View results

Respondent

12 Anonymous

47:38
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using an ultra-micro invasive approach

Your information

2. Name: *

Chandar Shekhar Biyani

3. Job title: *

Consultant

4. Organisation: *

St James's University Hospital, Leeds

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BAUS

7. Nominated/ratified by (if applicable):

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

4280185

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

9. 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.

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

    Are you familiar with the procedure/technology?

    I have not used it but I am trying to get this in our hospital. I have read the literature reading the initial results. Planning to visit a centre performing the procedure

11. 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.

    As far as I know, a centre in London is using it for the BPH. As transperineal biopsy is performed in most hospitals by urologists, radiologists and expert sonographers, this modality can be used by both specialists.

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

- [x] 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

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

Appropriate

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

Can be used by radiologists and urologists like cryotherapy for small renal masses.

16. 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.

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

It is possible. if medium-term results are satisfactory. Elderly patients with long-term catheters may benefit due to the simplicity of the procedure.

Current management

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

There are multiple options for fit patients and all require regional or general anesthesia. There are a few centre doing minimally invasive procedures (Urolift and Rezume) under local.

19. 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

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

2 specialities can use, can be done under local as a daycase

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

Patients with comorbidities.

22. 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?

Yes

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

Nothing new apart from technology.

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

Very limited, mainly about the laser

Safety and efficacy of the procedure/technology

25. 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

    urethral burn
    prostatic abscess
    https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10003190/

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

    Improvement in the symptom score
    Catheter free rate
    ma

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

    Patient tolerance under local
    A small number of published studies

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

    same as above

29. 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

30. 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.

    https://www.frontiersin.org/articles/10.3389/fruro.2023.1100386/full
    https://www.sciencedirect.com/science/article/pii/S2590089722000445
    https://link.springer.com/article/10.1007/s00345-023-04322-1
    https://www.mdpi.com/2077-0383/12/3/793

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

    https://ichgcp.net/clinical-trials-registry/NCT04044573
    It would be good to compare Urolift, Rezume and TPLA in the UK

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

chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.auajournals.org/doi/pdf/10.1097/JU.0000000000002021.05

Other considerations

33. 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)?

Difficult to predict. This can be used for Ca prostate patients with severe LUTS going for radiotherapy.

34. 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.

It should be the same as any technology for the BPH. However, should be tested in 5-7 hospitals with minimum 12 months of follow-up

35. 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:

2 years follow-up

Further comments

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

I think implementation should be in a controlled manner.

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.

37. Type of interest: *

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

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

Have met the rep a few times to understand the technology.

39. 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

40. Name: *

Chandar Shekhar Biyani

41. Date: *

19/07/2023

View results

Respondent

18 Anonymous

25:59
Time to complete

1. Project Number and Name - (Can be found on email) *

Newly Notified Procedure: IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using an ultra-micro invasive approach

Your information

2. Name: *

Dimitrios Moschonas

3. Job title: *

Consultant Urological Surgeon

4. Organisation: *

Royal Surrey NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BAUS

7. Nominated/ratified by (if applicable):

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

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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

9. 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.

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

    Are you familiar with the procedure/technology?

    I watched a demonstration of the technology used in 2 patients in outpatient setting with good tolerance from the patients and excellent outcomes. I have not had the chance to use it yet.

11. 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.

    I do not know the extent of use within the NHS at present but I am assuming given the outpatient nature of the procedure, the ease of use with short learning curve and the positive feedback alongside promising outcomes that the uptake would be exponential once endorsed by NICE.
    The technology is used by other specialities (thyroid, gynaecology etc)

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

- [x] 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

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

Yes

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

That seems to be a novel approach to treat BPH under la with laser that seems to be well tolerated in outpatient setting and offering excellent outcomes

16. 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.

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

It has the potential to replace BPH treatment under general anaesthetic , so it can be used for certain prostate volume range as a standard outpatient procedure

Current management

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

Current pathways involve medical treatment followed by surgical intervention (Rezum vs Plasma vs HOLEP)

19. 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?

TPLA is an ultrasound guided minimally invasive procedure requiring a biplanar TRUS and EchoLaser™ system. The procedure is performed with a Foley catheter in place and under local anaesthesia in an outpatient setting. The laser light is conveyed by the source to the tissues through 300m quartz optical fibres with a flat tip which are inserted percutaneously through 21G Chiba needles under transrectal ultrasound guidance. The laser light produces an ellipsoidal shaped area of coagulative necrosis around the tip of the fibre. A needle placement verification is required to guarantee the safety distances from the urethra and bladder neck. The procedure can be planned via the Echolaser Smart Interface (ESI), a dedicated device that allows the operator to establish the correct ellipsoidal shape area of coagulative necrosis on the prostatic tissue. Once the fibres are placed, the energy can be delivered. The maximum volume treated in a session and the extent of the ablation vary according to the prostatic volume, anatomy and surgeon preference. In some cases, especially in larger prostates, a pull back of applicators (retraction of 5–10mm along its trajectory) during the same treatment session allows for ablation of other areas of the prostatic tissue not treated in the previous illumination.
Rezum and Urolift can be offered in outpatient setting transurethrally whereas Plasma and Holep will be performed under ga as either a day case or with 1-2 night of hospital stay.

Potential patient benefits and impact on the health system

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

1. The fact that TPLA is a minimally invasive outpatient procedure performed under local anaesthesia does suggest that significant savings could be expected compared to other techniques.
2. Good tolerability under la makes the approach appealing to replace medical management of BPH

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

Patient not particularly fit for surgical treament of BPH under ga

22. 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?

    Definitely
    The technique adoption could lead to treatment of BPH with TPLA as an alternative to first line medical treatment with an impact on cost saving for the treatment of such a widely prevalent condition. Improved outcomes are related to the ablation of more excessive(surplus) tissue compared to other la treatment modalities. Furthermore the transperineal approach makes it easily tolerable and less intrusive for the patients

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

    Not requires

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

    The learning curve seems to be short

Safety and efficacy of the procedure/technology

25. 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

Table summarises complications rates in 400 patients from 7 studies

Summary of complications after TPLA.
Complication Number (%)
Transient hematuria 3 (0.75)
Prolonged haematuria 1 (0.25)
Orchitis 3 (0.75)
Urinary tract infections 2 (0.5)
Urethral burn 1 (0.25)
Transient urinary retention 7 (1.75)
Prostatic abscess 4 (1)
Dysuria 8 (2)

References

Cai HJ, Fang JH, Kong FL et al. Ultrasound-guided transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a new minimally invasive interventional therapy. Acta Radiol 2022; 63: 553-8.
de Rienzo G, Lorusso A, Minafra P et al. Transperineal interstitial laser ablation of the prostate, a novel option for minimally invasive treatment of benign prostatic obstruction. Eur Urol 2021; 80: 95-103.
Frego N, Saita A, Casale P et al. Feasibility, safety, and efficacy of ultrasound-guided transperineal laser ablation for the treatment of benign prostatic hyperplasia: a single institutional experience. World J Urol 2021; 39: 3867-73.
Manenti G, Perretta T, Calcagni A et al. 3-T MRI and clinical validation of ultrasound-guided transperineal laser ablation of benign prostatic hyperplasia. Eur Radiol Exp 2021; 5: 41.
Pacella CM, Patelli G, Iapicca G et al. Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study. Prostate Cancer Prostatic Dis 2020; 23: 356-63.
Patelli G, Ranieri A, Paganelli A, Mauri G, Pacella CM. Transperineal Laser Ablation for Percutaneous Treatment of Benign Prostatic Hyperplasia: A Feasibility Study. Cardiovasc Intervent Radiol 2017; 40: 1440-6.
Sessa F, Bisegna C, Polverino P et al. Transperineal laser ablation of the prostate (TPLA) for selected patients with lower urinary tract symptoms due to benign prostatic obstruction: a step-by-step guide. Urology Video Journal 2022; 15: 100167.

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

IPSS score, QoL and IIEF, PVR , Qmax

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

TPLA showed promising results in terms of functional outcomes and patient safety although patient numbers are limited. Clinical trials are ongoing. The lack of medium and long-term follow-up, hinder clinically meaningful conclusions on the safety and efficacy of TPLA beyond the short-term.

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

No

29. 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

30. 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.

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

    N/a

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

    N/a

Other considerations

33. 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)?

    At my hospital level between 100 and 200 patients every year.

34. 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.

    IPSS and IIEF, Flow rate and PVR, Clavien Dindo classification of complications

35. 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:

    Haematuria
    Infection
    Dysuria
    Retention
    Need for further treatment
    Retrograde ejaculation
    Erectile dysfunction

Further comments

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

    N/a

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.

37. Type of interest: *

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

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

N/a

39. 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

40. Name: *

Dimitrios Moschonas

41. Date: *

26/07/2023

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a super-mini invasive approach

Your information

Name:	RICCARDO BARTOLETTI
Job title:	PROFESSOR OF UROLOGY AND CHAIRMAN UNIVERSITY UROLOGY UNIT
Organisation:	UNIVERSITY OF PISA
Email address:	[redacted]
Professional organisation or society membership/affiliation:	European Association of Urology, Società Italiana Urologia
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	1019 Ordine dei Medici di Pistoia

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:

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I'm familiar with the use of the Technology and the Procedure
	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	I'm still using the Procedure although some refinements of the technique seem to be necessary I don't know exactly how much the procedure is currently adopted all around the world but there is a substantial perspective of short term excellent investigational and clinical results. The advantages of the procedure consist of obtaining satisfactory results in terms of urinary function in patients affected by benign prostate hyperplasia and maintain the integrity of sexual functions (when still present). The same procedure may be easily adopted in different specialties such as the ablation of thyroid nodules, or other nodular diseases which can take advantages from the focal therapy. My specialty is strongly involved in patient selection although at the moment all patients have been randomized on the basis of their obstruction but not according to provisional results in terms of definite disease resolution. The results obtained have to be considered as "excellent" since unsatisfactory results were found just on a limited number of cases and the technique remains

	procedure/technology, please indicate your experience with it.	attractive for patients with benign prostate hyperplasia.
2	− 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 clinical research on this procedure involving patients. I have published this research just on Congress Abstracts at the moment, waiting for the long term follow up time
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes This technology has to be considered as innovative due to the exerted effects of laser technology in comparison to previous methods used for temperature-induced tissue ablation such as radiofrequency, microwaves, HIFU , cryoablation , Rezum..... The method is mininvasive because applied in local anaesthesia, possibly in outpatients office regimen, with no risks for the patient safety. It consists of the placement of two or more 18G needles in the context of the hyperplastic tissue and provide the laser fiber insertion in each of the needles just before of the five minutes treatment. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
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?	Yes
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?	Yes. Some aspects of the procedure should have been still improved.

	Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No

Current management

6	Please describe the current standard of care that is used in the NHS.	The standard of care consists of different techniques applicable . The expected results may be easily described as “the need to obtain functional results” in terms of urinary function and sexual function preservation. Many of the available methods described as standard of care are incapable or have limited perspectives to preserve the patient sexual functions.
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?	There are several methods adopted for temperature induced prostate tissue ablation but none of them are comparable to the Echolaser application There are several methods adopted for Temperature induced prostate tissue ablation in current clinical practice although each of them have specific limitations due to back heating problems, incomplete thermal ablation with increased risk of recurrence, local short and long term complications or adverse events.

