National Institute for Clinical Excellence

Dyspepsia

Management of dyspepsia in adults in primary care

June 2005. The recommendations on referral for endoscopy in this NICE guideline have been amended in line with the recommendation in the NICE Clinical Guideline on referral for suspected cancer (*NICE Clinical Guideline* no. 27: referral guidelines for suspected cancer. June 2005. See www.nice.org.uk/CG027). The amended sections are on pages 5, 6, 11,12, 14, 21, 44 and 45.

For ease of reference, the original text in this document has been ~~struck through~~ and the revised text has been set in **bold** below it.

Clinical Guideline 17
August 2004

Developed by the Newcastle Guideline Development and Research Unit

Clinical Guideline 17
Dyspepsia: management of dyspepsia in adults in primary care

Issue date: August 2004

This document, which contains the Institute's full guidance on the management of dyspepsia in adults in primary care, is available from the NICE website (www.nice.org.uk/CG017NICEguideline).

An abridged version of this guidance (a 'quick reference guide') is also available from the NICE website (www.nice.org.uk/CG017quickrefguide). Printed copies of the quick reference guide can be obtained from the NHS Response Line: telephone 0870 1555 455 and quote reference number N0689.

Information for the Public is available from the NICE website or from the NHS Response Line (quote reference number N0690 for a version in English and N0691 for a version in English and Welsh).

This guidance is written in the following context:

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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The quick reference guide for this guideline has been distributed to the following:

- NHS trust chief executives in England and Wales
- Primary Care Trust (PCT) chief executives
- Local Heath Group general managers
- Local Health Board (LHB) chief executives
- Strategic health authority chief executives in England and Wales
- Medical and nursing directors in England and Wales
- Clinical governance leads in England and Wales
- Audit leads in England and Wales
- NHS trust, PCT and LHB libraries in England and Wales
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- Community Health Councils in Wales
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- Patient advocacy groups
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- Senior pharmacists and pharmaceutical advisors in England and Wales
- Directors of directorates of health and social care

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Contents

Key priorities for implementation

The following have been identified as priorities for implementation.

Referral for endoscopy

- Review medications for possible causes of dyspepsia (for example, calcium antagonists, nitrates, theophyllines, bisphosphonates, corticosteroids and non-steroidal anti-inflammatory drugs [NSAIDs]). In patients requiring referral, suspend NSAID use.
- Urgent specialist referral for endoscopic investigation[1] is indicated for patients of any age with dyspepsia when presenting with any of the following: chronic gastrointestinal bleeding, progressive unintentional weight loss, progressive difficulty swallowing, persistent vomiting, iron deficiency anaemia, epigastric mass or suspicious barium meal.
- ~~Routine endoscopic investigation of patients of any age, presenting with dyspepsia and without alarm signs, is not necessary. However, for patients over 55, consider endoscopy when symptoms persist despite *Helicobacter pylori* (*H. pylori*) testing and acid suppression therapy, and when patients have one or more of the following: previous gastric ulcer or surgery, continuing need for NSAID treatment, or raised risk of gastric cancer or anxiety about cancer.~~
- **Routine endoscopic investigation of patients of any age, presenting with dyspepsia and without alarm signs, is not necessary. However, in patients aged 55 years and older with unexplained[2] and persistent[2] recent-onset dyspepsia alone, an urgent referral for endoscopy should be made.**

[1] The Guideline Development Group considered that 'urgent' meant being seen within 2 weeks.

[2] **In the referral guidelines for suspected cancer (*NICE Clinical Guideline* no. 27) 'unexplained' is defined as 'a symptom(s) and/or sign(s) that has not led to a diagnosis being made by the primary care professional after initial assessment of the history, examination and primary care investigations (if any)'. In the context of this recommendation, the primary care professional should confirm that the dyspepsia is new rather than a recurrent episode and exclude common precipitants of dyspepsia such as ingestion of NSAIDs. 'Persistent' as used in the recommendations in the referral guidelines refers to the continuation of specified symptoms and/or signs**

Interventions for uninvestigated dyspepsia

- Initial therapeutic strategies for dyspepsia are empirical treatment with a proton pump inhibitor (PPI) or testing for and treating *H. pylori*. There is currently insufficient evidence to guide which should be offered first. A 2-week washout period following PPI use is necessary before testing for *H. pylori* with a breath test or a stool antigen test.

beyond a period that would normally be associated with self-limiting problems. The precise period will vary depending on the severity of symptoms and associated features, as assessed by the healthcare professional. In many cases, the upper limit the professional will permit symptoms and/or signs to persist before initiating referral will be 4–6 weeks.

Interventions for gastro-oesophageal reflux disease (GORD)

- Offer patients who have GORD a full-dose PPI for 1 or 2 months.
- If symptoms recur following initial treatment, offer a PPI at the lowest dose possible to control symptoms, with a limited number of repeat prescriptions.

Interventions for peptic ulcer disease

- Offer *H. pylori* eradication therapy to *H. pylori*-positive patients who have peptic ulcer disease.
- For patients using NSAIDs with diagnosed peptic ulcer, stop the use of NSAIDs where possible. Offer full-dose PPI or H_2 receptor antagonist (H_2RA) therapy for 2 months to these patients and, if *H. pylori* is present, subsequently offer eradication therapy.

Interventions for non-ulcer dyspepsia

- Management of endoscopically determined non-ulcer dyspepsia involves initial treatment for *H. pylori* if present, followed by symptomatic management and periodic monitoring.
- Re-testing after eradication should not be offered routinely, although the information it provides may be valued by individual patients.

Reviewing patient care

- Offer patients requiring long-term management of dyspepsia symptoms an annual review of their condition, encouraging them to try stepping down or stopping treatment.
- A return to self-treatment with antacid and/or alginate therapy (either prescribed or purchased over-the-counter and taken as required) may be appropriate.

***H. pylori* testing and eradication**

- *H. pylori* can be initially detected using either a carbon-13 urea breath test or a stool antigen test, or laboratory-based serology where its performance has been locally validated.

- Office-based serological tests for *H. pylori* cannot be recommended because of their inadequate performance.
- For patients who test positive, provide a 7-day, twice-daily course of treatment consisting of a full-dose PPI with either metronidazole 400 mg and clarithromycin 250 mg or amoxicillin 1 g and clarithromycin 500 mg.

The following guidance is evidence based. The full evidence base supporting each recommendation is provided in the full guideline (see Section 5). Brief summaries of the evidence are shown in this version to support some of the recommendations; they appear as bulleted statements below the recommendations. Please note that the grading scheme for evidence used in the NICE guideline (Appendix A) differs from that used in the full guideline.

1 Guidance

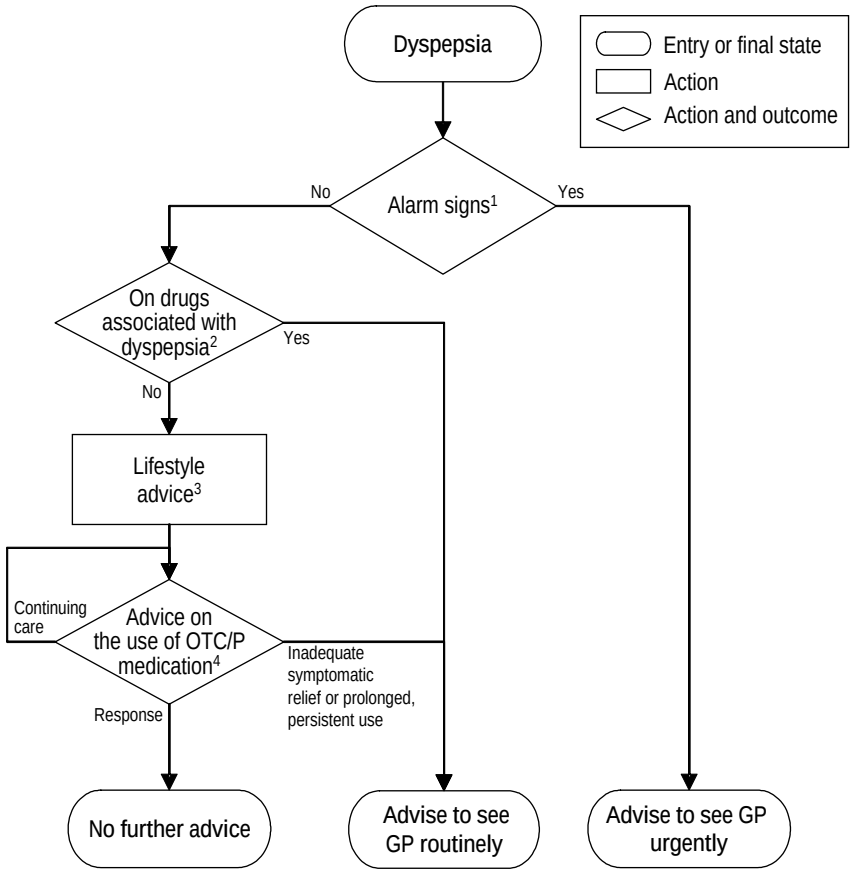
1.1 The community pharmacist

1.1.1 Offer initial and ongoing help for people suffering from symptoms of dyspepsia. This includes advice about lifestyle changes, using over-the-counter medication, help with prescribed drugs and advice about when to consult a general practitioner. **D**

1.1.2 Pharmacists record adverse reactions to treatment and may participate in primary care medication review clinics. **D**

See flowchart to guide pharmacist management of dyspepsia (page 10).

Flowchart to guide pharmacist management of dyspepsia



1 Alarm signs include dyspepsia with gastrointestinal bleeding, difficulty swallowing, unintentional weight loss, abdominal swelling and persistent vomiting.

