

National Institute for Health and Clinical Excellence

Dyspepsia  
**Scope Consultation Table**  
 24 February – 22 March 2012

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response  <u>(Please note that the numbering and lettering used in these responses relates to that used in the latest version of the scope that is being re-consulted on)</u>
SH	Alder Hey Children's NHS Foundation Trust	1.00	General	Given that this was an adult scoping event, the only comment would be that consideration be given to the topic in childhood- which I understand has been considered?	Thank you for your comment. A guideline on GORD in children is underway.
SH	British Nuclear Medicine Society	3.00	General	No comments on this consultation at this stage	Thank you for your comment.
SH	British Society of Gastroenterology	4.00	General	<p>I am particularly pleased that this guidance will look at secondary as well as primary care management of dyspepsia, including indications for referral, and that functional dyspepsia will be addressed.</p> <p>I suspect not all of the questions will have clear evidence-based answers (eg Barrett's surveillance, for which we await the results of the BOSS trial), but I would hope that lack of evidence isn't necessarily deemed lack of evidence of efficacy.</p> <p>I note that a review is intended of HP eradication regimes in the light of current patterns of antibiotic resistance, and (although not actually stated) I think there is also an intention to look at quad therapy and sequential therapy as discussed at the scoping meeting.</p> <p>They will be seeking to appoint 2 gastroenterologists to the</p>	<p>Thank you for your comments.</p> <p>The function of the scope is to define which areas the guideline will consider. The evidence will be reviewed during the development of the guideline.</p> <p>This will be one of the key review questions for the guideline, see 4.5 d).</p> <p>The Developers will consider including a</p>

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				<p>guideline development panel, including 1 with an HP interest, though I wonder if that is really necessary: HP is only a relatively small part of the scope and an HP specialist or 2 could be co-opted specifically to help with the relevant parts of the guidelines.</p>	<p>Gastroenterologist with a special interest in Helicobacter Pylori as a Co-opted member to the Guideline Development Group (GDG)</p>
SH	BSPGHAN	19.00	General	<p>In paediatrics we usually draw a very clear distinction between GOR and GORD particularly for infants and very young children. This was emphasized in the briefing paper and will be central to the GORD in children NICE clinical guideline (I.Davies wrote the briefing paper for this and NICE are in the process of assembling the group). However, in older children and adults the distinction is less important because the problem is usually defined as GORD by virtue of the symptoms at presentation. For example, benign vomiting and regurgitation in young adults would not be commonly recognized and GORD is usually suggested by the pain of erosive oesophagitis.</p> <p>The scope of this update is very broad and ambitious. I estimate it will be a massive piece of work and will require trawling the vast amount of pretty low level evidence in an effort to give objective / evidence based answers to a huge number (26) review questions (section 4.5).</p> <p>PPIs are very common medications in the adult population. They are also, in my opinion, used too frequently in the paediatric population. I think the scope should include a very</p>	<p>Thank you for your comments. We are liaising with the Developers of the GORD guideline in children to ensure any overlap between the guidelines is dealt with effectively.</p>

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				<p>clear dissection of the current evidence for complications and potential long term risks for this type of medication. My personal opinion is that in the long run we will discover that this class of drug is not without potential long term consequences.</p> <p>This update will be aimed at all level of health professional from primary care (pharmacists / GPs) through to secondary care / tertiary care. As most DGHs have gastroenterologists and upper GI surgeons this will very rarely (in reality) apply to tertiary specialists as would be applicable in the paediatric setting. However, it will be very challenging to produce a document which is equally applicable and acceptable to such a variety of professional levels. It is always difficult to please all interested parties and I anticipate that the eventual guideline will risk criticism from differing professional groups.</p> <p>The GORD in children guideline is far more likely to be aimed at primary care and the distinction between GOR / GORD. It is more likely to be very non-prescriptive in terms of the guidance offered to the tertiary specialist or paediatric surgeon.</p> <p>I think it will be very important for the children's GORD guideline and this adult guideline to be carefully "dovetailed". I think that a member of each group should be co-opted each way in a reciprocal fashion to ensure the two run smoothly in continuity. It will be very confusing for both patients and</p>	<p>The focus of the new guideline will be specialist management and referral. A couple of areas commonly undertaken in primary care (H pylori eradication, and selection of patients for endoscopy) will also be covered. Unless there is good evidence for different effectiveness within different settings, the guideline will provide recommendations that are generic as possible.</p> <p>The Centre for Clinical Practice is liaising with the Developers of the GORD guideline in children to ensure any overlap between the guidelines is dealt with effectively. We intend that there will be overlap / crossover of membership between the two GDGs to encourage coherence.</p>

