

Decision Aid Supporting Document – Gallstones

Version 9.0 (Sept 2023) planned review (3 years)

This document is designed to give further information about how we made the Decision Support Tool (Decision Aid).

This supporting document and the decision aid were written and researched by Leila Finikarides and Dr Alexandra Freeman.

Each tool had an expert advisory group nominated by NHS England, who commissioned the tools, the involvement of relevant charities or support groups, and was designed through rounds of redesign and feedback from clinicians, patients and members of the public who might use it. These were one-on-one interviews, and the feedback was collated and acted on in multiple rounds.

EasyRead versions were then made through a similar process of iterative testing with experts and users.

Users (patients and the general public) are our focus, we include them from the beginning of the process and their views and feedback throughout are at the very heart of what we aim to do. The decision aids are for them.

Each tool is made to comply with the guidelines or criteria on decision aid development by [IPDAS](#) and [NICE](#). Very often they go beyond what many might consider as a ‘decision aid’ because our work with patients and clinicians has emphasised how much patients want ‘everything in one place’ and clinicians find it helpful to have ‘the perfect consultation’ laid out to support them.

Patients particularly appreciated the help that the documents gave them in preparing for an appointment (knowing what might happen in advance, and helping prompt questions they might want to ask), pages that help them when they talk to their doctor, and those that remind them what’s going on, what might happen, and what did just happen (what did the doctor tell me in the room). The extra information can make the documents seem long, but patients preferred this extra length, as long as the sections were easily navigable.

In this document you can find out more about who helped design the tool, some of the reasoning behind key decisions, and what reference sources were used. You can also see the answers to some of the questions we posed to the people we tested it with about how they might use the tool, which led to key decisions about its design. These are only examples designed to give you a sense of how they were made – the full process is too detailed to document.



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Winton Centre for
Risk and Evidence Communication

In designing the graphical representations of the numbers, we use a large body of research into risk communication done over many years (some by us), plus the testing we do during the production of the tools. Graphic design was by the company Luna9.



Who was involved ?

	number	
Expert Advisory Group Clinicians & Patient Reps & their Declarations of Conflicts of Interest (COI)	X 9	<p>Mark Cheetham (Consultant General and Colorectal Surgeon, National Clinical Lead for General Surgery in Getting it Right First Time) No COI to declare</p> <p>Rosa Atkins (Laparoscopic & Benign UGI Specialist Nurse) No COI to declare</p> <p>Maxine Chaplen (Laparoscopic Nurse Specialist) No COI to declare</p> <p>Mr Ian Finlay (Consultant Upper GI Surgeon, Royal Cornwall Hospitals NHS Trust) No COI to declare</p> <p>Prof Kamal Mahawar (Consultant General Surgeon & Upper GI lead, South Tyneside and Sunderland NHSFT) No COI to declare</p> <p>Mr Kirk Bowling (Consultant Upper GI Surgeon, President of the British Benign UGI Surgical Society) No COI to declare</p> <p>Mr Marcos Kostalas MD FRCS Consultant Upper GI and Laparoscopic Surgeon Surgical College Tutor No COI to declare</p> <p>Dr Luke Summers (Consultant Gastroenterologist) No COI to declare</p> <p>Dr Phil Cox (GP) No COI to declare</p> <p>Dr Sam Finnikin (GP and NHSE National Clinical Specialist Advisor in Personalised Care) No COI to declare.</p> <p>Mr Guy Finch (Consultant General & Gastrointestinal Surgeon) No COI declared</p> <p>Kevin Reed (Patient with Experience of Inguinal Hernia)</p>