2 Ask about current and recent clinical and self care for dyspepsia. Ask about medications that may be the cause of dyspepsia, for example calcium antagonists, nitrates, theophyllines, bisphosphonates, corticosteroids and NSAIDs.

3 Offer lifestyle advice, including advice about healthy eating, weight reduction and smoking cessation.

4 Offer advice about the range of pharmacy-only and over-the-counter medications, reflecting symptoms and previous successful and unsuccessful use. Be aware of the full range of recommendations for the primary care management of adult dyspepsia to work consistently with other healthcare professionals.

1.2 Referral guidance for endoscopy

1.2.1 Immediate (same day) specialist referral is indicated for patients presenting with dyspepsia together with significant acute gastrointestinal bleeding. **D**

1.2.2 Review medications for possible causes of dyspepsia (for example, calcium antagonists, nitrates, theophyllines, bisphosphonates, corticosteroids and non-steroidal anti-inflammatory drugs [NSAIDs]). In patients requiring referral, suspend NSAID use. **D**

1.2.3 Consider the possibility of cardiac or biliary disease as part of the differential diagnosis. **D**

1.2.4 Urgent specialist referral or endoscopic investigation* is indicated for patients of any age with dyspepsia when presenting with any of the following: chronic gastrointestinal bleeding; progressive unintentional weight loss; progressive difficulty swallowing; persistent vomiting; iron deficiency anaemia; epigastric mass or suspicious barium meal. **C**

** The Guideline Development Group considered that 'urgent' meant being seen within 2 weeks.*

- *In a recent prospective observational study the prevalence of gastric cancer was 4% in a cohort of patients referred urgently for alarm features. Referral for dysphagia or significant weight loss at any age plus age older than 55 years with alarm symptoms would have detected 99.8% of the cancers found in the cohort. These findings are supported by other retrospective studies.*

- *Retrospective studies have found that cancer is rarely detected in patients younger than 55 years without alarm symptoms and, when found, the cancer is usually inoperable.*

- *In the UK, morbidity (non-trivial adverse events) and mortality rates for upper gastrointestinal endoscopy may be as high as 1 in 200 and 1 in 2000, respectively.*

1.2.5 ~~Routine endoscopic investigation of patients of any age presenting with dyspepsia and without alarm signs is not necessary. However, for~~

~~patients over 55, consider endoscopy if symptoms persist despite *H. pylori* testing and acid suppression therapy, and if patients have one or more of the following: previous gastric ulcer or surgery; continuing need for NSAID treatment; or raised risk of gastric cancer or anxiety about cancer.~~ **~~C~~**

1.2.5 **Routine endoscopic investigation of patients of any age presenting with dyspepsia and without alarm signs is not necessary. However, in patients aged 55 years and older with unexplained[3] and persistent[3] recent-onset dyspepsia alone, an urgent referral for endoscopy should be made. C**

1.2.6 Patients undergoing endoscopy should be free from medication with either a proton pump inhibitor (PPI) or an H_2 receptor antagonist (H_2RA) for a minimum of 2 weeks beforehand. **D**

- *One retrospective study showed that acid suppression therapy could mask or delay the detection of gastric and oesophageal adenocarcinoma.*

1.2.7 Consider managing previously investigated patients without new alarm signs according to previous endoscopic findings. **D**

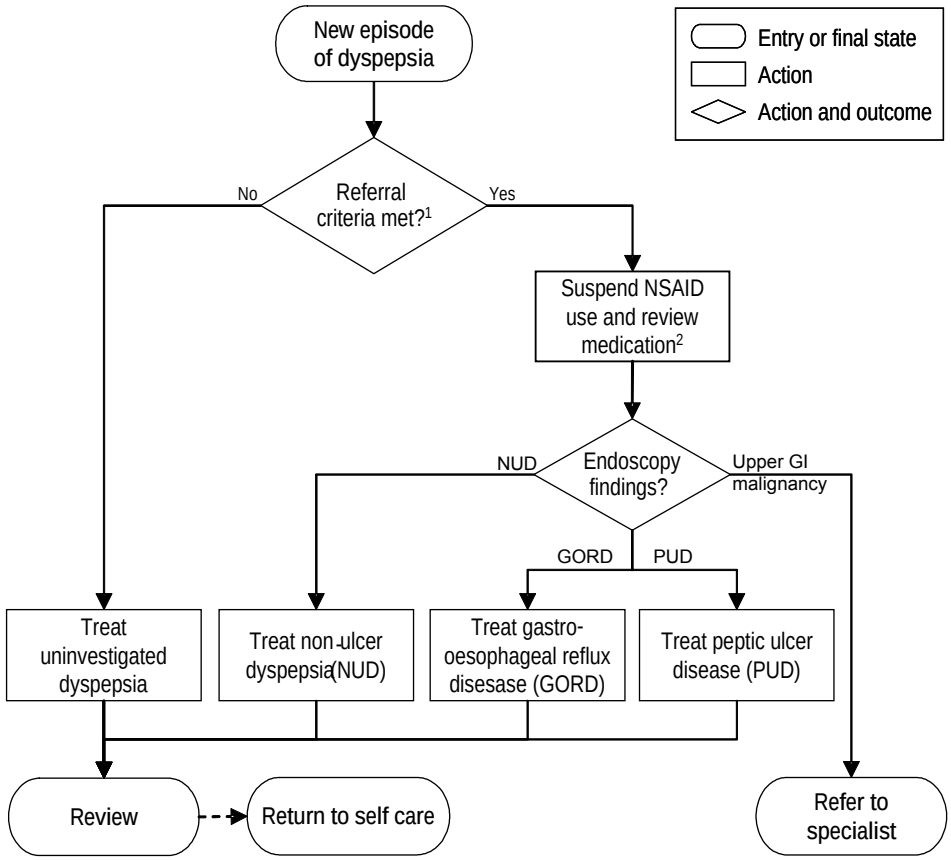
For patients not requiring referral for endoscopy, provide care for uninvestigated dyspepsia. See management of uninvestigated dyspepsia (page 19).

See flowchart of referral criteria and subsequent management (page 14).

[3] In the referral guidelines for suspected cancer (*NICE Clinical Guideline* no. 27), 'unexplained' is defined as 'a symptom(s) and/or sign(s) that has not led to a diagnosis being made by the primary care professional after initial assessment of the history, examination and primary care investigations (if any)'. In the context of this recommendation, the primary care professional should confirm that the dyspepsia is new rather than a recurrent episode and exclude common precipitants of dyspepsia such as ingestion of NSAIDs. 'Persistent' as used in the recommendations in the referral guidelines refers to the continuation of specified symptoms and/or signs beyond a period that would normally be associated with self-limiting problems. The precise period will vary depending on the severity of symptoms and associated features, as assessed by the healthcare professional. In many cases, the upper limit the professional will permit symptoms and/or signs to persist before initiating referral will be 4–6 weeks.

Specific recommendations are made for the care of patients following endoscopic diagnosis: gastro-oesophageal reflux disease (GORD) (page 21), gastric ulcer (pages 25 and 28), duodenal ulcer (pages 25 and 29), and non-ulcer dyspepsia (page 30).

Flowchart of referral criteria and subsequent management



1 Immediate referral is indicated for significant acute gastrointestinal bleeding.

Consider the possibility of cardiac or biliary disease as part of the differential diagnosis.

Urgent specialist referral* for endoscopic investigation is indicated for patients of any age with dyspepsia when presenting with any of the following: chronic gastrointestinal bleeding, progressive unintentional weight loss, progressive difficulty swallowing, persistent vomiting, iron deficiency anaemia, epigastric mass or suspicious barium meal.

~~Routine endoscopic investigation of patients of any age, presenting with dyspepsia and without alarm signs, is not necessary. However, for patients over 55, consider endoscopy when symptoms persist despite *Helicobacter pylori* (*H. pylori*) testing and acid suppression therapy, and when patients have one or more of the following: previous gastric ulcer or surgery, continuing need for NSAID treatment or raised risk of gastric cancer or anxiety about cancer.~~

Routine endoscopic investigation of patients of any age, presenting with dyspepsia and without alarm signs, is not necessary. However, in patients aged 55 years and older with unexplained** and persistent** recent-onset dyspepsia alone, an urgent referral for endoscopy should be made.

Consider managing previously investigated patients without new alarm signs according to previous endoscopic findings.

2 Review medications for possible causes of dyspepsia, for example, calcium antagonists, nitrates, theophyllines, bisphosphonates, steroids and NSAIDs. Patients undergoing endoscopy should be free from medication with either a proton pump inhibitor (PPI) or an H_2 receptor (H_2RA) for a minimum of 2 weeks.

