

Appendix B: Scope

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

Post publication note: The title of this guideline changed during development. This scope was published before the guideline title change and uses the previous title.

1. Guideline title

Cholelithiasis and cholecystitis: diagnosis and management of cholelithiasis and cholecystitis.

1.1 Short title

Cholelithiasis and cholecystitis.

2. The remit

The Department of Health has asked NICE to produce a guideline on the diagnosis and management of cholelithiasis and cholecystitis.

3. Clinical need for the guideline

3.1 Epidemiology

Cholelithiasis ('gallstones') is the term used to describe discrete, hard fatty or mineral deposits ('calculus') that are formed in the gallbladder. Approximately 15% of the UK adult population are thought to have the condition. Cholelithiasis is a generic term that includes both calculi found in the gallbladder (cholecystolithiasis) and those found in other parts of the biliary tree (choledocholithiasis).

Eighty per cent of people with cholelithiasis are asymptomatic meaning they experience no symptoms or have non-specific symptoms such as pain in their

abdomen, stomach, back or shoulder, which may be misattributed to other conditions such as dyspepsia or general back ache. In most cases, asymptomatic cholelithiasis is detected incidentally through imaging such as ultrasound or MRI as part of investigations for other conditions.

For about 20% of people with cholelithiasis, the condition is symptomatic and can cause the following complications that can be extremely painful and, in some cases, life-threatening and needing emergency treatment:

- biliary colic
- cholecystitis
- cholangitis
- obstructive jaundice
- pancreatitis.

Known risk factors for cholelithiasis include:

- (in women) taking oral contraception, having high-dose oestrogen therapy, or history of pregnancy
- increasing age
- family history of gallstones
- obesity
- recent weight loss (for example, after weight loss surgery)
- digestive disorders such as Crohn's disease or irritable bowel syndrome
- cirrhosis
- taking the antibiotic ceftriaxone.

Cholecystitis is inflammation of the gallbladder. In 90% of patients cholecystitis is caused by cholelithiasis. For the remaining 10%, cholecystitis develops as a result of serious illness or injury that causes damage to the gallbladder (acalculous cholecystitis) and is associated with more serious morbidity and higher mortality rates than cholecystitis caused by cholelithiasis.

3.2 Current practice

For asymptomatic cholelithiasis, a 'watch and wait' approach is usually taken. For symptomatic cholelithiasis a conservative approach is taken for conditions such as biliary colic that may spontaneously resolve. For these patients, analgesics are used to manage the painful episode. For patients with complications that are unlikely to resolve without additional intervention (such as cholecystitis, or recurrent biliary colic), a more radical approach is taken. For these patients, cholecystectomy (surgical removal of the gallbladder) is performed. Approximately 50,000 cholecystectomies are performed each year in the UK, about one third of which are for cholecystitis. This is one of the most common surgical procedures performed in the UK.

There are differences in the timing of cholecystectomy: some procedures are carried out within 7 days of the onset of symptoms (acute cholecystectomy), and some procedures are carried out at least 6 weeks after symptoms have settled (delayed cholecystectomy). It is widely perceived that delayed cholecystectomy is safer than acute cholecystectomy because the risk of complications such as infections is thought to be lower. However, acute cholecystectomy may have important benefits compared with delayed cholecystectomy, such as shorter length of stay and potential to avoid readmission and it may also be as safe and feasible as delayed cholecystectomy.

There are uncertainties about whether some people with asymptomatic gallstones should be offered prophylactic cholecystectomy to prevent future complications.

There are uncertainties about the optimal management of cholecystitis in people for whom surgery is not appropriate.

Guidance is therefore needed to improve the way that cholelithiasis and cholecystitis are diagnosed and managed so that treatments are equitable, cost effective and improve quality of life for people with the conditions.

4. The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

- Adults with signs and symptoms of, or diagnosed with, cholelithiasis in the gallbladder and/or the biliary tract.
- Adults with signs and symptoms of, or diagnosed with, acute cholecystitis.

