

Gallstone disease

NICE quality standard

Draft for consultation

July 2015

Introduction

This quality standard covers diagnosing and managing gallstone disease in adults. For more information see the [topic overview](#).

In this quality standard, the term 'gallstone disease' refers to stones in the gallbladder or common bile duct, and the symptoms and complications they cause.

Why this quality standard is needed

About 15% of adults are thought to have gallstone disease. Of these, around 80% have asymptomatic gallbladder stones (defined as stones that are confined to the gallbladder and do not cause symptoms). They are often found by investigations for other conditions, and adults with asymptomatic gallbladder stones may never develop symptoms or complications.

There is variation within the NHS in how asymptomatic gallbladder stones are managed once they have been diagnosed. Some adults are offered treatment to prevent symptoms and complications developing. Others are offered a watch-and-wait approach, and only have active treatment once the stones begin to cause symptoms.

Around 20% of people with the condition have symptomatic gallstone disease. The symptoms of gallstone disease range from mild, non-specific symptoms that can be difficult to diagnose, to severe pain and/or complications that are often easily recognised as gallstone disease by healthcare professionals:

Adults with mild, non-specific symptoms of gallstone disease may think their symptoms are caused by other conditions, or they may be misdiagnosed and have unnecessary investigations and treatment. This can have a negative effect on the

adult's quality of life and can be an unnecessary cost for the NHS. There is a need to identify whether there are any specific signs, symptoms or risk factors for gallstone disease and the best method of diagnosing it.

There are a range of endoscopic, surgical and medical treatments available to treat gallstone disease. Surgery to remove the gallbladder (cholecystectomy) is the most common way to treat biliary pain or cholecystitis caused by gallstones and is one of the most commonly performed surgical procedures in the NHS. There were 69,333 cholecystectomies performed in the UK in 2013/14, of these 64,347 were laparoscopic cholecystectomies.

The quality standard is expected to contribute to improvements in the following outcomes:

- quality of life for adults with gallstone disease
- acute admissions for adults with gallstone disease
- length of stay for adults with gallstone disease
- surgical complication rates for adults with gallstone disease.

How this quality standard supports delivery of outcome frameworks

NICE quality standards are a concise set of prioritised statements designed to drive measurable improvements in the 3 dimensions of quality – patient safety, patient experience and clinical effectiveness – for a particular area of health or care. They are derived from high-quality guidance, such as that from NICE or other sources accredited by NICE. This quality standard, in conjunction with the guidance on which it is based, should contribute to the improvements outlined in the following 2 outcomes frameworks published by the Department of Health:

- [NHS Outcomes Framework 2015–16](#)
- [Public Health Outcomes Framework 2013–2016](#).

Tables 1 and 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 2015–16](#)

Domain	Overarching indicators and improvement areas
3 Helping people to recover from episodes of ill health or following injury	<p>Overarching indicator</p> <p>3b Emergency readmission within 30 days of discharge from hospital (PHOF 4.11*)</p> <p>Improvement areas</p> <p>Improving outcomes from planned treatments</p> <p>3.1 Total health gain as assessed by patients for elective procedures</p> <p>i <i>Physical health-related procedures</i></p>
4 Ensuring that people have a positive experience of care	<p>Overarching indicator</p> <p>4b Patient experience of hospital care</p> <p>4c <i>Friends and family test</i></p> <p>4d <i>Patient experience characterised as poor or worse</i></p> <p>ii <i>Hospital care</i></p> <p>Improvement areas</p> <p>Improving people's experience of outpatient care</p> <p>4.1 Patient experience of outpatient services</p> <p>Improving hospitals' responsiveness to personal needs</p> <p>4.2 Responsiveness to in-patients personal needs</p> <p>Improving people's experience of accident and emergency services</p> <p>4.3 Patient experience of A&E services</p>
5 Treating and caring for people in a safe environment and protecting them from avoidable harm	<p>Overarching indicator</p> <p>5b <i>Severe harm attributable to problems in healthcare</i></p> <p>Improvement areas</p> <p>Improving the culture of safety reporting</p> <p>5.6 Patient safety incidents reported</p>
<p>Alignment with Adult Social Care Outcomes Framework and/or Public Health Outcomes Framework</p> <p>* Indicator is shared</p> <p><i>Indicators in italics are in development</i></p>	