** The Guideline Development Group considered that 'urgent' meant being seen within 2 weeks.*

*** In the referral guidelines for suspected cancer (NICE Clinical Guideline no. 27), 'unexplained' is defined as 'a symptom(s) and/or sign(s) that has not led to a diagnosis being made by the primary care professional after initial assessment of the history, examination and primary care investigations (if any)'. In the context of this recommendation, the primary care professional should confirm that the dyspepsia is new rather than a recurrent episode and exclude common precipitants of dyspepsia such as ingestion of NSAIDs. 'Persistent' as used in the recommendations in the referral guidelines refers to the continuation of specified symptoms and/or signs beyond a period that would normally be associated with self-limiting problems. The precise period will vary depending on the severity of symptoms and associated features, as assessed by the healthcare professional. In many cases, the upper limit the professional will permit symptoms and/or signs to persist before initiating referral will be 4–6 weeks.*

1.3 Common elements of care

1.3.1 For many patients, self-treatment with antacid and/or alginate therapy (either prescribed or purchased over-the-counter and taken 'as required') may continue to be appropriate for immediate symptom relief. However, additional therapy is appropriate to manage symptoms that persistently affect patients' quality of life. **D**

1.3.2 Offer older patients (over 80 years of age) the same treatment as younger patients, taking account of any comorbidity and their existing use of medication. **D**

- *Patients over 80 years of age are poorly represented in clinical trials and the balance of benefits and risks of treatments and investigations in this group is less certain. However, it is reasonable to assume that they will receive similar benefits in the absence of complicating factors.*

1.3.3. Offer simple lifestyle advice, including advice on healthy eating, weight reduction and smoking cessation. **C**

- *Available trials of lifestyle advice to reduce symptoms of dyspepsia are small and inconclusive.*

- *Epidemiological studies show a weak link between obesity and GORD, but no clear association between dyspepsia and other lifestyle factors: smoking, alcohol, coffee and diet. However, individual patients may be helped by lifestyle advice and there may be more general health benefits that make lifestyle advice important.*

1.3.4 Advise patients to avoid known precipitants they associate with their dyspepsia where possible. These include smoking, alcohol, coffee, chocolate, fatty foods and being overweight. Raising the head of the bed and having a main meal well before going to bed may help some people. **D**

- *One possible cause of reflux disease is transient relaxation of the lower oesophageal sphincter. Obesity, smoking, alcohol, coffee and chocolate may cause transient lower oesophageal sphincter relaxations, while fatty foods may delay gastric emptying. Lying flat may increase reflux episodes because gravity does not then prevent acid regurgitation. Thus raising the head of the*

bed and having a main meal well before going to bed may help some patients.

1.3.5 Provide patients with access to educational materials to support the care they receive. **D**

1.3.6 Psychological therapies, such as cognitive behavioural therapy and psychotherapy, may reduce dyspeptic symptoms in the short term in individual patients. Given the intensive and relatively costly nature of such interventions, routine provision by primary care teams is not currently recommended. **B**

- *In patients with non-ulcer dyspepsia, three small trials of psychological interventions showed decreases in dyspeptic symptoms at the end of the intervention at 3 months not persisting to 1 year.*
- *No formal cost-effectiveness analysis has been conducted although (in 2002) British Association for Counselling and Psychotherapy (BACP) accredited counsellors and community-based clinical psychologists cost typically £30 and £67 per hour of patient contact time to which travel, administrative and location costs must be added, net of changes to medication costs.*

1.3.7 Patients requiring long-term management of dyspepsia symptoms should be encouraged to reduce their use of prescribed medication stepwise: by using the effective lowest dose, by trying as-required use when appropriate, and by returning to self-treatment with antacid and/or alginate therapy. **D**

1.4 Interventions for uninvestigated dyspepsia

1.4.1 Dyspepsia in unselected patients in primary care is defined broadly to include patients with recurrent epigastric pain, heartburn, or acid regurgitation, with or without bloating, nausea or vomiting. **D**

- *In primary care, described symptoms are a poor predictor of significant disease or underlying pathology.*

Review common elements of care for managing dyspepsia (page 15).

1.4.2. Initial therapeutic strategies for dyspepsia are empirical treatment with a PPI or testing for and treating *H. pylori*. There is currently insufficient evidence to guide which should be offered first. A 2-week washout period following PPI use is necessary before testing for *H. pylori* with a breath test or a stool antigen test. **A**

1.4.3 Offer empirical full-dose PPI therapy for 1 month to patients with dyspepsia. **A**

- *PPIs are more effective than antacids at reducing dyspeptic symptoms in trials of patients with uninvestigated dyspepsia. The average rate of response taking antacid was 37% and PPI therapy increased this to 55%: a number needed to treat for one additional responder of six.*

- *PPIs are more effective than H_2RAs at reducing dyspeptic symptoms in trials of patients with uninvestigated dyspepsia. The average response rate in H_2RA groups was 36% and PPI increased this to 58%: a number needed to treat for one additional responder of five.*

- *Early endoscopy has not been demonstrated to produce better patient outcomes than empirical treatment.*

- *Test and endoscopy has not been demonstrated to produce better patient outcomes than empirical treatment.*

1.4.4 Offer *H. pylori* 'test and treat' to patients with dyspepsia. **A**

- H. pylori *testing and treatment is more effective than empirical acid suppression at reducing dyspeptic symptoms after 1 year in trials of selected patients testing positive for* H. pylori*. The average response rate receiving*

empirical acid suppression was 47% and H. pylori *eradication increased this to 60%: a number needed to treat for one additional responder of seven.*

- H. pylori *testing and treatment has not been demonstrated to produce better patient outcomes than endoscopy, although there is considerable variation in study findings. However, studies consistently demonstrate that test and treat dramatically reduces the need for endoscopy and provides significant cost savings.*

1.4.5 If symptoms return after initial care strategies, step down PPI therapy to the lowest dose required to control symptoms. Discuss using the treatment on an as-required basis with patients to manage their own symptoms. **A**

- *Evidence is taken from patients with endoscopy-negative reflux disease. Patients using PPI therapy as required (waiting for symptoms to develop before taking treatment) reported similar 'willingness to continue' to those on continuous PPI therapy.*

- *Patients taking therapy as required used about 0.4 tablets per day, averaged across studies of 6–12 months duration. Taking therapy when symptoms occur may help patients to tailor their treatment to their needs.*

1.4.6 Offer H_2RA or prokinetic* therapy if there is an inadequate response to a PPI. **A**

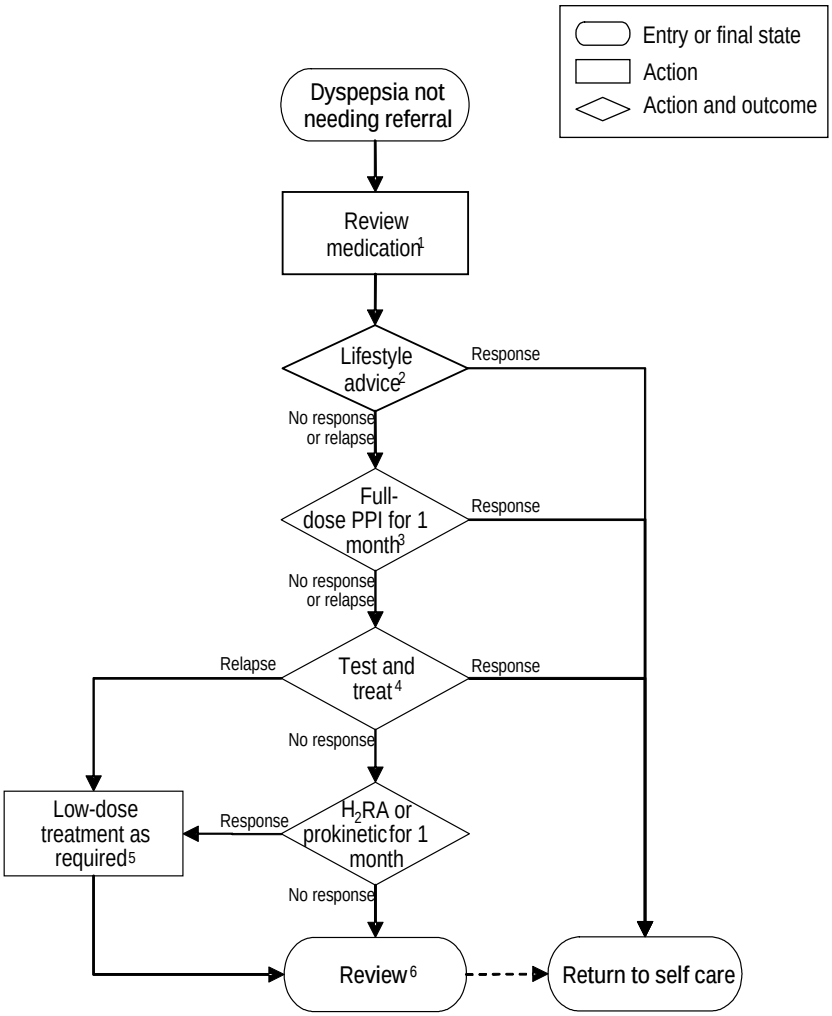
- *PPIs are more effective than H_2RAs at reducing dyspeptic symptoms in trials of patients with uninvestigated dyspepsia. However, individual patients may respond to H_2RA therapy.*

- *In one trial of 1-year duration, patients receiving a PPI or a prokinetic experienced similar time free of symptoms.*

** Cisapride is no longer licensed in the UK and evidence is sparse for domperidone or metoclopramide.*

See flowchart for management of patients with uninvestigated dyspepsia (page 19).

Management flowchart for patients with uninvestigated dyspepsia



1 Review medications for possible causes of dyspepsia, for example, calcium antagonists, nitrates, theophyllines, bisphosphonates, steroids and NSAIDs.

2 Offer lifestyle advice, including advice on healthy eating, weight reduction and smoking cessation, promoting continued use of antacid/alginates.

3 There is currently inadequate evidence to guide whether full-dose PPI for 1 month or *H. pylori* test and treat should be offered first. Either treatment may be tried first with the other being offered if symptoms persist or return.

4 Detection: use carbon-13 urea breath test, stool antigen test or, when performance has been validated, laboratory-based serology.

Eradication: use a PPI, amoxicillin, clarithromycin 500 mg (PAC_{500}) regimen or a PPI, metronidazole, clarithromycin 250 mg (PMC_{250}) regimen.

Do not re-test even if dyspepsia remains unless there is a strong clinical need.

5 Offer low-dose treatment with a limited number of repeat prescriptions. Discuss the use of treatment on an as-required basis to help patients manage their own symptoms.