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?	The potential benefits consist of resolving the functional problems related to the bladder outlet obstruction due to benign prostate hyperplasia maintaining the perspectives of sexual function complete recovery, by using a non invasive method applicable with local anaesthesia in the outpatients office environment without hospital stay and blood loss.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	At this moment we have still to provide different methods of patient selection to state if the procedure may be more suitable in a group of patients or another
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?	Yes Yes, fewer hospital visits, less invasive treatment, no need of general anaesthesia and operating theatre.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No need of special clinical facilities.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. The treatment needles should be inserted with adequate distance from specific areas and structures before the laser energy administration to avoid the risk of damage from increased local temperature of the surrounding tissues

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:	Any specific harms Urinary retention Acute infection of the prostate tissue

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	The reported studies on the topic are mainly cohort studies with different number of treated cases. Pacella et al described the results obtained in a series of 160 patients treated by TPLA . Only one patient reported a grade 3 complication whilst other 6 developed a grade 1 complication. The adverse events described were dysuria in 6 patients and loss of ejaculatory function in two. Frego et al and De Rienzo et al reported the results obtained in two series of 22 and 21 patients respectively with 3 episodes of acute urinary retention, 2 episodes of urinary infection, 1 loss of ejaculatory function. De Rienzo et al reported also a case of prostatic abscess drained percutaneously.
14	Please list the key efficacy outcomes for this procedure/technology?	Improvement of IPSS (International Prostatic Symptom Score) Improvement of QMax at uroflowmetry test Reduction of PVR (post voiding residual urine volume)
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No uncertainties regarding the procedure except for the time necessary to obtain significant functional results in terms of urinary function (at least 3-6 months after the procedure).
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No controversies except for the appropriateness of patient selection
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Yes. There is a prospective randomized controlled trial versus Rezum vapour therapy
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)?	All the men affected by benign prostate hyperplasia. Due the lower risk of developing complications in comparison with the other procedures, and the simple use of local anaesthesia, patients with concomitant anti-platelet medications or increased risk of systemic complications due to concomitant co-morbidities, may be safely enrolled other than receive a monthly substitution of the urinary catheter.
22	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. – Adverse outcome measures. These	Beneficial outcome measures: Improvement of urinary symptoms: • Improvement of the IPSS questionnaire (subjective urinary flow parameters) • Improvement of maximal urinary flow (Qmax) • at least 50% reduction in post-voiding urine residue (PVR) after 6 months • Maintenance of sexual functions including antegrade ejaculation • Improved quality of life with validated questionnaire (QoL-IPSS , SF36 questionnaire) • Maintenance of sexual function (IIEF-5 questionnaire) the timescales should be 3,6,12 months and once per year after the follow-up of 12 months. Adverse outcome measures:

	should include early and late complications. Please state the post procedure timescales over which these should be measured:	Complications should be classified by Clavien Dindo Classification. Evaluated 3 months after the procedure.

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	No comments to report. The technology can be used also for the focal laser ablation of localized prostate cancer.

NICE National Institute for Health and Care Excellence

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
Non-financial professional	No conflict of interest		
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:	**Riccardo Bartoletti**
Dated:	**25/07/2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach**

Your information

Name:	Gennaro Iapicca
Job title:	Urologist
Organisation:	Casa di Cura Santa Rita
Email address:	[redacted]
Professional organisation or society membership/affiliation:	EAU (European Association of Urology), SIU (Società Italiana di Urologia), SIUT (Società Italiana Urologia Territoriale), UROP (Urologi Ospedalità Gestione Privata)
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	(Av 3654, Ordine Medici Italiani

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:

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Yes, I am familiar with the procedure and technology (Echolaser device). I started using the procedure in 2018 and performed around 400 procedures.
	Have you used it or are you currently using it?	I am using the TPLA procedure.
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	I know that the technology is registered in UK and can be used. I think that the procedure is performed by a couple of doctor in UK and the interest is growing.
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	The procedure can be performed by Urologist or Radiologist (rarely).

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	My specialty is involved in patient selection, procedure and follow-up visit after the procedure.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research.
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes It's a novel micro invasive approach that do not eradicate the tissue but coagulate the tissue "in situ" through flexible fiber optics that are introduced in the tissue transperineally by 21g introducer needle. Infact, TPLA with EchoLaser device consists of the percutaneous insertion of optical fibers (one or two fibers per lobe depending on the basal volume and shape of the prostatic gland) via transperineal access, and the simultaneous delivery of laser energy for several minutes which causes the heating of the tissues until they are destroyed, followed by a progressive reduction of the volume of the prostatic lobe and subsequent disappearance of the symptoms. The first in a new class of procedure.
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?	TPLA can be used to replace or in addition to existing standard of care
5	Have there been any substantial modifications to the procedure technique or,	The procedure is performed with a laser device, Echolaser. The entire procedure is performed under ultrasound guidance.

	if applicable, to devices involved in the procedure?	EchoLaser system is composed of Echolaser X4, multi-source 1064 nm diode laser device and Echolaser Smart Interface (ESI), a stand-alone device for the planning of the treatment. The treatment is performed under local anaesthesia and in some cases also mild sedation. It's an outpatient procedure and can be performed in ambulatory settings. 1-2 fiber per prostatic lobe can be used according to the shape and volume of the prostate. The procedure is performed with a pre-determined power of 3-5 W, delivering a maximum total energy of 1800 J per fiber and illumination. In case of big prostate that develop in a longitudinal direction, it's possible to perform from 1 to 2 pull backs, retracting the applicators 10 mm along its trajectory, in order to perform other illuminations delivering 1200–1800 J laser energy. The procedure lasts around 30-45 minutes including the preparation of the patient.
	Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	At the moment there isn't NICE guidance of the procedure.

Current management

6	Please describe the current standard of care that is used in the NHS.	Current treatment options for patients presenting with symptoms is watchful waiting, prescription drugs and elective surgery. Specific drugs can alleviate urinary disorders associated with BPH, although their use is associated with side effects such as retrograde ejaculation, excessive reduction of blood pressure and decreased libido. If prostate enlargement causes urinary obstruction, pharmacological therapy is insufficient, and obstructive surgery is necessary. Men are offered surgery only if lower urinary tract symptoms [LUTS] are moderate to severe or if drug treatment and conservative management have been unsuccessful or are not appropriate.The gold standard has been transurethral resection of the prostate [TURP] that need general anaesthesia and hospitalization. TURP is generally associated with a complete loss of ejaculation after the procedure.

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?	A competing procedure available in the NHS can be the Rezum. This procedure, like TPLA, it takes 2-4 weeks before the patient begins to benefit from the treatment. Rezum is water vapour (steam) therapy for treating lower urinary tract symptoms associated with benign prostatic hyperplasia. The technology uses water vapour to destroy excess prostate tissue with the aim of relieving symptoms. The water vapour is injected into the prostate through a single-use device attached to a urological endoscope. The process is intended to disrupt cell membranes, leading to cell death and shrinking the prostate. The intention is to relieve obstructive symptoms without interfering with surrounding tissues that might impair sexual function. Differences between Rezum and TPLA consist of source of energy and type of applicators and above all transperineal approach for TPLA, instead of transurethral approach for Rezum.

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?	• Improved quality of life • Reduced lower urinary tract symptoms • Improved urinary flow • Reduced postvoid residual volume • Preservation of sexual and ejaculatory function • Preservation of continence In addition to the above, the benefit to patients of this procedure includes: • Local anaesthesia • Low risk profile • Minimal downtime • outpatient procedure
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with benign prostatic hyperplasia suffering of lower urinary tract symptoms (LUTS). In particular, patients with prostatic volume >30ml evaluating with a trans rectal ultrasound exam, pathologic Qmax, pathologic PVR (postvoid residual urine volume). The technique can be proposed to: patients who want to be offered an alternative to TURP or laser surgery; patients with LUTS who do not respond to or do not tolerate pharmaceutical therapy; patients who want to preserve ejaculation. Moreover can be proposed to catheter carrier patients or patients that cannot suspend anticoagulant/antiaggregant therapy.
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?	The procedure has the potential to change the current pathway. This procedure can alleviate pressure in the system, releasing key resources for more urgent cases: improvement in inpatient bed capacity (TPLA patients do not require an overnight stay); improvement in theatre capacity; reduced re-admission rates due to post-operative complications. Micro invasive treatment, no need of general/spinal anaesthesia, outpatient procedure, no need of operating theatre.

11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No need of particular clinical facilities. It's necessary Echolaser device to perform the technique with laser applicators and an ultrasound device
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training to urologist who are not familiar with transperineal biopsy is required. All the staff in the operating room need to be trained in the use of the device and laser safety.

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) Anecdotal adverse events (known from experience) Theoretical adverse events	Potential harms of the procedure • Pain • Blood in urine (hematuria) • Urinary Tract Infection (UTI) • Dysuria • Transient urinary retention after bladder catheter removal, requiring re-catheterization • Prostatic abscess • Skin Burn • Ejaculator disfunction The complications are usually classified according Clavien-Dindo classification and in most of the case are Clavien-dindo grade ≤2. The incidence is low. Please see the review publications available: Tafuri et al 2023 (10.3390/jcm12051860), Sessa et al 2023 (10.3390/jcm12030793)
14	Please list the key efficacy outcomes for this procedure/technology?	• Improved quality of life • Reduced lower urinary tract symptoms • Improved urinary flow • Reduced postvoid residual volume • Preservation of sexual and ejaculatory function • Preservation of continence

15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No. Clinical evidence (publications) regarding durability of the procedure after 3 years misses but there is one study in press with a follow-up of 5 years with very promising results.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No. There is also a Delphi consensus that has included 32 experts' opinions in Europe and USA. See the link of the publication below: 10.3390/jcm12030793
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	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.	- Eighteen-months outcomes of Transperineal Laser Ablation in 184 patients with benign prostatic hyperplasia G. Iapicca, M. Di Martino, G. Manno. European Urology Open Science 20(S2) (2020); S31–S19 DOI:10.1016/S2666-1683(20)35454-9 - Transperineal laser ablation in the clinic: One year results. Bianco F, Gonzalez PG, Avila LA, Kaufman AK, Lopez-Prieto AL, Gheiler EG. European Urology, Volume 83, Supplement 1, 2023,https:// doi.org/10.1016/S0302-2838(23)00288-9. - Transuretral water vapour thermal therapy (RezumTM) versus Transperineal Laser Ablation of the Prostate (TPLA) for the treatment of benign prostatic hyperplasia: A realworld prospective comparative analysis. Fernández-Pascual E, Bocchino AC, Balmori C, Martín C, Bianco Jr. FJ, Martínez Salamanca JI. European Urology, Volume 83, Supplement 1, 2023, Pages S334-S335, ISSN 0302-2838, https://doi.org/10.1016/ S0302-2838(23)00286-5.

