NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Dyspepsia and gastro-oesophageal reflux disease (GORD)

Date of Quality Standards Advisory Committee post-consultation meeting:
22 April 2015.

2 Introduction

The draft quality standard for Dyspepsia and GORD was made available on the NICE website for a 4-week public consultation period between 27 February and 27 March 2015. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 13 registered stakeholders, which included national organisations, professional bodies, and patient groups.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. For each quality statement what do you think could be done to support improvement and help overcome barriers?

Stakeholders were also invited to respond to the following statement specific questions:

4. For draft quality statement 1: Would it be possible to measure whether advice is provided by community pharmacists to people presenting with dyspepsia or GORD symptoms? Please explain your answer.

5. For draft quality statement 3: Are laboratory-based serology tests that are not locally validated currently being used to test for H Pylori? Can you provide examples of current practice in this area?

6. For draft quality statement 4: For how long should treatment be tried before a referral to a specialist service is discussed with a patient with persistent unexplained dyspepsia or GORD symptoms? Please explain your answer.

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- In general, stakeholders welcomed the quality standard.
- There was support for most quality statements and measures.
- Some stakeholders highlighted additional areas of quality improvement that could be considered for inclusion in the quality standard.
- The link between the quality standard and the February 2015 ‘Be Clear on Cancer’ campaign was highlighted.
- The need to update the quality standard in line with the updated guideline for suspected cancer (due to publish May 2015) was recognised.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Adults with dyspepsia or gastro-oesophageal reflux disease (GORD) symptoms are given advice about making lifestyle changes, taking medicines and when to consult their GP.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- There was support for the inclusion of community pharmacists within the statement but concern the statement may currently be too broad. A suggestion was made to separate this statement into two, one for community pharmacists and one for GPs.

- There was concern that the statement may not be measurable in its current form but could be if it was service based instead.
- It was felt that the term ‘taking medicines’ was too broad and more specific alternative terminology could be used.
- A stakeholder suggested the statement should include a medication review to check if medication could be the cause of symptoms.
- It was suggested that a clearer definition of ‘persistent symptoms’ is needed within the definition of ‘Advice about when to consult or return to their GP’.

Consultation question 4

Stakeholders made the following comments in relation to consultation question 4:

- There are no current recording methods in place for community pharmacists.
- It was queried if it would be useful to collect this data, as it is likely that if the pharmacist takes the trouble to collect the data they will also give the advice needed.
- Some suggestions were made for how the statement could be measured as follows:
  - A national audit.
  - If pharmacists had access to patient records they could record advice and actions taken which could then be shared with other healthcare professionals.
  - A read code would need to be created with GP’s recording it at presentation.
  - It may be possible to measure referrals from the pharmacist to the GP.

5.2 Draft statement 2

Adults with dyspepsia or gastro-oesophageal reflux disease (GORD) symptoms are referred for an endoscopy to take place within 2 weeks if they have alarm symptoms.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- It was noted that the definition of alarm symptoms and any age thresholds will need to be updated in line with the updated guideline (CG27).

- It was felt to be important to reflect within the rationale and outcomes that if cancer is detected following alarm symptoms, it may be too late for the cancer to be cured.
- It needs to be clearer when not to refer for endoscopy.

5.3 Draft statement 3

Adults with dyspepsia or gastro-oesophageal reflux disease (GORD) symptoms who are being tested for Helicobacter pylori (H pylori) have a carbon-13 urea breath test, a stool antigen test or a locally validated laboratory-based serology test.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- There was confirmation that while it is important to reduce antimicrobial resistance there is a lack of supporting evidence currently and a need to gather this.
- There was a concern that this statement may not be useful.
- Re-consider if all 3 process measures are needed.

5.4 Draft statement 4

Adults with persistent, unexplained dyspepsia or gastro-oesophageal reflux disease (GORD) symptoms that have not responded to treatment discuss referral to a specialist service with their GP.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- It was queried why the statement is focussed on a discussion about referral rather than actual referrals as referral data is easier to access.
- Additional measures were suggested as follows:
  - Diagnosis of low grade and high grade dysplasia
  - Participation in a surveillance programme
  - Reports to UK Barrett's Oesophagus registry.

Consultation question 6

Stakeholders made the following comments in relation to consultation question 6:

- The aim is to enable healing of oesophagitis which involves an 8 week course of PPI. If the healing dose does not work and full dosage PPI is considered necessary then a referral for an endoscopy should be made.
- A referral should be made if there is no improvement after 4 weeks treatment of Omeprazole 40mg daily. In most patients healing usually occurs within 2 weeks.
- The recent 'Be Clear on Cancer Campaign' timescale of 3 weeks was suggested. This would ensure that if the patient enters the 2 week wait pathway to direct endoscopy they will get their diagnostic test about 5-6 weeks after the onset of symptoms.

