

View results

Respondent

1

Anonymous

60:44

Time to complete

Your information

1. Name: *

Kasra Saeb-Parsy

2. Job title: *

Consultant Urologist

3. Organisation: *

Cambridge University Hospitals NHS Foundation Trust

4. Email address: *

[REDACTED]

5. Professional organisation or society membership/affiliation: *

6. Nominated/ratified by (if applicable):

7. Registration number (e.g. GMC, NMC, HCPC) *

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: <https://www.nice.org.uk/privacy-notice>

8. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

 I agree I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

9. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I specialise in the medical and surgical management of BPH and offer and have introduced a wide variety of surgical treatments in our trust including TURP, HoLEP and Rezum and tested out other treatments being offered. I sit on the trust BPH subcommittee for the trust

10. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

We are a tertiary centre for the management of BPH and receive referrals from around the region for many surgical treatments. We were one of the centres involved in the first trial of this new technology and used it initially. However, we are not currently using it awaiting further assessment by NICE. The wide adaptation of this new technology will depend on its assessment and approval by NICE. If the evidence reviewed by NICE is favourable and recommended it may prove useful if offering further treatment options

11. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.
- I have published this research.
- I have had no involvement in research on this procedure.
- Other

12. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

This is certainly a novel technology.

13. Which of the following best describes the procedure:

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

14. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

This procedure if proven successful can replace some current standard of care as well as provide an additional tool to the current standard of care and eliminate some of the potential side effects associated with the current treatment.

15. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

In the first phase of the new technique, there was a higher-than-acceptable risk of bleeding however, upon modification of the procedure this risk seems to have been reduced significantly. However, this requires further rigorous assessment of the data.

16. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

The evidence and publication is currently in very early stages and requires more rigorous multicentred assessment,

Current management

17. Please describe the current standard of care that is used in the NHS.

Surgical options currently widely available include: TURP, HoLEP. Green light laser, Rezum, Urolift, Prostatic artery embolisation and iTIND

18. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

No

Potential patient benefits and impact on the health system

19. What do you consider to be the potential benefits to patients from using this procedure/technology?

Potentially accurate cavitation, short learning curve, preservation of ejaculation, short operating time and potential for day case surgery

20. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Potentially suitable for all prostate sizes and can be performed under spinal and day case

21. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

shorter hospital stay and less invasive

22. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

non anticipated

23. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

The surgeon would need to be mentored on the new treatment

Safety and efficacy of the procedure/technology

24. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Higher risk of bleeding
damage to bladder neck or sphincter (theoretical)

25. Please list the key efficacy outcomes for this procedure/technology?

short procedure time
longevity of outcome

26. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

long term data is required due to access efficacy and safety

27. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

long term data is required

28. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Abstracts and ongoing studies

29. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

Can J Urol
. 2021 Aug;28(S2):17-21.

30. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

31. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

32. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

most patient with BPH would potentially be eligible for this procedure however, given the wide variety of option available only a subset of patients may opt for this procedure based on the appetite for risk and complications (bleeding and preservation of sexual function)

33. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Improvement in IPSS, QoL, longevity of improvement, hospital stay

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Bleeding, incontinence, erectile dysfunction, retrograde ejaculation, stricture formation, re-operation rate

Further comments

35. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

cost benefit assessment of the introduction of the new technology would be crucial in order to help wide spread adoption.

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

36. Type of interest: *

- Direct: financial
- Non-financial: professional
- Non-financial: personal
- Indirect
- No interests to declare

37. Description of interests, including relevant dates of when the interest arose and ceased. *

None

38. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- I agree
- I disagree

Signature

39. Name: *

Kasra Saeb-Parsy

40. Date: *

29/11/2022



Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information: Please complete as per instructions below and please ensure that your details are entered within the brackets provided. The brackets are expandable. Thanks.