Table 2 [Public health outcomes framework for England, 2013–2016](#)

Domain	Objectives and indicators
4 Healthcare public health and preventing premature mortality	<p>Objective</p> <p>Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities</p> <p>Indicators</p> <p>4.11 Emergency readmissions within 30 days of discharge from hospital (NHSOF 3b*)</p>

Alignment across the health and social care system

* Indicator shared

Patient experience and safety issues

Ensuring that care is safe and that adults have a positive experience of care is vital in a high-quality service. It is important to consider these factors when planning and delivering services relevant to gallstone disease.

NICE has developed guidance and an associated quality standard on patient experience in adult NHS services (see the NICE pathway on [patient experience in adult NHS services](#)), which should be considered alongside this quality standard. They specify that people receiving care should be treated with dignity, have opportunities to discuss their preferences, and are supported to understand their options and make fully informed decisions. They also cover the provision of information to patients. Quality statements on these aspects of patient experience are not usually included in topic-specific quality standards. However, recommendations in the development sources for quality standards that affect patient experience and are specific to the topic are considered during quality statement development.

Coordinated services

The quality standard for gallstone disease specifies that services should be commissioned from and coordinated across all relevant agencies encompassing the whole gallstone disease care pathway. A person-centred, integrated approach to providing services is fundamental to delivering high-quality care to adults with gallstone disease.

The Health and Social Care Act 2012 sets out a clear expectation that the care system should consider NICE quality standards in planning and delivering services, as part of a general duty to secure continuous improvement in quality.

Commissioners and providers of health and social care should refer to the library of NICE quality standards when designing high-quality services. Other quality standards that should also be considered when choosing, commissioning or

providing a high-quality gallstone disease service are listed in Related quality standards.

Training and competencies

The quality standard should be read in the context of national and local guidelines on training and competencies. All healthcare professionals involved in assessing, caring for and treating adults with gallstone disease should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard. Quality statements on staff training and competency are not usually included in quality standards. However, recommendations in the development source on specific types of training for the topic that exceed standard professional training are considered during quality statement development.

Role of families and carers

Quality standards recognise the important role families and carers have in supporting adults with gallstone disease. If appropriate, healthcare professionals should ensure that family members and carers are involved in the decision-making process about investigations, treatment and care.

List of quality statements

[Statement 1](#). Adults with acute cholecystitis have laparoscopic cholecystectomy within 1 week of diagnosis.

[Statement 2](#). Adults with common bile duct stones have prompt access to endoscopic retrograde cholangiopancreatography.

[Statement 3](#). Adults with gallstone disease who have not had their gallbladder or gallstones removed discuss their diet with their healthcare professional.

Questions for consultation

Questions about the quality standard

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

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?

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

Questions about the individual quality statements

Question 4 For draft quality statement 2: Can prompt be defined in this quality statement and if so can a definition be provided?

Quality statement 1: Acute cholecystitis

Quality statement

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

Rationale

The earlier a laparoscopic cholecystectomy is performed, the less potential there is for recurrent events such as inflammation and the infection spreading during the wait for surgery. If laparoscopic cholecystectomy cannot be performed within 1 week of diagnosis of acute cholecystitis surgery should be delayed until the acute episode has subsided (more than 4 weeks after diagnosis).

Quality measures

Structure

a) Evidence of local arrangements to ensure that adults with acute cholecystitis have laparoscopic cholecystectomy within 1 week of diagnosis.

Data source: Local data collection.

b) Evidence of local arrangements to ensure that secondary care services that offer laparoscopic cholecystectomy regularly perform the surgery.

Data source: Local data collection.

Process

Proportion of adults with acute cholecystitis who have a laparoscopic cholecystectomy within 1 week of diagnosis.

Numerator – the number in the denominator who have a laparoscopic cholecystectomy within 1 week of diagnosis.

Denominator – the number of adults with acute cholecystitis.

Data source: Local data collection.

Outcome

a) Acute readmission rates for adults with acute cholecystitis.

Data source: Local data collection.

b) Length of stay for adults with acute cholecystitis.

