Appendix B: Scope

B.1 Scope and Purpose [2004]

The National Guideline Research and Development Unit (NGRDU) was appointed by the National Institute for Clinical Excellence (the Institute) to develop an evidence-based clinical guideline for the management of dyspepsia in primary care. The Unit constituted the North of England Dyspepsia Guideline Development Group.

B.1.1 Guideline objectives

The aim of this guideline is to provide evidence-based recommendations to guide healthcare professionals, patients and carers in 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. Relevant existing national guidance is taken into consideration as part of the guideline development process, in this instance national guidance on the use of proton pump inhibitors [i]. 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.

B.1.2 Areas not covered

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

B.1.3 Clinical questions addressed

The guideline group posed the following questions:

- How is dyspepsia defined: what is and what isn't dyspepsia?
- What is the appropriate role of the pharmacist in managing dyspepsia?
- How should dyspepsia be diagnosed in primary care?
- How can dyspepsia in primary care be characterised in terms of its presentation, psychological influences and impact upon patient quality-of-life?
- What factors prompt patients to consult for dyspepsia?
- How should symptoms be assessed and interpreted?
- How should diagnosis be organised?
- How should dyspepsia be managed in primary care?
- How can communication be promoted, embracing patient expectation and promoting understanding?
- Do lifestyle interventions work?
- Which acid suppressing therapy should be used and for how long?
- Who should get *H pylori* eradication therapy and with which regimen?
- What is the relationship between NSAID therapy and dyspepsia?
- How should long term care be organised in its frequency and content and with regard to patient safety?

- What are appropriate grounds for referral?
- What are the risks of serious underlying pathology?
- How should these risks be conceptualised and discussed by clinicians and patients?
- What are alarm signals and what should be done when they occur?

In response to these questions this guideline addresses the following aspects of patient care:

- Investigation and management of dyspepsia including:
  - Quantifying patient risk
  - Lifestyle advice
  - Psychological interventions
  - Pharmacological therapy
  - Endoscopy
- Investigation and management of underlying causes of dyspepsia including:
  - Gastro-oesophageal reflux disease
  - Peptic ulcer disease
  - *H pylori*
  - The role of the pharmacist in patient care
- The cost-effectiveness of alternative strategies of care
- Evaluation of differences in particular groups of patients, for example in older patients and ethnic groups
- Identifying appropriate standards of care and audit points to assess these.

2.1.4 Patients and clinicians covered by this guideline

This document is intended to be most relevant to the primary care team, including general practitioners, nurses, community pharmacists and other primary care professionals who have direct contact with patients. It does not consider dyspepsia during pregnancy or secondary care treatments but provides criteria for referral to secondary care. To promote continuity of care, it is important that clinicians initiating treatment in secondary care are aware of the recommendations of this guideline

2.1.5 Disclaimer

The guideline development group assumes that healthcare professionals will use general medical knowledge and clinical judgement in applying the general principles and specific recommendations of this document to the management of individual patients. Recommendations may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in the light of circumstances presented by individual patients and available resources. Recommendations about drug treatment assume that clinicians will take account both of the response of individual patients and of the indications, contra-indications and cautions listed in the British National Formulary (BNF) or Summary of Product Characteristics. Clinicians will need to share appropriately the information within this guideline to enable patients to participate in the process of decision making to the extent they are able and willing [ii].

B.2 SCOPE [update 2014]

1 Guideline title

Dyspepsia and gastro-oesophageal reflux disease: investigation and management of dyspepsia, symptoms suggestive of gastro-oesophageal reflux disease, or both.

1.1 Short title

Dyspepsia and gastro-oesophageal reflux disease.

2 The remit

This is a partial update of ‘Dyspepsia’ (NICE clinical guideline 17). See section 4.3.1 for details of which sections will be updated. We will also carry out an editorial review of all recommendations to ensure that they comply with NICEs' duties under equalities legislation.

This update is being undertaken as part of the guideline review cycle.

