UNIVERSITY OF CAMBRIDGE
Winton Centre for
Risk and Evidence Communication

Decision Aid Supporting Document – Inguinal Hernia

Version 8.1 (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.

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 Representatives) **&** **their Declarations of Conflicts of Interest (COI)**	**X 8**	**Mark Cheetham** (Consultant General and Colorectal Surgeon, National Clinical Lead for General Surgery in Getting it Right First Time) COI: I have had travel and accommodation funded by BD medical to attend educational events related to hernia surgery in UK and Europe over 2022 and 2023. **Prof Aali J Sheen** (Consultant Surgeon, HPB & Hernia specialist Past President of BHS, MAHSC Hon Clinical Chair in Surgery) COI: I have no conflicts with any mesh/ hernia related surgical companies etc. I undertake some consultancy work for both Lexington medical and Bowa-lotus for HPB surgery. **Dr Sam Finnikin** (GP and NHSE National Clinical Specialist Advisor in Personalised Care) No COI to declare. **Mr David Sanders** (Consultant Upper GI and Abdominal Wall Surgeon, Clinical lead for Upper GI Surgery and the Abdominal Wall service, President British Hernia Society) COI : President British Hernia Society. Advisory contract with Medtronic. Advisory contract with Advanced Medical Solutions, Executive Director of Create Surgical Ltd. **Mr Praminthra Chitsabesan** (Colorectal Consultant Surgeon, Secretary British Hernia Society) No COI to declare. **Susannah Hill** (Patient representative for the British Hernia Society) No COI to declare. **Dr Mohan-pal Singh Chandan** (GP, Bearwood Medical Centre NHS England National Clinical Advisor Personalised Care and Respiratory) No COI to declare. **Jackie Bullock** (Patient Rep and Administrator for Hernia Patients Support Group) I have no conflicts of interest with any mesh companies. I am an administrator for Hernia patients support group.

Other clinicians (not part of the expert advisory group) who were interviewed or provided input or feedback	**x11**	Mr Srinivas Chintapatla (Consultant Colorectal Surgeon) 2 x Community Nurses 2 x Advanced Clinical Practitioners 2 x Nurses 1 x GP 1 x Retired Consultant General Surgeon 1 x 2nd Year Junior Doctor 1 x Stoma Nurse
Patients and public involved in 4 rounds of testing and feedback	x16	**Patients and public** x16 Range of ages, ethnicities, education levels 8 with experience of inguinal hernia 1 Equality & Inclusion professional
Organisations		British Hernia Society Hernia Patients Support Group
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.

What is the decision? **And / or** **What are the treatment options available?**	The decision is whether and when to choose treatment for an inguinal hernia and which treatment to choose. We included options guided by our expert group and NICE guidance (2023): - Do nothing and/or watch and wait - Things I can do myself - Surgery o Open or keyhole o Mesh repair or sutures Clinicians told us that people can have inguinal hernias for a long time before they decide they want surgery or they might wait a long time for surgery. Patients reminded us that hernias can greatly impact quality of life. The users (patients) wanted to know what would happen if they chose not to do anything. They wanted to know what would happen if they chose surgery. They wanted to know about pain, their discomfort and effect on their quality of life, and they wanted to know the likelihood of emergency situations. They wanted to know what they could do in the time between deciding to have surgery and waiting for that surgery. They very much wanted to know about how best to recover from surgery and how long recovery would take.
When in the pathway will it be used? (clinician answer)	e.g. Pre primary care, primary care, secondary care Clinicians told us this decision aid would be useful in primary and in secondary care (diagnosis and assessment for surgery).
When would it be useful? (patient answer)	At what point would you want the document? Patients who suspect they have a hernia said they would find the document useful to know whether to go to the GP or not. Patients who have a diagnosed inguinal hernia said they would find the document useful to help them 'watch and wait', and know what to look out

