NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Gallstone disease

Date of Quality Standards Advisory Committee post-consultation meeting:
02 September 2015

2 Introduction

The draft quality standard for gallstone disease was made available on the NICE website for a 4-week public consultation period between 9 July and 6 August 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 6 organisations, which included service providers, national organisations, professional bodies and others.

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 2: Can prompt be defined in this quality statement and if so can a definition be provided?

4 General comments

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

- In general stakeholders highlighted that the document was clear and concise and addresses the main areas for quality improvement.
- A concern was raised that the initial part of the clinical pathway, diagnosis, was missing from the quality standard.
- A stakeholder highlighted that data collection should be feasible for draft quality statements 1 and 2, but it may be more challenging for statement 3.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Adults with acute cholecystitis have laparoscopic cholecystectomy within 1 week of diagnosis.

Consultation comments

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

- A stakeholder stated that this will improve services for people with gallstone disease as there is variation in timely access to laparoscopic cholecystectomy.
- A stakeholder highlighted that while this statement is concise there are caveats that need to be addressed, it may be better to be referred to as uncomplicated acute cholecystitis.

5.2 Draft statement 2

Adults with common bile duct stones have prompt access to endoscopic retrograde cholangiopancreatography.

Consultation comments

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

- A stakeholder agreed that “prompt access” required definition without being able to provide this.

Consultation question 4

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

- A stakeholder highlighted the difficulties in defining “prompt” access due to different clinical circumstances. They offered definitions of 2 weeks for non-clinically urgent endoscopic retrograde cholangiopancreatography, 72 hours for those with jaundice due to common bile duct stones and within 24 hours as an emergency for those with acute cholangitis.

5.3 Draft statement 3

Adults with gallstone disease who have not had their gallbladder or gallstones removed discuss their diet with their healthcare professional.

Consultation comments

No comments were made by stakeholders specific to draft statement 3.

6 Suggestions for additional statements

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

- A stakeholder suggested a statement on diagnosis, with an emphasis on primary care as gallstone disease if often missed. They suggested that nausea and vomiting could raise suspicion that leads to further tests.
- A stakeholder highlighted the use of magnetic resonance cholangiopancreatography or endoscopic ultrasound before endoscopic retrograde cholangiopancreatography.
- A stakeholder suggested that a statement could be developed specifically on the use of endoscopic retrograde cholangiopancreatography during surgery, which can improve patient outcomes.
- A stakeholder felt that laparoscopic common bile duct exploration should be considered for development as this can result in a shorter hospital stay.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments[1]
001	British Liver Trust	General	The British Liver Trust suggests the inclusion of Dr Kurinchi Gurusamy (k.gurusamy@ucl.ac.uk) on the Gallstone disease: specialist committee
002	Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
003	Royal College of Nursing	General	The draft quality standard reads very well and seems clear and concise
004	NHS England	Question 2	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Fairly straightforward for 1 and 2 – less easy for 3
005	NHS England	Question 3	For each quality statement what do you think could be done to support improvement and help overcome barriers? Measurement and audit always tend to improve compliance with a standard. A specific CQUIN with penalties for failure of compliance will tend to focus providers on the issue
006	NHS England	Question 4	For draft quality statement 2: Can prompt be defined in this quality statement and if so can a definition be provided? Prompt is not easy to define because there are specific clinical circumstances. Common bile duct stones discovered as part of general work-up and with no specific symptoms are not clinically urgent and could attract a time limit of 2 weeks. Patients with jaundice due to common bile duct stones are at risk of rapid worsening and need an ERCP ideally within 48 hours, but because ERCP will rarely be provided at the weekend, it might be more practical to state 72 hours. Patients with active infection due to common bile duct stones (Acute Cholangitis) have a medical emergency with a measurable mortality and as such need ERCP on the next routine working day or as an emergency if sepsis is not settling.
007	British Society of Gastroenterology	Draft quality statement 1	This is a concise document, which addresses the main areas pertaining to gallstone disease. It is quite rightly suggested that there should be an expectation of laparoscopic cholecystectomy within 1 week, but there are no caveats/explanation for scenarios in which it may be entirely clinically correct to delay (eg perforated gallbladder). Would it be helpful to state 'uncomplicated acute cholecystitis?
008	The Royal College of General Practitioners	Draft quality statement 1	This statement reflects the Tokyo guidelines from 2013. It would be improved by being qualified by reference to the Tokyo guidelines which qualify and expand on the directive. The statement gives patients the chance of much improved care as at the moment there is not the capacity in many localities to act with such urgency. I have a patient whose operation was delayed because she had borderline hypothyroidism. The suffering caused by a repeat attack