Update 2014

3 Clinical need for the guideline

3.1 Epidemiology

a) Dyspepsia describes a range of symptoms arising from the upper gastrointestinal (GI) tract but it has no universally accepted definition. The British Society of Gastroenterology (BSG) defines dyspepsia as a group of symptoms that alert doctors to consider disease of the upper GI tract, and states that dyspepsia itself is not a diagnosis. These symptoms, which typically are present for 4 weeks or more, include upper abdominal pain or discomfort, heartburn, gastric reflux, nausea, or vomiting.

b) The UK prevalence depends on the definition of dyspepsia used, and ranges from 12% to 41%. Using the broad BSG definition, it is estimated that annually around 40% of the adult population experience dyspepsia. Dyspepsia accounts for between 1.2% and 4% of all consultations in primary care in the UK, half of which are for functional dyspepsia – that is,

dyspepsia of unknown aetiology (previously known as non-ulcer dyspepsia).

c) The aetiology of dyspepsia symptoms includes gastric and duodenal ulcers, gastro-oesophageal reflux disease (GORD), oesophagitis, and oesophageal or gastric cancers; however, the cause is often unknown (functional dyspepsia). In addition, certain foods and drugs (such as anti-inflammatory drugs) are believed to contribute to the symptoms and underlying causes of dyspepsia.

d) An endoscopy may be indicated for some people with dyspepsia in order to investigate the cause. Morbidity and mortality rates from diagnostic upper GI endoscopy are low.

e) *Helicobacter pylori* (*H pylori*) is widely present in the general population, often causing no harm, but it is strongly associated with gastric and duodenal ulcers. However, its role in functional dyspepsia and GORD is less clear. The prevalence of *H pylori* infection varies internationally, with over 80% of Japanese and South American people infected, compared with a rate of approximately 40% in the UK and 20% in Scandinavia.

f) Some evidence suggests that *H pylori* infection is associated with social deprivation and that its prevalence increases with age.

g) GORD is a chronic condition where gastric juices from the stomach (usually acidic) flow back up into the oesophagus. It can be severe or frequent enough to cause symptoms, or damage the oesophagus (for example, oesophagitis), or both. It can lead to an abnormality of the cells in the lining of the oesophagus (Barrett's oesophagus), which is itself considered the most important risk factor for oesophageal adenocarcinoma, the incidence of which has increased considerably in the past decade.

h) There are several risk factors for GORD including hiatus hernia, certain foods, heavy alcohol use, smoking, and pregnancy, but there is also a genetic component. Some studies have shown a weak link between

obesity and GORD. There is also some evidence to suggest that GORD is more likely to occur in socially disadvantaged people. Its prevalence increases with age. Functional heartburn is diagnosed when there are symptoms of reflux in the absence of pathology.

i) Hospital episode statistics data from 2010–11 showed that there were:

- over 41,000 consultant episodes for people with dyspepsia (39% male and 61% female)
- over 35, 000 consultant episodes for people with GORD with oesophagitis (59% male and 41% female)
- nearly 38,000 consultant episodes for people with GORD without oesophagitis (49% male and 51% female).

3.2 Current practice

a) Some of the costs associated with treating dyspepsia are decreasing, but the overall use of treatments is increasing. As a result, the management of dyspepsia continues to have potentially significant costs to the NHS.

b) The use of endoscopy has increased considerably over the past decade, as awareness of its value in diagnosing dyspepsia and GORD has grown.

c) The review of ‘Dyspepsia: management of dyspepsia in adults in primary care’ (NICE clinical guideline 17) highlighted some concerns about the drug regimens currently recommended in the guideline for *H pylori* eradication, as some bacterial resistance had developed. Overall, the review process concluded that guidance in this area should be updated, including an expansion to cover aspects of specialist hospital care.

d) NICE clinical guideline 17 covers the management of several underlying causes of dyspepsia in primary care but there is currently a lack of comprehensive national guidance about the management of GORD (in particular, surgical management) when pharmacological treatments fail. Given this, and the possible role of GORD (with the subsequent development of Barrett's oesophagus) as a risk factor for cancer, an

extension of the scope of the guideline to cover the management of GORD into secondary care is needed.

e) For the purpose of this guideline, specialist care will be defined as situations where treatment decisions are made by a consultant-led service in secondary or tertiary care.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) Adults (18 years and older) with symptoms of dyspepsia or symptoms suggestive of GORD, or both.

b) No subgroups of people have been identified as needing specific consideration.

c) Adults with a diagnosis of Barrett's oesophagus.