6 In some patients with an inadequate response to therapy it may become appropriate to refer to a specialist for a second opinion. Emphasise the benign nature of dyspepsia. Review long-term patient care at least annually to discuss medication and symptoms.

1.5 Reviewing patient care

1.5.1 Offer patients requiring long-term management of dyspepsia symptoms an annual review of their condition, encouraging them to try stepping down or stopping treatment*. **D**

- *Dyspepsia is a remitting and relapsing disease, with symptoms recurring annually in about half of patients.*

** Unless there is an underlying condition or comedication requiring continuing treatment.*

1.5.2 A return to self-treatment with antacid and/or alginate therapy (either prescribed or purchased over-the-counter and taken as-required) may be appropriate. **D**

1.5.3 Offer simple lifestyle advice, including healthy eating, weight reduction and smoking cessation. **C**

- *Available trials of lifestyle advice to reduce symptoms of dyspepsia are small and inconclusive.*

- *Epidemiological studies show a weak link between obesity and GORD, but no clear association between dyspepsia and other lifestyle factors: smoking, alcohol, coffee and diet. However, individual patients may be helped by lifestyle advice and there may be more general health benefits that make lifestyle advice important.*

1.5.4 Advise patients to avoid known precipitants they associate with their dyspepsia where possible. These include smoking, alcohol, coffee, chocolate, fatty foods and being overweight. Raising the head of the bed and having a main meal well before going to bed may help some people. **D**

- *One possible cause of reflux disease is transient relaxation of the lower oesophageal sphincter. Obesity, smoking, alcohol, coffee and chocolate may cause transient lower oesophageal sphincter relaxations, whereas fatty foods delay gastric emptying. Lying flat may increase reflux episodes, because gravity does not then prevent acid regurgitation. Thus, raising the head of the*

bed and having a main meal well before going to bed may help some patients.

~~1.5.5 Routine endoscopic investigation of patients of any age presenting with dyspepsia and without alarm signs is not necessary. However, for patients over 55, consider endoscopy when symptoms persist despite *H. pylori* testing and acid suppression therapy and when patients have one of more of the following: previous gastric ulcer or surgery, continuing need for NSAID treatment, or raised risk of gastric cancer or anxiety about cancer. C~~

1.5.5 **Routine endoscopic investigation of patients of any age presenting with dyspepsia and without alarm signs is not necessary. However, in patients aged 55 years and older with unexplained[4] and persistent[4] recent-onset dyspepsia alone, an urgent referral for endoscopy should be made. C**

1.6 Interventions for gastro-oesophageal reflux disease

1.6.1 Gastro-oesophageal reflux disease (GORD) refers to endoscopically determined oesophagitis or endoscopy-negative reflux disease. Patients with uninvestigated 'reflux-like' symptoms should be managed as patients with uninvestigated dyspepsia. **D**

1.6.2 Offer patients with GORD a full-dose PPI for 1 or 2 months. **A**

- *PPIs are more effective than H_2RAs at healing oesophagitis in trials. Healing occurred in 22% of patients on placebo, 39% of patients on H_2RAs (a number*

[4] In the referral guidelines for suspected cancer (*NICE Clinical Guideline* no. 27), 'unexplained' is defined as 'a symptom(s) and/or sign(s) that has not led to a diagnosis being made by the primary care professional after initial assessment of the history, examination and primary care investigations (if any)'. In the context of this recommendation, the primary care professional should confirm that the dyspepsia is new rather than a recurrent episode and exclude common precipitants of dyspepsia such as ingestion of NSAIDs. 'Persistent' as used in the recommendations in the referral guidelines refers to the continuation of specified symptoms and/or signs beyond a period that would normally be associated with self-limiting problems. The precise period will vary depending on the severity of symptoms and associated features, as assessed by the healthcare professional. In many cases, the upper limit the professional will permit symptoms and/or signs to persist before initiating referral will be 4–6 weeks.

needed to treat of six) and 76% of patients on PPIs (a number needed to treat of two). There is considerable variation in the findings of trials.

- *In trials, extending treatment to 2 months increased healing of oesophagitis by a further 14%.*
- *If patients have severe oesophagitis and remain symptomatic, double-dose PPI for a further month may increase the healing rate.*
- *Limited evidence shows that antacids are no more effective at healing oesophagitis than placebo.*
- *On balance, PPIs appear more effective than H_2RAs in endoscopy-negative reflux disease. In head-to-head trials 53% of patients became symptom-free on PPI compared with 42% receiving H_2RAs, although the difference was not statistically significant. The same pattern of benefit is apparent in placebo-controlled trials.*

1.6.3 If symptoms recur following initial treatment, offer a PPI at the lowest dose possible to control symptoms, with a limited number of repeat prescriptions. **A**

- *The majority of patients will experience a recurrence of symptoms within 1 year.*
- *PPIs are more effective than H_2RAs at maintaining against relapse of oesophagitis in trials of 6–12 months duration. Relapse occurred in 59% of patients on H_2RA and 20% of patients on PPI (a number needed to treat of three). There is considerable variation in the findings of trials.*
- *PPIs at full dose are more effective than PPIs at low dose in trials of 6–12 months duration. Relapse of oesophagitis occurred in 28% of patients on low-dose PPI and 15% of patients on full-dose PPI (a number needed to treat of eight). There is considerable variation in the findings of trials.*
- *There are no long-term trials in endoscopy-negative reflux disease. However, the most cost-effective approach appears to be to offer patients intermittent 1-month full-dose or as-required PPI therapy, rather than continuous therapy.*

1.6.4 Discuss using the treatment on an as-required basis with patients to manage their own symptoms. **A**

- *Patients with endoscopy-negative reflux disease and using PPI therapy as required (waiting for symptoms to develop before taking treatment) reported similar 'willingness to continue' to those on continuous PPI therapy.*

- *Patients taking therapy as required used about 0.4 tablets per day, averaged across studies of 6–12 months duration. Taking therapy when symptoms occur may help patients to tailor their treatment to their needs.*

1.6.5 Offer H_2RA or prokinetic therapy* if there is an inadequate response to a PPI. **C**

- *PPIs are more effective than H_2RAs or prokinetics at reducing dyspeptic symptoms in trials of patients with GORD. However, individual patients may respond to H_2RA or prokinetic therapy.*

** Cisapride is no longer licensed in the UK and evidence is sparse for domperidone or metoclopramide.*

1.6.6 Surgery cannot be recommended for the routine management of persistent GORD although individual patients whose quality of life remains significantly impaired may value this form of treatment. **A**

- *Open surgery is no better than long-term medical therapy at achieving remission from symptoms.*

- *Laparoscopic surgery is no better than open surgery at achieving remission from symptoms.*

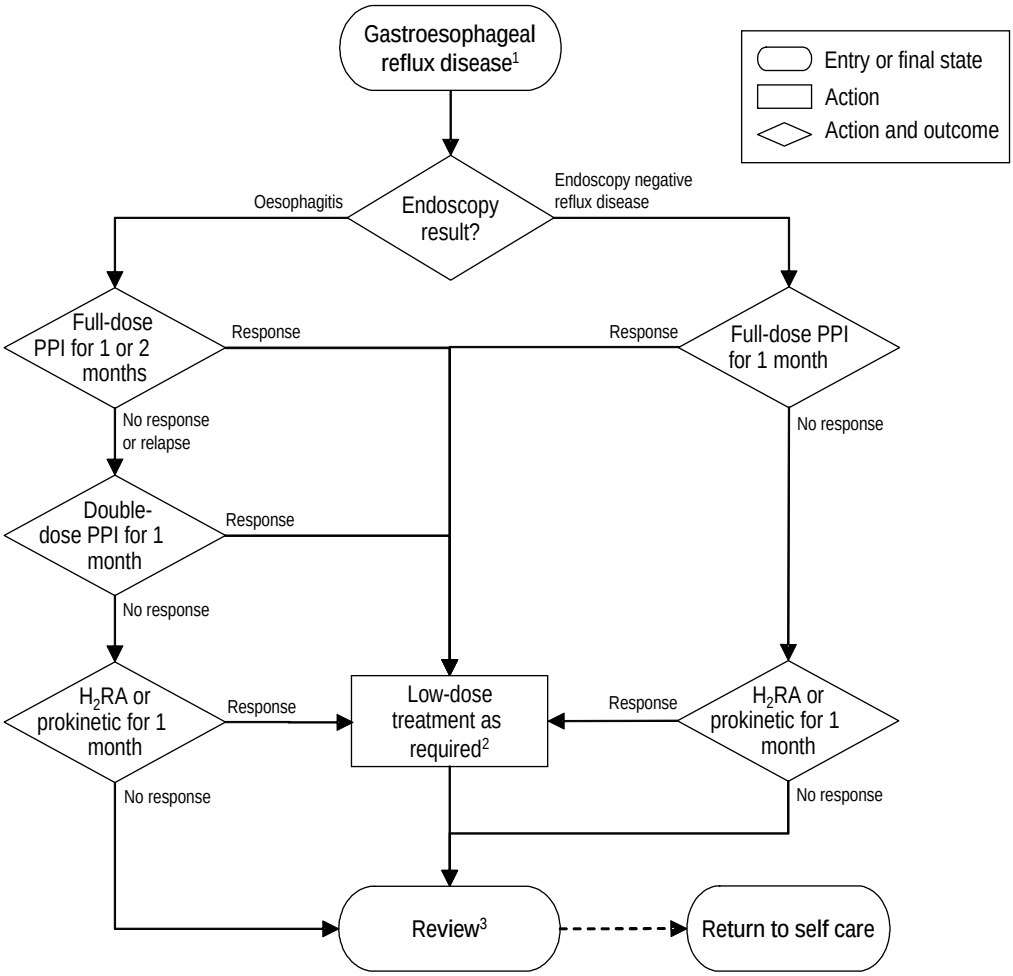
- *There is a small (0.1−0.5%) but important post-operative mortality associated with anti-reflux surgery.*

1.6.7 Patients who have had dilatation of an oesophageal stricture should remain on long-term full-dose PPI therapy. **D**

- *In one large randomised controlled trial (RCT) of patients who have had oesophageal stricture, 30% of the PPI group required repeat dilatation compared with 46% of the ranitidine group*.

