

2013

Commissioning guide:

Gallstone disease



Sponsoring organisation:
Date of evidence search:
Date of publication:
Date of review:

Association of Upper Gastrointestinal Surgeons
April 2013
October 2013
October 2016



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Glossary

Term	Definition
CBD	Common bile duct
ERCP	Endoscopic retrograde cholangiopancreatography
LFT	Liver function test
UGI	Upper gastrointestinal

Introduction

This guidance focuses on the treatment of patients aged 18 years and over with gallstones. In the UK around 10–15% of the adult population have gallstones.

The majority of people with gallbladder stones remain asymptomatic and require no treatment. The definitive treatment of symptomatic gallbladder stones is surgical removal of the gallbladder.

Common bile duct (CBD) stones may present with symptoms of jaundice, cholangitis or pancreatitis, or be asymptomatic. All CBD stones should be referred for treatment because of the risk of potential severe complications.

Around 57,000 cholecystectomies were performed in England in 2012 with over a threefold variation across clinical commissioning group (CCG) areas, ranging from 112 procedures per 100,000 population to 371 procedures per 100,000 population (Fig 1). This variation may be due to a variety of reasons including lower thresholds to perform surgery in some CCGs or underreferral in others.

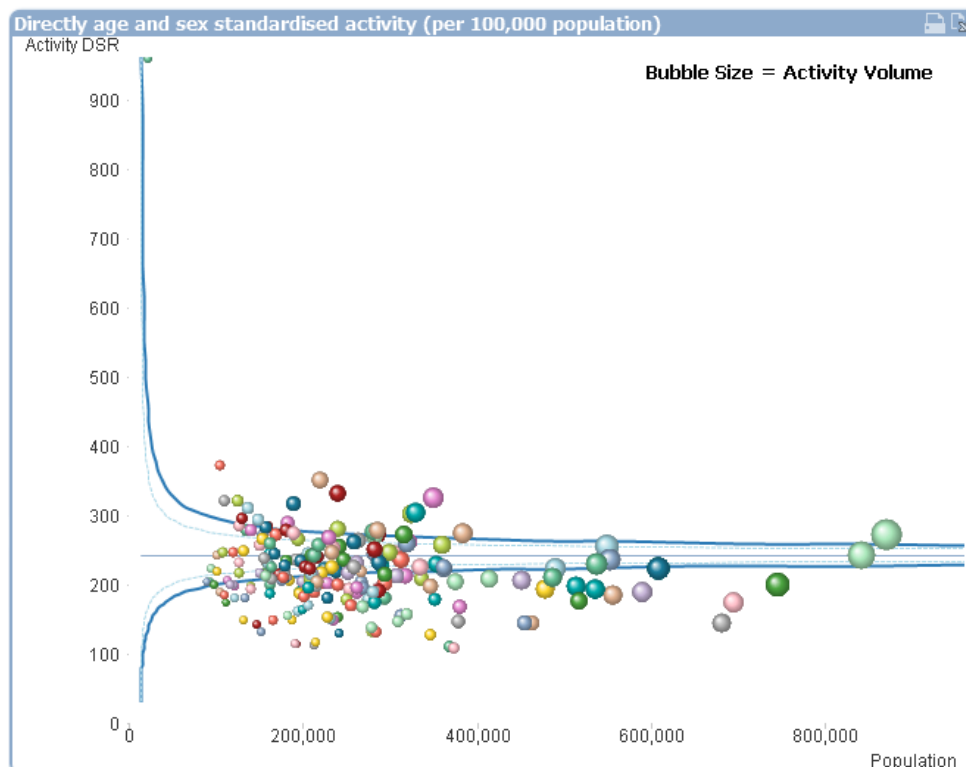


Figure 1: Age and sex standardised activity volume of cholecystectomies per 100,000 population per CCG (each bubble representing a CCG) for 2012

The above information is available in an [interactive web-based tool](#) allowing CCGs to drill down into their own data.

1 High value care pathway for gallstone disease

1.1 Primary care

Non-referral

- Patients with an incidental finding of stones in an otherwise normal gallbladder require no further investigation or referral.

Primary care management

- Most patients with symptomatic gallstones present with a self-limiting attack of pain that lasts for hours only. This can often be controlled successfully in primary care with appropriate analgesia, avoiding the requirement for emergency admission. When pain cannot be managed or if the patient is otherwise unwell (eg sepsis), he or she should be referred to hospital as an emergency.
- Further episodes of biliary pain can be prevented in around 30% of patients by adopting a low fat diet. Fat in the stomach releases cholecystokinin, which precipitates gallbladder contraction and might result in biliary pain.
- Patients with suspicion of acute cholecystitis, cholangitis or acute pancreatitis should be referred to hospital as an emergency.
- There is no evidence to support the use of hyoscine or proton pump inhibitors in the management of gallbladder symptoms. Antibiotics should be reserved for patients with signs of sepsis.
- There is no evidence of benefit from the use of non-surgical treatments in the definitive management of gallbladder stones (eg gallstone dissolution therapies, ursodeoxycholic acid or extracorporeal lithotripsy).