Data source: Local data collection.

c) Quality of life for adults with acute cholecystitis.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (such as secondary care services) ensure that surgeons are trained to perform laparoscopic cholecystectomy, and that the procedure is performed within 1 week of diagnosis of acute cholecystitis.

Healthcare professionals are trained to perform laparoscopic cholecystectomy, and perform this procedure within 1 week of diagnosis of acute cholecystitis.

Commissioners (such as clinical commissioning groups) monitor that services that offer laparoscopic cholecystectomy regularly perform the surgery, and that they perform laparoscopic cholecystectomy within 1 week of diagnosis acute cholecystitis.

What the quality statement means for patients and carers

Adults with acute cholecystitis (infection in the gallbladder) have keyhole surgery to remove their gallbladder (part of the digestive system) within 1 week of the infection being diagnosed, to reduce the risk of inflammation and the infection spreading while waiting to have surgery.

Source guidance

- [Gallstone disease](#) (2014) NICE guideline CG188, recommendation 1.2.4 (key priority for implementation)

Definitions of terms used in this quality statement**Diagnosing acute cholecystitis**

Acute cholecystitis is diagnosed using abdominal ultrasound to confirm the presence of gallstones and signs of acute gallbladder pathology [Expert opinion].

Laparoscopic cholecystectomy

Removal of the gallbladder through 'keyhole' surgery. It should be performed within 1 week of diagnosis of acute cholecystitis. If it cannot be performed within 1 week of diagnosis surgery should be delayed until the acute episode has subsided (more than 4 weeks after diagnosis). [[Gallstone disease](#) (NICE guideline CG188)].

Quality statement 2: Prompt endoscopic retrograde cholangiopancreatography

Quality statement

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

Rationale

Endoscopic retrograde cholangiopancreatography can be used to remove common bile duct stones. Common bile duct stones should always be removed, as they can cause jaundice, inflammation or infection of the common bile duct (cholangitis), or pancreatitis. This should be done promptly, to prevent complications while waiting for treatment.

Quality measures

Structure

Evidence of local arrangements to ensure that adults with common bile duct stones in have access to prompt endoscopic retrograde cholangiopancreatography.

Data source: Local data collection.

Process

Proportion of adults with common bile duct stones who have prompt access to endoscopic retrograde cholangiopancreatography

Numerator – the number in the denominator who have prompt access to endoscopic retrograde cholangiopancreatography

Denominator – the number of adults with common bile duct stones

Data source: Local data collection

Outcome

a) Rates of cholangitis in adults with common bile duct stones.

Data source: Local data collection.

b) Rates of pancreatitis in adults with common bile duct stones.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (such as secondary care services) ensure that healthcare professionals are trained to perform endoscopic retrograde cholangiopancreatography, and to provide prompt access to this procedure for adults with common bile duct stones.

Healthcare professionals are trained to carry out endoscopic retrograde cholangiopancreatography, and provide prompt access to this procedure for adults with common bile duct stones.

Commissioners (such as clinical commissioning groups) monitor that services that offer endoscopic retrograde cholangiopancreatography regularly perform this procedure, and that they provide prompt access to this procedure for adults with common bile duct stones.

What the quality statement means for patients and carers

Adults with common bile duct stones are able to have an endoscopy (inserting a thin, flexible tube down your throat to perform surgery inside your body) promptly, to remove the stones in their bile duct (part of the digestive system that is connected to the gallbladder) and prevent other problems such as blockages, inflammation or infection.

Source guidance

- [Gallstone disease](#) (2014) NICE guideline CG188, recommendation 1.3.2 (key priority for implementation)

Definitions of terms used in this quality statement

Access to endoscopic retrograde cholangiopancreatography

Bile duct clearance and laparoscopic cholecystectomy should be offered to adults with common bile duct stones.

The bile duct should be cleared either surgically at the time of laparoscopic cholecystectomy, or with endoscopic retrograde cholangiopancreatography before or at the time of laparoscopic cholecystectomy.