		No COI declared
Other clinicians (not part of the expert advisory group) who were interviewed or provided input or feedback	X 6	<p>Heather Davis General Surgical Registrar No COI to declare.</p> <p>Prof Kurinchi S Gurusamy (Professor of Evidence-based Medicine and Surgery)</p> <p>Prof Brian Davidson (Consultant HPB and Liver Transplant Surgeon, Professor of Surgery UCL)</p> <p>Prof Irfan Ahmed (Consultant HPB Surgeon)</p> <p>1x GP 2 x specialist nurses</p>
Patients and public involved in 4 rounds of testing and feedback	X 16	<p>Patients and public x16</p> <p>Range of ages, ethnicities, education levels</p> <p>8 with gallstones or had their gallbladder removed 2 people with autism</p>
Organisations		British Benign Upper Gastric Intestinal Society (BBUGSS)
Who are the Winton Centre for Risk & Evidence Communication?		The Winton Centre was funded by a philanthropic donation from the David & Claudia Harding Foundation to help communicate evidence ‘to inform, not persuade’. The team carried out research in how best to communicate numbers and uncertainty, created training courses to help professions who needed to communicate evidence in a balanced way, and produced tools to communicate evidence on different topics. They were commissioned, and funded, by NHS England to produce a series of printable decision support tools in 2022 and 2023. The funding for this work came from NHS England and the Winton Centre’s own core funding.

What questions do we ask of our expert group and user testers and why?

We interviewed the expert advisory group, regular patients and potential users of the decision aid and regular clinicians who might use the decision aid. We interviewed each tester (regular patients or users, and regular clinicians) via video call, usually for about an hour.

We need to understand which information to include and to what level of detail.

For users (patients):

We always first asked about their experience of the condition or the decision to be made. We asked them what did they want to know at the time and what would they have liked to have known. We asked them what they would tell someone now who was making the decision.

We then asked for their feedback on the decision aid.

We ask if they would like a clinician to go through the document with them.

Then we ask them:

- Whether they understood the purpose of the document (that it is a decision aid, not an information sheet).
- Whether they would read it, if they would find it useful, would it help them make a decision?
- Whether, if they were handed the document by a clinician, they would read it.
- Whether, if they saw this document on a table, for example in a clinic waiting room, they pick it up, and *want* to read it.

The aim of these decision aids is to help people make a decision. But in order to be useful and used, they need to be read. And in order to be read, they need to be picked up. We therefore amend and refine the documents and retest them (with a mix of the same and different testers) until the answers to these questions are “yes”.

If people want a clinician to go through the document with them, we make sure it's clear in the document that this is what they can do and, on the front page, which pages are (most) useful to be used in a consultation with a healthcare professional.

For clinicians (both our expert group and regular clinicians):

We ask:

- What is the decision being made? (what are the treatment options that are available)
- At which point in a patient's pathway/disease progression are they making the decision, and therefore what is the background knowledge of the potential user (what do they already know), and when and how would they physically receive this leaflet?

- Are there inclusion / exclusion criteria around the decision aid?
- How would the decision aid be used, e.g. by users 'on their own' before a consultation with a clinician, or always first with a clinician

The answers to these questions help us to understand which information to include in the leaflet, at what level of detail and language to use.

<p>What is the decision?</p> <p>And / or</p> <p>What are the treatment options available?</p>	<p>The decision aid is for people who have been diagnosed as having gallstones or are being referred to secondary care for tests because their GP suspects they have gallstones.</p> <p>People using this decision aid may be symptomatic or asymptomatic.</p> <p>We included options as guided by our expert group and NICE guidance (2023)</p> <p>The NHS does not commission the removal of asymptomatic gallbladders. If you have no gallbladder symptoms the recommendation is not to treat them but “watch and wait”, at the same time pursuing healthy lifestyle changes. This was reflected in the Decision Aid.</p> <p>Patients wanted to know what their treatment options were if they had symptoms, and what was their likelihood of getting symptoms if they did not have any in order to understand their present and future options.</p> <p>There are different procedures for removing gallstones depending on, where they are, the health of the patient, and the urgency of the situation. Some procedures are specialised, some done if the situation is an emergency for example.</p> <p>To make the decision aid simple and clear enough to use easily, without over complicating specialised operations or procedures that are performed less often, we described the treatment options of:</p> <ul style="list-style-type: none"> - Do nothing ('watch and wait') - What you can do yourself to manage symptoms and pain - Medicines you can take to manage symptoms and pain - ERCP, an endoscopic procedure to remove stones from the bile duct - Open or keyhole surgery to remove the gallbladder (and stones within it)
<p>When in the pathway will it be used? (clinicians' answers)</p>	<p>e.g. Pre primary care, primary care, secondary care</p> <p><i>“At diagnosis, after an initial conversation with a doctor who says that it’s probable that they have gallstones.”</i></p>



