National Institute for Health and Care Excellence

Gallstone Disease
Guideline Consultation Table
5th June – 17th July 2014

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Boston Scientific	1	NICE	6 9	0	CLEAR THE BILE DUCT is a key recommendation from the draft Guideline available for consultation However we would like to comment on 1.3.3 *If the bile duct cannot be cleared with ERCP, use biliary stenting to achieve biliary drainage only as a temporary measure until definitive endoscopic or surgical clearance.*	Thank you for your comment
SH	Boston Scientific	2	NICE	6 9	0	The guideline fails to recommend/identify the **type of available options for definitive endoscopic clearance.** **We would suggest that 1.3.3 is rephrased as follows:** *"If the bile duct cannot be cleared with ERCP, use biliary stenting to achieve biliary drainage only as a temporary measure until definitive endoscopic clearance (such as a repeat ERCP with or without cholangioscopy with EHL/laser) or surgical clearance."* The comparative evidence on different alternatives for definitive duct clearance is scarce. Boston Scientific carried out a systematic literature review in 2011 aiming to summarise this evidence and highlighting that there is an important place in the patient pathway and algorithm for direct-	Thank you for your comment. Reviewing the evidence on relative effectiveness of different sub-types of interventions for managing gallstone disease (including specific types of equipment used for clearing the bile duct) is not within the scope of this guideline. Therefore the evidence that you have provided does not meet the inclusion criteria for the guideline and cannot be considered. The guideline development group felt that decisions about specific sub-types of equipment used to manage gallstone disease, including bile duct clearance, should be taken locally. The recommendations have not been amended.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						visualisation cholangioscopy instead of repeat ERCPs with a limited success rate. [attachment #1] The success of ERCP for stone clearance ranges from 87% to 97%; however 70% of interventions result in additional testing and up to 25% of patients require two or more ERCP treatments *[Ref: Shojaiefard, A., M. Esmaeilzadeh, et al. Various techniques for the surgical treatment of common bile duct stones: a meta review. Gastroenterology research & practice 2009]* Thus, in patients who will typically have larger and more complicated stones, there is a need for alternative management options. Indeed, repeat ERCPs add unnecessary costs to the healthcare system and alternative, more efficient options are available. Cholangioscopy – ie **direct visual** diagnostic evaluation and simultaneous therapeutic intervention of the bile ducts – instead of 'retrograde' visualisation (ERCP) has been available for many years however systems available were very cumbersome and resource-intensive. ERCP-guided cholangiopancreatoscopy with the SpyGlass® Direct Visulation System appeared in 2006 as a new technique for CBD stone clearance. SpyGlass has advantages over previous techniques for cholangioscopy. It enables **single operator control** of the duodenoscope and the disposable access catheter, as opposed to the two operators required for conventional cholangioscopy. SpyGlass demonstrates a high degree of complete stone clearance (up to 92% in patients with complex large CBD stones) and	

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						proves high rates of clearance in difficult stones. It is also compatible with EHL. Without direct-visualisation cholangioscopy with SpyGlass, patients are likely to undergo many repeat ERCP procedures, the success rates of which may diminish as the pathway progresses. With SpyGlass®, success rates are expected to be higher in patients with large and complicated stones so fewer costly and invasive procedures are undertaken. Two studies are published on the Spyglass system and the good outcomes in terms of definitive endoscopic clearance from cholangioscopy: Draganov (2011)23 reported complete stone clearance in 24 (92.3%) of 26 patients with detected stones. Chen (2011)24 reported complete stone clearance in 47 (71%) of 66 patients. Clearance after single and multiple treatment sessions Of those who had complete stone clearance in the Draganov study (n=24), 22 (91.7%) achieved clearance after one SpyGlass® procedure, 1 (4.2%) required a second procedure to achieve clearance, and 1 (4.2%) required a third procedure. Whilst the Chen study did not report success rates with successive procedures, the 19 patients without stone clearance with the study SpyGlass procedure subsequently underwent a total of 29 procedures to clear stones: 15 by ERCP-directed conventional stone therapy and 14 by SpyGlass-guided EHL or laser lithotripsy.	

