

Decision Aid Supporting Document – BPH – Enlarged Prostate

Version 12.1 (Dec 2024) 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.

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Expert Advisory Group (Clinicians & Patient Representatives) & their Declarations of Conflicts of Interest (COI)	x12	<p>Expert advisory group:</p> <p>Mr John McGrath (Consultant Urologist, Chairman of the BAUS Academic Section and Executive Committee member of BAUS Section of Oncology) No COI declared</p> <p>Dr Clare Bent (Consultant Interventional Radiologist) 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 Richard Hindley (Consultant Urologist and Visiting Professor at the University of Winchester) COI: I have received payments for teaching and training of BPH treatments by Boston Scientific (Greenlight and Rezūm), and also Procept biorobotics (Aquablation).</p> <p>Dr Margaret Husted (Chartered Health Psychologist) No COI to declare</p> <p>Mr Oliver Kayes (Consultant Urological Surgeon) MBBS MD(Res) FRCS(Urol) University of Leeds - Honorary Senior Lecturer COI: consultant for Teleflex/Neotract</p> <p>Mr Mark Rochester (Consultant Urological Surgeon, NNUH, Service Director for Norfolk & Waveney Urology) COI: Consulting/proctoring for Neotract/Teleflex, consulting for Procept Biorobotics, consulting for Intuitive Surgical</p> <p>Mr Toby Page (Consultant urological surgeon)</p>



		<p>No COI to declare.</p> <p>Mr Feras Al-Jaafari (Consultant Urological Surgeon, BPH Editor - Journal of Clinical Urology/BAUS Endourology Executive Committee, Honorary Senior Lecturer/Speciality Education Lead, Topic advisor (Male LUTS -CG97) to The National Institute for Health and Care Excellence (NICE)) COI: Key opinion leader and Consultant for Boston Scientific (Rezūm/Greenlight laser) and Olympus (iTIND)</p> <p>Mrs Rachel Morrison (BMedSci BMBS MRCS MD FRCSUrol Consultant Urological Surgeon Harrogate District Foundation Trust) No COI to declare.</p> <p>Tom Stokes (Patient and Public involvement Group on PDA for BPH) No COI to declare.</p> <p>Peter Bruce (Patient and Public involvement Group on PDA for BPH) No COI to declare.</p>
Other clinicians (not part of the expert advisory group) who were interviewed or provided input or feedback	x4	<p>Other clinicians:</p> <p>2x GP 1 x retired Consultant Radiologist specialising in Prostate Cancer 1 x retired Specialist Nurse – prostate cancer</p>
Patients and public involved in 6 rounds of testing and feedback	x21	<p>21 patient testers</p> <ul style="list-style-type: none"> - 9 with diagnosed BPH - 2 who think they may have symptoms - 9 not BPH - 1 Equality & Inclusion Professional <p>6 rounds of testing</p>
Organisations		<p>Peer Leadership Network (Equality & Inclusion Professional)</p> <p>BAUS – Mr John McGrath</p> <p>Topic advisor (Male LUTS -CG97) to The National Institute for Health and Care Excellence (NICE) – Mr Feras Al-Jaafari</p>
Who are the Winton Centre for Risk &		<p>The Winton Centre was funded by a philanthropic donation from the David & Claudia Harding Foundation to help communicate</p>

Evidence Communication?		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.
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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>We included options guided by our expert group and NICE guidance CG97.</p> <p>Whether to choose treatment for symptoms of BPE (benign prostate enlargement) and if so, which treatment to choose.</p> <p>Treatment options included in the decision aid:</p> <ul style="list-style-type: none"> - Do nothing (you can always choose not to have treatment) - "Things I can do myself" (conservative treatment) - Medicines - Surgery (we describe 8 surgeries, chosen by the expert group as reflecting those available in the UK) - Catheter (short term catheter usually while you wait for surgery or post surgical recovery)
<p>When in the pathway will it be used? (clinician answer)</p>	<p>e.g. Pre primary care, primary care, secondary care</p> <p>This decision aid has been designed in two distinct parts.</p> <p>Part 1 is for use in primary care / possibly even pre-primary care.</p> <p>Part 2 is for use at point of referral to secondary care or at secondary care.</p>
<p>When would it be useful? (patient answer)</p>	<p>Patients said the leaflet would be useful when they have symptoms but no diagnosis as well as when they had been diagnosed.</p>