	<p>This usually, therefore, means in primary care. However, they may be used in secondary care if gallstones are found incidentally, or they are an emergency situation.</p> <p><i>“Good idea for patients to have it before they see a surgeon in clinic, they will then have a good idea of what might happen, so receiving it in Primary Care. If not, the nurses can give patients information in the waiting room at clinic.”</i></p> <p><i>“Patients should have access to it before meeting the GP. If the patient comes to me prepared it would be great. Empower patients. I’d like them to</i></p> <ul style="list-style-type: none"> - <i>Be prepared about what you’ll be asked</i> - <i>Think about your symptoms how bad they are, when they happen, how long you’ve been having them</i> - <i>What drugs are you currently taking”</i>
<p>When would it be useful? (patients’ answers)</p>	<p>At what point would you want the document?</p> <p><i>“It would be useful:</i></p> <ol style="list-style-type: none"> 1) <i>If you read this before you have an excruciating painful attack,</i> 2) <i>If you are waiting, before an ultrasound confirmation of gallstones, OR waiting for further treatment</i> <p><i>NOT Useful:</i></p> <ol style="list-style-type: none"> 1) <i>After you have already had a bad attack and were taken to hospital for it, by then the pain is too bad and you will do ANYTHING to make it stop”</i> <p><i>“You’d get [want] this leaflet when you know you have gallstones”</i></p> <p><i>“As soon as there is a hint that this might be gallstones related ... At the GP would be good ... pre-GP because you won’t see a GP for a long time so during telephone triage while picking up the next prescription for the painkillers to deal with it – ‘because we think it’s gallstone” ---helpful to see this prior to seeing a doctor – the leaflet with the appointment letter would be great”</i></p> <p><i>“At diagnosis - as early as possible - without scaring them or being too dramatic.”</i></p>
<p>How would it be used?</p>	<p>e.g. patients to use it on their own before a consultation or always with a clinician</p> <p>GP Clinician – how and would you use it? <i>“Yes, if it’s fast to load, easy to read, and can somehow customize information for each patient”</i></p> <p>Our decision aids are written where possible, in such a way as to be stand alone, the reader of any ability and any level of knowledge should be able to read it and understand their options. Given the preference by patients for a</p>