		- Transperineal Laser Ablation for Benign and Malignant Prostate Disease. Walser, E. et al. Journal of Vascular and Interventional Radiology, Volume 34, Issue 3, S130 - Abstract No. 287 https://doi.org/10.1016/j.jvir.2022.12.354 - V02-03 Transperineal Fusion Prostate Laser Ablation for The Treatment Of Benign Prostatic Hyperplasia: Technique And Results. Fernando Bianco, Luis Avila, Eusebio Luna, Alberto Lopez-Prieto, Ariel Kaufman, Pedro Gonzalez, David Cohen, and Edward Gheiler; https://doi.org/10.1097/JU.0000000000002528.03
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	A multicentre, international registry to evaluate the treatment of Lower Urinary Tract Symptoms in terms of long-term efficacy, functional outcomes and safety. The long-term efficacy of TPLA for LUTS will be measured by the time until surgical retreatment. *Registered clinical trial link :* https://clinicaltrials.gov/ct2/show/NCT03776006 This study (https://clinicaltrials.gov/study/NCT03653117) will be published soon.
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)?	The prevalence of benign prostatic hyperplasia is directly proportional to age so the number of affected subjects is growing worldwide. In Italy, over 6 million people over 50 are affected by benign prostatic hyperplasia: 50% of men aged between 51 and 60, 70% of 61-70 year olds, reaching a peak of 90% in octogenarians. The symptoms of the lower urinary associated with prostatic hyperplasia do not occur in all patients with the aforementioned pathology. Studies report an incidence ranging from 30 to 50% depending on the age of the subjects. It is therefore

		estimated that in Italy about 3 million subjects are affected by BPH with LUTS. It can be estimated that the percentage of the target population that could be referred to TPLA is 50%.
22	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. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: - Improvement in symptomatology and QoL evaluated preoperatively and those evaluated at follow-up with the validated IPSS questionnaire. - Improvement in urodynamic function (Qmax, maximum flow rate) through urodynamic/ultrasound examination - Improvement in Post Void Residual Volume in ml through urodynamic/ultrasound examination - Change in ejaculatory function with MSHQ-EjD validated questionnaire - Maintenance of urinary continence assessed with a validated questionnaire submitted 3 months after treatment. - Change in sexual function with IIEF-5 validated questionnaire. The timescales are: 3, 6, 12 months after the procedure and after the first years once per year. Adverse outcome measures: Use Clavien Dindo Classification to classify the complications. Evaluate the complication during the treatment and post operative until 3 months after the procedure.

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Nothing to report.

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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
Non-financial professional	No conflict of interest		
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:	**Gennaro Iapiica**
Dated:	**21/07/2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach**

Your information

Name:	Gianluigi Patelli
Job title:	Radiologist
Organisation:	ASST Bergamo Est: Azienda Socio Sanitaria Territoriale Bergamo Est, Seriate, BG, ITALY
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Click here to enter text.
Nominated/ratified by (if applicable):	SIRME, ECR, CIRSE
Registration number (e.g. GMC, NMC, HCPC)	5074 Ordine Medici Chirurghi di Bergamo

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.

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☒ 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:

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Yes, I am familiar with the procedure and technology (Echolaser device). I started using the procedure in 2014 (I was the first user of the procedure in the world) and performed around 250 procedures.
	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?	I am using the TPLA procedure. I know that the technology is registered in UK and can be used. The procedure can be performed by Interventional Radiologist or Urologist.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	My specialty is involved in patient selection, procedure and follow-up visit after the procedure.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research.
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes It's a micro-invasive treatment via transperineal access. The EchoLaser coagulates the tissue without need of tissue removal. Fine needles (21G) are used as introducers for optical fibers that, via the transperineal approach, under transrectal ultrasound guide, let the physician to be able to reach the target tissue. Up to 4 optical fibers can be inserted and activated simultaneously (up to two fibers per lobe) so there are no limits in volumes and morphology of the prostatic gland. After several minutes, up to 20 if multiple illuminations are needed, the tissue is destroyed by heating and then the reduction of the volume of the prostatic lobe will be. The first in a new class of procedure.
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?	TPLA can be used to replace or in addition to existing standard of care

5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	The TPLA procedure is performed by the EchoLaser, the laser source. It's an eco-guided procedure that can be controlled in real-time by the physician. The EchoLaser system is composed by the Echolaser X4, the 1064nm diode laser multi-source, plus the EchoLaser Smart Interface (ESI). The ESI is a medical device that can be an help for the physician in planning the treatment. Based on the volume and shape of the prostatic adenoma, the best trajectories for the insertion of the needles and fibers can be selected always looking at respecting the safety margins from critical structures. It's an outpatient procedure performed under local anaesthesia in an ambulatory setting. Low powers (3-5W) and low energies are used (up to 1800J per fiber and illumination). If needed, a second illumination can be performed in order to treat a larger area in the sagittal direction. The procedure time ranges from 6 minutes to 20 minutes (operative time). NICE guidance of the procedure is not available

Current management

6	Please describe the current standard of care that is used in the NHS.	Currently, watchful waiting, prescription drugs and elective surgery are offered to patients with symptoms. Specific drugs can relieve urinary discomfort associated with BPH even if they are associated to side effects such as retrograde ejaculation, excessive reduction of blood pressure and libido decrease. Drug therapy is insufficient if the enlarged prostate causes urinary obstruction. In this case the obstructive surgery is needed.

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?	The Rezum technology is for sure the competitive procedure. As TPLA, it takes up to 4 weeks before obtaining benefits from the treatment. Rezum is a water vapour technology that uses radiofrequency energy. As all the other techniques on the market aimed at the relief from LUTS, it has a transurethral access. The process is intended to destroy the prostatic tissue by shrinking the cells without causing complications to sexual function. The TPLA differs from Rezum for its unique transperineal approach and for the possibility to be performed under local anaesthesia only.

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?	The technology would reduce the waiting lists for BPH surgery, reducing hospitalizations, offering to patients an alternative to traditional surgery (i.e. TURP) ensuring safety and almost totally ejaculation preservation rates. The aim is to reduce the symptoms caused by the mass effect of benign prostatic hyperplasia on the bladder and urethra in order to improve the patient's quality of life.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with BPH associated with LUTS with International Prostate Symptoms (IPSS) ≥12, maximum urinary flow rate (Qmax) <15 ml/s estimated prostate volume >30 ml on transrectal ultrasonographic (TRUS) images, and post-void residual urine volume (PVR) of <400 ml The use of anticoagulants or indwelling urinary catheters for urinary retention was not a criterion for exclusion. Also, the presence of a large median lobe was not a contraindication to the treatment.
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?	The treatment with EchoLaser TPLA technology is easy to learn (especially if familiar with transperineal prostate biopsies), rapid, to be performed in an outpatient setting and without the need of general/spinal anaesthesia (just local). So, the waiting lists can be reduced and the pressure in the hospital can be alleviated. The ambulatory setting let the operating room free to be used for urgencies. Less operative time, less human resources so less costs.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No need of particular clinical facilities.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	No particular training if the doctor is expert of transperineal biopsy. All the staff in the operating room need to be trained in the use of the device and laser safety.

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) Anecdotal adverse events (known from experience) Theoretical adverse events	The risks and complications related to laser ablation in patients with benign prostatic hyperplasia are related, in the first hours or days after surgery, to a feeling of local tension or pain. Possible complications during the procedure may be related to local bleeding phenomena, subcapsular prostatic hematomas, colliquation of the treated area. In the following days (7-10) pain and increased prostate volume could appear with possible evolution in pseudo-cyst (possibly to be drained), perineal pain, hematuria, urinary tract infection. In a multicenter study (Pacella et al. Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study. Prostate Cancer Prostatic Dis. 2020 Jun;23(2):356-363. doi: 10.1038/s41391-019-0196-4), in which I participated with my population, 7/160 (4.3%) grade I and 1/160 (0.6%) grade III complication occurred. three patients experienced transient hematuria, three had acute urinary retention, and one had orchitis. One patient out of one hundred and sixty (0.6%) had prostatic abscess (Grade III complication) after TPLA, which was successfully drained.
14	Please list the key efficacy outcomes for this procedure/technology?	Reduction of lower urinary tract symptoms, Improvement of urinary flow and reduction of postvoid residual volume, Preservation of ejaculatory function and continence, low risk of complications
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Clinical evidence (publications) regarding durability of the procedure after 3 years misses but a publication with my population is under review with a follow-up greater than 3 years with very promising results.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No.

17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	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.	Nothing to report. I inform you about my previous publications: 1. Transperineal Laser Ablation for Percutaneous Treatment of Benign Prostatic Hyperplasia: A Feasibility Study. Patelli G, Ranieri A, Paganelli A, Mauri G, Pacella CM. Cardiovasc Intervent Radiol (2017). 2. Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study. Pacella CM, Patelli G, Iapicca G, Manenti G, Perretta T, Ryan CP, Esposito R, Mauri G. Prostate Cancer Prostatic Dis. 2019 Dec 11. 3. Pacella, C.M., Mauri, G., Manenti, G., Perretta, T., Patelli, G. (2020). Benign Prostatic Hyperplasia and Prostate Cancer Laser Ablation. In: Pacella, C., Jiang, T., Mauri, G. (eds) Image-guided Laser Ablation. Springer, Cham. https://doi.org/10.1007/978-3-030-21748-8_13
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	A multicentre, international registry to evaluate the treatment of Lower Urinary Tract Symptoms in terms of long-term efficacy, functional outcomes and safety. *Registered clinical trial link :* https://clinicaltrials.gov/ct2/show/NCT03776006

20	Please list any other data (published and/or unpublished) that you would like to share.	I would like to share some information about my study with long follow-up. The results are very promising and show that transperineal laser ablation produces durable benefits and is well tolerated in a population of 40 patients. Median duration of follow-up is around 60 months. The paper is under review in a peer-reviewed journal.

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)?	Hundred thousands of patients would be eligible for this kind of intervention.
22	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. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: - Improvement in urodynamic function (Qmax) - Improvement in symptomatology using theIPSS questionnaire. - Improvement of Quality of Life using the IPSS- QoL questionnaire - Improvement in Post Void Residual Volume in ml - Change in ejaculatory function with MSHQ-EjD validated questionnaire - Change in sexual function with IIEF-5 validated questionnaire. The timescales are: 3, 6, 12 months after the procedure and after the first years once per year. Adverse outcome measures: To classify the complications Clavien-Dindo Classification is used. The complications must be evaluated perioperative and after the treatment until 3 months.

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Nothing to report.

NICE National Institute for Health and Care Excellence

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
Non-financial professional	No conflict of interest		
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:	**Gianluigi Patelli**
Dated:	**25/07/2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach**

Your information

Name:	Francesco Sessa
Job title:	MD, PhD, Urologist
Organisation:	University of Florence – Careggi University Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	SIU/EAU
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Albo Provinciale dei Medici Chirurghi di ROMA (Ordine della Provincia di ROMA) n. 0000060781

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:

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I'm familiar with Echolaser TPLA and I'm currently using it. I started using the procedure in 2021 and actually I have treated more than 100 patients.
	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?	I was the proctor for the first procedure of TPLA in UK that was performed by Mr. Chris Ogden.
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	No in my center. The procedure can be performed also by radiologist.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	X I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). X I have done clinical research on this procedure involving patients or healthy volunteers. X I have published this research. I have had no involvement in research on this procedure. Other (please comment)
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes I think that this technique offers a novel ultra-micro invasive approach, with a very high safety profile and good functional results. As opposed to the current standard of care, it is feasible in an outpatient setting 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. X The first in a new class of procedure.

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?	I think it will be useful in addition to the existing standard of care
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No No

Current management

6	Please describe the current standard of care that is used in the NHS.	TURP - HoLEP
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?	There are several ultraminimally-invasive techniques for treating LUTS due to BPH (e.g. water vapor thermal therapy, prostatic urethral lift). TPLA differs from the overmentioned ones for its approach, avoiding urethral involvement and ensuring high rates of ejaculation preservation, and the possibility to be performed under local anaesthesia alone.