	<p>Patients very much wanted a decision aid that explained what an enlarged prostate was, the possible symptoms, what might happen in the future, and what they can do about it themselves.</p> <p>They then wanted to know what would happen at the GP; then how many people choose to have surgery; then which surgeries were available and help choosing which would be right for them.</p> <p>The process of design therefore attempted to incorporate all these needs.</p> <p>This meant that we created a decision aid where Part 1 would be useful for those who think they might have symptoms of enlarged prostate and are thinking of visiting their GP (pre-primary care), those who visit their GP with symptoms and the GP tells them that the symptoms are, or might be, due to an enlarged prostate.</p> <p>Part 2 is designed to be helpful for patients for whom lifestyle or medication from their GP hasn't helped, or has stopped helping, and they are being referred to a specialist.</p> <p>People wanted to read this part of the document before they see their specialist at the hospital and it was also very useful for them after they had seen their specialist, to refer back to.</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>Our decision aids are written, where possible, in such a way as to be stand alone. A reader of any ability and any level of knowledge should be able to read it and understand their options.</p> <p>Part 1 is designed to be understood and used before a visit to a GP, or following a first visit to a GP.</p> <p>Part 2 is designed to be used first with a clinician in secondary care. They would go through the different surgical options and highlight those that are available to the patient (some are more appropriate for smaller / larger prostates for example).</p>
<p>Are there any exclusion / inclusion criteria ?</p>	<p>The tool is relevant for patients who have symptoms from BPE.</p>
<p>Would you prefer a</p>	<p>We know from testing of previous decision aids that most clinicians would prefer these were electronic online tools.</p>



<p>printed version, online electronic version or both? (Patient answer)</p>	<p>NHS clinicians typically do say they have facilities to print (black and white only).</p> <p>Of the users who answered this question:</p> <ul style="list-style-type: none"> 6 would like it on paper only 5 would like it both on paper and online 2 would like it online only
<p>Any other comments?</p>	
<p>Were there any key decisions made when designing the document, and what was the reasoning behind them?</p>	<p>ONE DECISION AID OR TWO?</p> <p>During the development of the tool, it's scope changed. Initially it was commissioned as a tool for secondary care, about the surgical options. Talking to patients, though, made it clear that what they most valued was information about the condition and what they could do themselves to help symptoms, and then medications.</p> <p>There was talk amongst the expert group of removing the medications to make the document shorter, and talk about splitting the decision aid into two different documents. However, we decided on 'one long document' rather than two shorter ones because with the budget allocated we couldn't make two (but could make one long one) and with obvious sections, patients didn't mind and actually quite liked having part 1 even they were being referred for surgery.</p> <p>PROSTATE SIZE & APPLICABLE PROCEDURES</p> <p>The expert group initially discussed whether to mention prostate size when discussing treatment options (some procedures more suitable for smaller / larger prostates). It was decided that from the patient point of view, and because it would make the document more complicated, not to specify this per treatment. Instead we added a column on the page where each treatment was described where the specialist would 'tick' if it was suitable for the patient. That way they could explain at the time the individual's situation, and whether there were any treatments that are not available at that centre.</p> <p>MEDICATIONS</p> <p>There was discussion about which to include in the main table, and which to mention as 'also offered'. The expert group decided to keep the main table to those prescribed for BPH symptoms and not overactive bladder. Tadalafil was originally in the main table, then taken out to be a 'you may also be offered' with a caveat, "but it may not be available everywhere".</p>