	<p>printed document, they are not interactive, online tools that give individualised risk information, but the patients can fill them in to communicate personal information to a clinician.</p> <p>One autistic patient tester said <i>“I am able and capable to read it on my own but of course it is welcomed if someone wants to take the time to go through it with you. I wouldn’t expect this though. What I would really like is to know that I would be heard and that the paper and notes would be welcomed. My experience of going to a doctor as an autistic person is that they want to write most things off as anxiety and you really have to push to be heard. There is also a bit of eye-rolling at people who come in prepared with notes. I find I get better care if I pretend I don’t know things and defer to their seniority so I would have some nervousness at walking in with these notes. Although I think they are brilliant and helpful.”</i></p>
Are there any exclusion / inclusion criteria?	The decision aid is not designed for those with an emergency situation, or for all emergency procedures, although it may include useful information for a patient undergoing emergency cholecystectomy.
Would you prefer a printed version, online electronic version or both?	<p>We know from previous testing that most clinicians would prefer these were electronic online tools although a bigger proportion of gallstones clinicians would like both online and printed.</p> <p>NHS clinicians typically do say they have facilities to print (black and white only).</p> <p>Clinician – <i>“We can put it on our intranet, or posters in the waiting room, or QR linking to it in the waiting room”</i> (this clinician works in a deprived area and uses these techniques)</p> <p>Of the 14 patients and public and clinicians who answered this question:</p> <ul style="list-style-type: none"> - 7 wanted it as a printed piece of paper - 6 wanted it both online and printed - 1 said online only
Any other comments?	Waiting times are long for gallbladder removals. Patients want to know what to do while they’re waiting, and when to go to A&E and when to use self-management for pain.
Were there any key decisions made when designing the document, and	<p>There was a great deal of discussion around post cholecystectomy syndrome/pain after gallbladder removal. See the notes on ‘where we got our data from’, below.</p> <p>The expert group pointed out that there isn’t really a choice for open or keyhole surgery for the patient. The safest surgery is keyhole for gallbladder</p>



<p>what was the reasoning behind them?</p>	<p>removal and only if a patient is not suitable for some reason would they resort to open surgery. (It's to do with where they need to cut for open, on the diaphragm).</p> <p>One clinician said <i>"The column re. open surgery seems disproportionate – open surgery is only resorted to in very few cases started laparoscopically – it would be extremely unusual for a patient to be offered an open operation when discussing treatment. I think this column should be removed completely and replace with a comment somewhere along the lines of "very occasionally an operation cannot be completed laparoscopically and then an operation may need to be completed via a larger incision – open surgery""</i></p> <p>However, giving patients the likely outcomes of either surgery was important, and we tried to phrase the page about options to make it clear that not all options might be open to an individual patient.</p>
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<p>Some example answers from our patient and regular clinician testers and actions we took on the basis of them (organised by testing round)</p>	
<p>Round 1</p>	<ul style="list-style-type: none"> - Language: <i>"ERCP is a 'procedure' not a surgery."</i> <p>We asked patients <i>"What does a 'procedure' in hospital mean to you?"</i> And most said that would mean surgery to them.</p> <ul style="list-style-type: none"> - <i>"Think about what patients hope to gain: to eat normally, be pain free, avoid surgery"</i> - <i>"Open surgery not exactly an option – only done if you're not suitable for keyhole, it's higher risk and poorer recovery (scar is at diaphragm)"</i> - <i>"The question most commonly asked of the nurses are "How long is the waiting list?" and "When can I eat cheese?"</i>
<p>Round 2 – patients</p>	<ul style="list-style-type: none"> - <i>"My very first impression was "Wow! There are 12 pages of information here to help me understand what's going on for me!" I honestly think this is fantastic as the information provided currently is at best poor, but in reality pretty non-existent and it is not comfortable for me to go Googling symptoms as I can find myself drawn into opinions or bad experiences and these panic me. I only work well with clear facts from which I can make decisions so the fact that you have produced something with this intention is fantastic."</i> <p>Patients specifically asked for answers to questions they currently have:</p> <ul style="list-style-type: none"> - <i>How are gallstones formed?</i> - <i>What can you do to help yourself?</i>