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				<p>professionals if the guidelines appear to diverge. This is particularly important because the adult guideline is likely to be of far more relevance to the teenage population than the children's guideline. For this reason I think it is important that a paediatric gastroenterologist also be included in the development group.</p>	
SH	Department of Health	5.00	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
SH	Heartburn Cancer Awareness & Support	6.00	General	<p>HCAS welcomes the specific inclusion of gastro-oesophageal reflux symptoms as well as the diagnosis and management of Barrett's oesophagus.</p> <p>NICE may wish to be aware that the British Society of Gastroenterology is also in the process of revising the clinical guidelines for Barrett's oesophagus (including diagnosis, surveillance and management). The BSG are using a process in keeping with the NICE guidelines with a comprehensive review process with graded evidence and agreed upon using the AGREE instrument. These guidelines should be completed by June 2012. We (HCAS) would be pleased if NICE could take these into consideration so that they do not end up with conflicting guidance for clinicians.</p>	Thank you for highlighting the development of the BSG guidelines. The Centre for Clinical Practice is aware of this work and will continue to monitor its development.
SH	Health Protection Agency	7.00	General	I am happy with the scope and have no further comments.	Thank you for your comment.
SH	Airedale NHS Foundation Trust	8.00	General	No comments on the scope of this Guideline	Thank you for your comment.
SH	NHS Direct	9.00	General	NHS Direct welcome the guideline and have no comments on	Thank you for your comment.

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				the content of the scope as part of the consultation process.	
SH	NHS Swindon NHS Gloucestershire	10.00	General	The terminology of “new onset” and “persistent” is very confusing. Although the terms are defined fully elsewhere in the text, in my view this could be made much more clear.	Thank you. Your comment appears to refer to the existing guideline (CG17). However, we will take it into consideration during the development of this guideline which will replace CG17.
SH	NHS Swindon NHS Gloucestershire	10.01	General	Unexplained dyspepsia is also very unclear. What is meant by “unexplained” better guidance about what steps GPs should take to establish an explanation would be helpful	Thank you for your comment. We can confirm that the term ‘unexplained dyspepsia’ is not used in either the existing guideline (CG17) or this scope. However, it is possible that the consultee means that ‘uninvestigated’ dyspepsia is unclear. This relates to patients with dyspepsia symptoms before any tests (often endoscopy) have been used to identify the cause of symptoms.
SH	NHS Swindon NHS Gloucestershire	10.03	General	The multiplicity of flow charts is unhelpful	Thank you. Your comment appears to refer to the existing guideline (CG17). However, we will take it into consideration during the development of this guideline which will replace CG17  We will aim to unify these flow charts in the new guideline. NICE will also develop a pathway to illustrate the guideline recommendations.
SH	NHS Swindon NHS Gloucestershire	10.04	General	From a GP perspective and on clinical grounds it is difficult to separate out GORD from “dyspepsia”	Thank you for your comment. The definitions and terminology will be agreed at an early stage of the development process in association with the GDG. For the purposes of this scope we will amend the terminology to describe symptoms as ‘dyspepsia, heartburn, or other symptoms of reflux’ when

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					referring to GORD symptoms (as opposed to the reflux itself).
SH	NHS Swindon NHS Gloucestershire	10.05	General	A list of bullet points early on setting out points to check in history and examination and baseline investigations with guidance where results/findings are abnormal would be helpful	Thank you for your comment. Your comment appears to refer to the existing guideline (CG17). However, we will take it into consideration during the development of this guideline which will replace CG17.
SH	Oesophageal Patients Association	11.00	General	<p>Our general concern is the inequality of opportunity relating to age (and possibly also gender) for patients under 55 years in the existing NICE guideline "Routine endoscopic investigation for patients of any age... is not necessary". We believe that patients of any age with a history of persistent heartburn in the past, or who currently suffer from persistent heartburn, who are likely to be suffering from undiagnosed Barrett's Oesophagus, and are therefore at risk of developing oesophageal adenocarcinoma should be referred for endoscopy.</p> <p>So this history of persistent heartburn should be an additional criterion to merit an endoscopy.</p> <p>The age profile for diagnosis of oesophageal cancer includes 12% of cases where the patient is &lt;55 on diagnosis. 27% of the Barrett's oesophagus pre-cursor lesions are diagnosed in patients &lt; 55 years.</p> <p>Late diagnosis of oesophageal adenocarcinoma (70% of the 8000 oesophageal cancer cases in the UK) is a prime reason for poor outcomes. Barrett's Oesophagus is a pre-cursor</p>	<p>Thank you for your comment. The alarm signs and symptoms for routine endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.</p> <p>We intend to include a review question on surveillance for Barrett's oesophagus (review question 4.5 g) but appreciate that we may not be able to provide definitive recommendations as the BOSS trial will not have completed during the development timetable.</p>