[[Gallstone disease](#) (NICE guideline CG188) recommendations 1.3.1 and 1.3.2]

Question for consultation

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

Quality statement 3: Dietary advice

Quality statement

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

Rationale

Certain food and drink may trigger symptoms of gallstone disease, such as pain and discomfort. Adults with gallstone disease should be advised to avoid food and drink that triggers their symptoms while they are waiting for treatment. In addition, some adults may not be able to have treatment (for example because they are unwell), and should be given dietary advice to reflect this.

Quality measures

Structure

Evidence of local arrangements and written clinical protocols to ensure that adults with gallstone disease who have not had their gallbladder or gallstones removed discuss their diet with their healthcare professional.

Data source: Local data collection.

Process

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

Numerator – the number in the denominator who discuss their diet with their healthcare professional.

Denominator – the number of adults with gallstone disease who have not had their gallbladder or gallstones removed.

Data source: Local data collection.

Outcome

Patient experience.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (such as primary and secondary care services) ensure that systems are in place for adults with gallstone disease who have not had their gallbladder or gallstones removed to discuss their diet with their healthcare professional.

Healthcare professionals discuss diet with adults with gallstone disease who have not had their gallbladder or gallstones removed, and document it.

Commissioners (such as NHS England area teams and clinical commissioning groups) ensure that they commission services that make sure adults with gallstone disease who have not had their gallbladder or gallstones removed discuss their diet with their healthcare professional.

What the quality statement means for patients and carers

Adults with gallstone disease talk with their healthcare professional about avoiding any food or drink that triggers their symptoms until after their gallbladder (part of the digestive system) or gallstones are removed.

Source guidance

- [Gallstone disease](#) (2014) NICE guideline CG188, recommendation 1.4.1

Definitions of terms used in this quality statement

Discussion about diet

Adults with gallstone disease should be advised to avoid food and drink that triggers their symptoms until their gallbladder or gallstones are removed. Any discussion should include both oral and written information.

[Adapted from [Gallstone disease](#) (NICE guideline CG188) recommendation 1.4.1 and [Patient experience in adult NHS services](#) (NICE guideline CG138) recommendation 1.5.12]

Equality and diversity considerations

Discussions about gallstone disease should take into account any additional needs, such as physical, sensory or learning disabilities, and adults who do not speak.

Adults should have access to an interpreter or advocate if needed.

Healthcare professionals should also be aware that certain cultural groups may be more likely to eat food and drink that may trigger symptoms of gallstone disease.

Status of this quality standard

This is the draft quality standard released for consultation from 9 July to 6 August 2015. It is not NICE's final quality standard on gallstone disease. The statements and measures presented in this document are provisional and may change after consultation with stakeholders.

Comments on the content of the draft standard must be submitted by 5pm on 6 August 2015. All eligible comments received during consultation will be reviewed by the Quality Standards Advisory Committee and the quality statements and measures will be refined in line with the Quality Standards Advisory Committee's considerations. The final quality standard will be available on the [NICE website](#) from December 2015.

Using the quality standard

Quality measures

The quality measures accompanying the quality statements aim to improve the structure, process and outcomes of care in areas identified as needing quality improvement. They are not a new set of targets or mandatory indicators for performance management.

We have indicated if current national indicators exist that could be used to measure the quality statements. These include indicators developed by the Health and Social Care Information Centre through its [Indicators for Quality Improvement Programme](#). If there is no national indicator that could be used to measure a quality statement, the quality measure should form the basis for audit criteria developed and used locally.

See NICE's [What makes up a NICE quality standard?](#) for further information, including advice on using quality measures.

Levels of achievement

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of

100% should be aspired to (or 0% if the quality statement states that something should not be done). However, NICE recognises that this may not always be appropriate in practice, taking account of safety, choice and professional judgement, and therefore desired levels of achievement should be defined locally.

Using other national guidance and policy documents

Other national guidance and current policy documents have been referenced during the development of this quality standard. It is important that the quality standard is considered alongside the documents listed in Development sources

Diversity, equality and language

During the development of this quality standard, equality issues have been considered and [equality assessments](#) are available.

Good communication between healthcare professionals and adults with gallstone disease is essential. Treatment, care and support, and the information given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. Adults with gallstone disease should have access to an interpreter or advocate if needed.

Commissioners and providers should aim to achieve the quality standard in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.