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						We believe that these 2 studies should be included in order to advise the NHS on options for 'definitive endoscopic clearance' References: Chen YK, Parsi, MD, **Binmoeller KF, et al.** Single-operator cholangioscopy in patients requiring evaluation of bile duct disease or therapy of biliary stones (with videos). Gastrointest Endosc 2011;74:805-14 SpyGlass registry 2011.pdf [attachment #2] Draganov, P. V., T. Lin, et al. (2011). "Prospective evaluation of the clinical utility of ERCP-guided cholangiopancreatoscopy with a new direct visualization system." Gastrointestinal Endoscopy 73 (5): 971-979. ERCP systematic report FINAL211211 :	
SH	British Association of Day Surgery	1	FULL	General	General	Question 1 As requested above we do not think it would be useful to provide a list of signs and symptoms and believe that this is addressed elsewhere albeit with the caveat that the symptoms are numerous and non specific.	Thank you for your comment. A list of signs and symptoms will not be included in the guideline.
SH	British Association of Day Surgery	2	FULL	General	General	Question 2 A list would not be helpful	Thank you for your comment. A list of signs and symptoms will not be included in the guideline.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	British Association of Day Surgery	7	FULL	General	General	It appears that the data available to make recommendations are at best limited. Understanding that, would it be opportune to await the analysis of the results from the Chole S study. This has now closed and I understand that the analysis is under way. Although it is a purely observational study of current cholecystectomy practice it will have data from over 90 Trusts collected over a 3 month period. I have assumed, however, that currently you can only use published data and that any data from CholeS will probably have to wait for the next update.	Thank you for your comment. The guideline development group chose to include only randomised controlled trials in this guideline for questions about the management of people with gallstone disease. Therefore the Chole S study, when available would not meet this inclusion criteria and would therefore not be eligible for inclusion. However, the guideline development group acknowledged that consideration of observational evidence may be worthwhile in future updates of this guideline. This was because of concerns that randomised controlled trials may not be produced in this area as it would often be considered unethical to do so. This decision about including observational evidence will be undertaken during the next update of the guideline.
SH	British Association of Day Surgery	5	FULL	83	1 2,3	Is there sufficient data to enable a specific maximum time to be placed on what is "temporary" Should the recommended timing of a definitive procedure be defined.	Thank you for your comment. There was insufficient evidence available to define what 'temporary' should mean. Furthermore, the guideline development group (GDG) felt that biliary stenting is often used in complex cases where individual clinical circumstances are highly variable. The GDG agreed that stating a maximum time frame would not be useful, and doing so may lead to patient harms. Therefore no changes have been made to the guideline in response to your comment.
SH	British Association	6	FULL	83	7	Would your research recommendations extend to the point of suggesting whether we need to train	Thank you for your comment. Insufficient evidence is available to determine whether

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	of Day Surgery				8,9	surgeons in this procedure. If the analysis indicates that peri-operative ERCP is potentially the best option then it seems logical to train surgeons in the technique.	training surgeons in the use of intraoperative ERCP is beneficial. Such a decision could only be taken after sufficient research has been conducted to determine whether this intervention is practical for NHS.
SH	British Association of Day Surgery	3	FULL	95	3 4	Recommended that cholecystectomy performed within one week of diagnosis and yet a number of papers referred to cholecystectomy within 72 hours of the onset of symptoms. On this basis should the recommendation be as early as possible after diagnosis and a maximum of one week after the onset of symptoms.	Thank you for your comment. The evidence that suggested that cholecystectomy can safely be performed within 72 hours referred to the time between onset of symptoms and surgery, not the time between diagnosis and surgery. The guideline development group specifically avoided referring to the onset of symptoms because many people manage their symptoms at home, possibly for several days before seeking medical attention. Because of this, the committee felt that it would be impractical to recommend that surgery is offered within a specific timeframe from the onset of symptoms, because for some people this time period could have elapsed, or be very close to elapsing by the time they present for attention. Furthermore, the GDG were concerned that recommending that surgery should be performed within 72 hours of diagnosis would be unachievable in real-life NHS settings. Instead, the committee felt that it is more pragmatic to recommend that cholecystectomy is performed within a week of diagnosis, as this time frame is

