faltering growth.</p>

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Royal College of paediatrics and child health	35	General	We also think that cow's milk allergy/intolerance related GORD and the use of lactose-free/hydrolysed formulas should be included.	<p>Thank you for your comment.</p> <p>The guideline will examine the association between GOR and Cow's milk protein allergy as this is an established issue.</p> <p>We will not be looking in to lactose intolerance either primary or secondary.</p>
Royal College of Paediatrics and child health	36	General	Please include all neonates (i.e. not excluding preterm infants on NICUs) in this guideline which covers a topic hugely important and relevant to the neonatal intensive care population. The evidence so far for neonates is poor and is equally so for preterm babies therefore exclusion of the latter does not make good sense given the time and money that will be committed to this topic.	<p>Thank you for your comment.</p> <p>Neonates have been removed from the list of excluded groups.</p>
Royal College of Pathologists	1	General	We note that there are no specific references to histopathology but it is clear that several of the investigations will rely on evaluation of the histopathology of endoscopic biopsies. We urge that when consideration is given to these areas that appropriate histopathology expertise will be sought by the drafting group.	<p>Thank you for your comment.</p> <p>The focus of the guideline is the diagnosis, investigation and treatment of GOR in children up to tertiary care.</p>

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				As histopathology requires specialist tertiary level knowledge it will not be included.

These organisations were approached but did not respond:

Abbott Laboratories
Airedale NHS Trust
Alder Hey Children's NHS Foundation Trust
Allergy UK
Allocate Software PLC
Association of Anaesthetists of Great Britain and Ireland
Association of British Healthcare Industries
Association of Surgeons of Great Britain and Ireland
Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland
Astrazeneca UK Ltd
babyREFLUX
Barrett's Oesophagus Campaign
Bliss
Boehringer Ingelheim
Bolton Hospitals NHS Trust
Boston Scientific
Bradford District Care Trust
British Association of Paediatric Endoscopic Surgeons
British Association of Plastic, Reconstructive and Aesthetic Surgeons)
British Dietetic Association
British Geriatrics Society - Gastro-enterology and Nutrition Special Interest Group

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British Medical Journal
British National Formulary
British Nuclear Cardiology Society
British Nuclear Medicine Society
British Pain Society
British Psychological Society
British Specialist Nutrition Association
BUPA Foundation
Cambridge University Hospitals NHS Foundation Trust
Camden Link
Capsulation PPS
Care Quality Commission (CQC)
Children England
Children, Young People and Families NHS Network
Clarity Informatics Ltd
Cochrane Developmental, Psychosocial and Learning Problems
Croydon Health Services NHS Trust
Dako UK Ltd
Department of Health, Social Services and Public Safety - Northern Ireland
Dorset Primary Care Trust
Ealing Public Health
East and North Hertfordshire NHS Trust
Epsom & St Helier University Hospitals NHS Trust
Equalities National Council
Faculty of Dental Surgery
Faculty of Public Health
Fighting Oesophageal Reflux Together
General Medical Council
George Eliot Hospital NHS Trust
GlaxoSmithKline
Gloucestershire LINK
Great Western Hospitals NHS Foundation Trust
H & R Healthcare Limited
Hafan Cymru
Hammersmith and Fulham Primary Care Trust

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Health Protection Agency
Health Quality Improvement Partnership
Healthcare Improvement Scotland
Heartburn Cancer Awareness support
Hermal
Hertfordshire Partnership NHS Trust
Hindu Council UK
Hockley Medical Practice
Humber NHS Foundation Trust
Independent Healthcare Advisory Services
Information Centre for Health and Social Care
Institute of Sport and Recreation Management
Janssen
Joint Speciality Committee in Gastroenterology and Hepatology, Royal College of Physicians and
British Society of Gastroenterology
KCARE
Lancashire Care NHS Foundation Trust
Leeds Community Healthcare NHS Trust
Living with Reflux
Luton and Dunstable Hospital NHS Trust
Maidstone and Tunbridge Wells NHS Trust
Medicines and Healthcare products Regulatory Agency
Mendip Primary Care Trust
Ministry of Defence
National Childbirth Trust
National Institute for Health Research Health Technology Assessment Programme
National Patient Safety Agency
National Public Health Service for Wales
National Treatment Agency for Substance Misuse
Netmums
NHS Ashton, Leigh and Wigan
NHS Commissioning Board
NHS Connecting for Health
NHS County Durham and Darlington
NHS Gloucestershire & NHS Swindon Cluster

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NHS Plus
NHS Warwickshire Primary Care Trust
Norgine Limited
North Essex Mental Health Partnership Trust
North Essex Partnership Foundation Trust
North Tees and Hartlepool NHS Foundation Trust
North West London Perinatal Network
Nottingham University Hospitals NHS Trust
Nottinghamshire Healthcare NHS Trust
Novartis Pharmaceuticals
Oesophageal Patients Association
Oxford Health NHS Foundation Trust
Pancreatic Cancer Action
Parenteral and Enteral Nutrition Group
Peckforton Pharmaceuticals Ltd
PERIGON Healthcare Ltd
Primary Care Society for Gastroenterology
Proprietary Association of Great Britain
Public Health Wales NHS Trust
Royal Berkshire NHS Foundation Trust
Royal College of General Practitioners
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health , Gastroenetrology, Hepatology and Nutrition
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons of England
Royal Free London NHS Foundation Trust
Royal Pharmaceutical Society
Royal Society of Medicine
Sanofi
Scottish Intercollegiate Guidelines Network
Sheffield Childrens Hospital

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Sheffield Teaching Hospitals NHS Foundation Trust
SNDRi
Social Care Institute for Excellence
Society and College of Radiographers
South East Coast Ambulance Service
South London & Maudsley NHS Trust
South West Yorkshire Partnership NHS Foundation Trust
South Western Ambulance Service NHS Foundation Trust
Southport and Ormskirk Hospital NHS Trust
St Mary's Hospital
Stockport Clinical Commissioning Pathfinder
Sutton1in4 Network
Teva UK
The Association of the British Pharmaceutical Industry
The British In Vitro Diagnostics Association
The Rotherham NHS Foundation Trust
Torax Medical Inc.
UK Clinical Pharmacy Association
UK Pain Society
Unite - the Union
Vygon
Walsall Local Involvement Network
Welsh Government
West London CCG
Western Cheshire Primary Care Trust
Wishaw General Hospital
Worcestershire Acute Hospitals Trust
York Hospitals NHS Foundation Trust

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