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				<p>condition for virtually all oesophageal adenocarcinoma cases.</p> <p>The alarm symptoms (eg difficulty in swallowing) for oesophageal cancer are related to a developed tumour when the disease has reached a stage where curative treatment may not be possible. 20% of our members report that obtaining an endoscopy was either difficult when they were under 55 years, or that they had to go private to obtain their diagnosis (of cancer); or that they were private patients anyway.</p> <p>An additional reason for not excluding younger patients with a history of persistent heartburn is the quality-adjusted life years involved and the high cost of treatment for late diagnosed cancer.</p>	
SH	RCGP	12.00	General	No obvious omissions – reflux in children is a separate issue to consider. Also you might want to look at the relationship of aspirin/anticoagulants to dyspepsia and any recommendations on treatment modalities.	<p>Thank you for your comment. A guideline on GORD in children is underway.</p> <p>The assessment of factors such as concomitant medication that may precipitate dyspepsia, and prophylactic management in this situation was not considered to be a priority for this guideline.</p>
SH	Royal College of Nursing	13.00	General	The Royal College of Nursing welcomes proposals to develop this guideline. It is timely. The draft scope seems comprehensive.	Thank you for your comment.
SH	Royal College of Paediatrics and Child Health	14.00	General	The draft scope proposes to cover adults aged 18 years and over and the RCPCH does not have any substantive comments to make on the draft scope.	Thank you for your comment.

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SH	RCP	15.00	General	RCP would like to endorse the submission made by the British Society of Gastroenterology (BSG) on the general and specific areas of the draft scope (see order number 4.00 – 4.02)	Thank you for your comment.
SH	The Royal College of Radiologists (RCR) and the British Society for Gastrointestinal and Abdominal Radiology (BSGAR)	16.00	General	The scoping document does not cover alternative imaging tests to endoscopy, and advice as to their use – within the UK there remains significant use of radiological modalities such as barium swallow / meal as a first line diagnostic investigation.	Thank you for your comment. The Developers considered that barium swallow is not sufficiently relevant to the diagnosis of dyspepsia and as such was not considered to be a priority for this guideline.
SH	Reckitt Benckiser Healthcare (UK) Ltd	17.00	General	<p>It is our belief that the guideline title and the interchangeable use of the terms 'GORD' and 'dyspepsia' throughout the document is confusing and poorly defines the scope of the proposed guidelines. Consequently we would suggest that the disease terminology be used more selectively and be defined in greater detail, including explicit mention of whether symptoms related to extra oesophageal reflux are covered. Specifically the terms 'dyspepsia' and 'GORD' should not be used inter-changeably.</p> <p>As discussed in section 3.1a), there is no universally accepted definition of dyspepsia, similarly there is no consensus on the exact distinction between dyspepsia and GORD. However, the fact that dyspepsia and GORD are distinct entities has been well argued by Dent (DENT et al. <i>Gut</i> (2002) 50: (Supp 4) iv17-20) and the overlap between the</p>	Thank you for your comments. It was not the intention to use these terms interchangeably. The definitions and terminology will be agreed at an early stage of the development process in association with the GDG. However, the scope has been amended, where relevant, to be more consistent in the use of terminology (particularly when referring specifically to symptoms).

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				<p>conditions has been studied and reported recently by Choung et al.(CHOUNG et al. <i>Neurogastroenterol Motil.</i> (2012) 24(3): 229-234). Additionally, it is unclear from this current scope whether dyspepsia is intended to encompass the broader spectrum of reflux related syndromes resulting from extra-oesophageal reflux that GORD specifically does not.</p> <p>Two pieces of published work have attempted to define and separate the terms GORD and dyspepsia, although it is still widely recognised that these definitions are subject to interpretation.</p> <p>Vakil (VAKIL et al. <i>Am J Gastroenterol</i> (2006) 101: 1900-1920) acknowledged that there was no consensus on the distinction of gastro-oesophageal reflux disease (GORD) from dyspepsia and developed a global definition and classification for GORD using an international consensus group of 44 experts from 18 countries. Vakil proposed that a fixed global definition would allow for collaborative research and studies would become more generalizable across the world.</p> <p>The working group were in agreement that the global definition of GORD is “a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications”. Symptoms were classed as troublesome when they adversely affected an individual’s well being. This definition was supported by a population based study where symptoms of heartburn/upper abdominal pain reported as mild or worse were associated with a clinically meaningful reduction in well being.</p>	