See flowchart for management of patients with GORD (page 24).

Management flowchart for patients with GORD



1 GORD refers to endoscopically determined oesophagitis or endoscopy-negative reflux disease. Patients with uninvestigated 'reflux-like' symptoms should be managed as patients with uninvestigated dyspepsia.

There is currently no evidence that *H. pylori* should be investigated in patients with GORD.

2 Offer low-dose treatment, possibly on an as-required basis, with a limited number of repeat prescriptions.

3 Review long-term patient care at least annually to discuss medication and symptoms.

In some patients with an inadequate response to therapy or new emergent symptoms it may become appropriate to refer to a specialist for a second opinion.

Review long-term patient care at least annually to discuss medication and symptoms.

A minority of patients have persistent symptoms despite PPI therapy and this group remain a challenge to treat. Therapeutic options include doubling the dose of PPI therapy, adding an H_2RA at bedtime and extending the length of treatment.

1.7 Interventions for peptic ulcer disease

1.7.1 Offer *H. pylori* eradication therapy to *H. pylori*-positive patients who have peptic ulcer disease. **A**

- H. pylori *eradication therapy increases duodenal ulcer healing in* H. pylori-*positive patients. After 4–8 weeks, patients receiving acid suppression therapy average 69% healing; eradication increases this by a further 5.4%, a number needed to treat for one patient to benefit from eradication of 18.*

- H. pylori *eradication therapy reduces duodenal ulcer recurrence in* H. pylori-*positive patients. After 3–12 months, 39% of patients receiving short-term acid suppression therapy are without ulcer; eradication increases this by a further 52%, a number needed to treat for one patient to benefit from eradication of two. Trials all show a positive benefit for* H. pylori *eradication but the size of the effect is inconsistent.*

- H. pylori *eradication therapy does not increase gastric ulcer healing in* H. pylori-*positive patients, when compared with acid suppression alone in trials of 4–8 weeks duration.*

- H. pylori *eradication therapy reduces gastric ulcer recurrence in* H. pylori-*positive patients. After 3–12 months, 45% of patients receiving short-term acid suppression therapy are without ulcer; eradication increases this by a further 32%, a number needed to treat for one patient to benefit from eradication of three. Trials all show a positive benefit for* H. pylori *eradication but the size of the effect is inconsistent.*

- H. pylori *eradication therapy is a cost-effective treatment for* H. pylori-*positive patients with peptic ulcer disease. Eradication therapy provides additional time free from dyspepsia at acceptable cost in conservative models and is cost-saving in more optimistic models.*

See '*H. pylori* testing and eradication' (page 33).

1.7.2 For patients using NSAIDs with diagnosed peptic ulcer, stop the use of NSAIDs where possible. Offer full-dose PPI or H_2RA therapy for 2 months to these patients and if *H. pylori* is present, subsequently offer eradication therapy. **B**

- *In patients using NSAIDs with peptic ulcer,* H. pylori *eradication does not increase healing when compared with acid suppression therapy alone in trials of 8 weeks duration.*

- *In patients using NSAIDs with previous peptic ulcer,* H. pylori *eradication reduces recurrence of peptic ulcer. In a single trial of 6 months duration, recurrence was reduced from 18% to 10%.*

- *In patients using NSAIDs without peptic ulcer disease,* H. pylori *eradication reduces the risk of a first occurrence of peptic ulcer. In a single trial of 8 weeks duration, first occurrence was reduced from 26% to 7% of patients.*

- *See also evidence statements for eradicating* H. pylori *in peptic ulcer disease (see above).*

1.7.3 Patients with gastric ulcer and *H. pylori* should receive repeat endoscopy, retesting for *H. pylori* 6–8 weeks after beginning treatment, depending on the size of the lesion. **D**

1.7.4 Offer full-dose PPI or H_2RA therapy to *H. pylori*-negative patients not taking NSAIDs for 1 or 2 months. **B**

- *Full-dose PPI therapy heals peptic ulcers in the majority of cases.*

1.7.5 For patients continuing to take NSAIDs after a peptic ulcer has healed, discuss the potential harm from NSAID treatment. Review the need for NSAID use regularly (at least every 6 months) and offer a trial of use on a limited, as-required basis. Consider dose reduction, substitution of an NSAID with paracetamol, use of an alternative analgesic or low-dose ibuprofen (1.2 g daily). **C**

- *The risk of serious ulcer disease leading to hospitalisation associated with NSAID use is of the order of one hospitalisation per 100 patient-years of use in unselected patients. However, patients with previous ulceration are at higher risk.*

- *NSAID use is associated with increased risks of gastrointestinal bleeding in unselected patients, approximately five-fold for musculoskeletal pain and two-fold for secondary prevention of cardiovascular disease with low-dose aspirin.*

1.7.6 In patients at high risk (previous ulceration) and for whom NSAID continuation is necessary, offer gastric protection or consider substitution to a cyclo-oxygenase (Cox)-2-selective NSAID. **A**

- *In patients using NSAIDs without peptic ulcer disease, double-dose H_2RA therapy or PPIs significantly reduce the incidence of endoscopically detected lesions.*
- *In patients using NSAIDs without peptic ulcer disease, misoprostol at low dose is less effective than PPIs at reducing the incidence of endoscopically detected lesions, and has greater side-effects.*
- *In patients using NSAIDs without peptic ulcer disease, substitution to a Cox-2-selective NSAID is associated with a lower incidence of endoscopically detected lesions. The promotion of healing and prevention of recurrence in those with existing ulcer disease is unclear.*

1.7.7 In patients with unhealed ulcer, exclude non-adherence, malignancy, failure to detect *H. pylori*, inadvertent NSAID use, other ulcer-inducing medication and rare causes such as Zollinger-Ellison syndrome or Crohn's disease. **C**

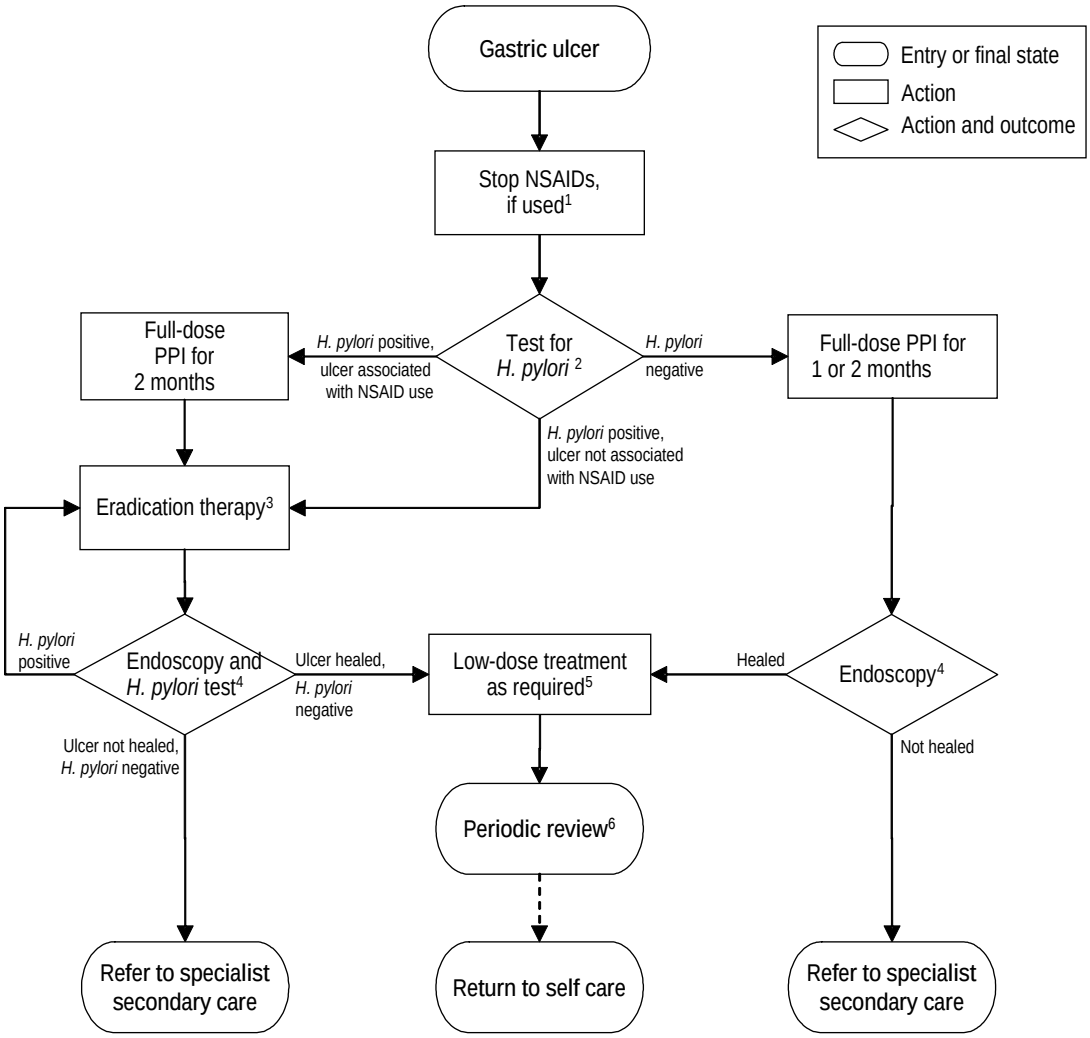
1.7.8 If symptoms recur following initial treatment, offer a PPI to be taken at the lowest dose possible to control symptoms, with a limited number of repeat prescriptions. Discuss using the treatment on an as-required basis with patients to manage their own symptoms. **B**

- *Evidence is taken from patients with endoscopy-negative reflux disease. Patients using PPI therapy as required (waiting for symptoms to develop before taking treatment) reported similar 'willingness to continue' to those on continuous PPI therapy.*
- *Patients taking therapy as required used about 0.4 tablets per day, averaged across studies of 6–12 months duration. Taking therapy when symptoms occur may help patients to tailor their treatment to their needs.*

1.7.9 Offer H_2RA therapy if there is an inadequate response to a PPI. **B**

See flowcharts for management of patients with gastric ulcer (page 28) and duodenal ulcer (page 29).