	<ul style="list-style-type: none"> - <i>I've been told I have a 'lot of gallstones' but in comparison to what?</i> - <i>How big is a gallbladder, how big are gallstones?</i> <p>We addressed these questions put by patients as well as those that clinicians told us they were commonly asked on a facts page. This was not directly related to making a decision but requested by patients.</p> <ul style="list-style-type: none"> - <i>"Need to use the word discomfort too. It's sometimes pain but also intense discomfort, which is different."</i> - <i>"You say I can live well without a gallbladder, can you explain more about that? Why? How?"</i> <p>We answered this query and explained that the bile will go directly from the liver.</p> <p>From an autistic tester: <i>"I like the fact that it has bold headers, lines dividing information, flowcharts, images, statistics. It makes it easy to read through and is much better than an information sheet that has just pages of text. It feels friendly and clear. I like the use of short sentences and small paragraphs. It sticks to facts and the different colours etc all make it an easy and welcome read."</i></p>
<p>Round 4</p>	<p>Recovery (clinicians)</p> <ul style="list-style-type: none"> - We had some discussion between healthcare professionals (and patients) on how long recovery from surgery really was. - <p><i>"People will likely be sore for weeks after surgery - post op recovery is probably longer than we've alluded to. People forget that while it's a common operation, it is a major operation and people might have unrealistic expectations from surgery - it will take a while to get back to normal, esp with keyhole. Even post surgery you might have to be careful about what you eat."</i></p> <p><i>"..where it says recovery takes 7-10 days for laparoscopic surgery. You can exercise when you feel comfortable and drive when you feel safe Maybe add 'you will need to avoid heavy lifting for 4 weeks'"</i></p> <p><i>"why do they need to avoid heavy lifting? I tell them they can do things as soon as they feel comfortable doing it"</i></p> <p>An example from a patient about recovery</p> <ul style="list-style-type: none"> - <i>"7-10 days? No way! Maybe if all goes well, but for me it took months!"</i>



	<p>(patients)</p> <ul style="list-style-type: none"> - We had specific feedback on layout and colours and illustrations from 2 autistic people in this round. - <i>“Well presented and attractive”</i> - <i>“Loved the prevalence figures – reassuring! You’re not alone...”</i> - <i>“The leaflet is in an advanced state and I liked the colour coding of the do nothing, self help, medicines or surgery options throughout.”</i> - PATIENTS often commented that they wanted <i>“interviews or comments from real patients’ – would you do it again, what was it like?”</i> <p>Patient testimonials and experiences can be incredibly powerful, and this is exactly why we don’t include them. Research (see reviews by Bekker et al. 2013: http://www.biomedcentral.com/1472-6947/13/S2/S9 and updated by Shaffer et al 2021: https://doi.org/10.1177/0272989X211011100) suggests that great care needs to be taken when including this kind of material to avoid it being persuasive, and we instead include as many self-reflection and interactive tasks as possible, as well as good design, to help people engage and understand the options, the decision-making process and their own preferences. We do, though, always include links to support groups and forums where people can hear about other patients’ experiences.</p> <ul style="list-style-type: none"> - <i>“Page 11 is asking if the patient knows enough about the potential benefits and harms of each option - We haven’t stated anything in the document about the risks of ERCP.”</i> <p>We added a section specifically on the risks of ERCP</p>
<p>Reading age range</p>	<p>Using https://readabilityformulas.com/readability-scoring-system.php Average Reading Age Consensus Calculator</p> <p>Average reading 8-9</p>



Easy Read development	
<p>When making the first Easy Read version of a decision aid (for Heavy Periods) we were able to create a basic structure and set of illustrations for the other easy read decision aids (see 'notes and lessons learned'). From this basis, we then made and tested each other decision aid in Easy Read version.</p> <p>This Easy Read was tested in 2 rounds of testing with x 7 easy readers and 5 professionals / clinicians</p>	
Number of Rounds of testing	x 2 rounds of testing
Professionals	<p>x 5 professionals</p> <ul style="list-style-type: none"> - Writers of Easy Reads and groups for those with learning difficulties - Gallstone clinicians and nurses and nurses who work with those with learning difficulties - 1 GP
Easy Read users	<p>7 Easy Reade users from:</p> <ul style="list-style-type: none"> - Camden People First
Notes and lessons learned from previous development	<p>To our knowledge there were no other decision aids / decision support tools in Easy Read format (i.e. documents helping readers make a treatment decision informed by evidence).</p> <p>Usually Easy Read users would be using the leaflets with a carer or clinician. We aimed for the language and illustrations to be as simple as possible but in some instances need to rely on carers or others to explain some concept. If users have profound disability such that they need help to understand they would always have someone with them to advocate for them or explain to them.</p> <p>Some feedback about images came from clinicians, for example, we initially showed a GP in a white coat. GPs (and other clinicians) pointed out that they do not wear white coats. We tested with the Easy Read users and asked 'what we could draw to show a doctor?' They suggested a desk, a monitor and a stethoscope.</p> <p>We developed and tested ways of expressing the concept of a 'choice' and presenting different options and outcomes in a way that the readers could make a decision (by themselves, if necessary).</p>