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?	the diffusion of this technique would allow to reduce waiting lists for BPH surgery, reducing hospitalizations for such procedures, and to offer a safe and effective alternative to conventional surgery, ensuring a high safety profile and very high ejaculation preservation rates.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients motivated to maintain ejaculation, patients for whom alpha-blockers are contraindicated (e.g. for hypotensive effects), highly comorbid patients for whom standard surgery might be contraindicated (high anaesthesiologic or bleeding risk)
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?	Yes, it would reduce the number of hospitalizations for BPH surgery, with a consequent impact on the treatment costs for this clinical condition
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None. It can be performed in an ordinary urologic clinic
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	is an extremely easy procedure to learn, especially if familiar with prostate biopsies with transperineal approach, a short training with an experienced operator or a specialist is sufficient.

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:	The technique has a low rate of adverse events. The most common postoperative complications are Clavien-Dindo I or II complications (dysuria, urinary tract infections, hematuria, acute urinary retention). The only Clavien-Dindo III postoperative adverse event reported in literature is prostatic abscess, with an incidence ranging from 0 up to 4.7%.

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Adverse events reported in literature: urethral burn, urine retention, prostatic abscess, dysuria, urinary tract infections, haematuria (Sessa, F.; Polverino, P.; Siena, G.; Bisegna, C.; Lo Re, M.; Spatafora, P.; Pecoraro, A.; Rivetti, A.; Moscardi, L.; Saladino, M.; et al. Transperineal Laser Ablation of the Prostate (TPLA) for Lower Urinary Tract Symptoms Due to Benign Prostatic Obstruction. J. Clin. Med. 2023, 12, 793. https://doi.org/10.3390/jcm12030793)
14	Please list the key efficacy outcomes for this procedure/technology?	Ejaculation preservation, high safety profile, good functional results
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Lack of long term follow-up and of RCTs. At the moment there is only one publication with 3 years follow-up (Minafra et al) and one publication of the results of an RCT study (Bertolo et al)
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. X 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

18	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	Polverino P, Bisegna C, Sessa F, Rivetti A, Re ML, Saladino M, Gallo ML, Pecoraro A, Siena G, Cocci A, Gacci M. 9-Emerging opportunities in minimally invasive BPO management: A single center experience with transperineal interstitial laser ablation of the prostate (TPLA). Continence. 2023 Jun 1;6:100607; Polverino P, Sessa F, Re ML, Bisegna C, Marzi VL, Gallo ML, Siena G, Rivetti A, Saladino M, Cocci A, Minervini A. 8-Transperineal laser ablation (TPLA) of the prostate with EchoLaser™ system: Assessing the 6-months Trifecta and Pentafecta in a single center cohort. Continence. 2023 Jun 1;6:100606;

	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.	Sessa F, Rivetti A, Polverino P, Lo Re M, Bisegna C, Saladino M, Siena G, Cocci A, Pecoraro A, Campi R, Minervini A, Serni S (2023). Ejaculation preservation in patients with benign prostatic obstruction: The safety and efficacy of transperineal interstitial laser ablation. European Urology. 83. S9. 10.1016/S0302-2838(23)00066-0; Bisegna C, Sessa F, Campi R, Rivetti A, Gallo ML, Barzaghi P, Vittori G, Tuccio A, Polverino P, Spatafora P, Cocci A. 7-Preliminary results of transperineal interstitial laser ablation for carefully selected patients with BPH: Is it a safe and feasible outpatient procedure?. Continence. 2022 Jun 1;2:100048; Bisegna C, Sessa F, Campi R, Rivetti A, Gallo ML, Barzaghi P, Vittori G, Tuccio A, Polverino P, Spatafora P, Minervini A. Transperineal interstitial Laser Ablation (TPLA) of the prostate for selected patients with benign prostatic obstruction: Step-by-step technique and preliminary findings. In EUROPEAN UROLOGY 2022 Feb 1 (Vol. 81, pp. S1763-S1763)
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	There is this multicentric registry in progress: - https://clinicaltrials.gov/study/NCT03776006 These clinical trials are concluded and the publications of the results are in press: - https://clinicaltrials.gov/study/NCT03653117 - https://clinicaltrials.gov/study/NCT04760483
20	Please list any other data (published and/or unpublished) that you would like to share.	Francesco Sessa, Claudio Bisegna, Paolo Polverino, Mauro Gacci, Giampaolo Siena, Andrea Cocci, Vincenzo Li Marzi, Andrea Minervini, Sergio Serni, Riccardo Campi. Transperineal laser ablation of the prostate (TPLA) for selected patients with lower urinary tract symptoms due to benign prostatic obstruction: a step-by-step guide. Urology Video Journal, Volume 15, 2022, 100167, ISSN 2590-0897, https://doi.org/10.1016/j.urolvj.2022.100167. Sessa F, Polverino P, Bisegna C, Siena G, Lo Re M, Spatafora P, Pecoraro A, Rivetti A, Conte FL, Cocci A, Villari D, Minervini A, Gacci M, Li Marzi V, Serni S and Campi R (2022) Transperineal laser ablation of the prostate with EchoLaser™ system: perioperative and short-term functional and sexual outcomes. Front. Urol. 2:969208. doi: 10.3389/fruro.2022.969208

		Sessa, F.; Polverino, P.; Siena, G.; Bisegna, C.; Lo Re, M.; Spatafora, P.; Pecoraro, A.; Rivetti, A.; Moscardi, L.; Saladino, M.; et al. Transperineal Laser Ablation of the Prostate (TPLA) for Lower Urinary Tract Symptoms Due to Benign Prostatic Obstruction. J. Clin. Med. 2023, 12, 793. https://doi.org/10.3390/jcm12030793

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)?	It's estimated that 3.4 million men in the United Kingdom and 24 million in countries of the European Union are affected by LUTS (Lower Urinary Tract Symptoms) (Rees J, Bultitude M, Challacombe B. The management of lower urinary tract symptoms in men. BMJ. 2014;348:g3861). We can estimate that hundreds of thousands of patients can be treated with this procedure per year,
22	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. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: - Urinary symptoms (measured by International Prostatic Symptoms Score questionnaire at 3-6-12 months, then yearly) - Obstruction (measured by uroflowmetry and post-void residual at 3-6-12 months, then yearly) - Ejaculation preservation (measured by Men Sexual Health Questionnaire – Short Form at 3-6-12 months, then yearly) - Quality of Life Adverse outcome measures: - Early complications (within 30 days): acute urinary retention, need for hospitalization - Late complications (after 30 days): prostatic abscesses (rare), treatment failure (need for other treatment)

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Randomized controlled trials and comparative studies comparing TPLA and standard of care or other ultraminimally invasive surgical techniques are needed.

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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
Non-financial professional	Proctor for Echolaser TPLA technology	**01/2022**	
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:	**Francesco Sessa**
Dated:	**24-07-2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach**

Your information

Name:	SIBONA Mattia
Job title:	MD
Organisation:	AOU Città della Salute – Molinette Hospital – Turin - Italy
Email address:	[redacted]
Professional organisation or society membership/affiliation:	OMCEO/AOU Città della Salute – Molinette Hospital – Turin – Italy/member of the Italian Society of Urology (SIU)
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	OMCEO Registration number 23388

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:

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? 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?	I am familiar with TPLA. I performed nearly 40 procedures at my center, in collaboration with other members of the urological equipe. We are now ended a clinical trial about TPLA and we are waiting for authorization to introduce permanently TPLA into clinical practice. Currently, TPLA is not used by other specialties than urology in my hospital, but it was previously tested by radiologists for the treatment of several neoplastic diseases (kidney, liver). Several publications are available on this topic. We observed a consistent diffusion of the TPLA procedure in the last years within different clinical context in Italy, with a subsequent increase of inherent publications.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	**X** I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). **X** I have done clinical research on this procedure involving patients or healthy volunteers. **X** I have published this research (ongoing peer review of a prospective original study from our center) I have had no involvement in research on this procedure. Other (please comment)
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes, the title is effective in describing the characteristics of the procedure. The TPLA procedure is classified as a Minimally Invasive Surgical Technique (MIST) for the treatment of Benign Prostatic Hyperplasia. As such, it is innovative and representing a new model for the surgical treatment of this disease. Moreover, the TPLA has some peculiar features (trans-perineal approach, laser technology) that make it different from other competitive technologies. Established practice and no longer new.

		A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. **X**Definitely novel and of uncertain safety and efficacy. To be considered a significant amount of recent literature which already established efficacy and safety in the short term. The first in a new class of procedure.
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?	Currently, TPLA could be introduced in addition to standard treatments. In specific subgroups of patients it could replace current treatments.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No significant modifications of the device or surgical technique have been made since introduction of the technology into clinical practice. Current evidence was obtained on the currently in-use device.

Current management

6	Please describe the current standard of care that is used in the NHS.	The current surgical standard of care for BPH is represented by trans-urethral resection of the prostate (TUR-P), endoscopic enucleation of the prostate (EEP) or open prostatectomy (OP).

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?	A possible competitor is represented by the Water Vapour Thermal Therapy (REZUM), which also belongs to the MIST group. WVTT is different than TPLA, being based on a different energy source (water vapour vs laser energy) and surgical approach (transurethral vs transperineal).

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?	Minimal invasiveness. Reduction of surgical complications. Introduction of the Day surgery or outpatient service setting for BPH surgical treatment.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	1) Younger, fit patients seeking treatment of urinary symptoms with sexual function preservation 2) Elderly and comorbid patients seeking BPH treatment with minimal risk for surgical complications
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?	Surely, the introduction of TPLA could improve waiting lists and reduce hospital stay and further accesses due to surgical complications in BPH patients.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	This procedure could be performed in every existent facility provided the existence of an operating room. The introduction of TPLA in the outpatient service setting could be considered.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	A limited initial training should be recommended to all new users.

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:	As for all surgical treatments for BPH, several possible complications should be considered. The most frequent are: 1) Urinary infections 2) Bleeding (hematuria) 3) Urinary retention

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Theoretically, possible damages to the rectum should be considered (no current similar reports). A full report of surgical complications after TPLA is available at: https://pubmed.ncbi.nlm.nih.gov/36917033/ https://pubmed.ncbi.nlm.nih.gov/37314812/
14	Please list the key efficacy outcomes for this procedure/technology?	Improvement of the IPSS score Improvement of the quality of life score (IPSS bother score) Improvement of the peak urinary flow
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Long term persistence of efficacy is still a concern. Retreatment rate in medium to long term must be determined.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No significant controversy except the long term outcomes of the procedure.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	**X**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

18	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).	Trans-perineal laser ablation of the prostate for the surgical treatment of lower urinary tract symptoms: where does the limit stand? First results from a prospective cohort of very high-risk patients. Destefanis P, Sibona M, Vitiello F, Vercelli F, Montefusco G, Bosio A, Bisconti A, Gontero P. European Urology Open Science 32:S11;DOI: 10.1016/S2666-1683(21)00711-4

	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Prospective trial from Molinette Hospital on the use of the TPLA procedure in elderly and comorbid patients (ongoing peer review).
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)?	TPLA is feasible in nearly all BPH patients, excluding those with severe hypocontractile bladder. In a more conservative estimate, TPLA could be particularly fit for the treatment of 25 to 30% of patients, considering both the younger and sexually active and the elderly and comorbid ones.
22	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.	Beneficial outcome measures: - IPSS total score improvement measured after 6 to at least 24 months after surgery - IPSS bother (quality of life) score - Peak urinary flow improvement (6-24 months) - Total prostate volume reduction Adverse outcome measures: - Surgical complications analysis according to the Clavien-Dindo classification, with particular attention to those of grade >=3 (severe complications).