Management flowchart for patients with gastric ulcer



1 If NSAID continuation is necessary, after ulcer healing offer long-term gastric protection or consider substitution to a newer Cox-2-selective NSAID.

2 Use a carbon-13 urea breath test, stool antigen test or, when performance has been validated, laboratory based serology.

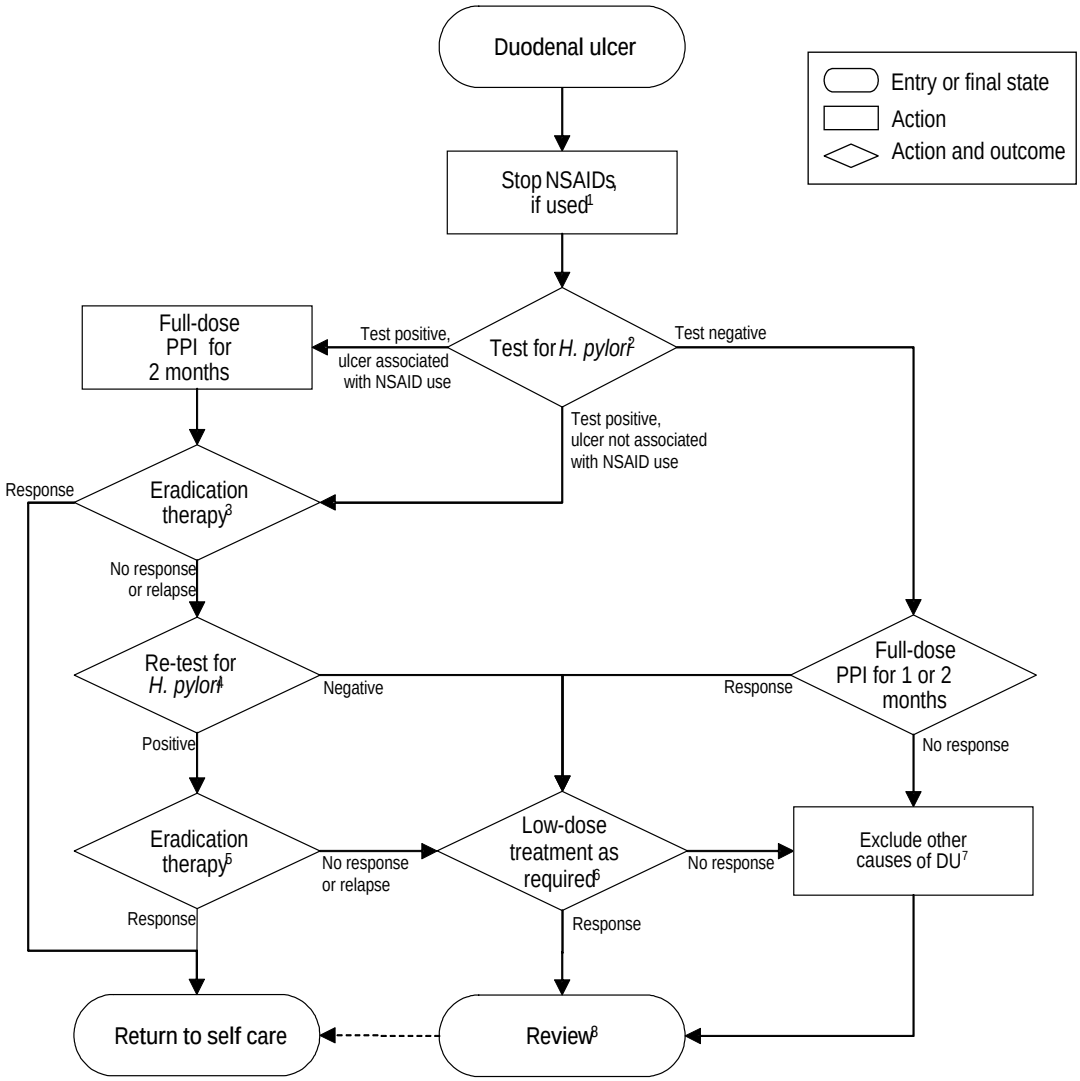
3 Use a PPI, amoxicillin, clarithromycin 500 mg (PAC_{500}) regimen or a PPI, metronidazole, clarithromycin 250 mg (PMC_{250}) regimen.
Follow guidance found in the *British National Formulary* for selecting second-line therapies.
After two attempts at eradication manage as *H. pylori* negative.

4 Perform endoscopy 6–8 weeks after treatment. If re-testing for *H. pylori* use a carbon-13 urea breath test.

5 Offer low-dose treatment, possibly used on an as-required basis, with a limited number of repeat prescriptions.

6 Review care annually, to discuss symptoms, promote stepwise withdrawal of therapy when appropriate and provide lifestyle advice. In some patients with an inadequate response to therapy it may become appropriate to refer to a specialist.

Management flowchart for patients with duodenal ulcer



1 If NSAID continuation is necessary, after ulcer healing offer long-term gastric protection or consider substitution to a newer Cox-2-selective NSAID.

2 Use a carbon-13 urea breath test, stool antigen test or, when performance has been validated, laboratory-based serology.

3 Use a PPI, amoxicillin, clarithromycin 500 mg (PAC_{500}) regimen or a PPI, metronidazole, clarithromycin 250 mg (PMC_{250}) regimen.

4 Use a carbon-13 urea breath test.

5 Follow guidance found in the *British National Formulary* for selecting second-line therapies.

6 Offer low-dose treatment, possibly on an as-required basis, with a limited number of repeat prescriptions.

7 Consider: non-adherence with treatment, possible malignancy, failure to detect *H. pylori* infection due to recent PPI or antibiotic ingestion, inadequate testing or simple misclassification; surreptitious or inadvertent NSAID or aspirin use; ulceration due to ingestion of other drugs; Zollinger Ellison syndrome, Crohn's disease.

8 Review care annually, to discuss symptoms, promote stepwise withdrawal of therapy when appropriate and provide lifestyle advice.

1.8 Interventions for non-ulcer dyspepsia

1.8.1 Management of endoscopically determined non-ulcer dyspepsia involves initial treatment for *H. pylori* if present, followed by symptomatic management and periodic monitoring. **A**

1.8.2 Patients testing positive for *H. pylori* should be offered eradication therapy. **A**

- *Symptoms will naturally improve in 36% of patients; 7% will improve due to eradication therapy but 57% of substantial symptoms will remain over a 3–12 month period.*

1.8.3 Re-testing after eradication should not be offered routinely, although the information it provides may be valued by individual patients. **D**

- *The effect of repeated eradication therapy on* H. pylori *status or dyspepsia symptoms in non-ulcer dyspepsia is unknown.*

1.8.4 If *H. pylori* has been excluded or treated and symptoms persist, offer either a low-dose PPI or an H_2RA for 1 month. **A**

- *Full-dose PPIs are no more effective than maintenance or low-dose PPIs in the management of non-ulcer dyspepsia but are more costly to prescribe (on average: £29.50 versus £15.40 per month).*

- *Low-dose PPIs are more expensive to prescribe than H_2RAs (on average: £15.40 versus £9.50 per month), although the evidence supporting PPIs is stronger.*

- *If PPIs or H_2RAs provide inadequate symptomatic relief, offer a trial of a prokinetic.*

1.8.5 If symptoms continue or recur following initial treatment offer a PPI or H_2RA to be taken at the lowest dose possible to control symptoms, with a limited number of repeat prescriptions. **D**

1.8.6 Discuss using PPI treatment on an as-required basis with patients to manage their own symptoms. **B**

- *Evidence is taken from patients with endoscopy-negative reflux disease. Patients using PPI therapy as required (waiting for symptoms to develop before taking treatment) reported similar 'willingness to continue' to those on continuous PPI therapy.*