The Be Clear on Cancer campaign states:

See your doctor straight away if you've had heartburn most days for 3 weeks or more. Even if you're taking medicine and it seems to help, you still need to see your doctor if you have heartburn for most days. Other symptoms of oesophageal or stomach cancer may include:

- Indigestion on and off for 3 weeks or more
- Food feels like it's sticking in your throat when you swallow
- Losing weight for no obvious reason
- Trapped wind and frequent burping
- Feeling full very quickly when eating
- Feeling bloated after eating
- Nausea or vomiting
- Pain or discomfort in your upper tummy area.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Advice for GP's on interventions for uninvestigated dyspepsia (whether to test for H pylori or treat symptoms & time period to be off PPIs before testing for H pylori)
- Identifying Barrett's oesophagus in those with persisting reflux symptoms that are controlled with medication
- Which alternative diagnoses should be considered and how should these be investigated, if symptoms fail to respond to treatment?
- Sedation for therapeutic GI endoscopic procedures
- Quality of upper GI endoscopy.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement No	Comments[1]
1	Royal Pharmaceutical Society	General	The Royal Pharmaceutical Society welcomes the quality standard for dyspepsia and gastro-oesophageal reflux disease and agrees with the draft quality statements. We have previously responded to the NICE Consultation on the dyspepsia and gastro-oesophageal reflux disease guidelines and believe the publication of this Quality Standard will align well with the NICE guidelines on this topic. In the section on Related NICE Quality Standards, we noticed your future quality standards. We would be interested in and look forward to seeing the following: - Managing medicines in care homes - Community pharmacy: promoting health and wellbeing - Long-term conditions, people with comorbidities, complex needs - Medicines management managing the use of medicines in community setting for people receiving social care. - Medicines optimisation (covering medicines adherence and safe prescribing) - Referral for suspected cancers. We believe this links into some of the campaigns we are currently working on including: Pharmacists improving care in care homes and Pharmacist-led care of people with long term conditions. The Royal Pharmaceutical supports the medicines optimisation agenda and we have developed several resources for our members to realise this, please see our website for further detail: http://www.rpharms.com/what-we-re-working-on/medicines-optimisation.asp.
2	Action Against Heartburn	General	Table 1, page 3 - Agree that this is relevant for the NHS Outcomes Framework for Improvements to the Under 75 mortality rate from cancer. Table 2, page 5 - Agree that this is relevant for the NHS Outcomes Framework for Health Improvement – Cancer diagnosed at Stage 1 and 2.
3	Oesophageal Patients' Association	General	Excellent material [information sheets, TV advert] for patients, GP's and Pharmacists was prepared for the NHS Be Clear on Cancer campaign which aired for one month from 26.01.15. This material should be re-shown if the campaign proves successful on analysis of results and should be permanently available.
4	Royal College of Nursing	General	This is to inform you that the Royal College of Nursing have no comments to submit to inform on the Dyspepsia quality standards consultation.
5	Digital assessment	General	We welcome the standard and have no comments as part of the consultation.

[1]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement No	Comments[1]
	services, NHS Choices		
6	Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
7	Royal College of Paediatrics and Child Health.	General	We have not received any responses for this consultation.
8	Primary Care Society of Gastroenterology	Questions for consultation – Question 1	There are a number of observations we would like to be considered by the guidelines development group as key ares for quality development 1. Advice on when to refer and when NOT to refer for upper GI endoscopy. 2. Advice on whether to test for H.pylori or treat symptoms. 3. Continuing treatment for chronic dyspepsia/GORD - when do indications for referral change? 4. Which alternative diagnoses should be considered and how should these be investigated, if symptoms fail to respond to treatment? 5. Support for patients who need to stop smoking and reduce their weight should be a priority for commissioners 6. When testing for H.pylori using the breath test, what is the optimal time period for the patient to be off PPIs? Many patients are buying OTC PPIs and this will reduce the sensitivity of the breath test.
9	British Society of Gastroenterology	Questions for consultation – Question 1	For both statements 1 and 2, apart from patients being appropriately referred, there needs to be an assessment of the quality of the upper GI Endoscopy procedures. It is well recognised from studies in the UK, US and Australia that there is a 'miss rate' of upper GI cancer of about 7-8%. This is recognised from studies of patients presenting with advanced oesophago-gastric cancer who have had an apparently normal Endoscopy in the previous 3 years. In my view one of the quality standards needs to be proportion of patients with advanced OG cancer who have had an apparently normal Endoscopy in the last 3 years prior to diagnosis. This might even apply to patients with known Barrett's in whom the issue is recognising subtle mucosal abnormalities heralding dysplasia/early cancer.
10	British Society of Gastroenterology	Questions for consultation – Question 1	No problems with statements 3 and 4, though I suspect most Barrett's will NOT be among the patients with poorly controlled symptoms, rather those (in statement 1) who have persisting reflux symptoms even if controlled with medication.
11	Royal College of GP's	Questions for consultation – Question 1	I think as an alternative statement that the sedation and harm caused by endoscopy should be considered. A 2004 report by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), "Scoping our Practice", found that there had been 1,818 deaths after therapeutic GI endoscopic procedures. NCEPOD advisors found that the sedation given was inappropriate in 14% of cases.
12	Royal College of GP's	Questions for consultation – Question 3	A standard 2 week wait form across the UK rather than individual trust forms with different formats and criteria.
13	Royal Pharmaceutical	Statement 1	We welcome the recognition of community pharmacists as providers of advice on lifestyle changes, medicines and

