NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health and social care directorate Quality standards and indicators Briefing paper

Quality standard topic: Dyspepsia

Output: Prioritised quality improvement areas for development.

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1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for dyspepsia. It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

1.1 Structure

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

1.2 Development source

The key development sources referenced in this briefing paper are:

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

NICE clinical guideline 184 (2014)

This is an updated guideline that replaces NICE clinical guideline 17 (2004). No review schedule presented.

Guideline on the diagnosis and management of Barrett's oesophagus. British Society of Gastroenterology (2013)

2 Overview

2.1 Focus of quality standard

This quality standard will cover the investigation and management of dyspepsia and gastro-oesophageal reflux disease (GORD) in adults 18 years and older. It will not include the diagnosis and management of oesophagogastric cancer as this will be covered by a separate quality standard.

2.2 Definition

Dyspepsia means 'bad digestion'. It is used to describe a range of symptoms arising from the upper gastrointestinal tract (GI) tract but has no universally accepted definition. However, commentators agree that dyspepsia represents a complex of symptoms not a diagnosis. In line with the guideline this quality standard adopts a broad definition of dyspepsia that includes both functional and organic causes. Dyspepsia describes a range of symptoms including upper abdominal pain or discomfort, heartburn, gastric reflux, nausea or vomiting, present for 4 weeks or more.

The causes of dyspepsia symptoms include gastric and duodenal ulcers, gastrooesophageal 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. The bacterium 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. Its role in functional
dyspepsia and GORD is less clear.

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.

2.3 Incidence and prevalence

The prevalence of dyspepsia is estimated to be between 23% and 41% of the general population with the approximate prevalence of GORD between 10% and 20%. 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.

The prevalence of H pylori infection varies internationally, with a rate of approximately 40% in the UK. Epidemiological evidence suggests that many people acquire the infection in childhood—social deprivation, household crowding, and number of siblings are important risk factors. The prevalence of infection increases with age.

For the majority of patients the consequence of dyspepsia is symptoms affecting their quality of life. The impact of dyspepsia upon quality of life is a personal experience; a recurring problem or a chronic complaint for which available treatments may be wholly effective or only partially relieve symptoms. Symptoms recur annually in about half of patients.

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). There has been an upward trend in the prescribing of drugs for dyspepsia, particularly proton pump inhibitors. The use of endoscopy has increased considerably over the past decade, as awareness of its value in diagnosing dyspepsia and GORD has grown. Hospital episode statistics data for England in 2012-13¹ showed that there were 42,994 hospital admissions for people with dyspepsia and 75,762 for people with GORD with the large majority having an endoscopic examination. 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.

2.4 Management

Services for managing dyspepsia are provided in both primary and secondary care. Patients with dyspepsia present at the pharmacy, general practice or the accident and emergency department with dyspeptic symptoms or upper gastrointestinal bleeding.

Almost all causes of dyspepsia are recurrent and intermittent in nature. The only definitive treatments for dyspepsia are H. pylori eradication therapy, and surgery. Other treatments do not address underlying reasons for dyspepsia; once treatment stops symptoms may return.

In most patients without alarm signs it is appropriate to manage symptoms without a formal diagnosis. After initial symptoms or acute pathologies have been managed, patients needing ongoing treatment should be offered a trial of low dose proton pump inhibitors (PPIs) using treatment as they feel they need it to control symptoms. Subsequent treatment can be tailored to the consequence of this trial but periodic review should empower patients to continue, reduce or cease therapy.

¹ Hospital episode statistics admitted patient care, 2012/13. Health and social care information centre

An endoscopy may be indicated for some people with dyspepsia in order to investigate the cause. Endoscopy is used to investigate alarm signs and to identify gastric and duodenal ulcers as well as rare cases of oesophageal and gastric cancer. Upper GI endoscopy is normally provided in secondary care, although some primary care centres and GP-run community hospitals also offer facilities

See appendices 1-7 for flowcharts to guide management and treatment from NICE clinical guideline 184.

2.5 National Outcome Frameworks

Tables 1–2 show the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

Table 1 NHS Outcomes Framework 2014–15

Domain	Overarching indicators and improvement areas		
1 Preventing people from	Overarching indicator		
dying prematurely	1a Potential Years of Life Lost (PYLL) from causes considered amenable to healthcare (PHOF 4.3***)		
	i Adults		
	1b Life expectancy at 75		
	i Males ii Females		
	Improvement area		
	Reducing premature mortality from the major causes of death		
	1.4 Under 75 mortality rate from cancer (PHOF 4.5*)		
2 Enhancing quality of life for	Overarching indicator		
people with long-term conditions	2 Health-related quality of life for people with long-term conditions (ASCOF1A**)		
	Improvement areas		
	Ensuring people feel supported to manage their condition		
	2.1 Proportion of people feeling supported to manage their condition		
	Improving functional ability in people with long-term conditions		
	2.2 Employment of people with long-term conditions (PHOF 1.8*, ASCOF 1E**)		
	Reducing time spent in hospital by people with long-term conditions		
	2.3i Unplanned hospitalisation for chronic ambulatory care sensitive conditions		
Helping people to recover	Improvement area		
from episodes of ill health or	Improving outcomes from planned treatments		
following injury	3.1 Total health gain as assessed by patients for elective procedures		
4 Ensuring that people have	Overarching indicator		
a positive experience of care	4a Patient experience of primary care		
	i GP services		
	4b Patient experience of hospital care		
	Improvement area		
	Improving people's experience of outpatient care		
	4.1 Patient experience of outpatient services		
Alignment across the health	· · · · · · · · · · · · · · · · · · ·		
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* Indicator shared with Public H	and social care system		

Table 2 Public health outcomes framework for England, 2013–2016

Domain	Objectives and indicators	
Vision: To improve and protect	Outcome measure	
the nation's health and wellbeing and improve the	Outcome 1) Increased healthy life expectancy, i.e. taking account of the health quality as well as the length of life	
health of the poorest fastest	Outcome 2) Reduced differences in life expectancy and healthy life expectancy between communities (through greater improvements in more disadvantaged communities)	
1 Improving the wider	Objective	
determinants of health	Improvements against wider factors which affect health and wellbeing and health inequalities	
	Indicators	
	1.8 Employment for those with long-term health conditions including adults with a learning disability or who are in contact with secondary mental health services (NHSOF 2.2*, ASCOF 1E**)	
	1.9 Sickness absence rate	
2 Health improvement	Objective	
	People are helped to live healthy lifestyles, make healthy choices and reduce health inequalities	
	Indicators	
	2.19 Cancer diagnosed at stage 1 and 2	
	2.23 Self-reported well-being	
4 Healthcare public health and	Objective	
preventing premature mortality	Reduced numbers of people living with preventable ill health and people dying prematurely, whilst reducing the gap between communities	
	Indicators	
	4.3 Mortality rate from causes considered preventable (NHSOF 1a***)	
	4.5 Under 75 mortality rate from cancer (NHSOF 1.4*)	
	4.13 Health-related quality of life for older people	
Alignment across the health a	and social care system	

- * Indicator shared with NHS Outcomes Framework (NHSOF)
- ** Indicator complementary with Adult Social Care Outcomes Framework (ASCOF)
- *** Indicator complementary with NHS Outcomes Framework (NHSOF)

3 Summary of suggestions

3.1 Responses

In total 5 stakeholders responded to the 2-week engagement exercise 30/10/14-13/11/14.