	for when it comes to emergency situations (strangulation or incarceration) and how to make their quality of life better whilst living with a hernia. Patients who are thinking about surgery, or have decided they would like to have surgery, said they would find the document useful pre-referral or at referral to help their conversation with their surgeon. - “[it would be useful] *…early on, on the NHS website, or first speak to the GP about it. They could send text messages to patients for them to read it, or definitely when you’re diagnosed”.* - *“Read it by yourself but ask follow up questions to the clinicians”.* - *“When? Waiting room of the specialist! Before I meet them”.*
How would it be used?	e.g. patients to use it on their own before a consultation or always with a clinician 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. This decision aid is aimed at people who already know they have an inguinal hernia or suspect they do and are visiting their GP or seeing a specialist. Most testers agreed that the leaflet is structured such that it gives them enough information to know when to seek help, and enough guidance to help them in consultations with their clinicians. - *“This doc gives you the chance to question the doctor. I believe you never remember everything”.* - *“How you’ve laid it out with questions what to ask – is very good. You can write it down - it’s great”.*
Are there any exclusion / inclusion criteria ?	The document is for people with an inguinal hernia. It has some generalised information about hernias but has not been written with other kinds of hernias in mind.
Would you prefer a printed version, online electronic	We know from testing of previous decision aids that most clinicians would prefer these were electronic online tools. NHS clinicians typically do say they have facilities to print (black and white only).

version or both? (Patient answer)	Of the 14 patients and public and clinicians who answered this question - 7 wanted it as a printed piece of paper - 6 wanted it both online and printed - 1 said online only
Any other comments?	During the period we were developing this decision aid (2023) there was considerable worry among patients about the use of surgical mesh. We read the 2021 SHTG report for the Scottish Government on mesh use in inguinal hernias, and spoke to people with a range of opinions and concerns. Body image is a big issue with inguinal hernia, as is being able to function doing daily activities. We tried to ensure all these concerns were adequately reflected in the document.
Were there any key decisions made when designing the document, and what was the reasoning behind them?	There are many ways in which an inguinal hernia can be repaired, and we discussed including information about: - TEP vs TAPP - Biological mesh vs synthetic mesh - Robotic surgery In these cases, we decided not to include information because it was not relevant to the users' decision (patients can't decide on the technique used), and the outcomes of the different techniques were not different enough to warrant separation on the 'risks and benefits' pages. However, we did decide to include information about sutures vs mesh repair. We considered including the risks and benefits of the two different techniques, but the expert group advised that the outcome statistics relied too much on how practised the individual surgeon is, and that in the UK very few surgeons can carry out a non-mesh repair, and those that do are not practised enough to have outcomes as good as the literature suggest. - *(Expert clinician) "Sutures are an option but very few people offer this in primary hernia repair. It needs to be clear that the figures given are for those who do the operation regularly, I.e. the good results seen in suture repair are only really for the few people who do it all the time i.e. 50-70 a year"* We discussed the issue with the British Hernia Society, and heard that a registry was currently being set up, and training in non-mesh repair being organised, but that currently there was nothing useful we could point to from the decision aid. This will hopefully change by the time of the next update,

	and we have left room in the design to add outcomes from non-mesh repair (although 5 year recurrence data will be longer coming). We also had considerable discussion about strangulation and recurrence rates (see section on ‘where did we get our data’ in this document).

Some example answers from our patient and regular clinician testers and actions we took on the basis of them (organised by testing round)	
Round 1	Patient feedback: - *“Clear, concise, not too hard to follow, easy language- but not too watered down. Lots of helpful info, that sounds a lot like what I have experienced.”* - *“Make sure good clear pictures are used”.* **In response to this, we worked hard testing and re-testing the images. We used one photograph for the first time in these tools because ‘seeing’ exactly what mesh looked like was really helpful for patients.** - *“Always helpful to see, to match up language to real life to help understanding. Doesn’t seem like this is just a "Treatment decision" but a "Treatment/journey support" tool”.* **We suggest the ‘what’s important to you’ page could be used like a diary, filling it in every month or so to emphasise this ‘journey support’ nature, which patients found helpful.** - *“The info is short and easy to understand, the pictures are helpful and the boxes help to break up what is there to make it more manageable”.* - *“It is a little long, 15 page "leaflet"? But it is full of information that can be useful to others. Could the personal pages be extra / separate / a tear off?”* **We made the sections more obvious and shortened to 11 pages** - Wording*: "As you get older..." - How old? I was 36, is that old? Maybe change to "over time, muscles can get weaker…".* **We changed this wording in response to the comment**