Name:	<input type="text" value="Neil Barber"/>
Job title:	<input type="text" value="Consultant Urological Surgeon"/>
Organisation:	<input type="text" value="Frimley Health NHS Foundation Trust"/>
Email address:	<input type="text" value="[REDACTED]"/>
Professional organisation or society membership/affiliation: eg Royal of Physicians	<input type="text" value="BAUS"/> FRCS (Eng) <input type="text" value=""/>

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see [our privacy notice](#).

I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:



Comment number	Page/section, line	Factual accuracy comment

Add more rows if required.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience

1	<p>Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p>	<p>I have been involved in this technology for nearly 7 years, initially as a centre within the WATER study, then the OPEN WATER study and since then have been offering this treatment to men on the NHS as well as in the private sector. I have performed over 300 cases. I am a recognised global Key Opinion Leader, and have widely taught and lectured on this procedure around the UK, Europe and the world. I have published the only UK series as alluded to in the proposed document as well as a co-author on most of the publications relating to this technology worldwide.</p> <p>To my knowledge there are 2 other centres in the UK who have started, this year, to offer aquablation to NHS patients. With approval from NICE, given the level of interest I have encountered, I would expect a relatively rapid uptake around the UK thanks to its unique</p>
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	<p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"> - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? - Is this procedure/technology performed/used by clinicians in specialities other than your own? - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. 	<p>attributes. This technology is designed for purpose only –that is the surgical management of symptomatic BPE, i cannot see it being utilised by other specialities.</p>
<p>2</p>	<ul style="list-style-type: none"> - Please indicate your research experience relating to this procedure (please choose one or more if relevant): <p>(Please highlight your choice or choices)</p>	<p>I have done bibliographic research on this procedure.</p> <p>I have done research on this procedure in laboratory settings (e.g. device-related research).</p> <p>I have done clinical research on this procedure involving patients or healthy volunteers.</p> <p>I have published this research.</p>
<p>3</p>	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p> <p>(Please highlight your choice/choices)</p>	<p>Aquablation of the prostate represents a completely novel approach to removing obstructive prostate tissue to relieve that obstruction and improve bothersome LUTS. Rather than the totally visual procedures of TURP and the lasers all of which employ heat energy in one form or another, aquablation is an ultrasound guided procedure, allowing software planning to adapt to the individuals anatomy on imaging and then using a non-thermal tissue removing and ablation energy ie a water jet, delivered automatically or robotically, following the planned contour of treatment, to develop a wide hole through the length of the prostate. The software planning also allows the opportunity to attempt to protect the area of the prostate relating to the delivery from the ejaculatory ducts in an effort to maintain normal antegrade ejaculation.</p>

		<p>Established practice and no longer new.</p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</p> <p>Definitely novel and of uncertain safety and efficacy.</p> <p>The first in a new class of procedure.</p> <p>I am not sure in 2022 if Aquablation of the prostate falls into any of these categories. With 5 year outcome and safety data from a global randomised trial, I'm not sure it can now be considered new and with FDA approval and cover from all the US Insurance companies, as well as widespread take up in Europe – in particular Germany - I understand some 20 000 cases have now been performed worldwide. Nevertheless in the scheme of things it remains new, particularly in the UK. Although novel in its approach, the aim of the procedure is to remove and ablate tissue creating a wide cavity through the prostate with the aim of relieving obstruction and improving symptoms. This is the basis of efficacy of all BPH surgery to a greater or lesser extent, so in effect it isn't a new concept on what it is hoping to achieve.</p>
4	<p>Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?</p>	<p>Yes. For patients it is attractive as Aquablation has proven efficacy in terms of symptom improvement, but it does so with a much lower risk of permanent dry ejaculation compared to TURP or the lasers and unlike those options it appears to carry no risk of negative impact on erectile function. For clinicians and hospitals, Aquablation represents a modality that can treat nearly all sizes of prostate with a relatively short learning curve compared to say HoLEP. Furthermore, the volume of the prostate has little impact upon the procedure time, meaning more predictable and more efficient use of theatre time. Given choice, therefore, I think it is likely that a significant proportion of both patients and clinicians would opt for Aquablation over either TURP or laser prostatectomy</p>