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							supported by evidence and does not preclude surgery being performed earlier. Therefore no changes have been made to the recommendation.
SH	British Association of Day Surgery	4	FULL	99	1	Should one of these recommendations be that all specialist societies provide a generic patient information leaflet with specific questions detailed advising as what to ask from their local provider.	Thank you for your comment. A version of this guideline for the public will be made available on publication of the guideline and will contain a list of questions about what people could ask their healthcare team. It is not the responsibility of NICE to recommend what information specialist societies should provide to patients.
SH	British Society of Gastroentero logy	1	FULL	General	General	I think this is a careful and considered document, which will provide clear guidelines for patient care. I have recorded comments and questions according to the pages in the document:	Thank you for your comment.
SH	British Society of Gastroentero logy	2	FULL	7	8	Typo "Xanthogranulomatous"	Thank you for your comment. This has been amended.
SH	British Society of Gastroentero logy	3	FULL	11	2	Laparoscopic cholecystectomy within 1 week of diagnosis of acute cholecystitis. This will certainly be a challenging time frame. Of note, the recent AUGIS/RCS guidance for commissioners on gallstones recommends cholecystectomy within 2 weeks of recovery from acute gallstone pancreatitis. In view of much greater risks related to a further attack of gallstone pancreatitis, as opposed to cholecystitis, it would be unfortunate if clinicians/patients/commissioners were to conclude that reconfiguration of services for cholecystectomy post cholecystitis is more urgent	Thank you for your comment. The recommendation is not intended to imply that acute cholecystitis is a higher priority than gallstone pancreatitis. The recommendation for early cholecystectomy for acute cholecystitis was based on evidence showing this is safe and cost effective. Insufficient evidence was available in relation to gallstone pancreatitis, and so the guideline

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						than post-pancreatitis. I think this issue merits further review, in order to avoid slightly contradictory documents (by implication, if not explicitly)	development group (GDG) were unsure if early surgery for this group of patients would be safe or harmful. Because of this uncertainty, the GDG chose not to recommend a timeframe for surgery for gallstone pancreatitis, and instead recommended that further research be done in this area to inform the development of future updates of this guideline. In addition, NICE will soon be developing a specific guideline on pancreatitis and so further guidance about this condition and its management will be provided in that guideline too. No changes have been made to the guideline recommendations in relation to your comments.
SH	British Society of Gastroentero logy	4	FULL	39	0	endoscopic ultrasound (EUS) stated to be "non-invasive", but P41 EUS stated to be "invasive test".	Thank you for your comment. EUS is invasive and this has been corrected on page 39 of the full guideline.
SH	British Society of Gastroentero logy	5	FULL	48	0	With respect to management of asymptomatic gallstones, should reference be made to the consideration of lap chole at time of gasric bypass (bariatric) surgery in patients with asymptomatic gallstones, in view of hugely added complexity of management in the setting of symptomatic CBDS, if these occur post bypass?	Thank you for your comment. Consideration of underlying conditions that cause cholelithiasis and cholecystitis such as bariatric surgery is outside the scope of this guideline and so will not be included.
SH	British	6	FULL	51	0	GDG recommend (I'm sure correctly) that	Thank you for your comment. The

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Society of Gastroenterology					asymptomatic CBDS should be managed the same as symptomatic CBDS, but this appears to be contradicted by flow chart on P57. This flowchart is confusing (at least to me!) What is meant by the semicircle arrows?	flowchart is not a patient pathway or treatment flow chart (this type of diagram is given on page 12 of the consultation version of the guideline). The diagram to which your comment relates is a representation of potential patient movements within the health economic model. The health economic model is a Markov state-transition model with 2 week cycles (described on page 56 of the consultation version of the guideline and in more detail in Appendix J). A semi-circle arrow indicates that it is possible (depending on the transition probabilities) for a patient to remain in that state for more than a 12-week cycle. The diagram is clearly labelled as a health economic model and so no changes have been made in light of your comments.
SH	British Society of Gastroenterology	7	FULL	59	7	line 7 reads "that" instead of "than"	Thank you for your comment. This typo has been corrected.
SH	British Society of Gastroenterology	8	FULL	95	3	Lap chole within 1 week. See above	Thank you for your comment. The recommendation is not intended to imply that acute cholecystitis is a higher priority than gallstone pancreatitis. The recommendation for early cholecystectomy for acute cholecystitis was based on evidence showing this is safe and cost effective. Insufficient

