



S I G N

**PROPOSED REVIEW OF SIGN GUIDELINE
CONSULTATION FORM**

Title of guideline	SIGN 68: Dyspepsia	
Date of publication	2003	
SIGN scoping search – sources	<p>MeSH headings for the condition specified and any common variations as free text, plus terms for the interventions and care processes discussed in the guideline</p> <p>Sources: Guidelines: NICE; National Library for Health guidelines finder; National Guidelines Clearinghouse; GIN Web site, CKS Knowledge Summaries. Technology appraisals: NICE; UK HTA database (Southampton); INAHTA database. Cochrane reviews: Cochrane Library. Other good quality systematic reviews: UK HTA database (Southampton); DARE. RCTs: MEDLINE</p>	
SIGN scoping search - summary	<p>Guidelines – 18 HTAs – 1 Cochrane reviews – 3 Other good quality systematic reviews – 24 RCTs - 432</p>	
Other guidelines/HTAs	<ul style="list-style-type: none"> ▪ National Institute for Health and Clinical Excellence. Managing dyspepsia in adults in primary care. August 2004. http://www.nice.org.uk/page.aspx?o=CG017&c=gi ▪ National Institute for Health and Clinical Excellence. Referral for suspected cancer. June 2005. http://www.nice.org.uk/page.aspx?o=cg027 ▪ Clinical Knowledge Summaries Topic. Dyspepsia - pregnancy-associated. 2008. www.cks.nhs.uk/dyspepsia_pregnancy_associated ▪ Clinical Knowledge Summaries Topic. Dyspepsia - proven GORD. 2008. www.cks.nhs.uk/dyspepsia_proven_gord ▪ Clinical Knowledge Summaries Topic. Dyspepsia - proven peptic ulcer – Management. 2008. www.cks.nhs.uk/dyspepsia_proven_peptic_ulcer ▪ Clinical Knowledge Summaries Topic. Dyspepsia - unidentified cause – Management. 2008. www.cks.nhs.uk/dyspepsia_proven_non_ulcer/view_whole_topic ▪ New Zealand Guidelines Group. Management of dyspepsia and heartburn. June 2004. http://www.nzgg.org.nz/guidelines/dsp_guideline_popup.cfm?guidelineCatID=53&guidelineID=77 ▪ Talley NJ, Vakil N; Practice Parameters Committee of the American College of Gastroenterology. Guidelines for the management of dyspepsia. Am J Gastroenterol. 2005 Oct;100(10):2324-37. ▪ Veldhuyzen van Zanten SJ, Bradette M, Chiba N, Armstrong D, Barkun A, Flook N, Thomson A, Burse F; Canadian Dyspepsia Working Group. Evidence-based recommendations for short- and long-term management of uninvestigated dyspepsia in primary care: an update of the Canadian Dyspepsia Working Group (CanDys) clinical management tool. Can J Gastroenterol. 2005 May;19(5):285-303. ▪ American Gastroenterological Association medical position statement: evaluation of dyspepsia. November 1997 (revised November 2005). http://www.guideline.gov/summary/summary.aspx?doc_id=8442&nbr=004711 ▪ Singapore Ministry of Health. Management of helicobacter pylori infection. Singapore: Singapore Ministry of Health; September 2004. 	

http://www.guideline.gov/summary/summary.aspx?doc_id=5947&nbr=003916

- Malfertheiner P, Megraud F, O'Morain C. Guidelines for the management of Helicobacter pylori infection. The **Maastricht 3 Consensus Report 2005**. http://www.helicobacter.org/content/guidelines/patient_management/report2005_frame_publ.htm
- **Royal Pharmaceutical Society of Great Britain**. Practice guidance: OTC omeprazole. March 2004 (revised May 2004). <http://www.rpsgb.org.uk/pdfs/otcomeprazoleguid.pdf>
- **British Society of Gastroenterology**. Guidelines for oesophageal manometry and pH monitoring. January 1996; revalidated January 2006. http://www.bsg.org.uk/pdf_word_docs/oesp_man.pdf
- Roderick, P. J. Systematic review and modelling of the cost-effectiveness of screening for helicobacter pylori to reduce mortality and morbidity from gastric cancer and peptic ulcer disease. **Health Technology Assessment** 2003; 7(6). <http://www.hta.ac.uk/1012>
- **ASGE Standards of Practice Committee**, Ikenberry SO, Harrison ME, Lichtenstein D, Dominitz JA, Anderson MA, Jagannath SB, Banerjee S, Cash BD, Fanelli RD, Gan SI, Shen B, Van Guilder T, Lee KK, Baron TH. The role of endoscopy in dyspepsia. *Gastrointest Endosc* 2007 Dec;66(6):1071-5.
- CKS. Dyspepsia: pregnancy associated. Last updated 2008. http://www.cks.nhs.uk/dyspepsia_pregnancy_associated#322550001
- CKS. Dyspepsia: proven non-ulcer. Last updated 2008. http://www.cks.nhs.uk/dyspepsia_proven_non_ulcer#324166001
- CKS. Dyspepsia: unidentified cause. Last updated 2008. http://www.cks.nhs.uk/dyspepsia_unidentified_cause#322951001