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

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

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

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

Print name:	**MATTIA SIBONA**
Dated:	**July 24th, 2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach**

Your information

Name:	Mr Alan Doherty
Job title:	Consultant Urologist
Organisation:	Queen Elizabeth Hospital, Birmingham
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	3279241

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.

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Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? 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	I am familiar with TPLA EchoLaser procedure. I am up to date with all published data on the EchoLaser and have also observed the treatment conducted in London. The procedure is currently being conducted in a private setting in the UK, but is soon to be conducted in the NHS also. There is a huge amount of interest in the EchoLaser in the UK, with multiple sites looking to implement the technology. The EchoLaser can also be used in other specialities, for example Liver and Thyroid. From my understanding, it is also being conducted by Interventional radiologists skilled in transperineal procedures.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure.
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes The TPLA procedure with the EchoLaser is a new, micro-invasive for BPH. It is the only system currently available that utilises a a Transperineal approach, so neither the urethra nor the bladder neck is touched during the procedure. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
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?	
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?	No

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

Current management

6	Please describe the current standard of care that is used in the NHS.	In the NHS, the current standard of care is a TURP.
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?	EchoLaser TPLA has no other competing or alternative procedure/technology available in the NHS due to its unique Transperineal approach.

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?	Micro-invasive procedure, low risk of complications, day-case procedure that can be conducted in an outpatient setting under local anaesthetic. Most patients return home the same day.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients suffering from symptoms of BPH, including patients that would like to minimise risks of sexual dysfunctions, those on anticoagulant medication and those that are not suitable for GA procedure.
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?	Due to the Transperineal approach taken with the EchoLaser TPLA, it has improved outcomes with very low complication rates, therefore fewer re-admissions. The EchoLaser also has the potential to reduce the number of patients requiring surgical procedure and thereby reducing overnight hospital stays. The procedure is conducted under local anaesthetic and therefore most patients can return home the same day.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Laser safety requirements
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Laser safety and ultrasound training. Specific EchoLaser training to be provided by Elesta/ims.

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:	Potential complications of the procedure could be UTI, hematuria, pain, prostatic absess

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Improvement to IPSS, QOL and flow rate.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	N/A
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	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	Newest publication for the EchoLaser: Transperineal laser ablation of the prostate as a treatment for benign prostatic hyperplasia and prostate cancer: The results of a Delphi consensus project. Cocci A et al. Asian Journal of Urology, 2023, ISSN 2214-3882, https://doi.org/10.1016/j.ajur.2023.07.001

	us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	TPLA for LUTS in Amsterdam
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)?	25,000 patients treated with TURP each year
22	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. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: • IPSS • QOL • Flow Rate Adverse outcome measures: • Infection • Retention

Further comments

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

NICE National Institute for Health and Care Excellence

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.	No interest to declare		
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:	**Mr Alan Doherty**
Dated:	**25/07/2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach**

Your information

Name:	Mr Chris Blick
Job title:	Consultant Urologist
Organisation:	Royal Berkshire NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6056963

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:

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have read all published data on TPLA EchoLaser and have seen the EchoLaser procedure performed on a 'phantom' during a wet lab session. I have also watched a number of online videos of the procedure being conducted in Europe.
	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?	No, the EchoLaser is not currently being used in the NHS but the first cases are scheduled for August 2023. Potentially, highly skilled interventional radiologists that are regularly completing Transperineal biopsies.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	Selection of patients should be completed by urologist.
2	− 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).
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes, the title of TPLA is fitting. The EchoLaser is a novel treatment for BPH, however a similar concept is already in use for the treatment of prostate cancer. We commonly use the Transperineal approach for biopsies, therefore this procedure is a variation of that technique. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
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?	This procedure would be an addition to the current standard of care (TURP).
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?	No

	Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No

Current management

6	Please describe the current standard of care that is used in the NHS.	The historical gold standard has been transurethral resection of the prostate (TURP), an effective procedure, although is associated with the risk of bleeding, TUR syndrome, and the need for general anaesthesia and hospitalisation. TURP is generally associated with a complete loss of ejaculation after the procedure. TURP procedures also place a considerable burden on resources, specifically theatre capacity and inpatient beds.
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?	There is no technology currently available to NHS using a Transperineal approach. The most similar procedure available would be Rezum, however this is not conducted under local anaesthetic or in an outpatient setting. Rezum is also limited by size.

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?	EchoLaser TPLA is the only system with a Transperineal approach, so neither the urethra nor the bladder neck is touched during the procedure. The advantages of EchoLaser TPLA are summarised below: • Micro-invasive approach (21G needles used) • Organ sparing procedure • Pre-planning software including real-time monitoring • Transperineal (not transurethral) • Local Anaesthesia in an outpatient setting • Short procedure time (30-40 minutes) • Allows catheter removal on patients with indwelling urinary catheters. • Lower risk profile compared to more invasive procedures Key efficacy outcomes for the patient are: • Improved quality of life • Reduced lower urinary tract symptoms • Improved urinary flow • Reduced postvoid residual volume • Preservation of sexual and ejaculatory function • Preservation of continence
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Many men experiencing LUTS as a result of BPH, specifically those that are not suitable for general anaesthetic and patients that want to preserve ejaculatory function and continence.
10	Does this procedure/technology have the potential to change the current pathway or	Yes. The procedure is less invasive, would increase efficacy and require fewer admissions.

	clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Laser safety requirements , e.g. blinds and signs.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Staff to be trained in Laser safety. Company to provide online and in-person competency 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) Anecdotal adverse events (known from experience) Theoretical adverse events	EchoLaser TPLA may lead to the following temporary and reversable adverse side effects: • Pain • Blood in urine (hematuria) • UTI • Dysuria • Transient urinary retention after bladder catheter removal, requiring re-catheterization • Prostatic abscess • Skin Burn The complications are usually classified according Clavien-Dindo classification and in most of the case are Clavien-dindo grade ≤2.
14	Please list the key efficacy outcomes for this procedure/technology?	Improvement to IPSS scores, flow rate, quality of life, reduction in residual volumes and correction of urinary retention.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	N/a

16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	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.	**Recent papers for EchoLaser/BPH:** • **Three years outcomes of transperineal laser ablation of the prostate.** Minafra P, DE Rienzo G, Gerbasi S, Cindolo L, Battaglia M, Ditonno P. Minerva Urol Nephrol. 2023 Jun 14. doi: 10.23736/S2724-6051.23.05270-9. • Ejaculatory Function following **Transperineal Laser Ablation versus TURP for Benign Prostatic Obstruction: A Randomized Trial.** Bertolo R, Iacovelli V, Cipriani C, Carilli M, Vittori M, Antonucci M, Maiorino F, Signoretti M, Petta F, Travaglia S, Panei M, Bove P. BJU Int. 2023 Mar 14. doi: 10.1111/bju.16008 • **Transperineal Laser ablation for Benign Prostatic Enlargement: A Systematic Review and Pooled Analysis of Pilot Studies.** Tafuri A, Panunzio A, De Carlo F, Luperto E, Di Cosmo F, Cavaliere A, Rizzo M, Tian Z, Shakir A, De Mitri R, Porcaro AB, Cerruto MA, Antonelli A, Cormio L, Carrieri G, Karakiewicz PI, Abreu AL, Pagliarulo V. J Clin Med. 2023 Feb 26;12(5):1860. • **Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study.** Pacella CM, Patelli G, Iapicca G, Manenti G, Perretta T, Ryan CP, Esposito R, Mauri G. Prostate Cancer Prostatic Dis. 2019 Dec 11.
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Amsterdam registry for BPH
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)?	More than 5,000 patients.
22	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. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: - Uroflowmetry parameters - IPSS - QoL - IIEF5 Adverse outcome measures: • Infection • Urinary retention

Further comments

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

NICE National Institute for Health and Care Excellence

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.	No interest to declare.		
Choose an item.			
Choose an item.			

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

Print name:	**Mr Chris Blick**
Dated:	**25/07/2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach**

Your information

Name:	PETR HOLY
Job title:	UROLOGY CONSULTANT
Organisation:	Kingston Hospital NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BAUS, EAU
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 6132386

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:

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am trained and using TPLA in my practice.
	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?	At this moment TPLA is not widely used in NHS. However it is likely to change the practice in future. Procedure can theoretically be used by interventional radiologist that is skilled in transperinaeal prostate procedures. Selection of patients and indication for management of bladder outlet obstruction should be done by urologist.

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure.
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes, TPLA is adequate title Innovation of this procedure is that it combines benefit of transperineal approach with thermal treatment of prostate in principle similar to REZUM technique. It represents novel concept. TPLA allows better control of thermal energy delivered to target tissue and bypassing urethral access reduce risks of complications related to urethral injury and UTIs. Definitely novel and of uncertain safety and efficacy.
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?	Yes. TPLA has a potential to change current practise and be used as an addition to existing portfolio of benign prostate procedures.
5	Have there been any substantial modifications to the procedure technique or,	Not that I am aware of.

	if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	There are more data published from different centres confirming efficacy and safety of procedure.

Current management

6	Please describe the current standard of care that is used in the NHS.	I will refer to surgical management of male LUTS as current standard of care.
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?	There is no comparable technique available to NHS. Closest procedure currently used would be REZUM. However it is using heat pulse delivered by vapour transurethrally. It has limitations related to size of prostate and transurethral approach inherently carries risks related to urethral damage and urinary infections / sepsis.

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?	It has all benefits of procedure performed in outpatient setting. Avoiding risks associated with aneasthesia and hospital stay.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Young patients that would like to minimise risks of sexual dysfunctions. Patients unfit for GA procedure
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?	TPLA has a potential to reduce number of invasive procedures and reduce number of hospital visits. It helps to improve hospital capacity to manage male LUTS as there is no need for anaesthetic pre-assessement.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Outpatient, laser fit clinic room
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Staff involved in TPLA should be trained for use of laser

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:	Commonly reported and experienced risks are: Heamatospermia Haematuria Urinary infection Discomfort

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Dysuria
14	Please list the key efficacy outcomes for this procedure/technology?	LUTS improvement Improvement of urinary flow Correction of urine retention
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	My personal experience with TPLA reflects safety and efficacy data reported.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not that I am aware of. TPLA uses known technology and treatment principles.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	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	I have used published literature that can be found using standard literature search.

	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	BPH registry Localised prostate cancer registry
20	Please list any other data (published and/or unpublished) that you would like to share.	n/a

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)?	I assume that up to 1/3 of patients that would be eligible for BPH surgery would be fit for TPLA.
22	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. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Standard LUTS management outcome measures including prostate size after 3 and 12 months post treatment. Adverse outcome measures: I would use adverse outcome measures similar to REZUM

Further comments

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

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	No interests to declare		
Choose an item.			
Choose an item.			