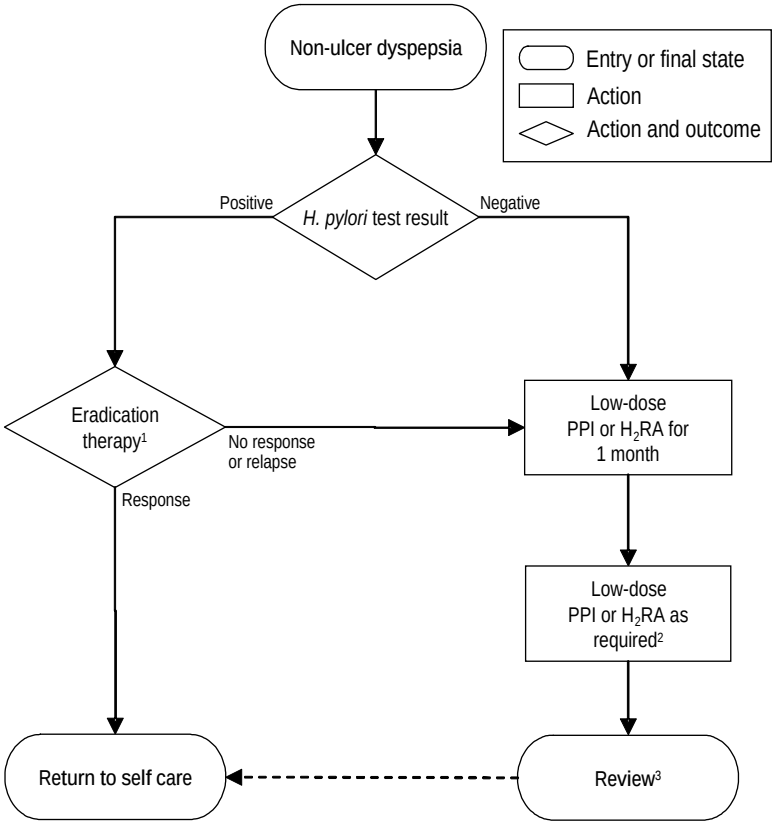
- *Patients taking therapy as required used about 0.4 tablets per day, averaged across studies of 6–12 months duration. Taking therapy when symptoms occur may help patients to tailor their treatment to their needs.*

1.8.7 Long-term, frequent dose, continuous prescription of antacid therapy is inappropriate and only relieves symptoms in the short term rather than preventing them. **A**

- *Antacid therapy is no more effective than placebo in reducing the symptoms of non-ulcer dyspepsia.*

See flowchart for management of patients with non-ulcer dyspepsia (page 32).

Management flowchart for patients with non-ulcer dyspepsia



1 Use a PPI, amoxicillin, clarithromycin 500 mg (PAC_{500}) regimen or a PPI, metronidazole, clarithromycin 250 mg (PMC_{250}) regimen. Do not re-test unless there is a strong clinical need.

2 Offer low-dose treatment, possibly on an as-required basis, with a limited number of repeat prescriptions.

3 In some patients with an inadequate response to therapy or new emergent symptoms it may become appropriate to refer to a specialist for a second opinion. Emphasise the benign nature of dyspepsia. Review long-term patient care at least annually to discuss medication and symptoms.

1.9 Helicobacter pylori: *testing and eradication*

1.9.1 *H. pylori* can be initially detected using a carbon-13 urea breath test or a stool antigen test, or laboratory-based serology where its performance has been locally validated. **C**

- *Evidence from evaluations of diagnostic test accuracy show that serological testing (sensitivity 92%, specificity 83%) performs less well than breath testing (sensitivity 95%, specificity 96%) and stool antigen testing (sensitivity 95%, specificity 94%). The resultant lower positive predictive value* (64% vs. 88% or 84%, respectively) leads to concerns about the unnecessary use of antibiotics when serology testing is used.*

** The likelihood that a positive test result is correct.*

- *Although some serological tests have been shown to perform at above 90% sensitivity and specificity, it is incorrect to assume that this will apply in all localities.*

1.6.2 Re-testing for *H. pylori* should be performed using a carbon-13 urea breath test. (There is currently insufficient evidence to recommend the stool antigen test as a test of eradication.) **D**

1.6.3 Office-based serological tests for *H. pylori* cannot be recommended because of their inadequate performance. **C**

1.6.4 For patients who test positive, provide a 7-day, twice-daily course of treatment consisting of a full-dose PPI, with either metronidazole 400 mg and clarithromycin 250 mg or amoxicillin 1 g and clarithromycin 500 mg. **A**

- *Eradication is effective in 80–85% of patients.*

- *Eradication may reduce the long-term reduced risk of ulcer and gastric cancer.*

- *Clarithromycin 250 mg twice-daily is as effective as 500 mg twice-daily when combined with metronidazole.*

- *PPI, amoxicillin, clarithromycin 500 mg (PAC_{500}) regimens and PPI, metronidazole, clarithromycin 250 mg (PMC_{250}) regimens achieve the same eradication rate.*

- *PMC_{250} used as a first-line therapy may induce resistance to both clarithromycin and metronidazole, whereas amoxicillin resistance does not seem to increase after use of a PAC regimen.*

- *Per course of treatment PAC_{500} costs about £36, while PMC_{250} costs £25.*

- *Although 14-day therapy gives an almost 10% higher eradication rate, the absolute benefit of* H. pylori *therapy is relatively modest in non-ulcer dyspepsia and undiagnosed dyspepsia and the longer duration of therapy does not appear cost-effective.*

- *In patients with peptic ulcer, increasing the course to 14 days duration improves the effectiveness of eradication by nearly 10% but does not appear cost-effective.*

1.6.5 For patients requiring a second course of eradication therapy, a regimen should be chosen that does not include antibiotics given previously (see the *British National Formulary* for guidance). **D**

2 Notes on the scope of the guidance

All NICE guidelines are developed in accordance with a scope document that defines what the guideline will and will not cover. The scope of this guideline was established at the start of the development of this guideline, following a period of consultation; it is available from http://www.nice.org.uk/article.asp?a=16738

The guideline addresses the appropriate primary care management of dyspepsia. A key aim is to promote the dialogue between professionals and patients on the relative benefits, risks, harms and costs of treatments. The guideline identifies effective and cost-effective approaches to managing the care of adult patients with dyspepsia including diagnosis, referral and pharmacological and non-pharmacological interventions.

This guideline does not address the management of more serious underlying causes of dyspepsia (for example, malignancies and perforated ulcers) but does describe the signs and investigations that may lead to referral for these conditions. The interface with secondary care is addressed by providing guidance for referral and hospital-based diagnostic tests.

3 Implementation in the NHS

3.1 In general

Local health communities should review their existing practice for the management of people with dyspepsia against this guideline. The review should consider the resources required to implement the recommendations set out in Section 1, the people and processes involved and the timeline over which full implementation is envisaged. It is in the interests of patients that the implementation timeline is as rapid as possible.

Relevant local clinical guidelines, care pathways and protocols should be reviewed in the light of this guidance and revised accordingly.

3.2 Audit

Suggested audit criteria are listed in Appendix D. These can be used as the basis for local clinical audit, at the discretion of those in practice.

4 Research recommendations

The following research recommendations have been identified for this NICE guideline.

Patient support

- The format and value of supporting educational materials should be reviewed, based on the findings of this guideline, to support patients' involvement in the management of their dyspepsia.

Uninvestigated dyspepsia and GORD

- Longitudinal data exploring the natural history of dyspepsia in primary care is absent; studies are needed to determine whether the predictions of modelling studies in this area are accurate.
- The cost-effectiveness of as-required, intermittent therapy with low-dose PPIs for empirical management of dyspepsia and GORD needs further research.

Non-ulcer dyspepsia

- Research is needed on the cost-effectiveness of cognitive behavioural therapy in non-ulcer dyspepsia.

Gastroesophageal reflux disease

- Research is needed on the long-term safety of as-required and intermittent therapies for oesophagitis.
- Research is needed on the cost-effectiveness of screening and surveillance strategies for Barrett's oesophagus.

Upper GI cancer

- Research is needed on the effectiveness of population screening and *H. pylori* eradication in preventing distal gastric cancer.
- Research is needed on the effect of long-term use patterns of PPI on the development of oesophageal adenocarcinoma.

Use of antibiotics

- Monitoring of resistance patterns in *H. pylori* will help inform about changes in antibiotic resistance.
- Research is needed on the optimal use of antibiotic agents to minimise increases in resistance rates.

Long-term care

- Research is needed on appropriate care and management of chronic sufferers of dyspepsia to understand the proportion of patients that can be managed appropriately by using low-dose treatments on an as-required basis.
- Research is needed to determine strategies to reduce or cease treatment at periodic reviews.

5 Other versions of this guideline

Full guideline

The National Institute for Clinical Excellence commissioned the development of this guidance from the Newcastle Guideline Development and Research Unit. The Unit established a Guideline Development Group, which reviewed the evidence and developed the recommendations. The full guideline, 'Dyspepsia: managing dyspepsia in adults in primary care', can be obtained in hard copy from the Centre for Health Services Research, University of Newcastle upon Tyne (telephone 0191 222 7045) and electronically from the NICE website (www.nice.org.uk) and the website of the National Electronic Library for Health (www.nelh.nhs.uk).

The members of the Guideline Development Group are listed in Appendix B. Information about the independent Guideline Review Panel is given in Appendix C.

The booklet *The guideline development process – an overview for stakeholders, the public and the NHS* has more information about the Institute's guideline development process. It is available from the Institute's website and copies can also be ordered by telephoning 0870 1555 455 (quote reference N0472).

Information for the public

A version of this guideline for people with dyspepsia, their advocates and carers, and for the public is available from the NICE website (www.nice.org.uk/CG017publicinfo) or from the NHS Response Line (0870 1555 455; quote reference number N0690 for an English version and N0691 for an English and Welsh version). This is a good starting point for explaining to patients the kind of care they can expect.

Quick reference guide

A quick reference guide for healthcare professionals is also available from the NICE website (www.nice.org.uk/CG017quickrefguide) or from the NHS Response Line (0870 1555 455; quote reference number N0689).

6 Related NICE guidance

Guidance on the use of cyclo-oxygenase (Cox) II selective inhibitors, celecoxib, rofecoxib, meloxicam and etodolac for osteoarthritis and rheumatoid arthritis. *NICE Technology Appraisal* No. 27 (2001). Available from www.nice.org.uk/page.aspx?o=18033

7 Review date

The process of reviewing the evidence is expected to begin 4 years after the date of issue of this guideline. Reviewing may begin earlier than 4 years if significant evidence that affects the guideline recommendations is identified

sooner. The updated guideline will be available within 2 years of the start of the review process.