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 3 for further consideration by the Committee.

NHS England's patient safety division did not submit any data for this topic.

Full details of all the suggestions provided are given in appendix 9 for information.

Table 3 Summary of suggested quality improvement areas

Suggested area for improvement	Stakeholders		
Advice	SCM		
Referral for endoscopy/specialist investigation	BSG, HCU, SCM		
Testing and eradication of Helicobacter pylori			
Improved testing	SCM		
Eradication	SCM		
Access to surveillance data	SCM		
Long-term management			
Long term acid suppression therapy	SCM		
Annual reviews	SCM		
Specialist investigation			
Non-invasive pepsin diagnostic	RDB		
Investigating dyspepsia	SCM		
Biopsy for specific conditions	SCM		
Laparoscopic fundoplication	SCM		
Additional areas			
Quality of upper GI endoscopy	BSG, SCM		
Rescope and biopsy of gastric ulcers	SCM		
BSG – British Gastroenterology Society			
HCU – Heartburn Cancer UK			
RDB – RDBiomed Ltd			
SCM – Specialist Committee Member			

4 Suggested improvement areas

4.1 Advice

4.1.1 Summary of suggestions

Stakeholders highlighted the importance of self-treatment for people with dyspepsia including access to self-help groups and suggested there needs to be improved advice to patients on when they should see their GP based on their symptoms.

Stakeholders also suggested people with dyspepsia should be given more advice about taking their medication. For example, specific information about when to take the medication relative to meal times in order to ensure it is most effective.

4.1.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 4 to help inform the Committee's discussion. Also refer to appendix 1 for further information.

Table 4 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Advice	The community pharmacist
	NICE CG184 Recommendation 1.1.1
	Common elements of care
	NICE CG184 Recommendations 1.2.1, 1.2.2, 1.2.3

The community pharmacist

NICE CG184 – Recommendation 1.1.1

Community pharmacists should offer initial and ongoing help for people with symptoms of dyspepsia. This includes advice about lifestyle changes, using overthe-counter medication, help with prescribed drugs and advice about when to consult a GP.

Common elements of care

NICE CG184 – Recommendation 1.2.1

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

NICE CG184 – Recommendation 1.2.2

Advise people 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.

NICE CG184 - Recommendation 1.2.3

Provide people with access to educational materials to support the care they receive.

4.1.3 Current UK practice

There is some evidence from two small studies:

- An audit² of the use of proton pump inhibitors in primary care in Cwm Taf Health Board found that only 29% of patients prescribed a high cost PPI had received lifestyle advice to manage their dyspepsia.
- An audit³ of patients with dyspepsia referred for endoscopy in Norfolk found that less than 5% had received lifestyle advice prior to referral.

² The role of a Proton Pump Inhibitor (PPI) 'switch' audit in encouraging appropriate use of PPIs in primary care. Riddell et al. Pharmacoepidemiology and drug safety 2012 vol 21

Upper GI Audits. Sampson. South Norfolk Healthcare CIC 2013

4.2 Referral for endoscopy/specialist investigation

4.2.1 Summary of suggestions

Stakeholders highlighted the need for improved selection of patients for referral for endoscopy as there is currently wide variation in practice. This can lead to geographical variation with missed detection of cancer in some areas and high demand for endoscopies that are not required in others. It was suggested that the dyspepsia guideline should be linked to endoscopy referral criteria.

One stakeholder suggested there should also be improved selection of patients for further specialist tests such as oesophageal manometry.

4.2.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 7 to help inform the Committee's discussion. Also refer to appendix 2 for further information.

Table 7 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Referral for endoscopy/specialist	Referral guidance for endoscopy
investigation	NICE CG184 Recommendations 1.3.1 (KPI), 1.3.2, 1.3.3, 1.3.4
	Interventions for gastro-oesophageal reflux disease (GORD)
	NICE CG184 Recommendation 1.6.1 (KPI)
	Referral to a specialist service
	NICE CG184 Recommendation 1.11.1 (KPI)

Referral guidance for endoscopy

NICE CG184 Recommendation 1.3.1 (KPI)

For people presenting with dyspepsia together with significant acute gastrointestinal bleeding, refer them immediately (on the same day) to a specialist.

NICE CG184 Recommendation 1.3.2

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

NICE CG184 Recommendation 1.3.3

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

NICE CG184 Recommendation 1.3.4

If people have had a previous endoscopy and do not have any new alarm signs, consider continuing management according to previous endoscopic findings.

Interventions for gastro-oesophageal reflux disease (GORD)

NICE CG184 Recommendation 1.6.11 (KPI)

Do not routinely offer endoscopy to diagnose Barrett's oesophagus, but consider it if the person has GORD. Discuss the person's preferences and their individual risk factors (for example, long duration of symptoms, increased frequency of symptoms, previous oesophagitis, previous hiatus hernia, oesophageal stricture or oesophageal ulcers, or male gender).

Referral to a specialist service

NICE CG184 Recommendation 1.11.1 (KPI)

Consider referral to a specialist service for people:

- of any age with gastro-oesophageal symptoms that are non-responsive to treatment or unexplained
- with suspected GORD who are thinking about surgery
- with H pylori that has not responded to second-line eradication therapy.

4.2.3 Current UK practice

An audit⁴ of primary care referrals for upper GI endoscopy at a hospital in Liverpool found that 19% of referrals did not meet NICE criteria for referral and 12% had a previous endoscopy within 3 years. The audit concluded that 31% of referrals were therefore inappropriate.