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

Print name:	**PETR HOLY**
Dated:	**24 Jul. 23**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach**

Your information

Name:	Click here to enter text. Utsav Reddy
Job title:	Click here to enter text. Consultant Urological Surgeon
Organisation:	Click here to enter text. Norfolk and Norwich University Hospitals NHS Foundation Trust
Email address:	Click here to enter text. [redacted]
Professional organisation or society membership/affiliation:	Click here to enter text. BAUS/BMA
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. GMC 7020667

How NICE will use this information:

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

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consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? 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?	I have seen the procedure being undertaken under local anaesthetic. The Echolaser has been purchased by a local acute NHS Trust. Currently TPLA is being used in the private sector and I believe is due to start in Scotland too.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	**I have had no involvement in research on this procedure.**
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes The concept of transperineal and transurethral energy delivery to ablate benign prostate tissue has been present for many years. Finding a replicable technique and appropriate energy modality is key and there seems to be some theoretical benefit in approaching the prostate through a transperineal approach avoiding direct prostatic urethral injury. **Definitely novel and of uncertain safety and efficacy.**
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?	This would be in addition to the standard of care
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?	Not known

	Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	Further longer term large volume prospective studies within world and UK practice would be useful

Current management

6	Please describe the current standard of care that is used in the NHS.	Depending on patient choice – HOLEP/TURP/PVP/Aquablation/Rezum/Urolift/PAE
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?	Rezum – transurethral approach is taken rather than Transperineal

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?	Transperineal approach – potentially limited transurethral sloughing
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those with medical comorbidities and patient choice
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?	Potentially could be undertaken in the office setting under local anaesthetic
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Echolaser, theatre environment
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, there will be a learning curve

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:	Damage to surrounding structures – external sphincter, urethra, neurovascular bundles

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Long term durability
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	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	**BPH** Three years outcomes of transperineal laser ablation of the prostate. Minafra P, DE Rienzo G, Gerbasi S, Cindolo L, Battaglia M, Ditonno P. Minerva Urol Nephrol. 2023 Jun 14. doi: 10.23736/S2724-6051.23.05270-9. Ejaculatory Function following Transperineal Laser Ablation versus TURP for Benign Prostatic Obstruction: A Randomized Trial. Bertolo R, Iacovelli V, Cipriani C, Carilli M, Vittori M, Antonucci M, Maiorino F, Signoretti M, Petta F, Travaglia S, Panei M, Bove P. BJU Int. 2023 Mar 14. doi: 10.1111/bju.16008

	us if you list any that you think are particularly important.	Transperineal Laser ablation for Benign Prostatic Enlargement: A Systematic Review and Pooled Analysis of Pilot Studies. Tafuri A, Panunzio A, De Carlo F, Luperto E, Di Cosmo F, Cavaliere A, Rizzo M, Tian Z, Shakir A, De Mitri R, Porcaro AB, Cerruto MA, Antonelli A, Cormio L, Carrieri G, Karakiewicz PI, Abreu AL, Pagliarulo V. J Clin Med. 2023 Feb 26;12(5):1860. Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study. Pacella CM, Patelli G, Iapicca G, Manenti G, Perretta T, Ryan CP, Esposito R, Mauri G. Prostate Cancer Prostatic Dis. 2019 Dec 11. **Prostate Cancer** Reliable Visualization of the Treatment Effect of Transperineal Focal Laser Ablation in Prostate Cancer Patients by Magnetic Resonance Imaging and Contrast-enhanced Ultrasound Imaging. van Riel LAMJG, van Kollenburg RAA, Freund JE, Almasian M, Jager A, Engelbrecht MRW, Smit RS, Bekers E, Nieuwenhuijzen JA, van Leeuwen PJ, van der Poel H, de Reijke TM, Beerlage HP, Oddens JR, de Bruin DM. European Urology Open Science, Volume 54, August 2023, Pages 72-79 A single-operator experience using EchoLaser SoracteLiteTMfor focal laser ablation of prostate cancer: One more arrow in the quiver for the conservative management of the disease. Meneghetti I, Giardino D, Morganti R, Marino V, Menchini Fabris F, Bartoletti R, Pinzi N. Arch Ital Urol Androl. 2022 Dec 27;94(4):406-412. doi: 10.4081/aiua.2022.4.406. PMID: 36576471.
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Registry: TPLA for LUTS - Full Text View - ClinicalTrials.gov
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)?	1 in 2 men over the age of 50 suffer from BPH in the UK.
22	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. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: • Quality of life • Increased flow rates • IPSS • PVR Adverse outcome measures: Clavien Dindo Classification to classify all complications during the procedure and following the procedure (3-6 months).

Further comments

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

NICE National Institute for Health and Care Excellence

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.	No interests to declare		
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:	**Click here to enter text. Utsav Reddy**
Dated:	**Click here to enter text. 24/7/23**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach**

Your information

Name:	Pierluigi
Job title:	Bove
Organisation:	Department of Urology – San Carlo di Nancy General Hospital, Rome
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Albo Provinciale dei Medici Chirurghi di ROMA (Ordine della Provincia di ROMA, Società Italiana di Urologia (SIU), European Association of Urology (EAU), Associazione Italiana di Endourologia (IEA), Endourological Society
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	0000049946

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:

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? 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?	Since the introduction of transperineal laser ablation (TPLA) of the prostate, I always experienced this technique in the fields of benign prostatic hyperplasia (BPH) and focal therapy for prostate tumors. I am currently using this technique as part of my surgical portfolio with very satisfying results. TPLA has been known by the urologists' associations in several congresses and its use is gradually increasing worldwide. This micro-invasive technique is currently used in endocrine surgery (thyroid), general surgery (liver) and by interventional radiologists for percutaneous focal therapies under CT/US control.

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I am doing bibliographic research on this procedure in order to systematically review its role on focal treatment of prostate cancer. I have done clinical research on this procedure involving patients and comparing TPLA for BPH and classic bipolar resection of the prostate (TURP). It was a registered randomized clinical trial. I have published this research. Reference is Bertolo R, Iacovelli V, Cipriani C, Carilli M, Vittori M, Antonucci M, Maiorino F, Signoretti M, Petta F, Travaglia S, Panei M, Bove P. Ejaculatory function following transperineal laser ablation vs TURP for benign prostatic obstruction: a randomized trial. BJU Int. 2023 Jul;132(1):100-108. doi: 10.1111/bju.16008. Epub 2023 Mar 30. PMID: 36917033.
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The title adequately reflects the procedure. TPLA is a novel micro-invasive technique of certain safety and efficacy. It is easily reproducible and not associated with major complications classified according to Clavien Dindo scale. Studies are currently validating these results.
4	Does this procedure/technology have the potential to replace current standard care or	This technology would be used as an addition to existing standard of care.

	would it be used as an addition to existing standard care?	
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No substantial modifications to the procedure technique has been introduced neither changes in its efficacy and safety profile.

Current management

6	Please describe the current standard of care that is used in the NHS.	Current surgical standard of care for BPH is transurethral resection of the prostate (TURP) or incision if the prostate volume is <= 30 ml. For low and intermediate localized prostate cancer, standard of care is either active surveillance, radical prostatectomy or radiation therapy.
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?	Currently, TPLA has not other competing or alternative procedure/technology available.

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?	This procedure is micro-invasive through its percutaneous and perineal approach. Complication rate is very low. Perioperative complications were not reported. Post-operative complications are rare (on continence and sexual outcomes).
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	For BPH: patient who wants to preserve ejaculation or the unfit for surgery. For prostate cancer: patients with MRI evidence of focal lesions that can be treated with TPLA.
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?	This procedure has the potential to change the current pathway or clinical outcomes to benefit the healthcare given the low complication rates. For prostate cancer: it may avoid more invasive treatment such as radical prostatectomy or radiotherapy.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The surgeon should be trained and skilled in ultrasound approach to prostate.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	The surgeon should be trained and skilled in ultrasound approach to prostate.

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:	The potential adverse events are: - Urinary retention (10%) - Urinary retention with need of reintervention (2%) - Urinary tract Infections (5%) - Stress Incontinence (<1%) - Retrograde ejaculation (<1%)

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	For BPH: improvement of urinary flow and a lower incidence of lower urinary tract symptoms. Preserving continence, potency and anterograde ejaculation. For prostate cancer: focal treatment with necrosis of the tumour. Preserving continence, potency and anterograde ejaculation.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	For BPH: prostate volumes >80-100 ml. For prostate cancer: multifocal tumors, high risk tumors, relapses after previous treatments.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	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	Last Congresses: 2023 European Association of Urology Congress attended in Milan, 2023 Italian Congress of the Society of Urodynamics Last pubblications: - Bertolo R, Iacovelli V, Cipriani C, Carilli M, Vittori M, Antonucci M, Maiorino F, Signoretti M, Petta F, Travaglia S, Panei M, Bove P. Ejaculatory function following transperineal laser ablation vs TURP for benign prostatic obstruction: a randomized trial. BJU Int. 2023 Jul;132(1):100-108.

	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.	- Minafra P, DE Rienzo G, Gerbasi S, Cindolo L, Battaglia M, Ditonno P. Three years outcomes of transperineal laser ablation of the prostate. Minerva Urol Nephrol. 2023 Jun 14. doi: 10.23736/S2724-6051.23.05270-9. Epub ahead of print. PMID: 37314812. - Tafuri A, Panunzio A, De Carlo F, Luperto E, Di Cosmo F, Cavaliere A, Rizzo M, Tian Z, Shakir A, De Mitri R, Porcaro AB, Cerruto MA, Antonelli A, Cormio L, Carrieri G, Karakiewicz PI, Abreu AL, Pagliarulo V. Transperineal Laser Ablation for Benign Prostatic Enlargement: A Systematic Review and Pooled Analysis of Pilot Studies. J Clin Med. 2023 Feb 26;12(5):1860. doi: 10.3390/jcm12051860. PMID: 36902647; PMCID: PMC10003190. - Laganà A, Di Lascio G, Di Blasi A, Licari LC, Tufano A, Flammia RS, De Carolis A. Ultrasound-guided SoracteLite™ transperineal laser ablation (TPLA) of the prostate for the treatment of symptomatic benign prostatic hyperplasia (BPH): a prospective single-center experience. World J Urol. 2023 Apr;41(4):1157-1162. doi: 10.1007/s00345-023-04322-1. Epub 2023 Feb 28. PMID: 36853444; PMCID: PMC10160153. - van Riel LAMJG, van Kollenburg RAA, Vis AN, van Leeuwen PJ, de Reijke TM, de Bruin DM, Oddens JR. Safety and Feasibility of Soractelite Transperineal Focal Laser Ablation for Prostate Cancer and Short-term Quality of Life Analysis from a Multicenter Pilot Study. Eur Urol Open Sci. 2022 Apr 2;39:48-54. doi: 10.1016/j.euros.2022.02.012. PMID: 35528781; PMCID: PMC9068724.
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	I am following a single cohort registered trial on TPLA focal therapy for low and intermediate prostate cancer.
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)?	BPH: hundred thousand. Prostate cancer: thousands.

22	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. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	**BPH** Beneficial outcome measures: - Uroflowmetry parameters - IPSS and IPSS QoL, IIEF5 questionnaires **Prostate cancer** Beneficial outcome measures: - Post-operative PSA - Multiparametric MRI at 3- and 12- months after treatment Adverse outcome measures: Early: - urinary retention, need to mantein the cathether for 7-14 days and outpatient re-evaluation - Infections: urinecolture after 1 month - Quality of life: outpatient evaluation after 1-, 3-, 6- 12- months

Further comments

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

NICE National Institute for Health and Care Excellence

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.			
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:	**Pierluigi Bove**
Dated:	**July 24th 2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach**

Your information

Name:	Vincenzo Pagliarulo
Job title:	Medical Doctor
Organisation:	Vito Fazzi Hospital, Lecce, Italy
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Società Italiana di Urologia
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Albo Provinciale dei Medici Chirurghi di BARI (Ordine della Provincia di BARI) n. 0000011603

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:

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? 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?	I am very familiar with the procedure. I have been using it extensively for more than a year. I m currently using it performing around 20 procedures per month. It is widely used also among endocrinologists for the treatment of benign thyroid adenomas.