- Easy Read users preferred photographs when a specific kind of medication or treatment was being referred to and they wanted to know what it looked like. Otherwise, cartoons were OK. There were several poses that they were used to seeing.
- If using a colour key (e.g. purple is always medicine in the leaflet), they asked us to explain this. For example, say clearly “medicines are always purple in this leaflet” - explaining what we were doing instead of assuming a key, colour code, shape etc would ‘speak for itself’.
- Because the leaflets are long, we clearly split them into sections, explaining at the start that you might not want to read it all at once. And that you don’t need to.

Risks and benefit visualisations

- We experimented with ways of showing the potential risks and benefits of the different options. In the standard versions of the same tools these are generally expressed as expected frequencies (number out of 100 expected to show each outcome), plus a bar to show the number visually; e.g. 20 in every 100 who have this treatment have this effect.
- We usually present ranges around the numbers to encompass the quantified uncertainty in the data available.
- We also usually present the evidence in the past tense (out of 100 people who HAD/CHOSE...) to emphasise that the numbers are not a prediction but are a summary of past numbers.

For Easy Read users

- For the Easy Read audience, these bars were not clear, and nor were the ranges. They also found the past tense more difficult than present tense.



- We also could not present outcomes 'out of 100' because this high number wasn't so easily imagined by the audience.
- Testing revealed that 'out of 10' outcomes were understandable for the audience, and generally provided as precise a number as they needed to inform their decision. So we present the risks and benefits out of 10.
- This of course means 'rounding' - sometimes in quite an extreme way. However, our testers felt that it gave them enough information to make comparisons.
- Easy Read users told us they were used to 'faces' as icons, to help them know which represented positive and which represented negative outcomes without having to check. This was useful on the 'amount of bleeding' outcome on heavy periods (even though we are describing a continuous outcome, not a frequency). For most other outcomes (frequencies), anthropomorphic icons were fine.
- They also told us that they were used to having the number that had a 'positive' outcome on the right hand side, and those that had a 'negative' outcome on the left hand side of an icon array, and to be consistent with that (rather than putting the number that 'had' the described outcome always on the left).
- Testers were very happy to see the information and have it presented so clearly. They were very engaged and happy to have been consulted.

It would not have been possible to make these Easy Read versions without multiple testing rounds. We consistently found language or images that we felt were clear, but did not make sense at all to the groups.



**Example feedback and
decisions specific to
GALLSTONES**

Help from the Easy Read users made illustrations clearer, e.g. image of an (keyhole) operation and image of an endoscopic procedure.

Gallstones was the second Easy Read we tested and feedback around illustrations and language to do with surgery was useful for other decision aids (e.g. hernia). When showing part of the body, e.g. abdomen or leg (veins), readers found it more useful to 'zoom out' and see the edge of the body or body part so that it's more obvious what the image represents.

"Specialist" was not understood. We use "hospital doctor" or a "doctor who knows more about...." across the series.

There was a query whether and how to differentiate an operation (e.g. keyhole or open surgery) from a procedure (e.g. endoscopy). Easy Read users preferred us to describe as well as use the word "operation" or "procedure".
e.g. "...an operation to remove your gallbladder..."
"...a procedure called ERCP... they put a very thin tube down your throat..."



Where did we get our numbers from?

This section explains what sources we used, and why.

How many people have the condition?