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				<p>Furthermore, the working group subclassified the disease into oesophageal and extra oesophageal syndromes including the recognition of laryngitis, cough, asthma, and dental erosions as possible GORD syndromes.</p> <p>The Rome III Diagnostic Criteria for Functional Gastrointestinal Disorders (2006) (available at <a href="http://www.romecriteria.org/assets/pdf/19_Romelll_apA_885-898.pdf">http://www.romecriteria.org/assets/pdf/19_Romelll_apA_885-898.pdf</a>) distinctly separates the classification of functional heartburn from functional dyspepsia.</p> <p>Functional heartburn falls within the category of functional oesophageal disorders where retrosternal burning is one of three symptoms which must be present for this diagnosis to be given.</p> <p>In comparison, functional dyspepsia is categorised within functional gastroduodenal disorders where a least one of the following symptoms must be present for diagnosis:</p> <ol style="list-style-type: none"> <li>1) bothersome postprandial fullness</li> <li>2) early satiation</li> <li>3) epigastric pain</li> <li>4) epigastric burning</li> </ol> <p>In addition, there must be no evidence of structural disease that is likely to explain the symptoms.</p> <p>From the definitions within the Rome III criteria, it is clear these 2 clinical manifestations of upper gastrointestinal disease are not viewed as the same and as such, the definition and term used in the guidance document should reflect this.</p>	

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				<p>The Rome III criteria suggests that GORD should be classified as a subset of syndromes within the broader definition of dyspepsia and not grouped together as one syndrome.</p> <p>We would encourage that the use of these terms throughout the document is reconsidered.</p>	
SH	Reckitt Benckiser Healthcare (UK) Ltd	17.01	3.1a)	<p>The use of the phrase "acid reflux" is inaccurate.</p> <p>Reflux is a result of the inappropriate localisation of the stomach contents, which could include acid, bile, pepsin and any undigested food at the moment of transient lower oesophageal sphincter relaxations.</p> <p>We suggest that this terminology is amended to more accurately reflect the true nature of gastric reflux.</p>	Thank you for your comment. Section 3.1a) has been amended.
SH	Reckitt Benckiser Healthcare (UK) Ltd	17.02	3.1b)	<p>The meaning of the phrase 'functional dyspepsia' is unclear.</p> <p>This section suggests that the term 'functional dyspepsia' refers to dyspepsia not known to be caused by ulcer disease, however, section 3.1c) suggests that functional dyspepsia refers to any dyspepsia of unknown aetiology.</p> <p>As noted previously this is a complex area in terms of descriptors and it would be beneficial for the terminology to be more explicitly defined.</p>	Thank you for your comment. Functional dyspepsia refers to dyspepsia of unknown aetiology. Section 3.1 b) refers to a historical term 'non-ulcer dyspepsia' that is no longer used. This has now been clarified further.
SH	Reckitt Benckiser	17.03	3.1c)	It is not clear what syndrome induces what symptom. Here	This section of the scope has been amended for

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	Healthcare (UK) Ltd			<p>GORD is said to be caused by dyspepsia, yet elsewhere the terms are used interchangeably.</p> <p>As recently shown by Herbella (HERBELLA et al. Dis Esophagus. (2011)), an unbuffered layer of acidity that escapes neutralisation by food (the 'acid pocket') has been demonstrated in both healthy volunteers and GORD patients. It is reported to be located in the proximal, postprandial stomach GORD patients reporting heartburn (KWIATEK et al. <i>Aliment Pharmacol Ther.</i> (2011) 34(1):59-66) detected by dual site pH monitoring as often postprandial reflux was more acidic than gastric contents (FLETCHER et al. <i>Gastroenterol</i> (2001) 123(6):2157-8, CLARKE et al. <i>Gut</i> (2009) 58: 904-909). The position of the acid pocket is a major determinant for the risk of acid reflux and when pinched at the level of the diaphragm acid reflux occurred (ROHOF et al. <i>Gut</i> (2012) Published online January 27<sup>th</sup> 2012).</p> <p>It is only possible to say this if GORD is a subset of symptoms of the wider clinical diagnosis of dyspepsia. Please refer to comment number 1 for further details on the confusing use of the terms GORD and dyspepsia throughout the guidance.</p>	clarification.
SH	Oesophageal Patients Association	11.01	3.1d)	We agree with referring patients for an endoscopy to investigate the cause, for the reasons stated above (order number 11.00)	Thank you for your comment. The alarm signs and symptoms for routine endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.
SH	Oesophageal	11.02	3.1g)	Barrett's oesophagus is well described, and investigation to	Thank you for your comment. The diagnosis of