	<p>We also removed the side effects for combination of alphablockers and 5-ARIs from the main table as they were essentially what you'd expect from the side effects of each individually and the extra numbers were adding complexity. We kept the benefits of combination therapy in, though, as that is not predictable and is commonly prescribed.</p>
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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	<p><u>Powerpoint T&F</u></p> <p>T&F expert - WHAT'S IMPORTANT TO ME</p> <p><i>"I would like to see a better balance between the list of "important things" - at the moment I don't think it reflects that well the range of issues that men feel are important and feels a little repetitive. I think the first bit of "circle" is good - but then perhaps we can look more at some of the Quality of Life factors and things highlighted in our research. I don't think the list needs to be as long - Could we then add instead a bit on the bottom where they list the 3 most important things to me are...."</i></p> <p>Need for visuals and better layout:</p> <ul style="list-style-type: none"> - <i>"Regarding the document at the moment it is overwhelming with too much information and too much text. We need more pictures or tables to illustrate points as I just got lost with it."</i> - <i>"I guess this has created a larger document than many anticipated. I suspect most of us perceived an aid with greater visual information than text."</i> <p>The surgeons in our expert group wanted to make clear that there is a split between minimally invasive procedures (Rezūm, Urolift, PAE, iTind) and formal surgeries (TURP, PAE, Aquablation, HoLEP):</p> <ul style="list-style-type: none"> - <i>"PAE - there is anecdotal evidence that it can improve erectile function due to the prostate stopping its action as a steal to the blood supply to the penis! But no firm evidence yet!!"</i> <p>Patient rep</p> <ul style="list-style-type: none"> - <i>"Suggest two documents, one for background and at the GP and one with the surgeries. Don't want to overwhelm the patients."</i> - <i>"Layout is extremely important and illustrations and graphs will help greatly."</i>
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	<p>T&F GP</p> <p><i>“We need a document that GPs understand how to use – don’t overwhelm the clinician with the length of the document”</i></p>
<p>Round 2</p>	<p>We had been asked to create a decision aid for secondary care, to help patients understand which surgery to choose if they were offered surgery.</p> <p>But when we began testing with patients, it became very clear that what they really were interested in was information about the prostate, how and why it can cause symptoms, what they can do about it themselves and whether their GP can help.</p> <ul style="list-style-type: none"> • <i>I thought I was starting to get symptoms like this and I haven’t been to the GP, but I might go after reading this. It’s reassured me enough to not be scared to go to the GP about my symptoms.</i> <p>They wanted to know how likely it was that they would have symptoms that need surgery.</p> <p>We had limited resources and could really only create one decision aid. The expert group had asked for a ‘secondary care’ decision aid but the patients wanted a primary care decision aid.</p> <p>We asked the 11 patients we had interviewed up to that point: if they had to choose, which would they rather</p> <ul style="list-style-type: none"> - A shorter decision aid that did not have surgical options - A shorter decision aid that only had surgical options - A much longer document that included both primary care information and options and surgical options? <p>Their answers: 6 said both 7 said primary care only None said surgery only</p> <p>So we came out of round 2 slightly re-structuring the document so that it was clearly in two parts: one to be used at or before visiting a GP, and the second to be used at referral or with a specialist.</p> <ul style="list-style-type: none"> - <i>“The whole thing is valuable, but if it has to be cut in length then I would keep the GP/lifestyle/drugs/general half, and ditch the details of operations. If my experience is anything to go by, patients who reach that maybe-surgery stage are likely to receive leaflets from the urologist and will be able to get the necessary information. What is</i>



not available (or not so easily available) at the moment is the earlier-stage stuff, from first presentation to cystoscopy/biopsy/referral for possible surgery”.

- *“It’s going to be a weighty document but for what it needs to do, it needs to be”.*

Structure and clear signposting of the different sections was important:

- *“And as I’m reading this, I’ve thought part 1, great, really helpful....And there’s so much in here that’s great, it’s really helpful....But then I go into part 2 and part 2 starts to scare you. So it’s definitely two separate things – part 1 should be explaining what an enlarged prostate is... there’s only a few people who really need part 2 – make that clear that it’s about going to hospital”.*

Example points from testing round 2 that we addressed:

Structure

- *“Move the ‘what’s important to you’ page to later on, once you’ve understood all the options”.*

Sometimes the “what’s important to you” pages come before we describe the treatment options. Sometimes it’s more useful to think about what is important to you before you know what’s available. For the prostate decision aid we put these reflective pages later in the document.

Things I can do myself

- *“Group them into ‘do and don’t’, make them easier to read and absorb”.*
- *“Include example drug names”*

We followed both these suggestions

References

- *“Good to include the sources to show that you didn’t just make up the data and to trust the document”*

Structure and content needs simplifying, there’s some repetition

- *“Could be simplified, there’s good information and it explains it well, but there’s not consistent formatting so you get a bit lost”.*