Where possible we try to use the most recent UK registry/audit data for the prevalence of a condition, or (if many who have the condition may not be diagnosed and hence recorded as having it), survey or other relevant methods of determining prevalence.

For data on prevalence of gallstones, we were able to find good data from a number of sources:

Khan 2009, <https://doi.org/10.1007/s10620-008-0682-3>
UK (Kent) - necropsy study of 9,175

Heaton 1992, <http://dx.doi.org/10.1136/gut.32.3.316>
UK (Bristol) - ultrasound study of 1,896

Miscigna 1999, <https://doi.org/10.1093/ajcn/69.1.120>
Italy - ultrasound study of 2,472

The Gurusamy 2013 Cochrane <https://doi.org/10.1002/14651858.CD005440.pub3> also gave prevalence figures, citing as its refs: GREPCO, Bates 1992, Halldestam 2004

All of these were roughly in accordance with each other. We created a range from the rounded bottom and top end of the prevalence for males and females separately so that we could state that women were in the top area of the range and men in the lower.

For the presence of bile duct stones, we could not find a similar autopsy study that would give us overall prevalence, but instead gave figures for the proportion of gallstone patients who turn out to have bile duct stones, using data from:

Johnson 1987 <https://doi.org/10.1002/bjs.1800740703>

Tazuma 2006 <https://doi.org/10.1016/j.bpg.2006.05.009>

Dasari Cochrane <https://doi.org/10.1002/14651858.CD003327.pub3>

These sources all agreed with each other.

Potential benefits & harms of different treatment options

For this section of each decision aid, we try to find the absolute risks (the number out of every 100 people who would have experienced the outcome) for each of the things that patients and clinicians tell us is important. Numbers can come from observational studies (where people choose their treatment and the outcomes are recorded), or from clinical trials (where people are assigned to a treatment at random). Which is more useful depends on the circumstances, but in some clinical trials some people assigned to one treatment ends up taking another (for different reasons). Some academic studies report the outcomes as if they

had taken the treatment they were originally assigned (called 'intention to treat' data), and some studies report the outcomes depending on the treatment that they actually took (called 'per protocol' or 'per treatment' data). We always try to find 'per protocol' data as this is more useful for an individual wanting to know what might happen if they have one treatment or another.

We usually start by looking at trustworthy summaries of evidence, such as those done by NICE or by the Cochrane collaboration.

If these summaries give us all the numbers that we need, and are considered up to date by the expert group, we would use those. If not, we would look for any large trial in a population that is relevant to the UK and use the findings of that. If there are many trials, we would collate them all and tend to cite a range based on the lowest and highest number for each outcome found across those studies (rounding the numbers to give an appropriate sense of the degree of certainty). Where there is consensus that there is 'no significant difference' between different outcomes, we will ensure this is reflected in the ranges we give.

The expert group will agree all the numbers, and suggest better sources for them, throughout the development process.

We started with the NICE guideline CG188 (2014) and the surveillance evidence review of 2018. This review had identified the two Norwegian studies by Schmidt et al. comparing conservative (no surgery) with surgery. We also identified the C-Gall trial from Scotland which had recently concluded and whose results were being presented at conferences, and contacted the authors. We used Google Scholar and consulted our expert group for observational data on long-term outcomes of cholecystectomy.

We also extracted data from the Keus (2006) Cochrane review on laparoscopic versus open surgery, and the Gurusamy (2013) Cochrane review on delayed versus early laparoscopic surgery.

We also used the AUGIS Commissioning guide from 2015 as a resource.

For the risks of cholecystectomy, we could find few sources that broke down the complications into specific causes. Laparoscopic and open also often had very similar figures.

We used data from:

van Dijk 2019 SECURE trial <http://dx.doi.org/10.1016/>

Data from the C-Gall trial, currently under review, but we were given access to a presentation given at a conference in July 2023.