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							evidence was available in relation to gallstone pancreatitis, and so the GDG were unsure if early surgery for this group of patients would be safe or harmful. Because of this uncertainty the guideline development group chose not to recommend a timeframe for surgery for gallstone pancreatitis, and instead recommended that further research be done in this area to inform the development of future updates of this guideline.
SH	British Society of Gastroentero logy	9	FULL	101	0	Choledocholithiasis misspelled	Thank you for your comment. This typo has been corrected.
SH	British Society of Gastroentero logy	10	NICE VERSION	7	0	suggest use “transabdominal” US to distinguish from “endoscopic” US.	Thank you for your comment. The term ‘ultrasound’ (abbreviated to US in the guideline) is well understood and the guideline development group did not feel it would add greater value to use the term ‘transabdominal’ to differentiate it from endoscopic ultrasound. The addition of ‘transabdominal’ may also create confusion and misunderstanding rather than alleviate it. Your suggestion has therefore not been included.
SH	Department of Health	1	FULL	General	General	Thank you for the opportunity to comment on the draft for the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this	Thank you for your comment.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						consultation.	
SH	NHS England	1	FULL	General	General	In response to the initial question about symptoms, I strongly feel there is one clinical area which would increase the diagnosis rate (and hence treatment rate) for gallstones. Many patients are referred by GP's for Gastroscopy or OP consultation with 'dyspepsia' who do not have peptic ulcer disease or helicobacter. Some of these have gallstones. It is my strong impression that those who have episodic and discrete symptoms (rather than on most days), and those in whom symptoms are accompanied by marked nausea and vomiting, more often have gallstones than those who don't have these clinical features. I think this would be a useful diagnostic pointer, although I appreciate that the evidence may not be there to support this contention.	Thank you for your comment. Whilst we acknowledge that many patients with gallstone disease may present with the symptoms that you suggest, there was no evidence available to confirm this. Since there is no evidence it would be problematic to make specific reference to these symptoms but not other symptoms that may also be associated with gallstone disease. Therefore your suggestion has not been included in the guideline.
SH	NHS England	2	FULL	14	5	I think the question of longer term stenting is something that has had few trials applied to it. However, it seems to me that there will be frail and elderly patients with symptomatic bile duct stones (e.g. cholangitis), in whom clearance of the CBD stones at a single definitive ERCP is not achieved, and biliary stents are inserted to maintain bile flow and hence avoid further cholangitis and jaundice. The guidance as written suggests that further surgical or endoscopic clearance should always be attempted. Should it not be stated that there are some very frail or elderly patients in whom stenting (to achieve good biliary flow in spite of ongoing CBD stones) is a good option for what may be the short remainder of a poor quality life, or following patient preference?	Thank you for your comment. The guideline recommends that biliary stenting should be used as a temporary measure prior to definitive clearance. This is because there is an increased risk of serious and life threatening complications (such as pancreatitis) that is associated with the use of biliary stents. Furthermore, the guideline development group felt that some older patients are not offered definitive treatment simply because of their age even though they may be clinically well enough to undergo ERCP or surgery. However the guideline development group acknowledged that definitive clearance may never be appropriate for some patients. The recommendation does not

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							preclude the use of long term biliary stenting, or other treatment modalities in managing gallstone disease when clinically appropriate and the risks associated with long term biliary stenting are considered alongside the risks of bile duct clearance. No changes to the guideline recommendations in relation to your comment have been made
SH	Royal College of Nursing	1	FULL	General	General	This is to inform you that there are no comments to submit on behalf of the Royal College of Nursing to inform on the draft Gallstones Disease Clinical Guidelines. Thank you for the opportunity to review this document.	Thank you for your comment.
SH	Royal College of Physicians	1	FULL	General	General	Please take this email as confirmation that the RCP wishes to endorse the submission of the BSG on the above consultation	Thank you for your comment.
SH	Royal College of Surgeons of Edinburgh	3	FULL	General	General	A small group of patients with significant co morbidities especially in old age can be a difficult problem. They may have symptomatic disease or have had problems with gall stone pancreatitis and obstructive biliary tree. The guidance regarding the treatment of these patients was a little ambiguous other than to recommend cholecystectomy. The problem lies with the risk to benefit of cholecystectomy in comparison to other modalities such as a simple ERCP. It would be useful and certainly helpful if the proposed NICE guidelines were to specify how likely a patient would be to have no further episodes of obstructive gall stone disease with complications such as pancreatitis if a sphincterotomy was performed. Is there any	Thank you for your comment. There was evidence available showing that cholecystectomy and ERCP are generally safe and effective for treating gallstone disease, and the guideline development group felt that the risks of ERCP were similar to those of cholecystectomy. The guideline development group also felt that some older patients are not offered definitive treatment simply because of their age even though they may be clinically well enough to undergo surgery. Furthermore, no evidence was found in relation to an age threshold or cut off to indicate if cholecystectomy could become