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	Patients Association			diagnose the condition is worthwhile in its own right.	Barrett's oesophagus was not identified as an area of priority for this guideline. However the scope will cover the surveillance of Barrett's oesophagus as detailed in review question 4.5 g).
SH	Reckitt Benckiser Healthcare (UK) Ltd	17.04	3.1g)	<p>It is an oversimplification to state that GORD is caused by excess gastric acid (LOWE et al. <i>GI motility</i> (2006) Published online 16<sup>th</sup> May 2006). Most patients suffering symptoms diagnosed as GORD are not assessed for or diagnosed with hyperacidity and it is commonly accepted that reflux results from the inappropriate localisation of gastric contents following transient lower oesophageal sphincter relaxation rather than any overproduction of acid. In addition, a systematic review of studies investigating persistent reflux by El-Serag (EL-SERAG et al. <i>Aliment Pharmacol Ther</i> (2010) 32: 720-737) provided evidence that acid suppressing therapy does not always result in complete resolution of symptoms in all patients.</p> <p>Furthermore this negates the role of non-acid reflux and specifically that of bile and pepsin as noted above in number 2.</p>	Thank you for your comment. Section 3.1 g) has been amended.
SH	Reckitt Benckiser Healthcare (UK) Ltd	17.05	3.2b)	<p>Although the use of endoscopy as a diagnostic test for GORD may have increased, it is known that this method is a very poor investigation for confirming the diagnosis of this condition.</p> <p>A recent study by Dent (DENT et al. <i>Gut</i> (2010) 59(6):714-21) demonstrated that around 1 in 3 diagnoses of GORD were incorrect based on endoscopy and a similar number of</p>	The function of the scope is to define which areas the guideline will consider. The relevant evidence will be reviewed during the development of the new guideline under review question 4.5 a).

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				<p>inaccuracies were observed using oesophageal pH monitoring.</p> <p>In another study, Fletcher (FLETCHER et al. <i>Gut</i> (2004) 53: 168-173) assessed patients with endoscopy-negative dyspepsia and no evidence of GORD with pH metry. The results showed that these patients had "short segment reflux" – i.e: they had reflux but it did not reach 5cm above the squamo-columnar junction. This study further suggests that even diagnostic measures used to detect the acidic component of reflux may not be fully adequate.</p> <p>This further re-enforces the requirement to provide clarity on the definition of GORD and the nature of refluxate (i.e: the symptoms are not related to hyperacidity).</p>	
SH	Oesophageal Patients Association	11.03	3.2d)	<p>The relationship between GORD, Barrett's oesophagus and oesophageal adenocarcinoma is well understood and reported. The Department of Health's priority for earlier detection of cancer is entirely justified. The issues may well turn on how clinical practice can be developed, and resources managed, to improve detection of a relatively rare condition from common symptoms. But a history of persistent heartburn is a clear signal!</p>	<p>Thank you for your comment. The alarm signs and symptoms for routine endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.</p>
SH	Oesophageal Patients Association	11.12	4 .5b)	<p>We have much anecdotal evidence that over the counter medication is often apparently effective at reducing the symptoms of heartburn. Patients do not realise that they have developed Barrett's oesophagus until some years later when they find themselves with a cancer diagnosis. So it is crucial for pharmacists to refer long term heartburn over-the-</p>	<p>Thank you for your comment. The alarm signs and symptoms for routine endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.</p>