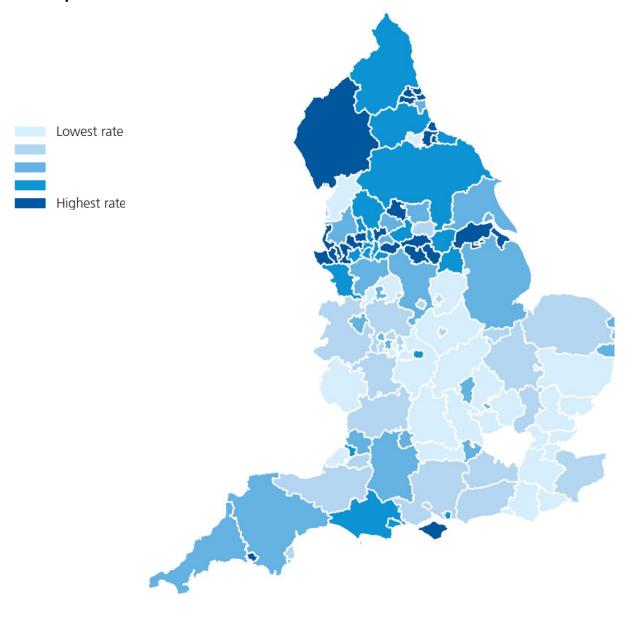
⁴ <u>Is the service provision of direct access upper GI endoscopy being used effectively beyond 2010?</u>
Mahmood et al. Gut 2012 61: A290

An audit⁵ of patients with dyspepsia referred for endoscopy in Norfolk concluded that only 39% of referrals for those under 55 years were appropriate compared with 78% of referrals for those aged 55 years or more, based on NICE guidance.

The NHS atlas of variation⁶ showed there was a 2.9-fold variation in the rate of gastroscopy across PCTs in England in 2009-10 (see Figure 1). The rate of gastroscopy per 100,000 ranged from 77.4 to 225.7 per 10,000 population. The report concludes that the degree of variation is greater than can be explained by variations in the incidence and prevalence of disease and may relate to referral thresholds by GPs and/or the amount of resources available for both diagnosis and surveillance.

Upper GI Audits. Sampson. South Norfolk Healthcare CIC 2013
 NHS atlas of variation 2011: Problems of the Gastro-Intestinal System. RightCare

Figure 1: Rate of activity for gastroscopy (upper gastro-intestinal endoscopy) per population by PCT: Indirectly standardised rate, adjusted for age, sex and deprivation 2009-10.





4.3 Testing and eradication of Helicobacter pylori

4.3.1 Summary of suggestions

Improved testing

It was highlighted that stool antigen and breath tests are not always being used to identify H.pylori as they are more expensive than less specific serological tests. Many laboratories use serological tests that do not differentiate between active and past infections. As the treatment of H.pylori is complex, clinicians should not prescribe unless they are certain of the diagnosis.

Eradication

Stakeholders suggested that if first and second line treatment for H.pylori is not successful or if the infection recurs, patients should be referred for culture and sensitivity testing to guide treatment as resistance is increasing. This is not common practice and only a small number of laboratories in the UK undertake routine culture. The importance of a national reference laboratory was emphasised.

Access to surveillance data

It was suggested that there is a need to establish a surveillance system to inform the choice of antibiotic combination to treat H.pylori across the UK.

4.3.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 6 to help inform the Committee's discussion.

Table 6 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations	
Improved testing	Helicobacter pylori testing and eradication - Testing	
	NICE CG184 Recommendations 1.9.1, 1.9.2 and 1.9.3	
Eradication	Helicobacter pylori testing and eradication - Eradication	
	NICE CG184 Recommendations 1.9.12	
	Referral to a specialist service	
	NICE CG184 Recommendations 1.11.1 (KPI)	
Access to surveillance data	Not directly covered in NICE CG184 and no recommendations are presented.	

Helicobacter pylori testing and eradication - Testing

NICE CG184 Recommendation 1.9.1

Test for H pylori using a carbon-13 urea breath test or a stool antigen test, or laboratory-based serology where its performance has been locally validated.

NICE CG184 Recommendation 1.9.2

Perform re-testing for H pylori using a carbon-13 urea breath test. (There is currently insufficient evidence to recommend the stool antigen test as a test of eradication.)

NICE CG184 Recommendation 1.9.3

Do not use office-based serological tests for H pylori because of their inadequate performance.

Helicobacter pylori testing and eradication – Eradication

NICE CG184 Recommendation 1.9.12

Seek advice from a gastroenterologist if eradication of H pylori is not successful with second-line treatment.

Referral to a specialist service

NICE CG184 Recommendation 1.11.1 (KPI)

Consider referral to a specialist service for people:

with H pylori that has not responded to second-line eradication therapy.

4.3.3 Current UK practice

Testing

No current practice data found.

Eradication

No current practice data found.

In developing the guideline the GDG recognised that, in some cases, both first- and second-line H pylori eradication regimens may be unsuccessful. In these situations, the GDG felt that it would be best to refer the person to a gastroenterologist.

Access to surveillance data

There is no surveillance system available in the UK.

4.4 Long-term management

4.4.1 Summary of suggestions

Long term acid suppression therapy

Stakeholder suggested there should be improved selection of patients for long term acid suppression therapy.

Annual reviews

It was highlighted that annual reviews are not always happening routinely. It is important as medication may still be being prescribed when it is no longer needed or could be used at a lower dose. Stakeholder suggested that patients should be encouraged to instigate this themselves if appropriate.

4.4.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 5 to help inform the Committee's discussion.

Table 9 Specific areas for quality improvement

Suggested quality improvement area	Suggested source guidance recommendations
Long term acid suppression therapy	Common elements of care
	NICE CG184 Recommendation 1.2.5
	Interventions for uninvestigated dyspepsia
	NICE CG184 Recommendation 1.4.5
	Interventions for gastro-oesophageal reflux disease (GORD)
	NICE CG184 Recommendations 1.6.3, 1.6.6, 1.6.9 (KPI), 1.6.10
	Interventions for peptic ulcer disease
	NICE CG184 Recommendations 1.7.7, 1.7.9
	Interventions for functional dyspepsia
	NICE CG184 Recommendations 1.8.5, 1.8.6, 1.8.7
Annual reviews	Reviewing patient care
	NICE CG184 Recommendations 1.5.1 and 1.5.2

Common elements of care

NICE CG184 – Recommendation 1.2.5

Encourage people who need long-term management of dyspepsia symptoms to reduce their use of prescribed medication stepwise: by using the effective lowest dose, by trying 'as-needed' use when appropriate, and by returning to self-treatment with antacid and/or alginate therapy (unless there is an underlying condition or comedication that needs continuing treatment).

Interventions for uninvestigated dyspepsia

NICE CG184 – Recommendation 1.4.5

If symptoms return after initial care strategies, step down PPI therapy to the lowest dose needed to control symptoms. Discuss using the treatment on an 'as-needed' basis with people to manage their own symptoms.