Best practice referral guidelines

- Epigastric or right upper quadrant pain, frequently radiating to the back, lasting for several minutes to hours (often occurring at night) suggests symptomatic gallstones. These patients should have liver function tests checked and be referred for ultrasonography.
- Confirmation of symptomatic gallstones should result in a discussion of the merits of a referral to a surgical service regularly performing cholecystectomies.
- Following treatment for CBD stones with endoscopic retrograde cholangiopancreatography (ERCP) and sphincterotomy, removal of the gallbladder should be considered in all patients. However, in patients with significant co-morbidities, the risks of surgery may outweigh the benefits.

- Patients with known gallstones with a history of acute pancreatitis should be referred for a cholecystectomy to a surgical service regularly performing the procedure.
- Patients with known gallstones and jaundice or clinical suspicion of biliary obstruction (eg significantly abnormal liver function tests) should be referred urgently to a gastroenterology or surgical service with expertise in managing biliary diseases.

1.2 Secondary care

- In patients with symptomatic gallstones, the decision to operate is made by the patient with guidance from the surgeon. This will include assessment of the risk of recurrent symptoms and complications of the gallstones (50% risk per annum of further episode of biliary colic and 1–2% risk per annum of development of serious complications), and the risks and complication rates of surgery in relation to the individual patient's co-morbidities and preference.
- Patients with acute gallstone pancreatitis should undergo definitive treatment (usually cholecystectomy although an endoscopic sphincterotomy may be appropriate in frail patients) within two weeks of recovery from the incident episode, as described in the [UK guidelines for the management of acute pancreatitis](#).
- If the cause of abnormal liver function tests +/- dilated bile ducts is unclear on initial imaging, further investigation is required. This will usually be with preoperative magnetic resonance cholangiopancreatography or endoscopic ultrasonography. ERCP should be reserved for therapy, not as a diagnostic test for bile duct stones. Preoperative on-table cholangiography is an alternative strategy in units that offer laparoscopic bile duct exploration.
- Patients with symptomatic CBD stones should undergo CBD stone extraction by ERCP or surgical bile duct exploration (laparoscopic or open). Patients with asymptomatic gallstones should also be considered for stone extraction.
- The laparoscopic approach to cholecystectomy should be considered the standard for the majority of patients.
- Secondary providers offering cholecystectomy must be able to offer intraoperative on-table cholangiography and have arrangements in place for urgent access to ERCP and interventional radiology for the management of postoperative complications.
- Patients who have a suspected bile duct injury should be referred to their regional tertiary hepatopancreatobiliary service.