ID	Stakeholder	Statement No	Comments[1]
	Society		when to consult their GP. As experts in medicines, pharmacists provide advice on how to take medicines, adverse effects, possible interactions and cautions, to raise patients' and carers' awareness and increase their understanding of their condition and therapy. Healthy Living Pharmacies have health champions who can promote wellbeing and support with responding to occasions where indigestion and heartburn frequency is greater than occasional. Pharmacist and pharmacy staff commonly offer smoking cessation services. A wide range of pharmacy (P) medicines to treat heartburn and indigestion are available and pharmacists can make individual recommendations. The Royal Pharmaceutical Society have produced quick reference guides for our members on: Alcohol use disorders, Oesophago-gastric cancer, Omeprazole and Smoking Cessation.
14	British Society of Gastroenterology	Statement 1	Pharmacist advice about whether to consult/return to GP should include a definition of 'persistent symptoms'. Should this simply mean symptoms unrelieved by medication provided OTC or (more likely) symptoms requiring continuous OTC medication for a defined period (eg 'at least 6 weeks' rather than 'several weeks')?
15	Royal College of GP's	Statement 1	Statement 1 should probably include a medication review of prescribed and over the counter medication to check none are potentially causing the GORD. These include calcium channel blockers, nitrates, NSAIDs, SSRI, Corticosteroids and bisphosphonates.
16	Royal Pharmaceutical Society	Statement 1 – question 4	*Would it be possible to measure whether advice is provided by community pharmacists to people presenting with dyspepsia or GORD symptoms? Please explain your answer.* This could be achieved through the use of a national audit. Pharmacists can complete the audit each time they are presented with a prescription or over-the-counter purchase of the following drug classes: Antacids, Compound Alginates, H2- receptor antagonists and proton pump inhibitors. The Royal Pharmaceutical Society has produced audit templates for our members. We are keen to understand how we may be able to support pharmacists with this. Pharmacist access to patient records would provide a suitable method to record any advice that is provided and ensure continuity of care, as other healthcare professionals will be able to see any advice and action taken.
17	Action Against Heartburn	Statement 1 – question 4	The regular consumers of Gaviscon and other over-the-counter heartburn remedies are a crucial target audience for awareness messages to persuade them to see a GP and obtain a definitive diagnosis of underlying causes. Some pharmacists adopt a system of writing a referral note to GPs. The issue of creating a recording system is likely to be more challenging because of the commercial environment of pharmacies, but further consultation with pharmacy companies would be instructive.
18	NHS England	Statement 1 – question 4	This would seem to be not at all easy – as far as I know, there are no current methods in place – in addition, it would seem surprising that any pharmacist who took the trouble to collect the data, would not take the trouble to give the advice needed.
19	Royal College of GP's	Statement 1 – question 4	No, this would require creation of a read code and GPs recording it at presentation possibly in a template.
20	Royal Pharmaceutical Society	Statement 2	Community pharmacies, through their accessibility to patients, are in a position to raise awareness and signpost patients to their GP when they present with alarm symptoms. Patients commonly visit pharmacies to purchase over-