Main conclusions from new evidence

- A systematic review concluded that neither clinical history nor computer models could adequately distinguish between organic and functional dyspepsia. *Guideline says that symptom assessment cannot be relied upon to diagnose the cause of dyspepsia (C).*
- Four large observational studies were identified concerning alarm features and risk of cancer. One study concluded that the sensitivity and specificity of alarm symptoms are poor; another found that the majority of dyspeptic patients who developed cancer or ulcer did not present with alarm symptoms; a multicentre database study found that age cut offs and alarm symptoms are inaccurate and result in high false negatives; and one study found that age, male sex, and alarm symptoms were independent risk factors for gastric cancer, but that alarm symptoms had poor predictive value and most malignancies were metastatic at time of diagnosis. *Guideline recommends: Community pharmacists should advise patients suffering from dyspepsia associated with alarm symptoms to consult their general practitioner (D) and that patients with dyspepsia and alarm features should be referred to a specialist (B)*
- A Cochrane review of initial management strategies for dyspepsia found that PPIs are effective and that early endoscopy or H. pylori testing may benefit some patients but are not cost effective. A further meta-analysis of helicobacter pylori 'test and treat' compared with empirical acid suppression for initial management of uncomplicated dyspepsia found little difference in symptom resolution or costs between the two strategies. *Guideline recommendations state: A non-invasive H. pylori test and treat strategy is as effective as endoscopy in the initial management of patients with uncomplicated dyspepsia who are less than 55 years old (A) and a non-invasive H. pylori test and treat policy may be as appropriate as early endoscopy for the initial investigation and management of patients over the age of 55 years presenting with uncomplicated dyspepsia (C).*
- A Cochrane review and further systematic review confirm the benefit of H. pylori eradication in non-ulcer dyspepsia. Also, a large RCT found that H. pylori eradication significantly decreased the incidence of gastric cancer. *Guideline recommends that H. pylori eradication therapy should be considered in the management of functional dyspepsia (A).*

	<ul style="list-style-type: none"> ▪ Two systematic reviews evaluated the accuracy of faecal antigen testing; the more recent review noted that PPIs affect accuracy. <i>The guideline says CUBT or faecal antigen tests are recommended for the pre-treatment diagnosis of H. pylori infection in the community (B).</i> ▪ One HTA found that a national H. pylori screening programme of prevalent 40- to 49-year-olds and incident 40-year-olds may be cost effective and would significantly reduce the incidence of gastric cancer and peptic ulcers. <i>Not addressed in guideline.</i> ▪ A Cochrane review of pharmacological interventions found that prokinetics (14 trials), H2Ras (11 trials), and PPIs (8 trials) were significantly more effective than placebo; bismuth sales (6 trials) were marginally superior to placebo; and antacids (1 trial) and sucralfate (2 trials) were not superior to placebo. The prokinetic and H2RA results could be subject to publication bias. Additionally, seven systematic reviews/meta-analyses evaluate and compare PPIs, H2Ras, and prokinetics. One meta-analysis concluded that patients' responses to serotonin agonists were similar to those to control agents. <i>Guideline found no evidence for the efficacy of antacids, stated that the value of prokinetic drugs is uncertain (no recommendation made), that it is not possible to make a recommendation on the role of cytoprotectives in the management of functional dyspepsia and recommends that "a trial of acid suppression therapy may be considered" (B).</i> ▪ One systematic review of herbal medicines for non-ulcer dyspepsia found that peppermint and caraway were of benefit. <i>Not addressed in guideline.</i> ▪ Ten systematic reviews evaluated specific pharmacological regimes for H. pylori eradication. These reviews considered whether it is beneficial to add a PPI or an H2RA, which is more effective, which PPI is most effective, which dose of PPI is most effective, which antibiotics are most effective, and whether triple or quadruple therapy should be recommended. The conclusions of these reviews sometimes contradict each other. <i>The guideline recommends (A) H. pylori eradication but does not specify how this is optimally achieved.</i> 	
New areas that could be added to the guideline	<ul style="list-style-type: none"> ▪ Dyspepsia: pregnancy associated 	
Summary of the recommendations that could be updated		Section:
	<ul style="list-style-type: none"> ▪ The recommendation (A) <i>H. pylori eradication therapy should be considered in the management of functional dyspepsia</i> could be expanded to include H. pylori eradication regimen 	5.4.2
	<ul style="list-style-type: none"> ▪ <i>Community pharmacists should advise patients suffering from dyspepsia associated with alarm symptoms to consult their general practitioner (D) and that patients with dyspepsia and alarm features should be referred to a specialist (B)</i> ▪ Alarm features and risk of cancer could be expanded 	2.1, 2.2, 2.4
	<ul style="list-style-type: none"> ▪ Recommendation to consider a trial of acid suppression therapy may be updated 	3.1, 5.4.3