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				counter remedy consumers for proper medical investigation. And equally important that such cases are not simply transferred on to PPIs without subsequent review and endoscopy.	
SH	Reckitt Benckiser Healthcare (UK) Ltd	17.06	4.1.1	As described by Vakil (VAKIL et al. <i>Am J Gastroenterol</i> (2006) 101: 1900-1920), GORD can be categorised into oesophageal or extra oesophageal syndromes. This should be covered here as there is no existing or proposed guidance that describes these conditions.	Thank you for your comment. The scope would not normally go in to this level of detail /complexity. These conditions may be defined during the development of the guideline.
SH	Oesophageal Patients Association	11.04	4.1.1c)	Adults with a diagnosis of Barrett's oesophagus are not included; but we should be aiming to diagnose that condition as a worthwhile thing in in its own right.	<p>Thank you for your comment. Patients with Barrett's oesophagus are included in this scope for this guideline.</p> <p>The diagnosis of Barrett's oesophagus was not identified as an area of priority for this guideline. However the scope will cover the surveillance of Barrett's oesophagus as detailed in review question 4.5 g).</p>
SH	Reckitt Benckiser Healthcare (UK) Ltd	17.07	4.3.1	<p>The occurrence of rebound acid hypersecretion (RAHS) in patients stopping acid suppressant therapy (PPIs, H2s) and the potential for this to induce the upper GI symptoms these medications may be given to treat is not mentioned in this section.</p> <p>This phenomenon was captured recently in the British National Formulary following a publication by Reimer et al. (BNF Ed 62. Sept 2011, REIMER et al. <i>Gastroenterol</i> (2009) 137: 80-87). A double blind, placebo controlled trial by</p>	Thank you for your comment. The scope will not include non specialist pharmacological management of dyspepsia as it was not identified as an area of priority for this guideline. However work on PPI prescribing will be covered in another NICE product – see section 6.1 of the scope.

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				<p>Niklasson (NIKLIASSON et al. <i>Am J Gastroenterol</i> (2010) also confirmed the occurrence of rebound/dyspeptic symptoms in patients discontinuing acid suppression.</p> <p>Following treatment with acid suppressing medication, RAHS can often lead to a failed attempt to step down/step off prescription medication and prevent a move to self care. This condition and its suggested management should be included in key clinical considerations.</p>	
SH	Oesophageal Patients Association	11.05	4.3.1e)	We agree that investigations for underlying causes are important	Thank you for your comment.
SH	Reckitt Benckiser Healthcare (UK) Ltd	17.08	4.3.1g)	<p>Alginates are a licensed pharmacological option for the treatment of GORD. Their use in this condition should be included here.</p> <p>In addition, a systematic review of studies investigating persistent reflux by El-Serag (EL-SERAG et al. <i>Aliment Pharmacol Ther</i> (2010) 32: 720-737) provided evidence that acid suppressing therapy does not always result in complete resolution of symptoms in all patients.</p>	Thank you for your comment. The scope will not include non specialist pharmacological management of dyspepsia as it was not identified as an area of priority for this guideline.
SH	Oesophageal Patients Association	11.06	4.3.1i)	Investigations to assess the response to treatment by means of endoscopy are important. There have been dramatic and creditable improvements of endoscopy waiting times over the last decade, but we now need to improve the referral of those at risk from Barrett's oesophagus and cancer by reducing the perceived rigidity of the guidelines. We are supportive of improving the training of endoscopists.	Thank you for your comment. The scope for this guideline will not cover re-endoscopy, but it is intended to include a review question on surveillance of Barrett's Oesophagus (section 4.5 g) of the new scope).

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SH	Reckitt Benckiser Healthcare (UK) Ltd	17.09	4.3.1j)	Alginates are a licensed pharmacological option for the treatment of GORD. Their use in this condition should be included here.	Thank you for your comment. The guideline will focus on specialist medical management under review question 4.5 f). The interventions that will be considered within this review question will be agreed with the GDG.
SH	Oesophageal Patients Association	11.07	4.3.1j) and 4.5t)	We understand that there is a 'bounce' effect when PPI medication is stopped, where an alginate might be usefully taken for a short period. A review of the patient's condition at a set period after being prescribed PPIs must surely be good practice to investigate underlying causes	Thank you for your comment. The problems associated with rebound acid hyper-secretion are not sufficiently relevant to specialist management of refractory symptoms to be considered a priority for this guideline.
SH	Reckitt Benckiser Healthcare (UK) Ltd	17.10	4.3.1m)	It is not clear what is meant by refractory dyspepsia here. In our opinion it would be more accurate to say non/weak-acid reflux, refractory to treatment with acid suppressing medication.  Please consider defining "refractory dyspepsia" in a clearer manner within this section.	Thank you for your comment. The meaning of the term 'refractory dyspepsia' has now been clarified in review question 4.5 f).
SH	Royal Bolton Hospital Foundation Trust	2.00	4.3.1p)	There are concerns that this consultation document is deciding on Barretts surveillance. This is a complete entity on its own and will be too big a topic to be touched on by the Dyspepsia document	Thank you for your comment. The scope will cover the surveillance of Barrett's oesophagus as detailed in review question 4.5 g). It was considered that this is a key clinical area where guidance is required. NICE has already published guidance on ablative therapy for the treatment of Barrett's oesophagus (CG106).
SH	Oesophageal Patients Association	11.08	4.3.1p)	We understand that in some parts of the UK Barrett's oesophagus patients are not placed under surveillance. There is a great need for this issue to be resolved.	Thank you for your comment. The scope will cover the surveillance of Barrett's oesophagus as detailed in review question 4.5 g). It was considered that this is a key clinical area where guidance is required.