Interventions for gastro-oesophageal reflux disease (GORD)

NICE CG184 – Recommendation 1.6.3

If symptoms recur after initial treatment, offer a PPI at the lowest dose possible to control symptoms.

NICE CG184 – Recommendation 1.6.6

People who have had dilatation of an oesophageal stricture should remain on long-term full-dose PPI therapy.

NICE CG184 – Recommendation 1.6.9 (KPI)

Offer a full-dose PPI long-term as maintenance treatment for people with severe oesophagitis, taking into account the person's preference and clinical circumstances (for example, tolerability of the PPI, underlying health conditions and possible interactions with other drugs), and the acquisition cost of the PPI.

NICE CG184 – Recommendation 1.6.10

If the person's severe oesophagitis fails to respond to maintenance treatment, carry out a clinical review. Consider switching to another PPI at full dose or high dose (see table 2 in appendix A), taking into account the person's preference and clinical circumstances, and/or seeking specialist advice.

Interventions for peptic ulcer disease

NICE CG184 – Recommendation 1.7.7

In people at high risk (previous ulceration) and for whom NSAID continuation is necessary, offer gastric protection or consider substitution with a cyclooxygenase (COX)-2-selective NSAID.

NICE CG184 – Recommendation 1.7.9

If symptoms recur after initial treatment, offer a PPI to be taken at the lowest dose possible to control symptoms. Discuss using the treatment on an 'as-needed' basis with people to manage their own symptoms.

Interventions for functional dyspepsia

NICE CG184 – Recommendation 1.8.5

If symptoms continue or recur after initial treatment, offer a PPI or H2RA to be taken at the lowest dose possible to control symptoms.

NICE CG184 - Recommendation 1.8.6

Discuss using PPI treatment on an 'as-needed' basis with people to manage their own symptoms.

NICE CG184 – Recommendation 1.8.7

Avoid long-term, frequent dose, continuous antacid therapy (it only relieves symptoms in the short term rather than preventing them).

Reviewing patient care

NICE CG184 – Recommendation 1.5.1

Offer people who need long-term management of dyspepsia symptoms an annual review of their condition, and encourage them to try stepping down or stopping treatment (unless there is an underlying condition or comedication that needs continuing treatment).

NICE CG184 – Recommendation 1.5.2

Advise people that it may be appropriate for them to return to self-treatment with antacid and/or alginate therapy (either prescribed or purchased over-the-counter and taken as needed).

4.4.3 Current UK practice

Long term acid suppression therapy

A study⁷ of patients aged 65 or more admitted to acute geriatric medicine beds in two hospitals in Scotland found that 41% of all patients had a prescription for PPI with 85% of PPI prescribed without indication. The authors suggested the high rate

⁷ Prescribing patterns of proton pump inhibitors in older hospitalised patients in a Scottish health board. Jarchow-MacDonald and Mangoni. Geriatrics and gerontology international 2013 v13.

of overprescribing may be explained by the common belief that PPI have a much greater beneficial effect on the overall health of a patient and a much better safety profile than has actually been shown. 17.6% of prescriptions were for high-dose PPI treatment which was unexpected as normal levels of PPI dosage are generally effective.

An audit⁸ of PPI usage among inpatients at Arrowe Park Hospital found that the indication was unclear for 26% of patients prescribed a PPI and the majority of patients were unaware of the indication for their PPI. It also found that for 51% of patients with a documented indication, the strength or frequency of PPI prescribed was outside local guidance.

A medicines optimisation review⁹ of patients prescribed PPIs in 3 GP practices in Lancashire found that it was possible to stop or reduce the PPI dose for 37% of patients leading to projected annual prescribing savings of £100,000 if the approach were extended across the clinical commissioning group. All patients who had their doses reduced or PPIs stopped received an acute supply of licensed alginate to help manage rebound hyperacidity, which may account for the low numbers of patients returning to original PPI usage. Following on from the project the rate of increase in PPI prescribing across the three practices was lower than the average for the northwest of England indicating that raising the issues around PPI prescribing and how to manage patients when stepping down or off treatment led to a change in prescribing behaviour.

Annual reviews

The audit of PPIs¹⁰ in primary care in Cwm Taf Health Board found that only 42% of patients prescribed a high cost PPI had annual reviews of their medication.

The audit of PPI usage at Arrowe Park hospital found that over three quarters of patients admitted on PPI therapy had been taking their PPI for longer than a year and only 14% of all patients admitted on PPI therapy were aware that a review of their PPI therapy had been undertaken.

The medicines optimisation review project in Lancashire arranged for reviews of patients prescribed PPIs to be carried out by practice nurses, gastroenterology nurse specialists and practice pharmacists and demonstrated that many patients are willing to adjust their usage of PPIs when they are involved in the review process.

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⁸ An audit of proton pump inhibitors usage at Arrowe Park hospital. Edgar and Morgan. Pharmacy Workforce North West (2011)

⁹ Medicines optimisation reviews in patients taking PPIs. Mark Spencer. Prescriber 5 May 2013 ¹⁰ The role of a Proton Pump Inhibitor (PPI) 'switch' audit in encouraging appropriate use of PPIs in primary care. Riddell et al. Pharmacoepidemiology and drug safety 2012 vol 21.

4.5 Specialist investigation

4.5.1 Summary of suggestions

Non-invasive pepsin diagnostic

Stakeholder suggested that a simple non-invasive pepsin diagnostic should be used for patients with GORD symptoms that do not respond to PPI to confirm if they have reflux with pepsin as a marker and to exclude a diagnosis of functional dyspepsia. This will reduce the need for expensive invasive endoscopic examinations.

It was also suggested that a pepsin diagnostic could be used to identify patients whose symptoms do not resolve despite medical management and/or surgery who have reflux as a result of pepsin and other enzymes rather than acid. This would improve patient experience and direct treatment while avoiding PH monitoring which is expensive and invasive and not suitable for this group of patients.

Investigating dyspepsia

Stakeholder suggested there should be data on how to investigate dyspepsia (uninvestigated and functional) nationally. Often patients have both oesophagitis and functional dyspepsia. This is supported by Hesa endoscopy day case data and specialist investigations.

Another stakeholder suggested that H.pylori should be looked for with biopsy in nonulcer dyspepsia as its eradication is important to prevent gastric cancer.

Biopsy for specific conditions

A stakeholder highlighted that in the surveillance of Barrett's oesophagus there should be 4 biopsies every 2 cms.