Care pathway for gallstone disease

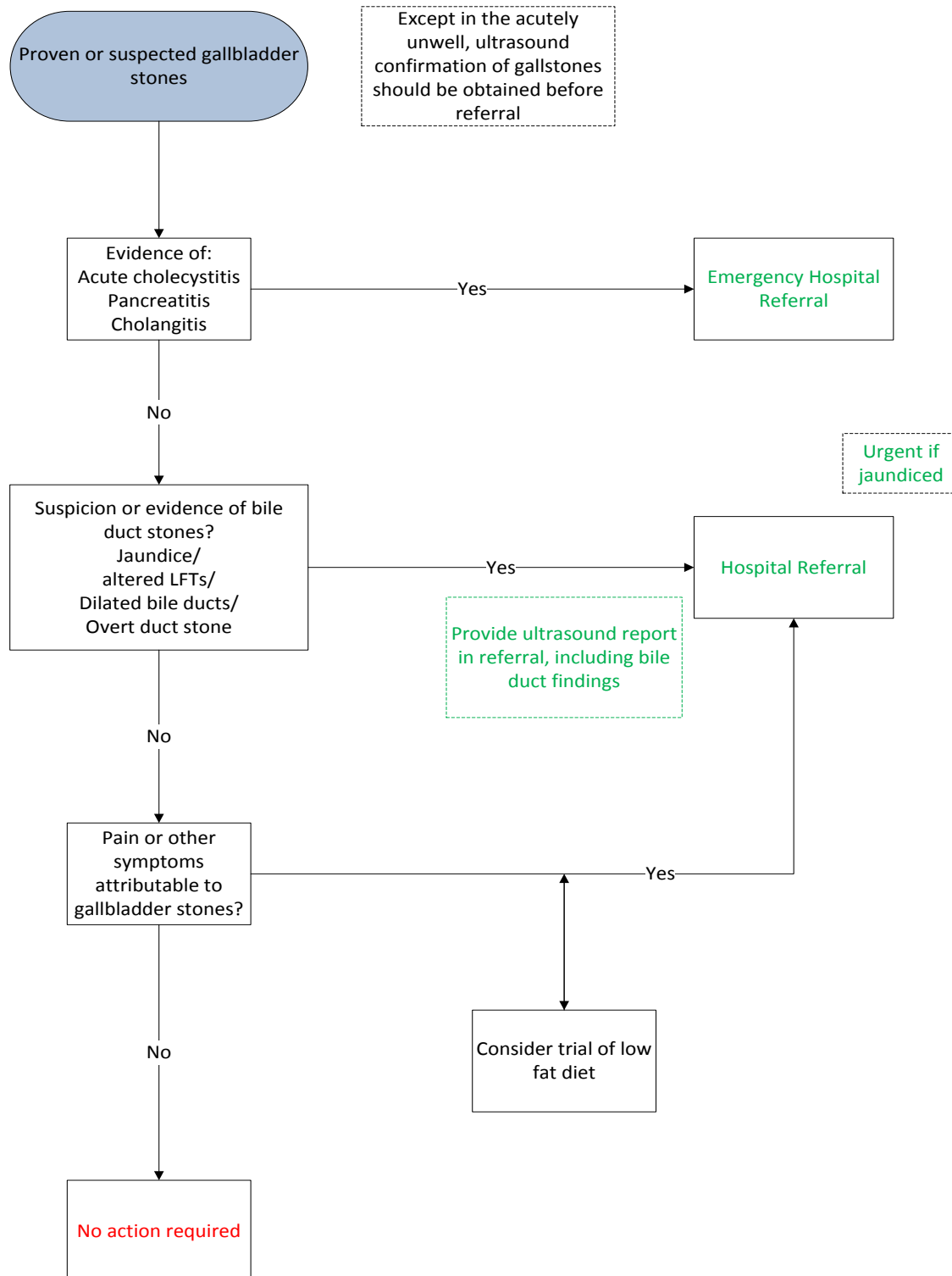


Figure 2: Patient pathway

2 Procedures explorer for gallstone disease

Users can access further procedure information based on the Hospital Episode Statistics data available in the quality dashboard to see how individual providers are performing against the indicators. This will enable CCGs to start a conversation with providers who appear to be ‘outliers’ from the indicators of quality that have been selected.

The procedures explorer tool is available via the [Royal College of Surgeons](#) website.

Within the tool there is also a [meta data document](#) to show how each indicator was derived. Full [instructions](#) are also available, which explain how to interpret the data.


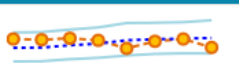
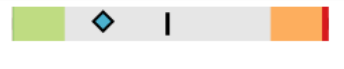
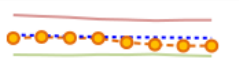


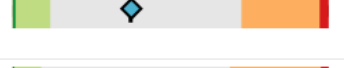





3 Quality dashboard for gallstone disease

The quality dashboard provides an overview of activity commissioned by CCGs from the relevant pathways and indicators of the quality of care provided by surgical units.

The quality dashboard is available via the [Royal College of Surgeons](#) website.

Example quality dashboard for Quarter 3 2012–2013:

NHS NOTTINGHAM CITY CCG General Surgery-Gall Bladder Disease Gallstones

Metric	Period	Value	Mean	Chart	Trend
Age/Sex Standardised Activity (per 100,000 population)	RY Q3 1213	96.93	108.09		
Average Length of Stay (Days)	RY Q3 1213	0.70	1.13		
7 Day Readmission Rate (%)	RY Q3 1213	8.58	5.30		
30 Day Readmission Rate (%)	RY Q3 1213	8.91	8.97		
30 Day Reoperation Rate (%)	RY Q3 1213	4.62	4.59		
Daycase Rate (%)	RY Q3 1213	60.73	44.22		

Bespoke Measures:

The following information is currently being developed for inclusion in the quality dashboards:

1. Proportion of patients with an emergency admission for gallstone disease (excluding pancreatitis) who have a cholecystectomy within ten days of initial admission date
2. Proportion of patients with an emergency admission for gallstone associated pancreatitis who have a cholecystectomy within 14 days of discharge from the initial admission
3. Proportion of elective cholecystectomies completed laparoscopically
4. Proportion of day-case cholecystectomy patients who are converted to inpatients
5. Rate of unscheduled readmission for gallstone disease within one year of any previous gallstone disease admission
6. Proportion of patients who have ERCP who have previously undergone one or more ERCP procedures for gallstone disease, within one year (attributed to site that performed the first ERCP)
7. Rate of bile duct injuries (defined as patients who go on to have major reconstruction, excluding patients with cancer)

4 Levers for implementation

4.1 Audit and peer review measures

The following measures and standards are those expected at primary and secondary care. Evidence should be made available to commissioners if requested.