Keus 2006 Cochrane <https://doi.org/10.1002/14651858.CD006231>

Gurusamy 2013 Cochrane



Post-cholecystectomy syndrome. We used Isherwood's 2019 review <https://doi.org/10.1016/j.surge.2018.04.001> to understand that the term is a term for those who have ongoing painful gastrointestinal symptoms which can have multiple underlying causes. Rather than use the term, we therefore chose merely to describe the number of people choosing surgery or no surgery who were pain-free after 1 year, and then to explain that there are multiple reasons why those who have had cholecystectomy might have ongoing pain.

The 'benefits' of either no surgery or surgery were very difficult to define, and were leading us to convoluted descriptions (e.g. 'avoided pancreatitis') so instead we decided to combine all as 'outcomes' so as to simplify descriptions.

These were also difficult to find good data on.

The outcome of most interest to patients is the percentage of patients pain-free in the medium to long term.

Unfortunately most papers report intention-to-treat results rather than per-protocol and with a substantial proportion of randomised patients crossing over (either refusing surgery or having surgery due to ongoing pain), these results are very difficult to use for patients. Also most papers report on mean improvement in a pain score, which again is of little use to patients, who want to know the percentages with pain that got better or worse.

Out of our potential sources of data, Vetrhus 2004 <https://doi.org/10.1080/00365520310008502> gave only intention-to-treat data C-Gall, the new trial reporting in 2023, was only able to provide us with mean improvement data

That left us with the SECURE trial, van Dijk 2019 [https://doi.org/10.1016/S0140-6736\(19\)30941-9](https://doi.org/10.1016/S0140-6736(19)30941-9)

This was a trial in which patients were not randomised to surgery or no surgery, but were randomised to how they would be *assigned* surgery or no surgery. So patients were selected as to the type of treatment they had. None-the-less, they did publish useful data on outcomes over the first year for those that had surgery and those that did not (Table 3), and we sent this to the C-Gall team to see whether it seemed to align with what they had seen in their randomised trial, even though they were unable to give us precise statistics.

Their figure on the proportion that had further pancreatitis or bile duct stones was also in alignment with a figure cited in Schmidt 2011, which gave us further confidence in using the SECURE data even though it was not randomised.

We also searched for observational data on long-term outcomes and pain and found:

Peterli 2000: <https://doi.org/10.1007/s002680010243>, observing 234 Swiss patients - mild symptoms (11% acute cholecystitis, 3% acute pancreatitis, 14% obstructive jaundice)

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Gui 1998 (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2502763/pdf/annrcse01611-0033.pdf>), observing 92 UK patients

Jagannath 2003 ([https://doi.org/10.1016/S0002-9610\(02\)01206-0](https://doi.org/10.1016/S0002-9610(02)01206-0)), observing 19 US patients with chronic gallstone symptoms

These all agreed with the results from the SECURE trial on pain. The expert group were concerned that these numbers on pain did not reflect their clinical experience, but the Peterli study helpfully separated patients with mild pain that did not interfere with their daily life from those with more severe pain. The expert group felt that this information would help patients, along with the explanations that those that had more severe pain before the operation were more likely to be helped by it. They felt that most patients in the NHS would be in more severe pain by the time they were deciding about an operation, and explained that most of those who suffered pain after surgery would be suffering either from another condition (such as IBS) or would have pain after eating fatty food after the operation.

We double-checked our numbers against those cited in Gurusamy's review paper in BMJ (<https://doi.org/10.1136/bmj.g2669>).

After one of our expert group advised us to list all medical side-effects of the surgery we did an extra search on what those were, and found new-onset diarrhoea as a possible, relatively common, risk of the surgery and used two systematic reviews to get numbers (<https://doi.org/10.4236/ss.2012.36065> and <https://doi.org/10.1136/bmjopen-2020-046172>).

As usual, we used ranges and rounded to the nearest 5 or 0 to give an appropriate impression of (im)precision.