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						literature that points towards this in peer reviewed journals? However a comment by the NICE guidance committee on the group of patients who may simply benefit from ERCP and sphincterotomy rather than high risk laparoscopic cholecystectomy would be extremely helpful in clinical practice.	inappropriate at a particular age. The guideline development group decided to recommend cholecystectomy because the risks associated with surgery are similar to those for ERCP, because surgery is a definitive treatment (whereas ERCP is not), and to ensure that patients are not discriminated against on the basis of their age alone. However, for some patients cholecystectomy may never be clinically appropriate, and some patients may choose not to undergo surgery. The recommendations do not preclude the use of other treatment modalities in managing gallstone disease. Decisions to use alternative treatment modalities should be taken on a case by case basis at a local level after consideration of the risks associated with the available treatment options. No changes to the guideline recommendations have been made.
SH	Royal College of Surgeons of Edinburgh	4	FULL	General	General	Although it is understood that it is outside the remit of the parameters of this study there is some cross over between the finding of gall stone disease and symptomatic patients and finding of gall bladder polyps. Occasionally it can be difficult to discern adherent cholesterol stones from gall bladder polyps despite repeat imaging. As far as is known there is little evidence to show removal of gall bladders that contain polyps if of significant benefit unless the gall bladder polyps reach a certain size.	Thank you for your comment. Gallbladder polyps are outside of the scope of this guideline and will not be considered.

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						The inclusion of gall bladder polyps in the evaluation of NICE guidelines due to the cross over with adherent stones would certainly be useful and helpful. .	
SH	Royal College of Surgeons of Edinburgh	5	FULL	General	General	The reports proposed by the NICE guidelines committee are extensive and complete.	Thank you for your comment.
SH	Royal College of Surgeons of Edinburgh	2	FULL	45 to 53	Whole section	2. There were significant recommendations regarding the treatment of patients with asymptomatic gall stone disease. Essentially reassurance of these patients and non operation is the recommended avenue of management. However, in practice there is often the case of significantly anxious patient's who are concerned about complications of biliary disease such as acute pancreatitis, cholangitis and cholecystitis. Sometimes, no matter how much reassurance is given, these patients will still be unhappy unless surgery is offered (although it is understood that in the vast majority of patients with asymptomatic disease no surgical intervention is warranted). Some guidance on these types of patients may be beneficial to clinicians especially if numeric value as to risk could be placed upon life time risk of complications. This was not evident on the literature review or research performed by the committee looking into gall stone disease.	Thank you for your comment. The guideline development group decided that surgery should not be offered to patients with asymptomatic gallbladder stones, since it was agreed that the risks associated with surgery outweighed its benefits. However, this does not preclude offering surgery for asymptomatic patients if this is felt to be the most appropriate course of action by both the patient and their clinician, and the patient is aware of the risks and lack of evidence supporting surgery for asymptomatic gallstones.
SH	Royal College of Surgeons of Edinburgh	1	FULL	88	Chart	With regards to the identification and diagnosis of gall stone disease it is mentioned in several paragraphs about the imaging of the biliary tree and the presence of deranged LFT's. Although this is definitely a sensible and evidence based practice there was a little ambiguity as to what was classed as derangement of liver function tests.	Thank you for your comment. The guideline development group (GDG) chose not to specify the type of liver function test (LFT) or values that could be considered as 'deranged' because there was no evidence to support making such a statement. The GDG felt that they should

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Certainly in current practice there is a variability between clinicians as to what they class as significant derangement requiring further investigations. It may well be of benefit for the NICE guidelines to specify what they would class as deranged enough to require imaging of the biliary tree in the form of MRCP or EUS as they recommend. Whether this involves derangement in alkaline phosphatise, bilirubin, transaminase or indeed gamma GT. Further clarification of this, I think would be of benefit to the guidance of clinicians practising laparoscopic cholecystectomy.	not specify values based on their knowledge and experience alone, because it was felt that this could cause harm. This is because setting values could be quite arbitrary as values that indicate derangement vary depending on individual patient factors. In some cases mildly deranged LFT values in one patient may be just as serious as severely deranged LFT values in another. Thus, the GDG agreed that clinical judgement must be used and the whole clinical picture considered in order to determine the significance of LFT results. Thus no changes have been made in response to your comment.