Please answer the following questions as fully as possible:

Specialties:	General Practice (2), Patient representation (1), Pharmacy (3), Gastroenterology (1), Radiology (1)	
1(a)	Is there still a requirement for an evidence-based guideline on this topic?	
	Yes	
1(b)	If no, should the guideline be withdrawn?	
	n/a	
2(a)	Do you agree with the assessment of the impact of the new evidence and its likely effect on recommendations?	
	<p>Unless the quality of evidence for herbal products is good, I would not recommend including this in the scope of the guideline.</p> <p>Given the vast numbers of studies on the pharmacological regimens for H pylori, the 'contradictory' outcomes from reviews and the need to integrate with local drug formularies which are often agreed on cost-effectiveness grounds, I'm not sure it's necessary to specify drug choices within pharmacological categories unless there is clear evidence to support one drug over another. This would generate a lot of interest with pharmaceutical companies.</p> <p>Another piece of evidence is the Cochrane Review comparing the 'test and treat' approach with empirical acid suppression therapy for the initial management of uncomplicated dyspepsia. I think this evidence reflects what happens in practice where empirical acid suppression therapy is probably the first line of approach in most patients.</p>	
2(b)	Based on the information given above, and your own clinical judgement, does the guideline require revision in the light of new evidence? Please give details.	
	<p>GPs would benefit from clear guidance regarding the indications for OGD and the risks of prolonged PPI use – what evidence exists about the risk of C diff., osteoporosis and gastric cancer. There may also be value in restating the importance of test and treat for H pylori if the evidence continues to support this.</p> <p>The important aspect is the sensitivity and specificity of alarm symptoms. This needs to be addressed because often the absence of alarm symptoms, which in themselves are often poorly defined, is an opportunity to take the patient's symptoms less seriously, when in fact there may be good reason to pay increased attention to the patient's symptoms.</p> <p>Section 4 - stool antigen seems to be the test of choice for H.pylori and it should be related to the evidence on why it is so.</p>	
3	Please list any additions to the remit of the guideline that you think would be beneficial	
	<p>Add pregnancy associated</p> <p>Consideration of screening for H pylori in the over 40's.</p> <p>Figure 1 needs to be revised and needs to reflect how patients should be clinically managed, taking into account any updates relating to alarm symptoms.</p> <p>I think the opportunity should also be taken to link this guideline to the SIGN 87 guideline on gastric and oesophageal cancer, which also looks at alarm symptoms and examines the need for surveillance in those with Barrett's oesophagus.</p> <p>Consideration of the increased prescribing of PPIs and the impact of this on C diff infections.</p> <p>Ensuring the short course use of PPIs for dyspepsia rather than continuous treatment, where appropriate.</p> <p>Dyspepsia is a symptom complex which may be due to ulcer or non-ulcer disease but not always easy to distinguish from other upper abdominal complaints such as gall bladder disease or pancreatic disease. Does there need to be an indication when ultrasound or CT should be considered?</p>	
4	Please tick your preferred option for reviewing this guideline	
	a. there is no new evidence that will affect existing recommendations and the guideline should not be reviewed at this time	✓
	b. some recommendations will change in the light of the new evidence and selected elements of the guideline should be reviewed	✓
	c. the entire guideline should be reviewed	✓
	d. the guideline should be withdrawn	

5 SIGN COUNCIL			Date: 11/11/2011
Revalidate	Refresh	Revise	Remove
	✓		