Audit	Description	Specification
Audit	Provider can demonstrate regular local audit for cholecystectomy and ERCP outcomes, in reference to any national guidelines	
Patient care pathway	Providers can demonstrate implementation of developed patient care pathway across primary, secondary and tertiary care	
Laparoscopic cholecystectomy (LC) for acute gallstone	Should conform with British Society of Gastroenterology (BSG) national	Quality dashboard

pancreatitis guidelines

4.2 Quality specification/CQUIN (Commissioning for Quality and Innovation)

Measure	Description	Data specification (if required)
Readmission rates after cholecystectomy within 30 days	Readmission rates should be <10%	Procedure explorer
Day-case rates	Provider demonstrates day-case rates for LC	Procedure explorer
Proportion of patients undergoing emergency cholecystectomy	High volume of patients treated by cholecystectomy within index admission	Quality dashboard (Bespoke Measure 1)
Proportion of patients undergoing elective laparoscopic surgery	Low rates of open cholecystectomy	Quality dashboard (Bespoke Measure 3)
Day -case LC admission rates	Low rates of admission after day-case LC	Quality dashboard
Timely management of gallstone disease	Patients with symptomatic gallstone disease sufficient to cause acute admission should have timely definitive management	Quality dashboard (Bespoke Measure 6)
Safety of LC	Zero bile duct injury rates	Quality dashboard (Bespoke Measure 7)

5 Directory

5.1 Patient information for gallstone disease

Publisher	Link
British Society of Gastroenterology	http://www.bsg.org.uk/patients/general/gallstones.html
British Liver Trust	http://79.170.44.126/britishlivertrust.org.uk/home-2/liver-information/liver-conditions/gallstones/
NHS Choices	http://www.nhs.uk/conditions/gallstones/

Right Care

<http://sdm.rightcare.nhs.uk/pda/gallstones/>

5.2 Clinician information for gallstone disease

Name	Publisher	Link
Gallstones	National Institute for Health and Care Excellence	http://www.evidence.nhs.uk/topic/gallstones
UK guidelines for the management of acute pancreatitis	UK Working Party on Acute Pancreatitis	http://gut.bmj.com/content/54/suppl_3/iii1.full
BSG Quality and Safety Indicators of Endoscopy	Joint Advisory Group on GI Endoscopy	http://www.thejag.org.uk/downloads%5CUnit%20Resources%5CBSG%20Quality%20and%20Safety%20Indicators.pdf

6 Benefits and risks of implementing this guide

Consideration	Benefit	Risk
Patient outcome	Ensure universal access to best quality, timely and effective surgical treatment	
Patient safety	Reduce injury and readmission rates arising from gallstone disease	Complications of surgery or ERCP
Patient experience	Improve access to patient information sites	Poor dissemination or uptake of pathway
Equity of access	Equalise access rates nationally	Increase in marginal decisions in favour of surgery
Resource impact	Reduce unnecessary referral to non-surgical units where intervention not available	Increase in demand for services and pressure on non-gallstone disease related services elsewhere

7 Further information

7.1 Research recommendations

- Patient reported outcome measures – treated versus untreated mildly symptomatic gallbladder stones
- Optimal management of large CBD stones

7.2 Other recommendations

- Development of a national registry for bile duct injuries

7.3 Evidence base

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7.4 Guide development group for gallstone disease

A commissioning guidance development group was established to review and advise on the content of the commissioning guide. This group met three times, with additional interaction taking place via email.

Name	Job title/role	Affiliation
Ian Beckingham	Chair Consultant General Surgeon	Association of Upper Gastrointestinal Surgeons (AUGIS)
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Nick Everitt	Consultant General Surgeon	AUGIS
Mark Deakin	Consultant General Surgeon	AUGIS
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7.5 Funding statement

The development of this commissioning guidance has been funded by the following sources:

- Right Care funded the costs of the guide development group, literature searches and contributed towards administrative costs.
- The Royal College of Surgeons of England and AUGIS provided staff to support the guideline development.

7.6 Conflict of interest statement

Individuals involved in the development and formal peer review of commissioning guides are asked to complete a conflict of interest declaration. It is noted that declaring a conflict of interest does not imply that the individual

has been influenced by his or her secondary interest. It is intended to make interests (financial or otherwise) more transparent and to allow others to have knowledge of the interest.

- No interests were declared by the group.