Current management

5	Please describe the current standard of care that is used in the NHS.	TURP, HoLEP, Greenlight laser, Urolift, Rezum
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	none

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Safe, effective treatment with a lower risk of negative side effects on sexual function, be it ejaculatory or erectile
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those with larger prostates for whom alternative procedures that seek to offer a treatment that protects sexual function are inappropriate because of prostate size/ shape or other factors eg chronic urinary retention
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Aquablation provides an opportunity to widen the capacity to treat larger prostates that often have to be sent to an overburdened regional site that delivers HoLEP thanks to its likely shorter learning curve. Op time is not greatly influenced by prostate size, unlike other modalities, offering a predictable and greater capacity in allotted operating room time. The procedure continues to evolve to a point where true day case procedures are now being performed - freeing up in-patient bed capacity.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Whilst initial capital outlay and consumable costs are not insignificant – the potential efficiency of delivery offers the opportunity to treat more people per operating session and with the possibility of a day case approach Required staffing is similar to other more standard options.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Beyond the hardware and disposables, Aquablation carries no extra burden in terms of resource allocation
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	none

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes – like all surgical procedures – theoretical and practical training through observation and on site support would be required to set up a service.
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Safety and efficacy of the procedure/technology

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>The last 7 years has seen an evolution in delivery of aquablation to a point over the last 2 years or more where a global consensus has been achieved. The main post operative issue of potential bleeding has been addressed, with a blood transfusion rate over that time falling to 0.8% globally. Otherwise, Aquablation carries no extra burden of risk over other options, with a similar profile, but it does have a much lower risk of dry ejaculation (10.8% in metanalysis) and no impact upon erectile function.</p>
15	Please list the key efficacy outcomes for this procedure/technology?	>70% improvement in IPSS, > 100% improvement in maximum flow rate
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	<p>We have 5 year outcomes from WATER, relating to prostate volumes of 30 – 80ml with similar re-treatment rates to TURP, but no randomised, long term data in the treatment of larger volume prostates, although single arm studies have confirmed efficacy and safety to 3 years. We have no comparative data vs the standard of care for the 80ml + prostate , HoLEP</p>
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As above
18	<p>If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):</p> <p>(Please highlight your choice/choices)</p>	Most or all district general hospitals.

Abstracts and ongoing studies

<p>19</p>	<p>Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).</p> <p>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.</p>	<p><i>WATER vs WATER II 3-Year Update: Comparing Aquablation Therapy for Benign Prostatic Hyperplasia in 30-80 cc and 80-150 cc Prostates.</i></p> <p>Assad A, Nguyen DD, Barber N, Bidair M, Gilling P, Anderson P, Badlani G, Humphreys M, Kaplan S, Kaufman R, So A, Paterson R, Desai M, Roehrborn C, Chughtai B, Zorn KC, Elterman D, Bhojani N.</p> <p>Urology. 2022 Jul;165:268-274.</p> <p><i>Aquablation Outcomes in Men With LUTS Due to BPH Following Single Versus Multi-pass Treatments.</i></p> <p>Bach T, Barber N, Elterman D, Humphreys M, Bhojani N, Zorn KC, Te A, Chughtai B, Kaplan S.</p> <p>Urology. 2022 Jul 19:S0090-4295(22)</p> <p><i>Functional and surgical outcomes of Aquablation in elderly men.</i></p> <p>Raizenne BL, Bouhadana D, Zorn KC, Barber N, Gilling P, Kaplan S, Badlani G, Chughtai B, Elterman D, Bhojani N.</p> <p>World J Urol. 2022 Aug 30</p> <p><i>Meta-analysis with individual data of functional outcomes following Aquablation for lower urinary tract symptoms due to BPH in various prostate anatomies.</i></p> <p>Elterman D, Gilling P, Roehrborn C, Barber N, Misrai V, Zorn KC, Bhojani N, Te A, Humphreys M, Kaplan S, Desai M, Bach T.</p> <p>BMJ Surg Interv Health Technol. 2021 Jun 23;3(1)</p> <p><i>First Multi-Center All-Comers Study for the Aquablation Procedure.</i></p> <p>Bach T, Gilling P, El Hajj A, Anderson P, Barber N.</p> <p>J Clin Med. 2020 Feb 24;9(2):603</p>
<p>20</p>	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	<p>WATER III – multicentred European trial from Germany – Aquablation vs HoLEP prostate volumes 80 - 180mls</p>