	<ul style="list-style-type: none"> - <i>“There’s a potential for a very useful document”</i> - <i>“In places there’s too much text... hits you as a big wadge of text, needs graphics”.</i> <p>We constantly refined the text and looked for places to add graphical break-up of the information to help people read it.</p> <p><u>Fill in to prepare for your appointment</u></p> <ul style="list-style-type: none"> - <i>“Make sure that you put that this is optional. If you have to start writing things down, you actually might not want to, you can’t face it. I’d use it, and for people who would fill it in, it’s really good, but make sure to say it’s optional”.</i> <p>We changed the phrasing to make it clear that this was optional.</p> <ul style="list-style-type: none"> - <i>“I’ve learnt so much in last 40 minutes – it’s bloody brilliant”</i>
<p>Round 3</p>	<p>Many testers said when they hear ‘prostate’ they usually hear ‘cancer’. That it’s not cancer needs to be really big and bold.</p> <ul style="list-style-type: none"> - <i>““what’s an enlarged prostate’ – and it says ‘it’s not cancer’ – is there any way of sticking that in bold red 24 point? Huge across the page? Because I think this is really important”.</i> - <i>“Because I naively would have assumed it would be a big flashing red light that it’s the big C. As a man you hear the word prostate you immediately follow it with the word cancer. And you shy away from anything about it. When really this isn’t about that at all”</i> <p>We tried to make “this is not cancer” one of the first sentences people read.</p> <p>The ‘Things I can do myself’ page was really popular</p> <ul style="list-style-type: none"> - <i>“This was brilliant! Because this is easy isn’t it? There are some things here I think, oh do you know what I can actually do these easily...”</i> - <i>“This is the best page out of all of them!”</i> <p>Catheter page</p> <ul style="list-style-type: none"> - <i>“This is really good, I didn’t know what they were at all and I have put this is one of the best 3 pages here”</i> <p>The statistics were also found useful:</p>



	<ul style="list-style-type: none"> - <i>"The chances of what you might get was great. Really good."</i>
Round 4	<p>Re. printed or online and the length of the document</p> <ul style="list-style-type: none"> - <i>"It is a long document to read electronically but not if it's printed out. With a printout you read the relevant bit and flick through and return to it".</i> <p>Images – we decided to include a basic image of the torso, kidneys, bladder, urethra, prostate because in testing it was clear that many testers didn't really know how they all connected. It was useful for them to understand the physiology when thinking about the symptoms, how BPE can affect symptoms and why":</p> <ul style="list-style-type: none"> - <i>"Ideas of the images to use are good - include kidneys, bladder, torso - top level."</i> - <i>"Needs more illustrations and fewer words".</i> - <i>"Maybe add something like "these are the things we'll cover""</i> <p>Side effects of medicines were thought very useful to know:</p> <ul style="list-style-type: none"> - <i>"Side effects are what I wish I had known!"</i> <p>Users asked us to add in reassurance for those who are embarrassed to talk about symptoms:</p> <ul style="list-style-type: none"> - <i>"Add something in about don't be embarrassed to discuss things like ejaculation, and erections and urinary symptoms with your doctors or nurses. they deal with it every day. if you want to talk to someone different about your issues..."</i>
Round 5	<p>Some testers were asked to review the document early on and later. This tester reviewed the document in round 2 and round 5</p> <ul style="list-style-type: none"> - <i>"Overall summary: is it's much clearer, easier to read, and makes the distinction between the two sections pretty clear I would say. It seems overall less scary to pick up and I would be more likely to read it without giving up"</i>

Reading age range	V8.0	Using https://readabilityformulas.com/readability-scoring-system.php Average Reading Age Consensus Calculator Average reading age 11-12
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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 5 easy readers and 4 specialist clinicians</p>	
Number of Rounds of testing	x 2 rounds of testing
Professionals	<p>x 5 professionals</p> <ul style="list-style-type: none"> - 4 surgeons - 1 GP
Easy Read users	<ul style="list-style-type: none"> - 5 Easy Read users from Tameside 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> <ul style="list-style-type: none"> - 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
ENLARGED PROSTATE**

**We were able to use feedback from the previous testing
to write this leaflet.**

The prostate leaflet is slightly different from the others in the series in that it covers two decision time points: what to do if you have symptoms from an enlarged prostate and you visit your GP (primary care), and also what to do if you have symptoms from an enlarged prostate and you are seen in secondary care and offered one of (currently) 8 procedures, each with a slightly different risk and benefit profile.

The document is split into two parts. In the standard version and in this Easy Read version, we anticipated that part 2 should be used with a clinician. They would explain which procedures are suitable for you and can explain the nuance of differences.

To make this clear, and because some of the Easy Read feedback prompted it, we added “read this page with your carer and doctor” to some pages.

“The group did mention that somewhere it might be best saying ‘ask your carer to help you understand this document’ - even though we’re trying to make it as easy as possible, it still requires some help.”

“General feedback is that it is great, well structured, easy to follow and the pictures are relevant.”