[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 number	Comments[1]
			far outweighs the possible small risk with borderline hypothyroidism.
009	British Society of Gastroenterology	Draft quality statement 2	Although difficult to define, I would suggest that some definition of 'prompt' access to ERCP is indicated. Is prompt 1 day, or 1 month...?
010	British Liver Trust	Additional statements	In addition we would like NICE to consider the following research papers too: Should people with suspected common bile duct stones receive any test prior to ERCP? i: Morris S, Gurusamy KS, Sheringham J, Davidson BR. Cost-effectiveness analysis of endoscopic ultrasound versus magnetic resonance cholangiopancreatography in patients with suspected common bile duct stones. PLoS One. 2015 Mar 23;10(3):e0121699. doi: 10.1371/journal.pone.0121699. eCollection 2015. PubMed PMID: 25799113; PubMed Central PMCID: PMC4370382. ii: Giljaca V, Gurusamy KS, Takwoingi Y, Higgie D, Poropat G, Štimac D, Davidson BR. Endoscopic ultrasound versus magnetic resonance cholangiopancreatography for common bile duct stones. Cochrane Database Syst Rev. 2015 Feb 26;2:CD011549. doi: 10.1002/14651858.CD011549. Review. PubMed PMID: 25719224. The above systematic review and cost-effectiveness analyses show that people with suspected common bile duct stones should receive an MRCP or EUS prior to ERCP. This has been incorporated in the BSG guidelines of common bile duct stones. When should ERCP and stone removal be performed? i: Gurusamy K, Wilson E, Burroughs AK, Davidson BR. Intra-operative vs pre-operative endoscopic sphincterotomy in patients with gallbladder and common bile duct stones: cost-utility and value-of-information analysis. Appl Health Econ Health Policy. 2012 Jan 1;10(1):15-29. doi: 10.2165/11594950-000000000-00000. PubMed PMID: 22077427. ii: Gurusamy K, Sahay SJ, Burroughs AK, Davidson BR. Systematic review and meta-analysis of intraoperative versus preoperative endoscopic sphincterotomy in patients with gallbladder and suspected common bile duct stones. Br J Surg. 2011 Jul;98(7):908-16. doi: 10.1002/bjs.7460. Epub 2011 Apr 7. Review. PubMed PMID: 21472700. The above systematic review and cost-effectiveness analyses show that if ERCP and stone removal is performed intra-operatively, the outcomes are better for patients. What about laparoscopic common bile duct exploration? Dasari BV, Tan CJ, Gurusamy KS, Martin DJ, Kirk G, McKie L, Diamond T, Taylor MA. Surgical versus endoscopic treatment of bile duct stones. Cochrane Database Syst Rev. 2013 Dec 12;12:CD003327. doi: 10.1002/14651858.CD003327.pub4. Review.

ID	Stakeholder	Statement number	Comments[1]
			PubMed PMID: 24338858. The above systematic review shows that laparoscopic common bile duct exploration results in fewer hospital stay. BSG guidelines acknowledges this and states that surgeons should be trained in this.
011	NHS England	Additional statements	Does this draft quality standard accurately reflect the key areas for quality improvement? I remain concerned that there is nothing about diagnosis and that doctors (particularly in primary care) are often missing gallstones for a long time because all upper abdominal symptoms are assumed to be 'dyspepsia'. Nausea and vomiting should raise suspicion and should lead to an ultrasound examination

Registered stakeholders who submitted comments at consultation

- British Liver Trust
- British Society of Gastroenterology
- Department of Health
- NHS England
- Royal College of General Practitioners
- Royal College of Nursing