	- *"Need more space for contacts - you will probably see a few people, nurses, consultants, surgeons, etc…. More space for next steps too so that you can keep up to date with appointments and current plans."* **We left as much room as possible within the design, without lengthening it (which people didn't want). We were aware, though, that with 11 pages, if printed double-sided, people would have a 'spare back page' for further notes if required.** - *"I like how much it looks like the varicose veins one. Would be amazing if these became recognisable information and decision supporting documents throughout the NHS".* [From a nurse who helped test more than one decision aid and was aware of the suite we produced last year] - *"Maybe some of the headings could be clearer and the document reordered as sometimes I felt like I had read it in the wrong order. The information on treatments seems to be split up too much."* **We worked on the order to make it flow better**
Round 2	Retired consultant – *"Who would be responsible for issuing these and keeping them up to date?"* - Patient – *"We learn more every day, updating the document is really important, how will you do that?"* **We added review date and responsibility to this supporting document** - *"Good document - more info more depth = better. Covers a lot of things which I think should be covered. Patient focused."* - *"Really important to explain about the different kinds of mesh."* - *LGBTQ+ rep – "If you're specifying men or women (and not including non-binary for example), think about why you're doing it."* **We bore this in mind across all decision aids. Here we're specifying men or women occasionally because those are the populations of the data we're presenting.** - *"More space to write on the back pages"* **As above, we weighed up the document length and decided to prompt for answers and keep the document shorter, assuming that if the document is**

	printed one side only there would be more space to write, and if double-sided there would be a spare 'back page'. - *"Would like an editable PDF - to fill in the boxes electronically"* **This was not possible for this suite of tools, but the suggestion has been noted for others that may be produced in the future.** - *"First impression - Far too much information – that amount of info would worry people // put people off"*
Round 3	- *"Move the reasons why you might have a hernia to later."* **We made this change** - *"Language terms – 'minimally invasive' makes the open one sound scarier – call it 'keyhole surgery'"* **We made this change** - *"Like the colour theme/ want to read- looks appealing"* - *"Swap the order of 'may cause pain' - don't put that first"* **We instead said "sometimes you have pain or discomfort"** - *"Risk of strangulation data: it 1980s 1990s – felt like it wasn't up to date information"* **We used the most up to date information we could find, but were glad that people were picking up the quality of the evidence from the way we represented the sources of data in the document.**
Round 4	- Nurse: *"Post op pain that might occur, pain might have been hernia or might have been something else."* - Surgeon: *"One significant omission is what is the risk of ongoing pain from a mesh repair which appears to be a significant problem in the patients I see and I think borne out in the literature also."* - Patient representative: *"Pain is unique to the person who experiences it, there is no way of measuring pain and no one has the right to dismiss your pain. ... Although as patients we are quick to blame mesh for chronic pain because the mesh wasn't there before*

	the pain developed it is often not the main contributor. Surgery itself is likely the biggest contributor to chronic pain with the mesh then contributing to the pain for example the mesh may be placed over a nerve or it may not sit flat." **We were careful to ensure that the decision aid was clear about different levels of ongoing pain that might be expected after surgery.** - Nurse: *"Is this still a decision aid - is it more of a treatment support doc?"* **It is true that we put in more information than patients would need just to make the decision, but most patients so very much appreciated having 'all information in one place' and having a fuller understanding of the condition and what to expect throughout their journey that we decided it was better to do this, as long as it remained a manageable size, than reduce the content.** - *"Good document. One of the better ones I have read."* - *"Flows nicely and explains everything well."* - *"I like the images of open and keyhole surgery"*