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	70 – 80% of all men undergoing prostate surgery for symptomatic BPE
22	Are there any issues with the usability or practical aspects of the procedure/technology?	no
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	none
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	No
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. - Adverse outcome measures. These should include early and late 	<p>Beneficial outcome measures: IPSS/ QoL, Qmax, decrease in PVR, SHIM, MSHQ – ejaculation questionnaires</p> <p>Day case potential</p> <p>Adverse outcome measures: blood transfusion, urethral stricture and bladder neck contracture rates, incontinence rates, return to theatre rates, UTI/ urosepsis rates – first year post surgery</p>

	complications. Please state the post procedure timescales over which these should be measured:	
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Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	As above
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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the [NICE policy on declaring and managing interests](#) as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	Proctor/ lecturer/ Advisor Procept Biorobotics	2015	On going
Choose an item.	Proctor / lecturer Neotract now Teleflex - Urolift	2013	On going
Choose an item.	Proctor/ lecturer Olympus (Meditate) - iTIND	2018	On going
	Proctor/ lecturer Boston Scientific (previously Laserscope and AMS) – Greenlight laser	2002	2020

I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	<input type="text" value="Neil Barber"/>
Dated:	<input type="text" value="07/11/2022"/>

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Toby Page"/>
Job title:	<input type="text" value="Urological surgeon"/>
Organisation:	<input type="text" value="Newcastle upon tyne hospitals trust"/>
Email address:	<input type="text" value="[REDACTED]"/>
Professional organisation or society membership/affiliation:	<input type="text" value="BAUS, RCS(eng)"/>
Nominated/ratified by (if applicable):	<input type="text" value="GMC"/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="4600741"/>

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see [our privacy notice](#).

I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	<p>Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"> - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? - Is this procedure/technology performed/used by clinicians in specialities other than your own? - If your specialty is involved in patient selection or referral to another specialty for this 	<p>I familiar with aquablation and attended some training from manufacturer, but have not treated any patients.</p> <p>Not currently using</p> <p>Limited use in the uk- currently only frimely park offering</p> <p>No</p> <p>I am involved in patient selection</p>
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	procedure/technology, please indicate your experience with it.	
2	<p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have done bibliographic research on this procedure.</p> <p>Other (please comment)</p>
3	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>Novel approach</p> <p>Definitely novel and of uncertain safety and efficacy.</p>
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	In addition to standard of care
5	<p>Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?</p> <p>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?</p>	Not aware of much changes in procedure

Current management

6	Please describe the current standard of care that is used in the NHS.	Turp/holep/green light / urolift
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Echo laser

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Reproducibility of procedure and any size of prostate, lack of thermal energy
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Larger prostates 80cc+
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Not determined as yet
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Specialist equipment from manufacturer
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Specialist training

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature)	Bleeding/ incontinence/ hospitalisation Blood transfusion Clot retention, and pain
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	Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Qmzx, voiding efficiency and catheter times
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Longevity, post op bleeding risk, increased rate of transfusion
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Post op bleeding and efficacy
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK. Cannot predict at present.

Abstracts and ongoing studies

18	<p>Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).</p> <p>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.</p>	
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19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Open water trial from manufacturer
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	5000
22	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. - Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: 	<p>Beneficial outcome measures:</p> <p>Length of stay Catheter time Flow rate Post void residual Ipps score Iciq mluts score</p> <p>Adverse outcome measures:</p> <p>Post op bleeding Re admission</p>

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	
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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the [NICE policy on declaring and managing interests](#) as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	None		
Choose an item.			
Choose an item.			

I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	<input type="text" value="T page"/>
Dated:	<input type="text" value="20/12/22"/>