Development sources

Further explanation of the methodology used can be found in the quality standards [Process guide](#).

Evidence sources

The documents below contain recommendations from NICE guidance or other NICE-accredited recommendations that were used by the Quality Standards Advisory Committee to develop the quality standard statements and measures.

- [Gallstone disease](#) (2014) NICE guideline CG188

Policy context

It is important that the quality standard is considered alongside current policy documents, including:

- British Society of Gastroenterology (2014) [ERCP – The way forward: A standards framework](#)

Definitions and data sources for the quality measures

- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138

Related NICE quality standards

Published

- [Surgical site infection](#) (2013) NICE quality standard 49
- [Patient experience in adult NHS services](#) (2012) NICE quality standard 15

In development

- [Dyspepsia and gastro-oesophageal reflux disease](#). Publication due July 2015

Future quality standards

This quality standard has been developed in the context of all quality standards referred to NICE, including the following topics scheduled for future development:

- Out of hours care
- Pancreatitis (including acute pancreatitis)
- Perioperative care

The full list of quality standard topics referred to NICE is available from the [quality standards topic library](#) on the NICE website.

Quality Standards Advisory Committee and NICE project team

Quality Standards Advisory Committee

This quality standard has been developed by Quality Standards Advisory Committee 1. Membership of this committee is as follows:

Dr Gita Bhutani

Professional Lead, Psychological Services, Lancashire Care NHS Foundation Trust

Mrs Jennifer Bostock

Lay member

Dr Helen Bromley

Consultant in Public Health, Cheshire West and Chester Council

Dr Hasan Chowhan

GP, NHS North East Essex Clinical Commissioning Group

Ms Amanda de la Motte

Service Manager/Lead Nurse Hospital Avoidance Team, Central Nottinghamshire Clinical Services

Mr Phillip Dick

Psychiatric Liaison Team Manager, West London Mental Health Trust

Ms Phyllis Dunn

Clinical Lead Nurse, University Hospital of North Staffordshire

Dr Nourieh Hoveyda (until May 2015)

Consultant in Public Health Medicine, London

Dr Ian Manifold

Head of Measures Development, National Peer Review Programme, NHS England

Mr Gavin Maxwell

Lay member

Ms Teresa Middleton

Deputy Director of Quality, NHS Gloucestershire Clinical Commissioning Group

Mrs Juliette Millard

UK Nursing and Health Professions Adviser, Leonard Cheshire Disability

Hazel Trender

Senior Vascular Nurse Specialist, Sheffield Teaching Hospital Trust

Dr Hugo van Woerden

Director of Public Health, NHS Highland

Professor Bee Wee (Chair)

Consultant and Senior Clinical Lecturer in Palliative Medicine, Oxford University Hospitals NHS Trust and Oxford University

Ms Karen Whitehead

Strategic Lead Health, Families and Partnerships, Bury Council

Ms Alyson Whitmarsh

Programme Head for Clinical Audit, Health and Social Care Information Centre

Ms Jane Worsley

Chief Operating Officer, Options Group, Alcester Heath, Warwickshire

Dr Arnold Zermansky

GP, Leeds

The following specialist members joined the committee to develop this quality standard:

Mrs Elaine Dobson Evans

Lay member

Mr Simon Dwerryhouse

Consultant Upper Gastrointestinal Surgeon, Gloucestershire Hospitals NHS Foundation Trust

Mrs Gerri Mortimore

Lead Nurse Specialist Hepatology, Royal Derby Hospital Foundation Trust

Dr Kofi Oppong

Consultant Gastroenterologist, Newcastle upon Tyne NHS Foundation Trust

Dr Luke Williams

Consultant Gastrointestinal Radiologist, Salford Royal NHS Foundation Trust and Central Manchester NHS Foundation Trust

NICE project team

Nick Baillie

Associate Director

Karen Slade

Consultant Clinical Adviser

Stephanie Birtles

Technical Adviser

Shaun Rowark

Lead Technical Analyst

Esther Clifford

Programme Manager

Jenny Mills

Project Manager

Jenny Mills

Co-ordinator

About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

The methods and processes for developing NICE quality standards are described in the [quality standards process guide](#).

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