It was also suggested that the number of biopsy taken for upper GI ulceration for patients with reflux disease where metaplastic epithelium is found is another priority.

4.5.2 Selected recommendations from development source

Table 8 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 8 to help inform the Committee's discussion.

Table 8 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Non-invasive pepsin diagnostic	Not directly covered in NICE CG184 and no recommendations are presented.
	Note this area is relevant to CG184 research recommendation 2.5 Specialist investigation.
Investigating dyspepsia	Not directly covered in NICE CG184 and no recommendations are presented.
	Note this area is relevant to CG184 research recommendation 2.5 Specialist investigation.
Biopsy for specific conditions	Surveillance for people with Barrett's oesophagus
	NICE CG184 Recommendation 1.12.1 (KPI)
	BSG guideline on the diagnosis and management of Barrett's oesophagus - Practicalities of endoscopic surveillance.

Surveillance for people with Barrett's oesophagus

NICE CG184 Recommendation 1.12.1 (KPI)

Consider surveillance to check progression to cancer for people who have a diagnosis of Barrett's oesophagus (confirmed by endoscopy and histopathology), taking into account:

- the presence of dysplasia
- the person's individual preference
- the person's risk factors (for example, male gender, older age and the length of the Barrett's oesophagus segment).

Emphasise that the harms of endoscopic surveillance may outweigh the benefits in people who are at low risk of progression to cancer (for example, people with stable non-dysplastic Barrett's oesophagus).

BSG guideline on the diagnosis and management of Barrett's oesophagus - Practicalities of endoscopic surveillance

Adherence to a quadrantic, 2 cm biopsy protocol in addition to sampling any visible lesions is recommended for all patients undergoing surveillance. This should also apply to long segments.

4.5.3 Current UK practice

Non-invasive pepsin diagnostic

No current practice data found.

Investigating dyspepsia

No current practice data found.

Biopsy for specific conditions

No current practice data found.

4.6 Laparoscopic fundoplication

4.6.1 Summary of suggestions

Stakeholder indicated there should be improved selection of patients for referral for anti-reflux surgery to ensure it is cost effective.

4.6.2 Selected recommendations from development source

Table 9 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 9 to help inform the Committee's discussion.

Table 10 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Laparoscopic fundoplication	Laparoscopic fundoplication
	NICE CG184 Recommendation 1.10.1

Laparoscopic fundoplication

NICE CG184 Recommendation 1.10.1

Consider laparoscopic fundoplication for people who have:

- a confirmed diagnosis of acid reflux and adequate symptom control with acid suppression therapy, but who do not wish to continue with this therapy long term
- a confirmed diagnosis of acid reflux and symptoms that are responding to a PPI, but who cannot tolerate acid suppression therapy.

4.6.3 Current UK practice

No current practice data found.

4.7 Additional areas

4.7.1 Summary of suggestions

The improvement areas below were suggested as part of the stakeholder engagement exercise, however they were felt to be either outside the remit of the quality standard referral and the development sources, covered by an existing quality standard or require further discussion by the Committee to establish potential for statement development.

There will be an opportunity for the QSAC to discuss these areas at the end of the session on 17 December 2014.

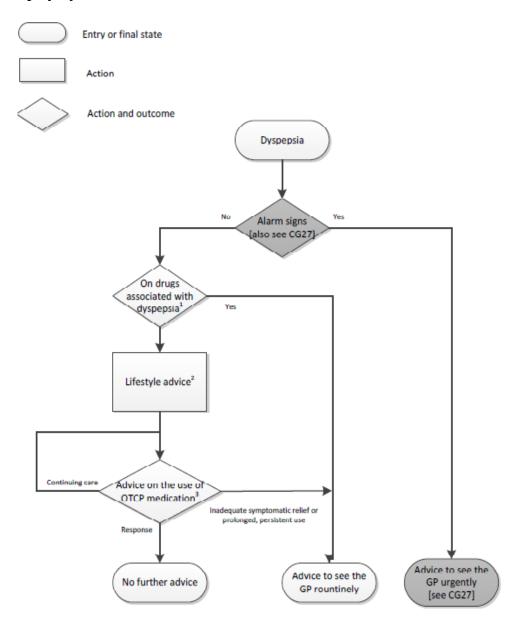
Quality of upper GI endoscopy

Based on evidence that early gastric and oesophageal cancer is missed in 6-10% of people in the 3 years before diagnosis, it was suggested there is a need to improve the quality of upper gastrointestinal endoscopic investigations including inadequate cleansing of the upper GI tract.

Rescope and biopsy of gastric ulcer

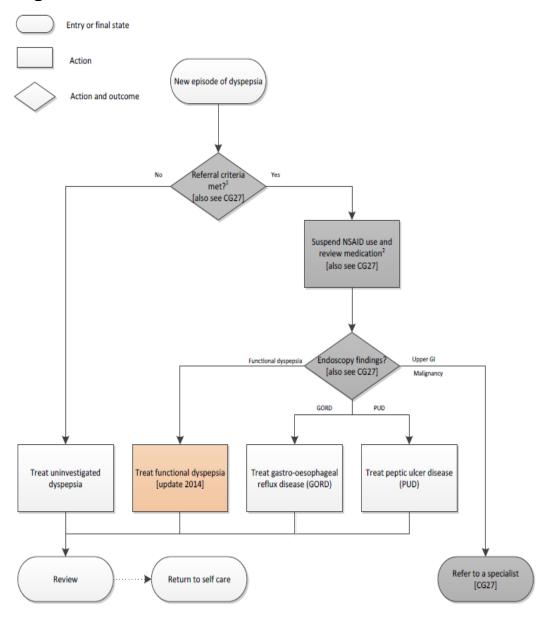
The rescope and biopsy of gastric ulcer was prioritised as it is important to confirm if the gastric ulcer is benign or malignant in order to exclude gastric cancer.

Appendix 1: Flowchart to guide pharmacist management of dyspepsia



- 1. 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, steroids and NSAIDs.
- 2. Offer lifestyle advice, including healthy eating, weight reduction and smoking cessation.
- 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.