These organisations were approached but did not respond:

Aintree University Hospital NHS Foundation Trust

Airedale NHS Trust

Alder Hey Children's NHS Foundation Trust

Allocate Software PLC

Archimedes Pharma Ltd

Association of Anaesthetists of Great Britain and Ireland

Association of Laparoscopic Surgeons of Great Britain and Ireland

Association of Surgeons of Great Britain and Ireland

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland
Barnsley Hospital NHS Foundation Trust
Belfast Health and Social Care Trust
British Association of Paediatric Endoscopic Surgeons
British Infection Association
British Liver Trust
British Medical Association
British Medical Journal
British National Formulary
British Nuclear Cardiology Society
British Psychological Society
British Red Cross
British Society of Gastrointestinal and Abdominal Radiology
British Society of Paediatric Gastroenterology Hepatology and Nutrition
British Specialist Nutrition Association
BSPGHAN
Cambridge University Hospitals NHS Foundation Trust
Care Quality Commission
Clarity Informatics Ltd
Croydon Clinical Commissioning Group
Croydon Health Services NHS Trust
Croydon University Hospital
Cumbria Partnership NHS Trust
CWHHE Collaborative CCGs
Department of Health, Social Services and Public Safety - Northern Ireland
Dr Falk Pharma UK Ltd
East and North Hertfordshire NHS Trust

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

East Kent Hospitals University NHS Foundation Trust
Ethical Medicines Industry Group
Five Boroughs Partnership NHS Trust
Gloucestershire Hospitals NHS Foundation Trust
GP update / Red Whale

Health & Social Care Information Centre
Health and Care Professions Council
Healthcare Improvement Scotland
Healthcare Infection Society
Healthcare Quality Improvement Partnership
Healthwatch East Sussex
Herts Valleys Clinical Commissioning Group
Hockley Medical Practice
Humber NHS Foundation Trust
Institute of Biomedical Science
Johnson & Johnson Medical Ltd
Joint Royal Colleges Ambulance Liaison Committee
King Fahd Military Medical Complex
Liver4Life
Local Government Association
Luton and Dunstable Hospital NHS Trust
Maidstone Hospital
Medicines and Healthcare products Regulatory Agency
Ministry of Defence (MOD)
National Association of Primary Care
National Clinical Guideline Centre
National Collaborating Centre for Cancer

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Deaf Children's Society
National Institute for Health Research Health Technology Assessment Programme
National Institute for Health Research
National Patient Safety Agency
NHS Barnsley Clinical Commissioning Group
NHS Choices
NHS Connecting for Health
NHS County Durham and Darlington
NHS Cumbria Clinical Commissioning Group
NHS Hardwick CCG
NHS Health at Work
NHS Improvement
NHS Medway Clinical Commissioning Group
NHS Plus
NHS Sheffield
NHS South Cheshire CCG
NHS Wakefield CCG
NHS Warwickshire North CCG
North of England Commissioning Support
North West London Hospitals NHS Trust
Northern Health and Social Care Trust
Northern Region Endoscopy Group
Nursing and Midwifery Council
Oxfordshire Clinical Commissioning Group
Parenteral and Enteral Nutrition Group

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

PHE Alcohol and Drugs, Health & Wellbeing Directorate
PrescQIPP NHS Programme
Primary Care Pharmacists Association
Primrose Bank Medical Centre
Public Health England
Public Health Wales NHS Trust
Queen Elizabeth Hospital King's Lynn NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons of England
Royal Cornwall Hospitals NHS Trust
Royal Pharmaceutical Society
Salford Royal NHS Foundation Trust
Scottish Intercollegiate Guidelines Network
Sheffield Children's Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Social Care Institute for Excellence
Society and College of Radiographers
South Eastern Health and Social Care Trust

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

South London & Maudsley NHS Trust
South West Yorkshire Partnership NHS Foundation Trust
Southern Health & Social Care Trust
Southport and Ormskirk Hospital NHS Trust
St Mary's Hospital
Staffordshire and Stoke on Trent Partnership NHS Trust
Stockport Clinical Commissioning Group
The Association for Clinical Biochemistry & Laboratory Medicine
The Patients Association
UK Thalassaemia Society
University Hospital Birmingham NHS Foundation Trust
University Hospitals Birmingham

Walsall Local Involvement Network
Welsh Government
Welsh Scientific Advisory Committee
Western Health and Social Care Trust
Western Sussex Hospitals NHS Trust
Wigan Borough Clinical Commissioning Group
York Hospitals NHS Foundation Trust

PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.