Reading age range	V8.0	Using https://readabilityformulas.com/readability-scoring-system.php Average Reading Age Consensus Calculator Average reading age 11-12

Easy Read development	
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. **This Easy Read was tested in 2 rounds of testing with x 12 easy readers and 3 specialist clinicians**	
Number of Rounds of testing	x 2 rounds of testing
Professionals	x 3 professionals

	- 2 surgeons - 1 specialist nurse / advanced clinical practitioner
Easy Read users	- 8 Easy Reader users from Camden People First - 4 Easy Read users from Tameside People First
Notes and lessons learned from previous development	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). 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. 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. 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). - 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 aways 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 HERNIA	*“Really liked to read about things I can do myself if I have hernia pain.”* One of the risks of having an operation is that pain will come back. The numbers are 4% if you don’t have an operation and 0.4% if you have an operation. For the Easy Read audience, ‘out of 100’ is difficult. Normally we show risks and benefits as a number out of 10, but for this comparison, that shows the same, ‘half an icon’. Testers and our graphics team both suggested to use ‘out of 20’ in this one instance. So we would see half a face for 0.4% and a full face for 4% A reminder that Easy Read users do not know the word “glossary” and to use “word list” instead.

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.

In this case, for prevalence, we used Neutra 1981 (https://doi.org/10.1016/0021-9681(81)90018-7) reporting a Colombian study from 1960s which is often used by others. We also obtained lifetime risk data from Primatesta 1996 (https://doi.org/10.1093/ije/25.4.835) based on numbers admitted for hernia operations in Oxford in the 1970s.

For the risk of strangulation, we used numbers from Gallegos 1991 (https://doi.org/10.1002/bjs.1800781007) and Rai (1998) – as well as records from several thousand patients in the 1980s and 90s: https://doi.org/10.1111/j.1445-2197.1998.tb04837.x

Of those who have a hernia, how many have pain, was a more difficult number, because it depends on how ‘pain’ is measured and defined.

We used Page 2002 (https://doi.org/10.1046/j.1365-2168.2002.02186.x) who gave figures for those who recorded pain ‘at rest’ as well as doing different activities.

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 Technological Assessment for laparoscopic repair (2004) www.nice.org.uk/guidance/ta83 the ASGBI 2013 Commissioning Guide for groin hernia, the McCormack 2003 Cochrane review on laparoscopic versus open (https://doi.org/10.1002/14651858.CD001785) and (for mesh) the SHTG report on the use of mesh in hernia repair (2021) and the Scott 2001 Cochrane collaboration review (https://doi.org/10.1002/14651858.CD002197).

When looking for outcomes from open surgery versus laparoscopic surgery versus no surgery, there were difficulties finding good data on pain, the most important outcome for patients. This is partly because the measurement of pain is so variable, so it was difficult to compare or combine outcomes from different trials (‘pain that interferes with daily life’ versus ‘moderate pain’ versus ‘some groin pain’ etc), and the studies also had different lengths, meaning we had outcomes of pain from 3 months, 12 months, 2 years, 5 years etc.

We couldn’t rely solely on the Cochrane collaboration review (McCormack 2003) as that was considering open surgery versus laparoscopic surgery only, so that meant that we needed to go to individual trials, which we found from the references in the Cochrane review and subsequent searches using Google Scholar and the expert group’s knowledge.