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					NICE has already published guidance on ablative therapy for the treatment of Barrett's oesophagus (CG106).
SH	Royal Bolton Hospital Foundation Trust	2.01	4.3.2	Once again there is a mention that Treatment of Barretts will not be covered in this document. It is surprising that the document will be covering some aspects of the disease but will not tackle other issues.	Thank you for your comment. The scope will cover the surveillance of Barrett's oesophagus as detailed in review question 4.5 g). It was considered that this is a key clinical area where guidance is required. NICE has already published guidance on ablative therapy for the treatment of Barrett's oesophagus (CG106).
SH	Oesophageal Patients Association	11.09	4.3.2a)	The alarm symptoms for oesophogastric cancer do in fact include persistent heartburn, hiccoughs and other symptoms related to dyspepsia, and it is important that the linkage is not lost.	Thank you for your comment. The alarm signs and symptoms for routine endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.
SH	Oesophageal Patients Association	11.11	4.4h)	We agree that the occurrence of Barrett's oesophagus and its rate of progression to adenocarcinoma is an important issue. The statistical burden of less severe outcomes should not prevent good diagnostic investigation.	Thank you for your comment.
SH	Royal Bolton Hospital Foundation Trust	2.02	4.5 y)	Once again Barretts surveillance has been mentioned. It is quite a challenge.	Thank you for your comment. The scope will cover the surveillance of Barrett's oesophagus as detailed in review question 4.5 g). It was considered that this is a key clinical area where guidance is required. NICE has already published guidance on ablative therapy for the treatment of Barrett's oesophagus (CG106).

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SH	British Society of Gastroenterology	4.01	4.5a)	Prescribed drugs causing oesophageal damage – some of these (aspirin, clopidogrel, dipyridamole, SSRIs) cause gastroduodenal rather than oesophageal damage so the scope should be widened beyond oesophageal damage.	Thank you for your comment. This has been changed.
SH	United Kingdom Clinical Pharmacy Association (UKCPA)	18.00	4.5a)	The use of PPIs by physicians for the prevention of dyspepsia in patients with chronic kidney disease and patients receiving chemotherapy is widespread. What is the effectiveness of prophylactic treatments using PPIs for the prevention of dyspepsia in patients with chronic conditions e.g. chronic kidney disease and patients receiving chemotherapy?  Although the guideline is titled dyspepsia/GORD will the group consider looking into evidence in using PPIs for the prophylaxis of stress ulceration in critically ill patients? This practice is also widespread in the ICU setting.	Thank you for your comment. Prophylaxis in patients taking concomitant medication that might precipitate dyspepsia including patients with chronic kidney disease, and those who are critically ill were not considered a priority for this guideline.
SH	British Society of Gastroenterology	4.02	4.5b)	Pharmacist advised therapy should include H2RAs (eg Ranitidine) as these are more commonly used OTC than PPIs. However, I don't know that there is much new evidence in the OTC arena.	Thank you for your comment. Pharmacological management with over the counter drugs was not considered a priority area for this guideline.
SH	Oesophageal Patients Association	11.13	4.5g)	A history of persistent heartburn either still present, or if it appears to have resolved itself (ie the oesophageal cells have changed to acquire the protective effect against acid of stomach cells) is a sign of Barrett's oesophagus	Thank you for your comment. The alarm signs and symptoms for routine endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.
SH	NHS Swindon NHS Gloucestershire	10.02	4.5m) and 4.5n)	Uninvestigated dyspepsia. Not clear which patients it is reasonable NOT to investigate. How does recurrent dyspepsia fit in? What about patients who have been	Thank you for your comment. 'Uninvestigated' in this sense refers to patients where endoscopy has not yet been used to investigate further. This does not