“Re. language, request to use “big prostate” instead of “enlarged prostate” throughout the document.”

“Re. language, request to use “doctor” over GP, and “hospital doctor” over “specialist.””

We also had requests for further clarification of some terms, e.g. PSA test, catheter, decongestant and antihistamine.

Readers didn’t understand the word “flow”. “Flow is weak when I pee” we changed to “When I pee it does not come out strongly”.



	<p>This group struggled with the word “compare”. We have used this word in other decision aids but in this leaflet we amended the relevant sentence to “Helping you decide about...”</p> <p>“Symptoms” was also used a lot throughout the leaflet and users struggled with this. We changed the word to ‘problems’ and gave examples such as needing to pee more often.</p> <p>There is a page where we compare medicine outcomes over 4 years, where the outcomes are “got worse”, “stayed the same” and “got better”. We used a scale of smiling or frowning or flat mouthed faces. Users needed a little help with this page but “...were all able to identify the bottom option as being the best option”</p> <p>In one example we use the phrase “4 in every 100”. This is difficult for easy readers, 100 is difficult to visualise. We discussed alternatives and agreed that actually there is no better way to do it and that this page was one where the readers would have a carer or doctor to help them.</p> <p>There are some quite complex ideas to weigh up in this leaflet. It helped that the leaflet is split into two parts (primary and secondary care). It helps that they are signposted to have someone to help them read some pages, and the carers and those who work with people with learning difficulties, said they found the pages with icons and numbers were helpful for them to explain.</p>
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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 prevalence data, we used:

Overall numbers from autopsies of over 1000 men, from Berry 1984:

[https://doi.org/10.1016/S0022-5347\(17\)49698-4](https://doi.org/10.1016/S0022-5347(17)49698-4)

Number with symptoms from a study of over 2000 men in the US, from Chute 1993:

[https://doi.org/10.1016/S0022-5347\(17\)35405-8](https://doi.org/10.1016/S0022-5347(17)35405-8)

We also looked at the TRIUMPH study from Verhamme 2002 of 80,774 men in Netherlands.

How many choose treatment when they go to the doctor?

A survey of 12,000 people, internationally (The Multinational Survey of the Aging Male (MSAM-7), from Rosen, 2003: <https://doi.org/10.1016/j.eururo.2003.08.015>

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 evidence behind guideline CG97 from NICE, from 2015:

<https://www.nice.org.uk/guidance/cg97/evidence>.

Just before publication of the decision aid, they also released an evidence review on Aquablation (<https://www.nice.org.uk/guidance/ipg770/evidence/overview-final-pdf-13136516461>) which contained the same evidence as we had gathered.

The review by the Cochrane collaboration (Franco, 2021:

<https://doi.org/10.1002/14651858.CD013656.pub2>) did not give absolute risks or cover many of the outcomes of interest, but we were able to use the reference list to find studies.

We also had the NHS/GIRFT/BAUS guide from 2022: Urology: towards better care for patients with bladder outlet obstruction (https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2021/12/Urology_2021-12-10_Guidance_Bladder-cancer.pdf), and

contacted BAUS to get the most recent audit data to look at real-world outcomes from the different surgeries.

We also used a qualitative study of 20 men (Husted 2022) for some guidance on what was important to people during shared decision making around enlarged prostate

(<https://doi.org/10.1177/10497323221129262>).

Medications

For medications, we were able to use a few large clinical trials as the sources for most of our data:

Data from the MTOPS clinical trial in 3047 people in the US, from 2003:

<https://doi.org/10.1056/NEJMoa030656>

the CombAT clinical trial in 4844 people, worldwide, from 2009:

<https://doi.org/10.1016/j.eururo.2009.09.035>

and a clinical trial in 879 people in the US (published by Kaplan et al.), from 2006:

<https://doi.org/10.1001/jama.296.19.2319>

For the benefits, the MTOPS and CombAT clinical trials gave us the percentage that had 'got worse' over a 4 year period ('increased symptoms' as measured by points on the IPSS scale, combining both trials to give a range). The CombAT trial also gave us the percentage with 'decreased symptoms', as did the shorter term Kaplan trial for alpha-blockers. Only the Kaplan trial (12 weeks) gave us the percentage improved taking placebo, so we only had short term data for that. All percentages were rounded to the nearest 5% to give a sense of the uncertainties.