4.1.2 Groups that will not be covered

- Children and young people, as cholelithiasis and cholecystitis in this group are relatively rare and have a different aetiology from the adult conditions.
- Adults without signs and symptoms or a diagnosis of cholelithiasis or acute cholecystitis.
- Adults with cholecystitis that is caused by another condition such as serious illness or injury.

4.2 Healthcare setting

- All settings in which NHS care is received.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

- Procedures for diagnosing symptomatic and asymptomatic cholelithiasis.
- Procedures for diagnosing acute cholecystitis.
- The relative effectiveness of different types of surgical and non-surgical interventions for the management of symptomatic and asymptomatic cholelithiasis and acute cholecystitis.

- The timing of surgery for acute cholecystitis.
- Management of acute cholecystitis in people for whom surgery is not appropriate.
- Information for the public.

4.3.2 Clinical issues that will not be covered

- Ongoing management of conditions caused by cholelithiasis (such as cholangitis, jaundice and pancreatitis), except cholecystitis.
- Management of other underlying conditions that cause cholelithiasis and cholecystitis.
- Conditions that are not caused by cholelithiasis (for example, gallbladder injury).
- Gallbladder cancer.
- The relative effectiveness of different sub-types of open surgery (such as small incision versus open surgery).
- The relative effectiveness of different sub-types of laparoscopic surgery (such as single incision versus robot assisted).
- The relative effectiveness of different sub-types of pharmacological interventions (such as opioids versus non-opioids).

4.4 Main outcomes

- Diagnostic accuracy and clinical utility.
- Relief of symptoms (short- and long-term).
- Symptomatic stones remaining/migrated post-cholecystectomy.
- Post-cholecystectomy symptoms (including the onset of new symptoms as a result of gallbladder removal, such as diarrhoea).
- Mortality.
- Complications of surgical and non surgical interventions (such as conversion rates, injury to ducts, perforation, recovery time, post-operative care,).
- Health-related quality of life.
- Resource use and costs.

4.5 Review questions

Review questions guide a systematic review of the literature. They address only the key clinical issues covered in the scope, and usually relate to interventions, diagnosis, prognosis, service delivery or patient experience. Please note that these review questions are draft versions and will be finalised with the Guideline Development Group.

4.5.1 Diagnosis

- a) What signs and symptoms should prompt a clinician to suspect symptomatic cholelithiasis and/or acute cholecystitis in adults presenting to healthcare services?
- b) What is the most accurate strategy for diagnosing cholelithiasis and/or acute cholecystitis in adults suspected of the condition?

4.5.2 Prognosis

- c) What factors predict which patients with asymptomatic cholelithiasis who will develop acute complications?

4.5.3 Interventions

- d) Which surgical and non surgical strategies should be used for:
 - Asymptomatic cholelithiasis in patients who are at risk of acute complications
 - Asymptomatic cholelithiasis in patients who are not identified as being at risk of acute complications
 - Symptomatic cholelithiasis
 - Acute cholecystitis in patients for whom surgery is appropriate
 - Acute cholecystitis in patients for whom surgery is not appropriate
 - Any other subgroups described in the evidence.
- e) For patients with acute cholecystitis for whom cholecystectomy is appropriate, when should cholecystectomy be performed?

4.5.4 Patient information

- f) What are the education and information needs of people with a diagnosis of cholelithiasis and/or cholecystitis and their carers?

4.6 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

4.7 Status

4.7.1 Scope

This is the final scope.

4.7.2 Timing

The development of the guideline recommendations will begin in March 2013.

5. Related NICE guidance

5.1 Published guidance

5.1.1 Other related NICE guidance

- [Patient experience in adult NHS services](#). NICE clinical guideline 138 (2012).
- [Single-incision laparoscopic cholecystectomy](#). NICE interventional procedure guidance 346 (2010).
- Surgical site infection. NICE clinical guideline 74 (2008).
- [Dyspepsia](#). NICE clinical guideline 17 (2004).

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

- Dyspepsia and gastro-oesophageal reflux disease. Partial update of NICE clinical guideline 17. Publication date to be confirmed.

6. Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

- [How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS](#)
- [The guidelines manual](#).

Information on the progress of the guideline will also be available from the [NICE website](#).