Appendix A: Grading scheme

The grading scheme and hierarchy of evidence used in this guideline are shown in the table below. Please note the full guideline used a different system for grading of the evidence that was being piloted by the Newcastle Guideline Development and Research Unit.

Hierarchy of evidence	
Grade	Type of evidence
Ia	Evidence from a meta-analysis of randomised controlled trials
Ib	Evidence from at least one randomised controlled trial
IIa	Evidence from at least one controlled study without randomisation
IIb	Evidence from at least one other type of quasi-experimental study
III	Evidence from observational studies
IV	Evidence from expert committee reports or experts
Grading of recommendation	
Grade	Evidence
A	Directly based on category I evidence
B	Directly based on category II evidence or extrapolated from category I evidence
C	Directly based on category III evidence or extrapolated from category I or II evidence
D	Directly based on category IV evidence or extrapolated from category I, II or III evidence

Adapted from the Agency for Healthcare Policy and Research (AHCPR) system US Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research (1992). *Acute pain management: operative or medical procedures and trauma*. Rockville MD: Agency for Health Care Policy and Research Publications.

Appendix B: The Guideline Development Group

The members of the Guideline Development Group are (in alphabetical order):

Mr Mohammed Naseem (Joe) Asghar

Regional Pharmaceutical Advisor, University of Newcastle upon Tyne

Dr James Dalrymple

General Practitioner, Norwich

Dr Brendan Delaney

Technical Lead and General Practitioner, University of Birmingham

Dr Keith MacDermott

General Practitioner, York

Professor James Mason

Methodologist and Technical Support, University of Newcastle upon Tyne

Professor Paul Moayyedi

Consultant Physician and Technical Support, University of Birmingham and City Hospitals NHS Trust

Dr Anan Raghunath

General Practitioner, Hull

Mrs Mary Sanderson

Patient Representative, Harrogate

Dr Malcolm Thomas (Group Leader)

General Practitioner, Northumberland

Dr Robert Walt

Consultant Physician, Birmingham Heartlands Hospital

Dr Stephen Wright

Consultant in Primary Care Medicine, Rotherham Primary Care Trust

Appendix C: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring its quality. The Panel includes experts on guideline methodology, health professionals and people with experience of the issues affecting patients and carers. The members of the Guideline Review Panel were as follows.

Dr Robert Walker (Chair)
Clinical Director, West Cumbria Primary Care Trust

Professor Mike Drummond (declared a conflict of interest and stood down from the Guideline Review Panel for this guideline)
Director, Centre for Health Economics (CHE), University of York

Dr Kevork Hopayian
General Practitioner, Suffolk

Mr Barry Stables
Patient/Lay Representative

Dr Imogen Stephens
Joint Director of Public Health, Western Sussex Primary Care Trust

Appendix D: Technical detail on the criteria for audit

Audit criteria based on key recommendations

The following audit criteria have been developed by the Institute to reflect the key recommendations. They are intended to assist with implementation of the guideline recommendations. The criteria presented are considered to be the key criteria associated with the priorities for implementation.

Possible objectives for an audit

Audits on the priority recommendations can be carried out in any primary care setting. Possible objectives for audit on dyspepsia treated in a primary care setting could include the following.

- Ensure that people with uninvestigated dyspepsia and specific signs or symptoms are referred appropriately and on a timely basis to a specialist or for endoscopic investigation.
- Ensure that people with dyspepsia are treated appropriately.
- Ensure that people with the following disorders are treated appropriately:
  - GORD
  - peptic ulcer disease
  - non-ulcer dyspepsia
  - *H. pylori.*

People that could be included in an audit

In general practices or other primary care settings in which people might be investigated, an audit could be carried out on a reasonable number of people with dyspepsia seen consecutively, for example over 6 months, to measure whether people with uninvestigated dyspepsia are referred and treated appropriately.

For people in that audit population who are identified as having GORD, peptic ulcer disease, non-ulcer dyspepsia or *H. pylori*, audit measures could be

applied to ensure that people with any of these disorders are treated appropriately.

Measures that could be used as a basis for an audit

The measures that could be used as a basis for audit are in the table. The first measure applies to referring people with dyspepsia appropriately. The remaining measures apply to people with disorders caused by dyspepsia.

Criterion	Exception	Definition of terms
A. An individual who has dyspepsia is referred on an urgent basis to a specialist or for an endoscopic investigation if the individual has any one of the following: a. chronic gastrointestinal bleeding **or** b. progressive unintentional weight loss **or** c. progressive difficulty swallowing **or** d. persistent vomiting **or** e. iron deficiency anaemia **or** f. epigastric mass **or** g. suspicious barium meal	A. The individual declines referral	'Dyspepsia' means any symptom of the upper gastrointestinal tract including recurrent pain, heartburn, or acid regurgitation, with or without bloating, nausea or vomiting. 'Urgent' means that the individual is seen within 2 weeks of the referral. Clinicians will need to agree locally on definitions of the following for audit purposes: chronic gastrointestinal bleeding, progressive unintentional weight loss, progressive difficulty swallowing, persistent vomiting, iron deficiency anaemia, epigastric mass and suspicious barium meal. Local agreement will also be needed on how an individual declining referral will be documented.
B. An individual who has dyspepsia but does not have an alarm sign is not referred for a routine endoscopic investigation	~~The individual meets all of the following:~~ ~~A. The individual is over 55~~ **~~and~~** ~~B. The individual's symptoms persist despite *H. pylori* testing and acid suppression therapy~~ **~~and~~**	~~Clinicians will need to agree locally on how the following conditions are identified for audit purposes: previous gastric ulcer or surgery, continuing need for NSAID treatment, raised risk of gastric cancer or anxiety about cancer.~~ **'Unexplained' is defined as 'a symptom(s) and/or**

	~~C. The individual has any one of the following:~~ ~~1) previous gastric ulcer or surgery **or**~~ ~~2) continuing need for NSAID treatment **or**~~ 3) ~~raised risk of gastric cancer or anxiety about cancer~~ **The individual meets all of the following:** **C. The individual is aged 55 or older** and **D. The individual has unexplained and persistent recent-onset dyspepsia alone**	**sign(s) that has not led to a diagnosis being made by the primary care professional after initial assessment of the history, examination and primary care investigations (if any)'. In this context, the primary care professional should confirm that the dyspepsia is new rather than a recurrent episode and exclude common precipitants of dyspepsia such as ingestion of NSAIDs. 'Persistent' as used in the recommendations in the referral guidelines refers to the continuation of specified symptoms and/or signs beyond a period that would normally be associated with self-limiting problems. The precise period will vary depending on the severity of symptoms and associated features, as assessed by the healthcare professional. In many cases, the upper limit the professional will permit symptoms and/or signs to persist before initiating referral will be 4–6 weeks.**
A. An individual who has dyspepsia is treated with either or both of the following: a. PPI **or** b. testing for and treating *H. pylori*	None	If the individual has been prescribed PPI, check whether there has been a 2-week washout period before testing for *H. pylori* with a breath test or a stool antigen test.
B. An individual with GORD is offered the following treatment: c. a full-dose PPI for 1 or 2 months **and** d. a PPI at the lowest	None	'GORD' refers to endoscopically determined oesophagitis or endoscopy-negative reflux disease. 'PPIs' include omeprazole, esomeprazole,

possible dose to control symptoms, if symptoms recur following initial treatment		lansoprazole, pantoprazole and rabeprazole. Clinicians will need to agree locally on how the following are defined and recorded for audit purposes: an 'offer' of treatment, 'full-dose', a 'month' of treatment and the determination of the lowest possible dose to control symptoms.
C. An individual with the following conditions is offered *H. pylori* eradication therapy if the individual is *H. pylori* positive: a. peptic ulcer disease **or** b. non-ulcer dyspepsia as determined endoscopically	None	'Peptic ulcer' includes gastric and duodenal ulcers. 'Eradication therapy' means a 7-day twice-daily course of treatment consisting of a full-dose PPI, with either a metronidazone 400 mg and clarithromycin 250 mg or amoxicillin 1 g and clarithromycin 500 mg. '*H. pylori* positive' means as detected by either a carbon-13 urea breath test or a stool antigen test or laboratory-based serological tests for *H. pylori*. Clinicians will need to agree locally on how the offer of treatment is recorded for audit purposes.
6. An individual who has non-ulcer dyspepsia and who has been treated for *H. pylori* if present is treated as follows: a. symptomatic management **and** b. periodic monitoring **and** c. not routinely retested after eradication	None	'Symptomatic management' means either a PPI or a H_2RA at the lowest dose possible to control with patients being encouraged to use long-term treatment on an as-required basis (taking therapy when symptoms occur) to manage their own symptoms. 'Periodic monitoring' means at least annually.
7. An individual who has dyspepsia requiring	None	Clinicians will need to agree locally on how the

long-term management is offered an annual review		offer of an annual review is documented for audit purposes.

Alternative approaches to audit of dyspepsia

Alternative approaches to audit of the care of people with dyspepsia could include the following:

1. Significant event audit of any individuals who are diagnosed with an upper GI cancer. The audit could review the care provided before diagnosis including the following:

    - whether or not the presence or absence of alarm signs or symptoms was recorded in notes and

    - if alarm signs and symptoms were detected, whether or not the patient was referred for endoscopy.

2. Review of prescriptions for high- and low-dose PPIs. Read codes related to dyspepsia and treatments prescribed are detailed in the full guideline (see www.nice.org.uk/CG017fullguideline).