We also used two reviews of studies specifically on the sexual side effects, from 2006:

<https://doi.org/10.2165/00003495-200666030-00002> and 2015:

<https://doi.org/10.1016/j.purol.2014.12.003>

Alongside the NICE guidelines.



Surgeries

For patients, average change in symptoms on a scale is less helpful than percentage who respond to treatment. It was harder to find evidence on percentage of patients who had a benefit (defined by reduction on IPSS scale), but we were able to get evidence from:

Sham surgery and TURP: A clinical trial in 80 people from 2016: <https://doi.org/10.1111/bju.13714>, and one in 175 people from 2020: <https://doi.org/10.1016/j.urology.2020.12.022>.

Also for **TURP:** 2021/2 UK audit data from BAUS and the WATER trial in 181 people from 2019: <https://doi.org/10.1016/j.urology.2018.12.002>.

For **Aquablation:** the WATER trial above plus a study in 47 people with large prostates from 2021: <https://doi.org/10.1097/JU.0000000000001982>.

For **HoLep:** 2021/2 UK audit data from BAUS.

For **Greenlight:** A study in 68 people: <https://doi.org/10.1016/j.urology.2012.01.063> and expert opinion that it is the same as TURP.

For **Urolift:** A study of 86 people from 2019: <https://doi.org/10.1007/s00345-018-2494-1>, and the BPH6 trial in 80 people from 2015/6: <https://doi.org/10.1016/j.eururo.2015.04.024> & <https://doi.org/10.1111/bju.13714>.

For **Rezūm:** A clinical trial in 197 people from 2016: <https://doi.org/10.1016/j.juro.2015.10.181>, a study of 131 people from 2017: <https://doi.org/10.2147/RRU.S143679>, a study in 47 people with large prostates from 2021: <https://doi.org/10.1097/JU.0000000000001982>, and a study of 262 people from 2022: <https://doi.org/10.1038/s41391-022-00587-6>.

For **PAE:** 2021/2 UK audit data from BAUS, a study in 255 people from 2012: <https://doi.org/10.1007/s00330-012-2714-9>; a study in 1072 people, from 2022: <https://doi.org/10.1007/s00270-022-03199-8>; and a clinical trial with 15 people from 2015: <https://doi.org/10.1007/s00270-015-1202-4>.

For **iTind:** a clinical trial in 175 people from 2020: <https://doi.org/10.1016/j.urology.2020.12.022>.

How many have another surgery within 5 years because symptoms come back?

HoLep: A review of studies, from 2010: <https://doi.org/10.1007/s00345-009-0504-z>, an analysis of data from 20,038 HoLep patients in Korea, from 2021: <https://doi.org/10.1016/j.urology.2021.04.019>.

Aquablation: The WATER trial in 181 people (5 year results): https://www.canjurol.com/html/free-articles/Cdn_JU29_I1_05_FREE_DrGilling.pdf)



Greenlight: A trial in 120 people from 2010: <https://doi.org/10.1016/j.eururo.2010.05.026>, the GOLIATH trial in 281 people from 2016: <https://doi.org/10.1016/j.eururo.2015.07.054>, study of 3627 people from 2021: <https://doi.org/10.1007/s00345-021-03688-4>, a study in 367 people from 2017: <https://doi.org/10.1007/s11255-016-1494-6>, a study of 102 people from 2019: <https://doi.org/10.1016/j.euf.2017.10.006>, and a study of 370 people from 2018: <https://doi.org/10.5489/cuaj.4895>.

Rezūm: A study of 179 people from 2023 (4 year data): <https://doi.org/10.1097/JU.0000000000003299.13>.

Urolift: Only 1-2 year data available – A study of 86 people from 2019: <https://doi.org/10.1007/s00345-018-2494-1>, the LIFT clinical trial in 137 people reported in 2016: <https://doi.org/10.1016/j.ucl.2016.04.008>, the BPH6 clinical trial in 80 people from 2015: <https://doi.org/10.1016/j.eururo.2015.04.024>, and a study in 102 people from 2013: <https://doi.org/10.1016/j.eururo.2013.01.008>.

TURP: The GOLIATH trial in 281 people from 2016: <https://doi.org/10.1016/j.eururo.2015.07.054>, the WATER trial in 181 people: https://www.canjurol.com/html/free-articles/Cdn_JU29_I1_05_FREE_DrGilling.pdf, a study in 340 people from 2022: <https://doi.org/10.1177/20514158221132102>, a study of 188 people from 2015: <https://doi.org/10.1007/s10103-015-1721-x>, an analysis of data from 38,308 TURP patients in Korea, from 2021: <https://doi.org/10.1016/j.urology.2021.04.019>.