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure and published a systematic review (Tafuri A, Panunzio A, De Carlo F, Luperto E, Di Cosmo F, Cavaliere A, Rizzo M, Tian Z, Shakir A, De Mitri R, Porcaro AB, Cerruto MA, Antonelli A, Cormio L, Carrieri G, Karakiewicz PI, Abreu AL, Pagliarulo V. Transperineal Laser Ablation for Benign Prostatic Enlargement: A Systematic Review and Pooled Analysis of Pilot Studies. J Clin Med. 2023 Feb 26;12(5):1860. doi: 10.3390/jcm12051860. PMID: 36902647; PMCID: PMC10003190.
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The title is adequate in my opinion. It is an important innovation as it enables adequate treatment for benign prostatic hyperplasia without the need for any general or spinal anaesthesia. Further, in our experience as well as in others it has been shown to be extremely safe. The first in a new class of procedure.
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?	Current evidence cannot prove it will replace current standards, however it is an important option for a wide range of patients in addition to existing standard of care

5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	Not to my knowledge No

Current management

6	Please describe the current standard of care that is used in the NHS.	TURP
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?	REZUM It differs as it delivers energy by means of an endoscopic procedure and it requires spinal anestesia, while echolaser is feasible by means of local perineal anestesia

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?	No risk of ejaculatory disfunction Very low risk of bleeding Outpatient procedure
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients not willing to lose ejaculation Prostate volume lower than 100 cc Patients under antiaggregation Patients not suitable for spinal or general anaesthesia
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?	Yes, definitely
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Outpatient ambulatory setting
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, knowledge of trans rectal ultrasound and transperineal percutaneous prostate biopsy

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology?	Emospermia Ematuria Prostatitis and prostatic abscess

	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	
14	Please list the key efficacy outcomes for this procedure/technology?	Stop using drugs for BPH Reduction of post void residual urine Increase in IPSS questionnaire Significant benefit in all voiding endpoints
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No long term (more than 3 years) results.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present.

Abstracts and ongoing studies

18	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	https://clinicaltrials.gov/ct2/show/NCT03776006
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)?	As this technology is really reducing the operating room burden, and as we are observing an important satisfaction from the patients, in my center we are offering this technology to more than 50% of patients unsatisfied with medical treatment
22	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.	Beneficial outcome measures: IPSS Variation in post voidal residual urinary volume, Need for medical treatment afeter the procedure Variation in urinary flow parameters Adverse outcome measures: Fever

	– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Pain Bleeding Prostatic infection

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	No comments

NICE National Institute for Health and Care Excellence

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.	No conflict of ineterest		
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:	**Vincenzo Pagliarulo**
Dated:	**26/07/2023**

View results

Respondent

16 Anonymous

11:09
Time to complete

1. Project Number and Name - (Can be found on email) *

'Newly Notified Procedure: IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using an ultra-micro invasive approach'

Your information

2. Name: *

S Alan McNeill

3. Job title: *

Consultant Urological Surgeon

4. Organisation: *

NHS Lothian

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BAUS

7. Nominated/ratified by (if applicable):

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

GMC 3342250

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

9. 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.

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

    Are you familiar with the procedure/technology?

    Yes

11. 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.

    Not yet

12. 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.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

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

Variation on a theme used to treat prostate cancer with focal therapy

16. 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.

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

Likely additional to current methods

Current management

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

19. 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?

Rezum uses steam to cause cell death in BPH and is deployed transurethrally. Whereas echolase is deployed Transperineally and uses laser to cause cell death

Potential patient benefits and impact on the health system

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

Daycase, probably under local anaesthetic block

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

Men with symptoms caused by BPH.
Also lof benefit for focal therapy in men with early prostate cancer

22. 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?

Yes - potentially daycase

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

Same facilities as are already used for Transperineal prostate biopsies

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

Yes - will require proctored learning

Safety and efficacy of the procedure/technology

25. 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

    Urethral irritation and need for temporary catheterisation
    Unlikely that there would be more serious adverse events unless used inappropriately

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

    Improvement in lower urinary tract symptoms associated with BPh

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

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

29. 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

30. 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.

    I have only seen demonstrations at conferences

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

    Not sure

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

Other considerations

33. 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)?

10-20% of men suffering symptoms associated with BPH

34. 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.

IPSS improvement
Urinary flow rate improvement

35. 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:

Haematuria
Dysuria
Pain

Further comments

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

Nol

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.

37. Type of interest: *

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

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

N/A

39. 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

40. Name: *

    Alan McNeill

41. Date: *

    25/07/2023

View results

Respondent

15 Anonymous

140:24
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach

Your information

2. Name: *

Chris Ogden

3. Job title: *

Consultant urologist

4. Organisation: *

University College London Hospital

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

RCS BAUS EUA RSM

7. Nominated/ratified by (if applicable):

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

2967661

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

9. 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.

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

    Are you familiar with the procedure/technology?

    Yes I trained in Rome and have performed the first cases on NHS and private patients in the UK

11. 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.

    Yes I am currently using it and Kings Lynn hospital has bought the device to treat NHS patients. I have introduced and trained five consultant Urologists in TPLA with the device.I beleive the uptake will be rapid as most urologyconsultants are very well versed in transperineal biopsy of the prostate so will adopt the procedure with ease.It is performed on Liver, kidney and thyroid tumours.

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

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

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

Yes

15. 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 procedure has a unique role by ablating prostate tissue without surgical incision or destroying the prostatic urethra and bladder neck like all other transurethral cystoscopic proceedures.

16. 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.

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

An addition to standard care

Current management

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

TURP

19. 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?

There are other laser proceedures but they are transurethral and compromise the prostaic urethra and bladder neck often resecting prostatic tissue like TURP

Potential patient benefits and impact on the health system

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

Very low risk of complications, no bleeding and preservation of ejacultaory and sexual function which is often the case with the drugs used for BPH and other surgical interventions. As well as an outpatient local anaesthetic day case procedure

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

Patients unhappy with the drug therapy and who want to preserve sexual funtion.

22. 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?

Yes it is quick and requires minimal hospital resource. It is easy for Urologists to adopt safely and effectively, so has the potential to have a huge impact on the NHS waiting list at relatively low cost.

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

Clinic

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

Minimal for Urologists already performing transperineal biopsy of the prostate which is most Urologists

Safety and efficacy of the procedure/technology

25. 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

    Very low side effect profile. Practically no incidence of incontinence, severe bleeding or sexual dysfunction, unlike TURP or other interventions and drug therapies. Very rare risk of prostate abscess usually occurring when procedure performed in presence of UTI, less than one in a thousand risk.

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

    Resolution of troublesome urinary voiding symptoms. Improved urinary flow and reduced post void residuals.

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

    We have Italian data showing good efficacy to four years. The longer term outcomes remain unknown.

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

    None

29. 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

30. 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.

I presented a peer reviewed paper of my experience of the first UK patients at our national annual conference in Birmingham in June 2023

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

Yes we are registering all patients and outcomes with the European Registry.

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

Please see attached

Other considerations

33. 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% of patients needing treatment for Bladder out flow obstruction and troublesome lower urinary tract symptoms. A large healthcare need.

34. 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.

All patients are followed up with flow rate and bladder residual assessments and IPSS questionnaires, and data added to the existing European data registry for TPLA BPH treatment.

35. 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:

We are following patients up for at least ten years

Further comments

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

I have found the procedure very safe and easy to deliver and feel it offers great potential to very cost effectively address the huge health burden faced by the NHS. With the potential to role it out to all Urology departments very quickly meeting the need in a short time frame. Overall cost effectiveness will depend on the impact on reducing the drug bill and inpatient care of the surgical alternatives and the sustainability of its effectiveness beyond the known four years.It also is being used for focal treatment for prostate cancer in Europe with very promising results.

Declarations of interests

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37. Type of interest: *

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

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

I have invested a small amount in the distribution company of the device over five years ago for a different urological device

39. 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

40. Name: *

    Chris Ogden

41. Date: *

    25/07/2023

View results

Respondent

21 Anonymous

74:24
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using an ultra-micro invasive approach'

Your information

2. Name: *

jennifer uribe

3. Job title: *

research fellow

4. Organisation: *

royal surrey NHS foundation trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

royal society of medicine

7. Nominated/ratified by (if applicable):

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

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How NICE will use this information:

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

9. 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.

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

    Are you familiar with the procedure/technology?

    yes

11. 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.

    yes

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

- [x] 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.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

yes

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

novel approach/concept/design

16. 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.

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

has the potential to replace current standard care

Current management

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

brachytherapy, cryotherapy, HIFU and others

19. 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?

There are various technologies with different ablative energy sources

Potential patient benefits and impact on the health system

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

EchoLaser TPLA showed promising results in terms of functional outcomes and patient safety although patient numbers are limited. Clinical trials are ongoing

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

Too soon to know until trial results are available

22. 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?

It would be another option for minimally invasive treatment of BPO and localised prostate cancer

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

Similar to minimally invasive procedures such as LDR brachytherapy, cryotherapy or HIFU

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

Yes

Safety and efficacy of the procedure/technology

25. 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

Complication Number (%)
Transient hematuria 3 (0.75)
Prolonged haematuria 1 (0.25)
Orchitis 3 (0.75)
Urinary tract infections 2 (0.5)
Urethral burn 1 (0.25)
Transient urinary retention 7 (1.75)
Prostatic abscess 4 (1)
Dysuria 8 (2)

REFS

1.Cai HJ, Fang JH, Kong FL et al. Ultrasound-guided transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a new minimally invasive interventional therapy. Acta Radiol 2022; 63: 553-8.
2.de Rienzo G, Lorusso A, Minafra P et al. Transperineal interstitial laser ablation of the prostate, a novel option for minimally invasive treatment of benign prostatic obstruction. Eur Urol 2021; 80: 95-103.
3.Frego N, Saita A, Casale P et al. Feasibility, safety, and efficacy of ultrasound-guided transperineal laser ablation for the treatment of benign prostatic hyperplasia: a single institutional experience. World J Urol 2021; 39: 3867-73.
4.Laganà A, Di Lascio G, Di Blasi A et al. Ultrasound-guided SoracteLite™ transperineal laser ablation (TPLA) of the prostate for the treatment of symptomatic benign prostatic hyperplasia (BPH): a prospective single-center experience. World Journal of Urology 2023.
5.Manenti G, Perretta T, Calcagni A et al. 3-T MRI and clinical validation of ultrasound-guided transperineal laser ablation of benign prostatic hyperplasia. Eur Radiol Exp 2021; 5: 41.
6.Pacella CM, Patelli G, Iapicca G et al. Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study. Prostate Cancer Prostatic Dis 2020; 23: 356-63.
7.Patelli G, Ranieri A, Paganelli A, Mauri G, Pacella CM. Transperineal Laser Ablation for Percutaneous Treatment of Benign Prostatic Hyperplasia: A Feasibility Study. Cardiovasc Intervent Radiol 2017; 40: 1440-6.
8.Sessa F, Bisegna C, Polverino P et al. Transperineal laser ablation of the prostate (TPLA) for selected patients with lower urinary tract symptoms due to benign prostatic obstruction: a step-by-step guide. Urology Video Journal 2022; 15: 100167.

