NICE National Institute for Health and Care Excellence

NICE quality standard

Gallstone disease

Quality standard

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Contents

This standard is based on CG188.

This standard should be read in conjunction with QS96, QS49 and QS15.

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 (stones that are only found in the gallbladder and that cause no 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 their 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. Based on data from Hospital Episode Statistics 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
- readmission rates 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 2013–16.

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	*Overarching indicator* 3b Emergency readmission within 30 days of discharge from hospital (PHOF 4.11*) *Improvement areas* **Improving outcomes from planned treatments** 3.1 Total health gain as assessed by patients for elective procedures i *Physical health-related procedures*
4 Ensuring that people have a positive experience of care	*Overarching indicator* 4b Patient experience of hospital care 4c *Friends and family test* 4d *Patient experience characterised as poor or worse* ii *Hospital care* *Improvement areas* **Improving people's experience of outpatient care** 4.1 Patient experience of outpatient services **Improving hospitals' responsiveness to personal needs** 4.2 Responsiveness to in-patients personal needs **Improving people's experience of accident and emergency services** 4.3 Patient experience of A&E services
5 Treating and caring for people in a safe environment and protecting them from avoidable harm	*Overarching indicator* *5b Severe harm attributable to problems in healthcare* *Improvement areas* **Improving the culture of safety reporting** 5.6 Patient safety incidents reported

Alignment with Adult Social Care Outcomes Framework and/or Public Health Outcomes Framework
* Indicator is shared
Indicators in italics are in development

Table 2 Public health outcomes framework for England, 2013–16

Domain	Objectives and indicators
4 Healthcare public health and preventing premature mortality	*Objective* Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities *Indicators* 4.11 Emergency readmissions within 30 days of discharge from hospital (NHSOF 3b*)
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(s) 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 causing jaundice have endoscopic retrograde cholangiopancreatography within 72 hours of diagnosis.

Statement 3. Adults with common bile duct stones who need emergency endoscopic retrograde cholangiopancreatography have it within 24 hours.

Statement 4. Adults with symptomatic gallstone disease who have not had their gallbladder or gallstones removed are advised to avoid food and drink that triggers their symptoms.

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 procedure.

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. National data can be collected from the Health and Social Care Information Centre's Hospital Episode Statistics.

b) Length of stay for adults with acute cholecystitis.

Data source:Local data collection. National data can be collected from the Health and Social Care Information Centre's Hospital Episode Statistics.

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 adults with acute cholecystitis can have the procedure within 1 week of diagnosis.

Healthcare professionals (such as upper gastrointestinal surgeons) are trained to perform laparoscopic cholecystectomy, and provide it to adults with acute cholecystitis within 1 week of diagnosis.

Commissioners (such as clinical commissioning groups) monitor services that offer laparoscopic cholecystectomy to ensure that they regularly perform it, and that adults with acute cholecystitis can have the procedure within 1 week of diagnosis.

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 pain, swelling, 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).

[Adapted from gallstone disease (NICE guideline CG188)]

Quality statement 2: Urgent endoscopic retrograde cholangiopancreatography within 72 hours

Quality statement

Adults with common bile duct stones causing jaundice have endoscopic retrograde cholangiopancreatography within 72 hours of diagnosis.

Rationale

Endoscopic retrograde cholangiopancreatography can be used to treat common bile duct stones. Adults should have the procedure performed within 72 hours of diagnosis of common bile duct stones if these are causing jaundice, to prevent further complications such as cholangitis while waiting for treatment.

Quality measures

Structure

Evidence of local arrangements to ensure that adults with common bile duct stones causing jaundice have endoscopic retrograde cholangiopancreatography within 72 hours of diagnosis.

Data source: Local data collection.

Process

Proportion of adults with common bile duct stones causing jaundice who have endoscopic retrograde cholangiopancreatography within 72 hours of diagnosis.

Numerator – the number in the denominator who have endoscopic retrograde cholangiopancreatography within 72 hours of diagnosis.

Denominator – the number of adults with common bile duct stones causing jaundice.

Data source: Local data collection.

Outcome

Rates of cholangitis 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 that adults can have it within 72 hours of diagnosis of common bile duct stones, if these are causing jaundice.

Healthcare professionals (such as gastroenterologists, radiologists and upper gastrointestinal surgeons) are trained to perform endoscopic retrograde cholangiopancreatography, and provide it for adults within 72 hours of diagnosis of common bile duct stones, if these are causing jaundice.

Commissioners (such as clinical commissioning groups) monitor services that offer endoscopic retrograde cholangiopancreatography to ensure that they regularly perform it, and that adults can have this procedure within 72 hours of diagnosis of common bile duct stones, if these are causing jaundice.

What the quality statement means for patients and carers

Adults with common bile duct stones causing jaundice are able to have an endoscopy (inserting a thin, flexible tube down their throat to perform surgery inside their body) within 72 hours of getting their diagnosis. The endoscopy is 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) and expert consensus.
- Royal College of Surgeons (2013) Commissioning guide: gallstone disease, section 1.2.

Quality statement 3: Emergency endoscopic retrograde cholangiopancreatography within 24 hours

Quality statement

Adults with common bile duct stones who need emergency endoscopic retrograde cholangiopancreatography have it within 24 hours.