PAE: A study in 1072 people, from 2022: <https://doi.org/10.1007/s00270-022-03199-8>; 2-3 year data from the UK-ROPE clinical trial in 305 people, from 2015: <https://doi.org/10.1111/bju.14249>; a study of 255 patients from 2013: <https://doi.org/10.1007/s00330-012-2714-9>.

However, we did feel it was important to illustrate the degree of improvement that might be expected, and so illustrated this on a scale without showing the numbers. The numbers we used to construct the scale, however, were the average improvement in QMax taken from some of the key clinical trials:

TURP: The WATER trial, Gilling et al 2019: <https://doi.org/10.1016/j.urology.2018.12.002>; the BPH6 trial, Sonksen 2015: <https://doi.org/10.1016/j.eururo.2015.04.024>; Hurle 2002: [https://doi.org/10.1016/S0090-4295\(02\)01812-5](https://doi.org/10.1016/S0090-4295(02)01812-5)

HoLEP: Hurle 2002: [https://doi.org/10.1016/S0090-4295\(02\)01812-5](https://doi.org/10.1016/S0090-4295(02)01812-5)

Greenlight: GOLIATH trial, Thomas 2016: <https://doi.org/10.1016/j.eururo.2015.07.054>; Ajib 2018: <https://doi.org/10.5489/cuaj.4895> (data on 370 people in Canada)

Rezūm: McVary 2016: <https://doi.org/10.1016/j.juro.2015.10.181>; Darson 2017: <https://doi.org/10.2147/RRU.S143679>; Campobasso 2022: <https://doi.org/10.1038/s41391-022-00587-6> (data on 262 people in Italy)



Urolift: Sonksen 2015: <https://doi.org/10.1016/j.eururo.2015.04.024>

PAE: Pisco 2013: <https://doi.org/10.1007/s00330-012-2714-9>

iTind: Chughtai 2020: <https://doi.org/10.1016/j.urology.2020.12.022>; Porpiglia 2015: <https://doi.org/10.1111/bju.12982>

Aquablation: The WATER trial, Gilling et al 2019: <https://doi.org/10.1016/j.urology.2018.12.002>; WATER II trial, Bhojani 2019: <https://doi.org/10.1016/j.urology.2019.04.029>

What are the potential risks of surgery?

Technical Guidance from NICE from 2022: <https://doi.org/10.1007/s40258-022-00735-y> and the evidence behind guideline CG97 from NICE, from 2015: <https://www.nice.org.uk/guidance/cg97/evidence> for all risks of the surgeries.

Three reviews specifically of sexual side effects of each surgery, from 2019: <https://doi.org/10.23736/S0393-2249.19.03588-4>; 2020: <https://doi.org/10.1007/s11934-020-01012-y> and 2021: <https://doi.org/10.1007/s00345-021-03682-w>

Additionally:

For **TURP**: the WATER trial in 181 people from 2019: <https://doi.org/10.1016/j.urology.2018.12.002> (for incontinence, ejaculation and stricture); the GOLIATH trial in 281 people from 2016: <https://doi.org/10.1016/j.eururo.2015.07.054> (for incontinence, stricture and blood transfusion); a clinical trial in 200 people from 2004: <https://doi.org/10.1097/01.ju.0000136218.11998.9e> (for incontinence, ejaculation and erectile dysfunction); the BPH6 clinical trial in 80 people from 2015: <https://doi.org/10.1016/j.eururo.2015.04.024> (for all risks); a study in 50 people from 2011: <https://doi.org/10.1016/j.eururo.2011.05.043> (for stricture and blood transfusion); a clinical trial in 117 people from 2020: <https://doi.org/10.1111/bju.14926> (for incontinence, ejaculation and blood transfusion).

For **HoLep**: a clinical trial in 200 people from 2004: <https://doi.org/10.1097/01.ju.0000136218.11998.9e> (for incontinence, ejaculation and erectile dysfunction), a study of 1000 people, from 2010: <https://doi.org/10.1016/j.juro.2009.11.034> (for incontinence and structure); a review of studies, from 2010: <https://doi.org/10.1007/s00345-009-0504-z> (for incontinence, stricture and blood transfusion); a clinical trial in 182 people from 2020: <https://doi.org/10.1111/bju.15161> (for incontinence, ejaculation and blood transfusion).