Appendix 2: Flowchart of referral criteria and subsequent management

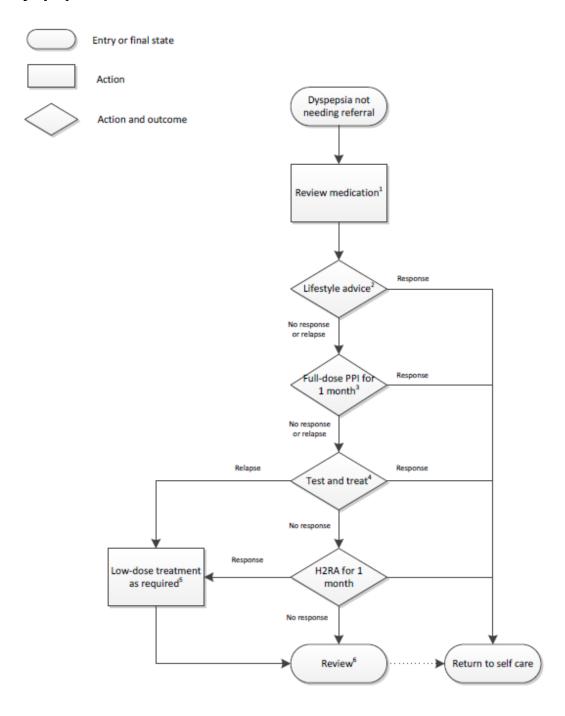


- Immediate referral is indicated for significant acute gastro-intestinal bleeding.

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

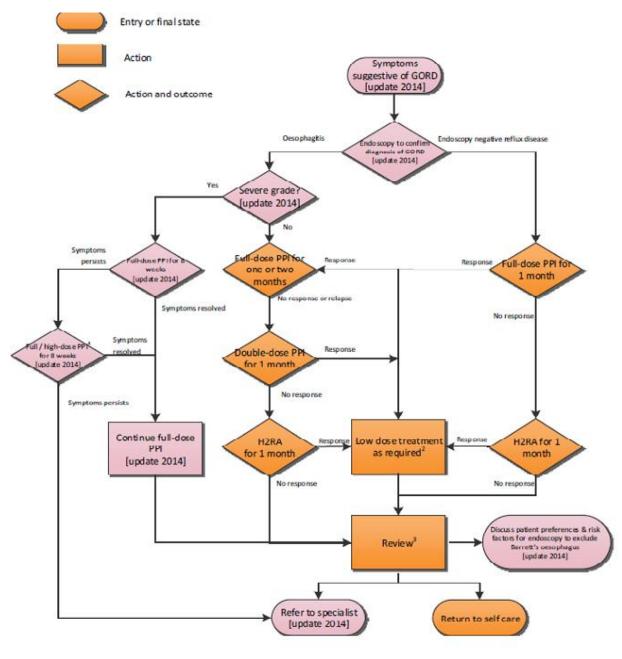
 Consider managing previously investigated patients without new alarm signs according to previous endoscopic findings.
- 2. Review medications for possible causes of dyspepsia, e.g. calcium antagonists, nitrates, theophyllines, bisphosphonates, steroids and NSAIDs.

Appendix 3: Flowchart for the interventions for uninvestigated dyspepsia



- Review medications for possible causes of dyspepsia, e.g. calcium antagonists, nitrates, theophyllines, bisphosphonates, steroids and NSAIDs.
- Offer lifestyle advice, including 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 one month or *H pylori* test and treat should be offered first. Either treatment may be tried first with the other being offered where symptoms persist or return.
- 4.Detection: use carbon-13 urea breath test, stool antigen test or, when performance has been validated, laboratory-based serology.
- 5.Offer low-dose treatment Discuss the use of treatment on an on-demand 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. Emphasize the benign nature of dyspepsia. Review long term patient care at least annually to discuss medication and symptoms.

Appendix 4: Flowchart for interventions for GORD



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.

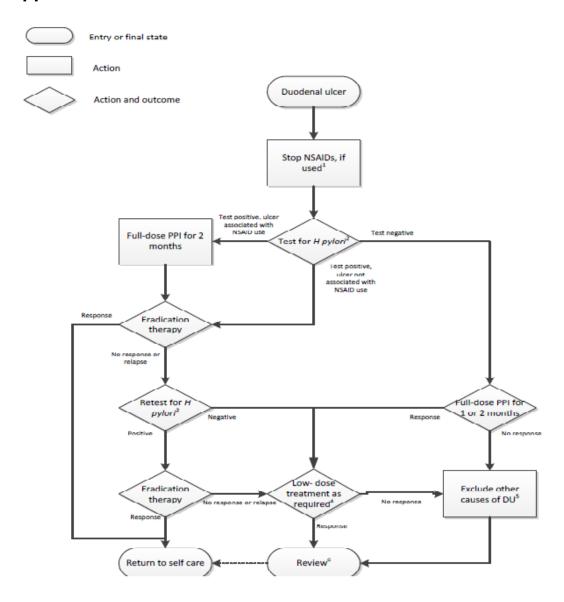
^{3.} Review long term patient care at least annually to discuss medication and symptoms.

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.

A minority of patients have persistent symptoms despite PPI therapy and this group remain a challenge to treat. Therapeutic options include adding an H_2 receptor antagonist at bedtime.

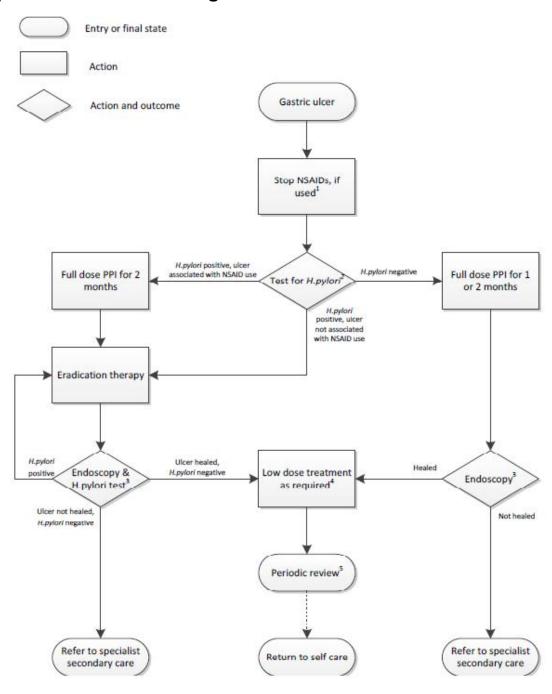
^{4.} Consider a high-dose of the initial PPI, switching to another full-dose PP or switching to another high-dose PPI.