4.1.2 Groups that will not be covered

a) Children (younger than 18 years).

b) People with a diagnosis of oesophagogastric cancer.

4.2 Healthcare setting

a) All settings where care is delivered for NHS patients.

Update 2014

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

Areas from the original guideline that will be updated

Investigation and referral

a) Indications for endoscopy in patients with dyspepsia or GORD symptoms.

b) Exclusion of Barrett's oesophagus by endoscopy in patients with symptoms suggestive of GORD.

c) Criteria for referral to specialist medical or surgical services.

d) Use of proton pump inhibitors (PPIs) to treat patients with severe erosive reflux disease.

H pylori

e) Pharmacological management for eradication of *H pylori* in patients with confirmed infection.

Update 2014

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

Areas not in the original guideline that will be included in the update

Specialist management

f) Specialist pharmacological management of dyspepsia, heartburn, other symptoms of reflux and GORD.

g) Specialist medical and surgical management of GORD using total or partial laparoscopic fundoplication.

Surveillance for Barrett's oesophagus

h) Surveillance of patients with Barrett's oesophagus.

4.3.2 Clinical issues that will not be covered

Areas from the original guideline that will not be updated but will appear in the final guideline

Investigation and referral

a) Investigation and referral for oesophagogastric cancer.

b) Differential diagnosis of the cause of dyspepsia (other than the use of endoscopy).

c) Psychological interventions for functional dyspepsia.

d) Effectiveness of lifestyle interventions (such as diet, alcohol intake and smoking).

e) Community pharmacist management of dyspepsia symptoms, provision of patient information and recording of adverse events, and advice on over the counter medication.

f) Comparison between different pharmacological treatments in the non-specialist management of dyspepsia and GORD and sequencing of these treatments.

g) Management of dyspepsia in patients receiving concomitant non-steroidal anti-inflammatory drug (NSAID) treatment.

h) Step-down protocols and move to self treatment.

i) The provision of patient information.

j) Psychological interventions for dyspepsia.

H pylori

k) Type of *H pylori* test (breath, stool, laboratory-based serology).

l) Retesting and re-endoscopy for *H pylori*.

Update 2014

Areas not covered by the original guideline or the update

m) Prophylactic treatment using PPIs or *H pylori* test-and-treat for the prevention of dyspepsia symptoms or pathological changes to the oesophagus in patients taking prescribed drugs that might precipitate these.

n) Effectiveness of over the counter PPIs.

o) Investigations for the diagnosis of GORD and assessment of disease impact (such as oesophageal manometry, pH monitoring, and oesophageal impedance testing).

p) Diagnosis and management of functional heartburn (including the use of tricyclic antidepressants for management).

q) The role of *H pylori* eradication in the management of GORD.

r) Specialist diagnosis and assessment of GORD with pH monitoring, impedance testing, and manometry.

s) Specialist surgical management of dyspepsia.

t) Diagnosis and management of oesophagogastric cancer.

u) Treatment of Barrett's oesophagus.

v) Heartburn in pregnancy.

w) Treatment of Zollinger–Ellison syndrome, achalasia, or hiatus hernia (the investigation and management of dyspepsia and reflux symptoms in patients with these conditions will be covered).

x) Emergency management of bleeding or perforated ulcers.

y) Emergency management of acute upper GI bleeding.

z) Management of dysphagia.

aa) Surgical dilatation of strictures in patients with GORD.

bb) Minimally invasive surgical techniques for GORD (except laparoscopic fundoplication), including:

- endoscopic gastroplication
- endoscopic radiofrequency ablation
- endoscopic augmentation of the lower oesophageal sphincter with hydrogel implants.