Rationale

Endoscopic retrograde cholangiopancreatography can be used to treat common bile duct stones. Not everybody will need this procedure within 24 hours, but emergency endoscopic retrograde cholangiopancreatography can improve outcomes for adults with acute cholangitis or acute pancreatitis if their condition is not responding to antibiotics or intravenous fluids. Delaying endoscopic retrograde cholangiopancreatography for adults with these conditions risks complications such as sepsis.

Quality measures

Structure

Evidence of local arrangements to ensure that adults with common bile duct stones who need emergency endoscopic retrograde cholangiopancreatography have it within 24 hours.

Data source: Local data collection.

Process

Proportion of adults with common bile duct stones who need emergency endoscopic retrograde cholangiopancreatography who have it within 24 hours.

Numerator – the number in the denominator who have endoscopic retrograde cholangiopancreatography within 24 hours.

Denominator – the number of adults with common bile duct stones who need emergency endoscopic retrograde cholangiopancreatography.

Data source: Local data collection.

Outcome

Rates of sepsis 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 that adults with common bile duct stones who need this procedure in an emergency can have it within 24 hours. For 24-hour endoscopic retrograde cholangiopancreatography, service providers may need to be aware of local networks.

Healthcare professionals (such as gastroenterologists, radiologists and upper gastrointestinal surgeons) are trained to perform endoscopic retrograde cholangiopancreatography, and provide it for adults with common bile duct stones who need it in an emergency within 24 hours.

Commissioners (such as clinical commissioning groups) monitor services that offer endoscopic retrograde cholangiopancreatography to ensure that they regularly perform it, and that adults with common bile duct stones can have it as an emergency within 24 hours if needed.

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 their throat to perform surgery inside their body) within 24 hours if they need it in an emergency. The endoscopy is 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) and expert consensus.
- Royal College of Surgeons (2013) Commissioning guide: gallstone disease, section 1.2.

Definitions of terms used in this quality statement

Emergency endoscopic retrograde cholangiopancreatography

Emergency endoscopic retrograde cholangiopancreatography (within 24 hours) is needed for adults with common bile duct stones and acute cholangitis or acute pancreatitis when indicated.

[Adapted from gallstone disease (NICE guideline CG188) recommendations 1.3.1 and 1.3.2, and Royal College of Surgeons (2013) Commissioning guide: gallstone disease, section 1.2 and expert consensus]

Quality statement 4: Advice to prevent symptoms

Quality statement

Adults with symptomatic gallstone disease who have not had their gallbladder or gallstones removed are advised to avoid food and drink that triggers their symptoms.

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 be 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 symptomatic gallstone disease who have not had their gallbladder or gallstones removed are advised to avoid food and drink that triggers their symptoms.

Data source: Local data collection.

Process

Proportion of adults with symptomatic gallstone disease who have not had their gallbladder or gallstones removed who are advised to avoid food and drink that triggers their symptoms.

Numerator – the number in the denominator who are advised to avoid food and drink that triggers their symptoms.

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

Data source: Local data collection.

Outcome

a) Patient experience.

Data source:Local data collection.

b) Quality of life for adults with gallstone disease.

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 symptomatic gallstone disease who have not had their gallbladder or gallstones removed to be advised to avoid food and drink that triggers their symptoms.

Healthcare professionals (such as GPsand gastroenterologists) advise adults with symptomatic gallstone disease who have not had their gallbladder or gallstones removed to avoid food and drink that triggers their symptoms. Healthcare professionals should document the advice that is given.

Commissioners (such as NHS England area teams and clinical commissioning groups) ensure that they commission services that make sure adults with symptomatic gallstone disease who have not had their gallbladder or gallstones removed are advised to avoid food and drink that triggers their symptoms.

What the quality statement means for patients and carers

Adults with symptomatic gallstone disease who have not had their gallbladder or gallstones removed are advised by their healthcare professional to avoid any food or drink that triggers their symptoms.

Source guidance

- Gallstone disease (2014) NICE guideline CG188, recommendation 1.4.1.

Definitions of terms used in this quality statement

Advice

Any advice given by a healthcare professional should include both oral and written information.

[Patient experience in adult NHS services (NICE guideline CG138) recommendation 1.5.12]

Equality and diversity considerations

Advice about gallstone disease should take into account any additional needs, such as physical, sensory or learning disabilities, and adults who do not speak English. 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. People who are homeless may also be less able to avoid certain food and drink.

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
- Royal College of Surgeons (2013) Commissioning guide: gallstone disease

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

- Health and Social Care Information Centre (2015) Hospital Episode Statistics
- Patient experience in adult NHS services (2012) NICE guideline CG138

Related NICE quality standards

Published

- Dyspepsia and gastro-oesophageal reflux disease (2015) NICE quality standard 96
- Surgical site infection (2013) NICE quality standard 49
- Patient experience in adult NHS services (2012) NICE quality standard 15

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

QSAC 1

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

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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.

This quality standard has been incorporated into the NICE pathway on gallstone disease.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

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Endorsing organisation

This quality standard has been endorsed by NHS England, as required by the Health and Social Care Act (2012)

Supporting organisations

Many organisations share NICE's commitment to quality improvement using evidence-based

guidance. The following supporting organisations have recognised the benefit of the quality standard in improving care for patients, carers, service users and members of the public. They have agreed to work with NICE to ensure that those commissioning or providing services are made aware of and encouraged to use the quality standard.

- Royal College of General Practitioners
- Royal College of Nursing