Appendix 5: Flowchart for duodenal ulcer



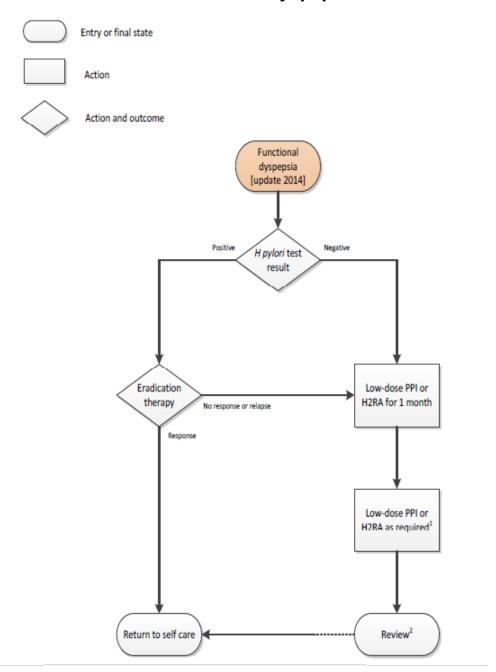
- If NSAID continuation is necessary, after ulcer healing offer long-term gastric protection or consider substitution to a newer COXselective NSAID.
- 2. Use a carbon-13 urea breath test, stool antigen test or, when performance has been validated, laboratory-based serology.
- 3. Use a carbon-13 urea breath test.
- 4. Offer low-dose treatment, possibly on an as required basis.
- 5. Consider: non-compliance 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.
- A small number of patients with chronic, refractory peptic ulceration may require maintenance acid suppression. In some patients with an inadequate response to therapy it may become appropriate to refer to a specialist for a second opinion.
- 6. Review care annually, to discuss symptoms, promote stepwise withdrawal of therapy when appropriate and provide lifestyle advice.

Appendix 6: Flowchart for gastric ulcer



- 1. If NSAID continuation is necessary, after ulcer healing offer long term gastric protection or consider substitution to a newer COX-selective NSAID.
- 2. Use a carbon-13 urea breath test, stool antigen test or, when performance has been validated, laboratory-based serology.
- 3. Perform endoscopy 6-8 weeks after treatment. If retesting for H. pylori use a carbon-13 urea breath test.
- 4. Offer low dose treatment, possibly used on an as required basis.
- 5. 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.

Appendix 7: Flowchart for functional dyspepsia



^{1.} Offer low-dose treatment, possibly on an as required basis.

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. Emphasize the benign nature of dyspepsia. Review long term patient care at least annually to discuss medication and symptoms.

Appendix 8: Key priorities for implementation (CG184)

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

Referral guidance for endoscopy

For people presenting with dyspepsia together with significant acute gastrointestinal bleeding, refer them immediately (on the same day) to a specialist.

Interventions for uninvestigated dyspepsia

Leave a 2-week washout period after proton pump inhibitor (PPI) use before testing for Helicobacter pylori (hereafter referred to as H pylori) with a breath test or a stool antigen test.

Interventions for gastro-oesophageal reflux disease (GORD)

Offer people a full-dose PPI for 8 weeks to heal severe oesophagitis, taking into account the person's preference and clinical circumstances (for example, underlying health conditions and possible interactions with other drugs).

Offer a full-dose PPI long-term as maintenance treatment for people with severe oesophagitis, taking into account the person's preference and clinical circumstances (for example, tolerability of the PPI, underlying health conditions and possible interactions with other drugs), and the acquisition cost of the PPI.

Do not routinely offer endoscopy to diagnose Barrett's oesophagus, but consider it if the person has GORD. Discuss the person's preferences and their individual risk factors (for example, long duration of symptoms, increased frequency of symptoms, previous oesophagitis, previous hiatus hernia, oesophageal stricture or oesophageal ulcers, or male gender).

Interventions for peptic ulcer disease

Offer H pylori eradication therapy to people who have tested positive for H pylori and who have peptic ulcer disease.

For people using NSAIDs with diagnosed peptic ulcer, stop the use of NSAIDs where possible. Offer full-dose PPI or H₂RA therapy for 8 weeks and, if H pylori is present, subsequently offer eradication therapy.

Offer people with peptic ulcer (gastric or duodenal) and H pylori retesting for H pylori 6 to 8 weeks after beginning treatment, depending on the size of the lesion.

Referral to a specialist service

Consider referral to a specialist service for people:

- of any age with gastro-oesophageal symptoms that are non-responsive to treatment or unexplained
- with suspected GORD who are thinking about surgery
- with H pylori that has not responded to second-line eradication therapy.

Surveillance for people with Barrett's oesophagus

Consider surveillance to check progression to cancer for people who have a diagnosis of Barrett's oesophagus (confirmed by endoscopy and histopathology), taking into account:

- the presence of dysplasia
- the person's individual preference
- the person's risk factors (for example, male gender, older age and the length of the Barrett's oesophagus segment).

Emphasise that the harms of endoscopic surveillance may outweigh the benefits in people who are at low risk of progression to cancer (for example, people with stable non-dysplastic Barrett's oesophagus).

Appendix 9: Suggestions from stakeholder engagement exercise

IC	Report section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
1	4.1	SCM1	Key area for quality improvement 1	Selection of patients to self refer to GP	Symptoms and access to self help groups. Includes self-treatment and the threshold every patient makes in order to see their GP.	publications
2	4.1	SCM2	Key area for quality improvement 1	Patients need to be given details as to when to take PPI as they are more effective if taken at certain times relative to meals	They are not always given this information which may vary with PPI	Personal experience
3	4.2	SCM1	Key area for quality improvement 3	Selection of patients for investigation including referral for endoscopy and further specialist tests like oesophageal manometry	Hesa data	
4	4.2	SCM2	Key area for quality improvement 3	More guidance as when to offer an endoscopy	A balance needs to be drawn between overloading the endoscopy service and the detection of more serious conditions	
5	4.2	Heartburn Cancer UK	Access to endoscopy with a much clearer statement for GPs to understand who to refer	Rates of referral for gastroscopy from primary care show wide variation suggesting a spectrum of clinical practice and differing interpretation of guidelines.	To ensure persisting inequalities in referral do not continue. OG cancer patients from GP practices with low rates of gastroscopy were at increased risk of poor outcome for OG cancer.	Gut October 31st 2014. Endoscopy – Shawihdi et al.
6	4.2	British Society of Gastroenterology	Key area for quality improvement 1 Quality of upper gastrointestinal	There is good national and international evidence that early gastric and oesophageal cancer are	The potential for earlier diagnosis of treatable upper GI cancer by more	Data from the second UK National Oesophago-gastric Cancer Audit published this