The data used in the final tool was from:

Fitzgibbons 2006 https://doi.org/10.1001/jama.295.3.285 a randomised controlled trial (RCT) in 720 men in USA

deGoede 2017 https://doi.org/10.1097/SLA.0000000000002243 RCT in 528 patients in US

O'Dwyer 2006
https://doi.org/10.1097/01.sla.0000217637.69699.ef RCT in 528 patients in US

(These first three giving us data on watchful waiting)

Page 2002
https://doi.org/10.1046/j.1365-2168.2002.02186.x 323 patients in UK

MRC Trial Group 1999
https://doi.org/10.1016/S0140-6736(98)10010-7 RCT in 928 patients in UK

Liem 1997
https://doi.org/10.1056/NEJM199705293362201 RCT in 994 patients in Netherlands

Stoker 1994
https://doi.org/10.1016/S0140-6736(94)92148-2 RCT in 528 patients in UK

Eklund 2010
https://doi.org/10.1002/bjs.6904 RCT in 1370 patients in Sweden

Berndsen 2007
https://doi.org/10.1007/s10029-007-0214-7 RCT in 867 patients in Sweden

We chose the outcomes that patients most wanted to know, which experts thought important and/or which were over 1%, and which could be most consistently reported from this selection of trials. As usual, we created ranges by taking the lowest and highest figures reported, and rounding them to give an appropriate impression of (im)precision.

For data on mesh versus non-mesh surgery, there was some controversy over how much to emphasise the availability of non-mesh surgery. Based on the fact that it is available (and this is mentioned in the patient information of most NHSE hospitals), and the outcomes of the 2021 SHTG report for the Scottish Government we decided that patients should be given information about the outcomes of having mesh repair, but not the outcomes of having non-mesh repair (stitches), because the outcome of the surgery is so dependent on the experience of the surgeon and, at least in England in 2023, there are no surgeons doing non-mesh repair frequently enough to have outcomes likely to be as good as those cited in the literature. This may change in the future.

The data for the outcomes of open mesh repair were from:

Scott 2001 Cochrane (https://doi.org/10.1002/14651858.CD002197) and Lockhart 2018 Cochrane (https://doi.org/10.1002/14651858.CD011517.pub2) – we had to calculate the percentages for the different outcomes by using the absolute numbers from the first set of evidence tables for the analyses.

EU Hernia Group 2002 meta-analysis:
https://doi.org/10.1097/00000658-200203000-00003

Nguyen 2014 meta-analysis:
https://doi.org/10.1001/jamasurg.2013.5014

The EU Hernia group analysis only gave us a figure for recurrence, which fell within the range given by the Cochrane and Nguyen meta-analyses. The figures from Nguyen (2014) were higher than those found in the Cochrane, but both showed a higher rate of seroma with mesh, and a higher rate of recurrence with stitches. Other outcomes were not significantly and/or clinically different. We decided, therefore, to present the figures for these two outcomes, and to use a rounded range based on the figures from these two sources. The other figures from Lockhart 2018 that was significantly different between the two was neurovascular injury and urinary retention, but this was not an outcome that we had data on for the comparison of open versus laparoscopic surgery, so we decided not to present it.

We also looked at papers covering other outcomes from surgery and mesh, such as infections, rejection/migration of mesh, effects on sperm and testicles of surgery etc.

These included, for example:
Johanet 2011 https://doi.org/10.1016/j.jviscsurg.2011.09.005
Gossetti 2019 https://doi.org/10.1007/s10029-019-01905-z
Oberg 2018 https://doi.org/10.1016/j.surg.2017.12.017
See 2020 https://doi.org/10.1016/j.engreg.2020.05.002
BMJ News report: https://doi.org/10.1136/bmj.k4104
Dong 2018 https://doi.org/10.1186/s12978-018-0510-y
Falagas 2004 https://doi.org/10.1111/j.1469-0691.2004.01014.x
Forester 2022 https://doi.org/10.1007/s00464-021-08442-w
Jisova 2023 https://doi.org/10.1007/s10029-023-02749-4
Kordzadeh 2017 https://doi.org/10.1007/s10029-016-1560-0
Kowalik 2022 https://doi.org/10.1007/s10029-021-02553-y

We did not find any quantification of effects in these that we could cite in the tool.