For **Greenlight**: a clinical trial in 50 patients from 2011: <https://doi.org/10.1016/j.eururo.2011.05.043> (for incontinence, ejaculation and stricture); a clinical trial in 182 people from 2020: <https://doi.org/10.1111/bju.15161> (for incontinence, ejaculation and blood transfusion), clinical trial in 510 people from 2011: <https://doi.org/10.1016/j.urology.2011.03.072> (for incontinence and blood transfusion); a



study of 158 people from 2017: <https://doi.org/10.1159/000447202> (for incontinence, scarring and blood transfusion); a study of 3627 people from 2021: <https://doi.org/10.1007/s00345-021-03688-4> (for incontinence, scarring and blood transfusion); a clinical trial in 117 people from 2020: <https://doi.org/10.1111/bju.14926> (for incontinence, ejaculation, scarring and blood transfusion); the GOLIATH clinical trial from 2014/16: <https://doi.org/10.1016/j.eururo.2013.10.040> & <https://doi.org/10.1016/j.eururo.2015.07.054> (for incontinence, scarring, blood transfusion).

For **Urolift**: the LIFT clinical trial in 137 people reported in 2016: <https://doi.org/10.1016/j.ucl.2016.04.008> (for incontinence, ejaculation and erectile dysfunction); a clinical trial in 80 people from 2016: <https://doi.org/10.1111/bju.13714> (for ejaculation and erectile dysfunction); a clinical trial in 114 people from 2014: <https://doi.org/10.1148/radiol.13122803> (for stricture and blood transfusion); the BPH6 clinical trial in 80 people from 2015: <https://doi.org/10.1016/j.eururo.2015.04.024> (for all risks).

For **Rezūm**: a study of 262 people from 2022: <https://doi.org/10.1038/s41391-022-00587-6> (for incontinence, ejaculation and erectile dysfunction), early studies testing the method, from 2015: <https://doi.org/10.1016/j.urology.2015.05.046> (for incontinence); a clinical trial in 197 people in 2016: <https://doi.org/10.1016/j.juro.2015.10.181> (for ejaculation); a record of recorded adverse events in a US database from 2021: <https://doi.org/10.1097/JU.0000000000002007.04> (for blood transfusion). Stricture: expert opinion only.

For **PAE**: a study of 255 people from 2013: <https://doi.org/10.1007/s00330-012-2714-9> (incontinence, ejaculation and erectile dysfunction, blood transfusion); a clinical trial in 80 men from 2020: <https://doi.org/10.1016/j.eururo.2019.11.010> and study in 1072 people, from 2022: <https://doi.org/10.1007/s00270-022-03199-8> (incontinence); the UK-ROPE clinical trial in 305 people from 2015: <https://doi.org/10.1111/bju.14249> (ejaculation and blood transfusion); a clinical trial in 114 people from 2014: <https://doi.org/10.1148/radiol.13122803> (blood transfusion); a clinical trial with 15 people from 2015: <https://doi.org/10.1007/s00270-015-1202-4> (ejaculation).

For **Aquablation**: the WATER trial in 181 people from 2019 & 2020: <https://doi.org/10.1016/j.urology.2018.12.002>, https://www.canjurol.com/html/free-articles/Cdn_JU27_I1_05_FREE_DrGilling.pdf (for incontinence, ejaculation and stricture); the WATER II study of 101 people from 2019 & 2020: <https://doi.org/10.1111/bju.14360> & <https://doi.org/10.1007/s11884-020-00596-y> (for incontinence and blood transfusion).

For **iTind**: initial testing of the method in 32 people, from 2015: <https://doi.org/10.1111/bju.12982> (incontinence, due to misplaced device); a clinical trial in 175 people from 2020: <https://doi.org/10.1016/j.urology.2020.12.022> (ejaculation, erectile dysfunction and blood transfusion) and a follow-up from 2022: <https://doi.org/10.1089/end.2022.022674> (ejaculation and erectile dysfunction); the MT-02



study of 81 people from 2020: <https://doi.org/10.1007/s00345-020-03140-z> (ejaculation, erectile dysfunction and blood transfusion); stricture: expert opinion only.

Risks for people with a catheter:

A study of 2076 people with a catheter from 2018:

<https://www.doi.org/10.1001/jamainternmed.2018.2417>, and a review of data from 2868 people with a catheter from 2013: <https://doi.org/10.7326/0003-4819-159-6-201309170-00006>.