-	7	4.2	SCM5			Unfortunately I don't believe this happens and therefore GPs are	
					use the guideline and use it appropriately. The best way to do that is link the guideline to endoscopy referral criteria. Most endoscopy services in England are going through JAG accreditation. The basis of the accreditation is meeting the standards on the Global Rating Scale (GRS). The GRS has standards looking at appropriateness and vetting of	encouraged to refer outside of the NICE dyspepsia guideline in the knowledge that the patient will be scoped regardless. The BSG endoscopy standards look at the completion of the procedure but not the indication. Perhaps NICE could work with the BSG to link the standards.	
**	3	4.3	SCM3	diagnostic tests with very high sensitivity and specificity and positive predictive value should be available for the diagnosis of <i>Helicobacter pylori</i>	3 antibiotics.Thus clinicians should not prescribe unless they are certain of the diagnosis. Some tests are less specific and therefore with a low prevalence the PPV may be very low	only using serology that	Guidance indicates that stool antigen and urea breath test are first choice.
Ç)	4.3	SCM3	Clinicians should have access to a reliable culture service for when patients relapse on treatment	The treatment of H.pylori is complex and difficult and requires a PPI and 3 antibiotics. Resistance is increasing—but treatment is empirical in the majority of cases without any culture available. Guidance recommends that patients are referred for culture if	undertake routine culture	NICE . Guidance recommends that patients are referred for culture if there is relapse more than twice.

			rates and therefore the service should be	
			broadened.	

10 4.3	SCM3	Key area for quality improvement 3 Clinicians should have access to surveillance data that can inform which antibiotic combination should be used.	The treatment of H.pylori is complex and difficult and requires a PPI and 3 antibiotics. Resistance is increasing – but treatment is empirical in the majority of cases without any culture available. Therefore it is important that a surveillance system is in place to inform antibiotic choice across the UK	system available in the UK	There is no surveillance system available in the UK
11 4.3	SCM4	Key area for quality improvement 4	Eradication of Helicobacter	Evidence for eradication for cancer prevention. Helicobacter pylori should be looked for with biopsy in non-ulcer dyspepsia.	Prevention of gastric cancer
12 4.3	SCM4	Key area for quality improvement 5	Helicobacter sensitivity testing	Recurrent infection eradication. If eradication fails should culture occur?	NICE guidelines
13 4.4	SCM1	Key area for quality improvement 2	Selection of patients for long term acid suppression therapy	Nhs data on prescription rates	
14 4.4	SCM2	Key area for quality improvement 2	Annual reviews do not happen routinely although recommended. Patients should be encouraged to instigate this themselves if appropriate	Medication may still be being prescribed when it is no longer needed or could be used at a lower dose	Personal experience
15 4.5	SCM1	Key area for quality improvement 4	Data on how to investigate dyspepsia nationally. Includes uninvestigated dyspepsia and functional dyspepsia.	Often patients have both oesophagitis and functional dyspepsia. Hesa endoscopy data but also specialist investigations	publications
16 4.5	RDBiomed Limited	Use of simple non-invasive pepsin diagnostic to exclude diagnosis of functional dyspepsia (GORD)	Recommended research in current NICE guideline. People with uninvestigated dyspepsia that fails to respond to PPIs or H2RAs, despite optimum primary care, can have a poor quality of life		The non-invasive lateral flow device Peptest has undergone validation in various patient groups and has sensitivity of 69-95% and specificity of 63-100%. The test is rapid, non-

		patient, who continues to experience very real symptoms. Confirming reflux with pepsin as a marker can simply exclude the functional dyspepsia diagnosis with one of GORD. The development of a simple non-invasive diagnostic alternative in primary care to referrals for expensive invasive endoscopic examinations in secondary care will help relieve budgetary and resource pressure for commissioners.	Dettmar PW. (2012) Int J Otolaryngol 2012:doi:10.1155/2012/646901 De Bortoli et al (2012) Gut 61 (Suppl3):A199 Bor et al (2012) Gut 61 (Suppl 3) A83 De Bortoli et al (2013) Gastroenterology 144 (5 Suppl 1): S118
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177	4.5	RDBiomed Limited	Use of simple non-invasive pepsin diagnostic in the management of patients with GORD symptoms despite PPI therapy and optimum primary care.	Recommended research in current NICE guideline. There is a small group of people whose symptoms do not resolve, despite medical management and/or surgery for reflux. The group should be divided into people with proven (by pH monitoring) GORD and people with symptoms but no diagnosed reflux.	pH monitoring is expensive and invasive and reflux symptoms are often caused by pepsin and other enzymes not only acid. Having a simple, inexpensive, non-invasive confirmation of reflux will improve patient experience and direct treatment strategy in many cases. The development of a simple non-invasive diagnostic alternative in primary care to referrals for expensive invasive endoscopic examinations in secondary care will help relieve budgetary and resource pressure for commissioners.	
18	4.5	SCM4	Key area for quality improvement 1	Number of Biopsy per segment of Barrett's Oesophagus	4 biopsy every 2 cms of barrett's	BSG Guidelines
19	4.5	SCM4	Key area for quality improvement 2	Upper GI ulceration	Number of biopsy taken for patients with reflux disease and metaplastic epithelium is found.	AUGIS and BSG Guidelines
20	4.6	SCM1	Key area for quality improvement 5	Selection of patients to refer for anti reflux surgery	Cost effectiveness	publications
21	4.7	SCM4	Key area for quality improvement 3	Rescope and biopsy of gastric ulcer	Is the gastric ulcer benign or malignant? To exclude gastric cancer.	Missed cancer in guidelines
22	4.7	British Society of Gastroenterology	Key area for quality improvement 1 Quality of upper gastrointestinal endoscopic investigations	There is good national and international evidence that early gastric and oesophageal cancer are missed in 6-10% of people in the 3	The potential for earlier diagnosis of treatable upper GI cancer by more accurate endoscopy	Data from the second UK National Oesophago-gastric Cancer Audit published this year:

	years before diagnosis. In many cases this is because on inadequate inspection or inadequate cleansing of upper GI tract resulting in miss of early treatable. In order to achieve this, standards for referral for upper GI endoscopy need to be developed and audited to ensure patients who do require endoscopy are being referred and patients who do not (according to CG 184) are not overloading the system.	Chadwick G, Groene O, Hoare J, Hardwick RH, Riley S, Crosby TD, Hanna GB, Cromwell DA. A population-based, retrospective, cohort study of esophageal cancer missed at endoscopy. Endoscopy. 2014 46: 553-60. Also other Australian and Scottish data data: Raftopoulos SC, Segarajasingam DS, Burke V, Ee HC, Yusoff IF. A cohort study of missed and new cancers after esophagogastroduodenoscopy. Am J Gastroenterol. 2010;105:1292-7. Yalamarthi S, Witherspoon P, McCole D, Auld CD. Missed diagnoses in patients with upper gastrointestinal cancers. Endoscopy. 2004; 36:874-9. The BSG is in the process of developing standards for upper GI endoscopy
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