4.4 Main outcomes

General

a) Reduction in symptoms (severity/frequency).

b) Biopsy findings (pathology).

c) Endoscopic appearance of oesophagus.

d) Health-related quality of life (measured using EQ-5D and/or disease-specific tools, if available).

e) Reduction in medication requirement (frequency and dose).

f) Adverse effects of interventions (diagnostic or treatment).

g) Resource use and costs.

GORD-specific

h) Occurrence of Barrett's oesophagus and progression to adenocarcinoma.

4.5 Draft review questions

4.5.1 Investigation and referral

a) What signs and symptoms indicate the need for endoscopy?

b) What characteristics/symptoms of GORD or symptoms suggestive of GORD indicate endoscopy to exclude Barrett’s oesophagus?

c) What patient characteristics/criteria indicate referral of a patient with dyspepsia, heartburn, or confirmed GORD to a consultant-led medical or surgical service?

d) What is the clinical effectiveness of PPIs in patients with severe erosive reflux disease?

4.5.2 H pylori

a) i) What is the clinical effectiveness of eradication regimens for *H pylori* in patients with symptoms of dyspepsia who are positive for *H pylori*?

ii) What *H pylori* eradication regimens should be offered as second-line (or third-line) treatments when first-line treatments fail?

4.5.3 Specialist management

a) What is the effectiveness of fundoplication compared with medical management in patients with GORD?

b) What other medical management is effective for patients who do not respond to PPIs, H_2 receptor antagonists, or *H pylori* eradication despite optimum primary care, or patients who have relapsed following surgery?

4.5.4 Surveillance for Barrett's oesophagus

a) Should surveillance be used for patients with Barrett's oesophagus to detect progression to cancer?

4.6 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

4.7 Status

4.7.1 Scope

This is the final version of the scope.

4.7.2 Timing

The development of the guideline recommendations will begin in July 2012.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be updated

This guideline will update the following NICE guidance:

- Dyspepsia. NICE clinical guideline 17 (2004).

5.1.2 Other related NICE guidance

- Acute upper gastrointestinal bleeding. NICE clinical guideline 141 (2012).
- Patient experience in adult NHS services. NICE clinical guideline 138 (2011).
- Service user experience in adult mental health. NICE clinical guideline 136 (2011).
- Minimally invasive oesophagectomy. NICE interventional procedure guidance 407 (2011).
- Endoluminal gastroplication for gastro-oesophageal reflux disease. NICE interventional procedure guidance 404 (2011).
- Barrett's oesophagus. NICE clinical guideline 106 (2010).
- Chest pain of recent onset. NICE clinical guideline 95 (2010).
- Endoscopic submucosal dissection of gastric lesions. NICE interventional procedure guidance 360 (2010).
- Endoscopic mucosal resection and endoscopic submucosal dissection of non-ampullary duodenal lesions. NICE interventional procedure guidance 359 (2010).
- Endoscopic submucosal dissection of oesophageal dysplasia and neoplasia. NICE interventional procedure guidance 355 (2010).

- Photodynamic therapy for Barrett's oesophagus. NICE interventional procedure guidance 350 (2010).
- Epithelial radiofrequency ablation for Barrett's oesophagus. NICE interventional procedure guidance 344 (2010).
- Medicines adherence. NICE clinical guideline 76 (2009).
- Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease. NICE interventional procedure guidance 292 (2007).
- Photodynamic therapy for early oesophageal cancer. NICE interventional procedure guidance 200 (2006).
- Catheterless oeosophageal pH monitoring. NICE interventional procedure guidance 187 (2006).
- Endoscopic injection of bulking agents for gastro-oesophageal reflux disease. NICE interventional procedure guidance 55 (2004).

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

- Laparoscopic insertion of a magnetic bead band for gastro-oesophageal reflux disease. NICE interventional procedure. Publication expected September 2012.
- GORD in children. NICE clinical guideline. Publication to be confirmed.
- Suspected cancer (update of CG27). NICE clinical guideline. Publication to be confirmed.

6 Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

- ‘How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS’
- ‘The guidelines manual'.

Information on the progress of the guideline will also be available from the NICE website.

372