ID	Stakeholder	Statement No	Comments[1]
			the-counter medicines for the treatment of dyspepsia and GORD symptoms. Pharmacists commonly discuss medicines-related issues with patients and conduct medicine use reviews with patients on chronic medications and this can often be an opportunity to identify patients presenting with alarm symptoms and initiate appropriate referral.
21	Action Against Heartburn	Statement 2	Page 13 Endoscopy Referral – Rationale - Referral for endoscopy for alarm symptoms of dysphagia will often be too late for curative treatment for a cancerous tumour.
22	Action Against Heartburn	Statement 2	Page 14 Outcome - Delete the word 'early', since alarm symptoms will normally be detected too late to detect the early stage cancers and the outcome has to be expressed realistically.
23	Oesophageal Patients Association	Statement 2	I think it's a very good draft and on page 15, its excellent. Can we add positive family history for Barrett's or OG cancer please? These need earlier OGD then most especially if they have GORD.
24	Royal College of GP's	Statement 2	Statement 2 does not identify age but does explain in the full statement what constitutes alarms symptoms. I think it would be useful to expand and incorporate age in case this is not interpreted correctly in primary care. Some patients may be too frail or refuse.
25	Oesophageal Patients' Association	Statement 2	The use of the wording 'of any age' for referral for endoscopy is welcome. There should also be no gender bar: some previous recommendations were for 'male over 55 years'. The current wording is in agreement with CG 184 and CG 57.
26	The Royal College of Radiologists	Statement 2	The quality standard document sites NICE Guideline CG27 (2005). This has just been updated by NICE with the draft following consultation version released in February 2015. As the QS draft notes, the section on "Alarm symptoms" (p15) will need to be updated in light of this as the guidelines have changed from those currently included.
27	Royal College of GP's	Statement 3	I am not sure how useful Statement 3 is.
28	NHS England	Statement 3 – question 5	I do not have sufficient expertise to give a useful answer. The expertise is held by Microbiologists.
29	Royal College of pathologists	Statement 3 – question 5	It's important to cover the value of the diagnostic tests available to test for H.pylori e.g serology versus stool antigen test versus carbon-13 urea breath test. Evidence of antimicrobial resistance emerging in cases treated inappropriately must be reviewed and used as supporting evidence.
30	Royal College of GP's	Statement 3 – question 5	This statement appears to be directed at Point of care testing. This statement may hamper clinical innovation closer to the patient.
31	Action Against Heartburn	Statement 4	In addition to incidence of Barrett's Oesophagus, it would be logical to include those also diagnosed with low grade dysplasia and high grade dysplasia, those entered into a surveillance programme, and those reported to UK Barrett's Oesophagus registry
32	Royal College of GP's	Statement 4	I am unclear why this is recording discussions rather than acute referrals. Numerator is described as the number in the denominator who are referred to a specialist service. This is easier to search GP clinical system for as it will be coded.

ID	Stakeholder	Statement No	Comments[1]
33	Action Against Heartburn	Statement 4 – Question 6	For how long should treatment be tried before referral for specialist investigation? In the absence of alarm symptoms requiring urgent endoscopy, the aim is to enable healing of oesophagitis (if present) and then assess the response. This involves an 8 week course of PPI. If this alleviates the symptoms, or if they can be suppressed by minimal maintenance therapy eg OTCs or H_2RAs, then OK to continue, but if full dosage PPI contemplated, then endoscopy should be mandatory, as it is if no response to the healing dose. If we are to achieve cancer outcomes equivalent to those in the best parts of Europe, we do need to investigate more patients with endoscopy, with or without a preliminary process such as cytosponge. There is a continuing need to assist GPs to understand the nature and risks involved with persistent heartburn, GORD and Barrett's Oesophagus.
34	NHS England	Statement 4 – Question 6	Three weeks – there is no hard and fast guidance – but this has been the time-scale used in the recent 'Be Clear on Cancer Campaign' – it also means that if the patient then enters the two-week-wait pathway to direct endoscopy, they will get their diagnostic test about 5-6 weeks after the onset of symptoms.
35	Royal College of GP's	Statement 4 – Question 6	I would refer if the patient had no improvement after 4 weeks treatment of Omeprazole 40mg daily. The data compendium sheet on omeprazole starts the recommended dose in patients with an active duodenal ulcer is Omeprazole 20mg once daily. In most patients healing occurs within two weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further two weeks treatment period. In patients with poorly responsive duodenal ulcer Omeprazole 40mg once daily is recommended and healing is usually achieved within four weeks.

Registered stakeholders who submitted comments at consultation

- Action Against Heartburn
- British Society of Gastroenterology
- NHS England
- Oesophageal Patients Association
- Primary Care Society of Gastroenterology
- Royal College of GP's
- Royal College of Pathologists

- Royal College of Radiologists
- Royal Pharmaceutical Society