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				investigated several years earlier, been symptom free for years then developed new symptoms?	<p>prejudice suitability of such tests, but illustrates existing practice where treatments are selected based on symptoms alone on an empirical basis.</p> <p>The alarm signs and symptoms for routine endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development. Regarding recurrent dyspepsia, the definition will be agreed in association with the GDG.</p>
SH	Oesophageal Patients Association	11.14	4.5s)	A repeat endoscopy to assess response to treatment should be a viable option. There may be cases where one would not otherwise know whether the treatment has succeeded or failed?	Thank you for your comment. Repeat endoscopy or retesting for H Pylori were not considered a priority for this guideline.
SH	Oesophageal Patients Association	11.15	4.5y)	<p>Surveillance of Barrett's oesophagus patients to detect progression to cancer is important. It is particularly important to have an endoscopy without delay if the patient has noticed changes.</p> <p>We understand that the literature is not unequivocal on the issue, and we need to understand the pattern of progression. We do believe that the availability of endoscopy resources should be adjusted to meet the clinical need. There are training needs involved. There are issues with adherence to the BSG guidelines.</p> <p>The consequences of getting this wrong are serious, especially when the rise in dyspepsia issues may be driving up the long term incidence of oesophagogastric cancer.</p>	Thank you for your comment. The alarm signs and symptoms for routine endoscopy will be addressed by the update of guideline CG27 'Referral for suspected cancer' which is currently being scheduled for development.
SH	Reckitt Benckiser	17.11	5.1.2	Please highlight the following guidance which may also be of	Thank you for your comment. The Developers

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	Healthcare (UK) Ltd			use: - Cough - Upper respiratory tract	believe that all of the relevant NICE guidance is listed in section 5 of the scope.

**These organisations were approached but did not respond:**

Abbott Laboratories  
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  
Barrett's Oesophagus Campaign  
Boehringer Ingelheim  
Boston Scientific  
Bradford District Care Trust  
British Association for Psychopharmacology  
British Geriatrics Society - Gastro-enterology and Nutrition Special Interest Group  
British Medical Association  
British Medical Journal  
British National Formulary  
British Pain Society

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British Psychological Society  
British Society for Antimicrobial Chemotherapy  
British Society of Paediatric Gastroenterology Hepatology and Nutrition  
BUPA Foundation  
Cambridge University Hospitals NHS Foundation Trust  
Camden Link  
Care Quality Commission (CQC)  
Coeliac UK  
Dako UK Ltd  
Department of Health, Social Services and Public Safety - Northern Ireland  
Digestive Disorder Foundation  
Dorset Primary Care Trust  
Eisai Ltd  
Eli Lilly and Company  
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  
Hafan Cymru  
Health Quality Improvement Partnership  
Healthcare Improvement Scotland  
Hertfordshire Partnership NHS Trust

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Hindu Council UK  
Humber NHS Foundation Trust  
Independent Healthcare Advisory Services  
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  
Liverpool Primary Care Trust  
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 Cancer Action Team  
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  
Neonatal & Paediatric Pharmacists Group  
NHS Ashton, Leigh and Wigan  
NHS Connecting for Health  
NHS Plus  
NHS Warwickshire Primary Care Trust  
Norgine Limited  
North Essex Mental Health Partnership Trust

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Nottinghamshire Healthcare NHS Trust  
Novartis Pharmaceuticals  
Pancreatic Cancer Action  
Peckforton Pharmaceuticals Ltd  
PERIGON Healthcare Ltd  
Pfizer  
Pharmaceutical Services Negotiating Committee  
Primary Care Society for Gastroenterology  
Proprietary Association of Great Britain  
Public Health Wales NHS Trust  
Royal Berkshire NHS Foundation Trust  
Royal College of Anaesthetists  
Royal College of General Practitioners in Wales  
Royal College of Midwives  
Royal College of Obstetricians and Gynaecologists  
Royal College of Paediatrics and Child Health, Gastroenterology, Hepatology and Nutrition  
Royal College of Surgeons of England  
Royal Pharmaceutical Society  
Royal Society of Medicine  
Scottish Intercollegiate Guidelines Network  
Sheffield Teaching Hospitals NHS Foundation Trust  
SNDRi  
Social Care Institute for Excellence  
Society and College of Radiographers  
Society for General Microbiology  
South East Coast Ambulance Service  
South Western Ambulance Service NHS Foundation Trust

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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 Pain Society  
Welsh Government  
Welsh Scientific Advisory Committee  
Western Cheshire Primary Care Trust  
Wirral University Teaching Hospital NHS Foundation Trust  
Worcestershire Acute Hospitals Trust  
York Hospitals NHS Foundation Trust

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