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

pls see following references

Laganà A, Di Lascio G, Di Blasi A et al. Ultrasound-guided SoracteLite™ transperineal laser ablation (TPLA) of the prostate for the treatment of symptomatic benign prostatic hyperplasia (BPH): a prospective single-center experience. World Journal of Urology 2023.

Tafuri A, Panunzio A, De Carlo F et al. Transperineal Laser Ablation for Benign Prostatic Enlargement: A Systematic Review and Pooled Analysis of Pilot Studies. J Clin Med 2023; 12.

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

Unsure at this stage

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

In medium and long term unsure at this as reports of follow up are short term

29. 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

30. 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.

    Only aware of standard lit searches.

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

    https://www.clinicaltrials.gov/search?term=TPLA

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

Other considerations

33. 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)?

    Not sure

34. 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.

Description of clinical trials cover all of these aspects

Trial ID Indication Device Primary Outcome(s) Country
NCT03653117 BPO Echolaser • Technical feasibility.
• Adverse events (CTCAE v5). Netherlands

NCT03776006 BPO Echolaser • Long-term treatment efficacy. Netherlands

NCT04760483 BPO Echolaser • Feasibility and tolerability. USA

NCT04198103 BPO Echolaser • Clinical symptom change 6 and 12mo post-TPLA Italy

NCT04044573 BPO Echolaser • Symptoms 1-year post-TPLA
• Complications needing readmission or reintervention. Italy

NCT04781049 BPO Echolaser vs
TURP • Change in pain (VAS).
• Change in ejaculatory function.
• Change in sexual function. Italy

NCT05163197 PCa Echolaser • Oncological control Netherlands

NCT05584787 PCa (low-int.) Echolaser • Oncological outcomes 3 to 12 mo post-TPLA Italy

NCT04170478 PCa focal Echolaser • Histological ablative efficacy (size of ablation zone in RP specimen). Netherlands

NCT04045756 PCa focal
(low-int.) Echolaser • Disease-free survival.
• Post-procedure complications by mpMRI. Italy

35. 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:

Pls see question regarding adverse outcomes.Time period should be 5 years.

Further comments

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

Lack of health economics data

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.

37. Type of interest: *

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

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

NONE

39. 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

40. Name: *

jennifer uribe

41. Date: *

26/07/2023

View results

Respondent

19 Anonymous

60:46
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1956

Your information

2. Name: *

Krishnan Anantharamakrishnan

3. Job title: *

Consultant Urological Surgeon

4. Organisation: *

The Sherwood Forest NHS Foundation Trusts

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Association Of Urological Surgeons

7. Nominated/ratified by (if applicable):

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

4588780

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

9. 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.

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

    Are you familiar with the procedure/technology?

    somewhat familiar and have some understanding of the procedure

11. 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.

this procedure is at its infancy stage.

I reckon the speed of the uptake would be swift and would be comparable to that of currently widely used Minimally Invasive UroLift Procedures

yes this technology is being used elsewhere in other organs such as thyroid.

The main applications of EchoLaser Thermal Ablation currently involve:
• Benign Thyroid Nodules (BTN) (ModìLite) and enlarged prostate volume due to BPH (SoracteLite), with the aim of producing a reduction in volume of the tissue due to the Laser Induced CytoReduction (LICR) process;

• Primary and secondary malignant liver lesions (PBLite) and localised low risk prostate and kidney cancer (SoracteLite) and papillary thyroid carcinoma (Modìlite) with the aim of tumour complete ablation with a sufficient safety margin.

Elesta is developing other EchoLaser Thermal Ablation applications on soft tissue lesions such as breast, lung and pancreas.

Elesta gives to each application procedure a dedicated name to differentiate the procedure performed with EchoLaser (micro- invasiveness and multi-fiber approach in a single system) from the other thermal ablation techniques.

Depending on the tissue, anatomical district, size and nature (benign or malignant) of the mass to be treated, the objectives of laser ablation treatment with EchoLaser can be the following:

• Determine a volumetric reduction of the target ablation tissue due to the cytoreduction process induced by laser ablation (LICR, acronym for Laser Induced CytoReduction) with consequent improvement or disappearance of the symptomatology. The ablation is carried out in an internal area of the mass in order to obtain an area of necrosis inside it that the body's natural process will eliminate in the weeks following the treatment. This objective is generally pursued in the case of benign pathology, such as benign thyroid nodule or prostate adenoma, but sometimes also in malignant pathologies when the ablation treatment is performed for palliative purposes;

• Produce a complete ablation of the mass with a sufficient safety margin in order to achieve its total destruction. This objective is pursued in case of malignant or even benign pathology when the anatomical conditions allow it.

My experience is in treating the BPH patients. predominantly involved in selecting those patients who would benefit from minimally invasive procedures. essentially they have to be day case and those that could be performed in the outpatients set-up.

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

- [x] 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.
- [x] I have carefully sieved out the literature available on this procedure

13. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) could be better than that of ECHO Laser

14. Is the proposed indication appropriate? If not, please explain

yes it is appropriate

15. 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 a minor variation

Laser ablation is a standard practice, all along in a variety of settings such as stones, cancer and benign lesions

Approach is also pretty much similar to the transperineal template biopsies, and so the uptake would be similar to that procedure

The Urologist are particularly well versed with this perineal technique approach and so, let us consider this ECHO laser as a novel design/concept/approach but with minor variation

16. 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.

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

I am feeling [my gut feeling] that this procedure is the way forwards for the next decade

this would certainly replace the current standard care such as TURP

This procedure could be repeated if the prostate regrows again

on balance, not only this procedure could be stand alone to replace standard care but also could supplant the standard care such as TURP

This is a remarkable procedure since could be offered under local anaesthetic and for comorbidity

Current management

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

Transurethral Resection of Prostate

19. 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?

Not aware of any competing or alternative procedure/technology that which have the similar function / mode of action to the ECHO laser

Potential patient benefits and impact on the health system

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

good urine flow

improvement of lower urinary tract symptoms

Day case treatment

ejaculation and sexual function preserved

no risk of urinary incontinence

no permanent implantation of a medical device

rapid recovery time

minimal post operative pain

precise treatment - accurate localisation

can treat larger sizes of prostate >100gram

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

poor comorbidity

those who are deemed high risk for general anaesthesia

Epidural anaesthesia contraindicated

those on anticoagulants

22. 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?

This procedure has the capability to change current pathways in improved outcomes

less invasiveness

day case procedure rather than an operation

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

none

could be adopted straightaway in the outpatient settings

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

yes

laser safety training

learn the modality of ECHO laser

Safety and efficacy of the procedure/technology

25. 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

adverse events;

failure of the procedure

failure to achieve desired outcome

urine infections

failure to void following removal of temporary catheter

need to be on medications, despite having had the procedure

inability to target prostate if the organ is small

potential risks;

perforation of surrounding structures such as rectum

laser burns to the skin itself if not applied correctly

staff risks if the laser protocol not followed appropriately

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

able to void well

able to empty bladder fully well

improve urine flow

patient productivity increased

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

concerns - training of personnel and staff

safe environment - i.e. laser proof situation

uncertainties - do not have any medium term or long term data

concerns - how do we translate the experimental efficacy to the real time prostate ablation

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

not to my knowledge, No

29. 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

30. 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.

    Ejaculatory Function following Transperineal La- ser Ablation versus TURP for Benign Prostatic Ob- struction: A Randomized Trial.
    Bertolo R, Iacovelli V, Cipriani C, Carilli M, Vittori M, Antonucci M, Maiorino F, Signoretti M, Petta F, Travaglia S, Panei M, Bove P.
    BJU Int. 2023 Mar 14. doi: 10.1111/bju.16008. Epub ahead of print. PMID: 36917033.

    Ultrasound-guided SoracteLiteTM transperineal laser ablation (TPLA) of the prostate for the treatment of symptomatic benign prostatic hyperplasia (BPH): a prospective single-center experience.
    Laganà A, Di Lascio G, Di Blasi A. et al.
    World J Urol (2023). https://doi.org/10.1007/ s00345-023- 04322-1

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

    TPA register

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

    not applicable

Other considerations

33. 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)?

30% of those who needed intervention for their prostate

34. 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.

short term audits - improvement in IPSS and urine flow

medium term - have they gotten rid of their medications such as alpha blockers

long term - any re-intervention needed for the prostate

35. 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:

needing re treatment

injury to surrounding structures

failure to void completely

Further comments

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

issues with usability - could be done in operating theatres first, due the familiarity of theatre staff with laser

implementation - patient and colleagues awareness of the procedure

further research - a proper registry and a follow-up would suffice

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.

37. Type of interest: *

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

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

none to declare

39. 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

40. Name: *

    Dr Krishnan Anantharamakrishnan

41. Date: *

    26/07/2023

View results

Respondent

13 Anonymous

88:59
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1956- Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using an ultra-micro invasive approach

Your information

2. Name: *

Mr Chidi Molokwu

3. Job title: *

Consultant Uro-oncologist

4. Organisation: *

Bradford Teaching Hospitals NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

European Association of Urology, Societe International du Urologie, American Association of Cancer Research, British Association of Urological Surgeons

7. Nominated/ratified by (if applicable):

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

GMC 4745651

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

9. 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.

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

    Are you familiar with the procedure/technology?

    I have read technology briefings and watched the technology and procedure demonstrated in a video and dry lab setting

11. 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.

    The technology is being used in 1 UK centre presently with others soon to come on board. The technology is in use for ablation of liver lesions in 1 centre in the NHS.

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

- [x] I have done bibliographic research on this procedure.
- [x] 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

13. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) The technology has also been successful with focal ablation of prostate cancer lesions

14. Is the proposed indication appropriate? If not, please explain

The indications could be widened to include focal therapy of localised prostate cancer lesions

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

It is an innovative approach. The transperineal approach avoids urethral instrumentation, allowing the procedure to be done under local anaesthetic in appropriate cases. When used for prostate cancer ablation, the imaging and targeting software allow precise targeting of lesions compared to existing focal therapy modalities.

16. 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.

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

It could be used as an addition to existing standard of care

Current management

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

Transurethral Resection of Prostate (TURP)

19. 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

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

Reduction in prostate tissue and improved voiding. Avoidance of urethral instrumentation. Potential to be performed under local anaesthetic. Minimise side effects of erectile dysfunction and stress urinary incontinence.

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

Potentially all men with bladder outflow obstruction due to benign prostatic enlargement. If used for ablation of prostate cancer lesions, all men with anterior intermediate risk T2a disease.

22. 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?

Yes, It could be used in a day case or out patient setting and redduce the demand on teatres and in-patient beds

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

Laser proofed procedure rooms

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

Laser safety training. Procedure-specific training.

Safety and efficacy of the procedure/technology

25. 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

    Pacella CM et al. Prostate Cancer Prostatic Dis. 2020 Jun;23(2):356-363
    Analysis was performed on data 160 patients with at least 6 months follow and of 83 patients with at least 12 months follow-up. 4.3% grade I and 0.6% grade III complication occurred.

    Frego N et al. World J Urol. 2021 Oct;39(10):3867-3873
    Twenty-two consecutive patients. 13.6% experienced acute urinary retention and 9.1% of them urinary tract infection requiring major antibiotic treatment. Ejaculatory function was preserved in 95.5%.

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

    Improvement in IPSS scores.
    Improvement in flow rate.

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

    Efficacy is uncertain for men with intravesical protrusion of median or lateral lobes of the prostate.

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

    No

29. 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

30. 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.

BPH:
Three years outcomes of transperineal laser ablation of the prostate. Minafra P, DE Rienzo G, Gerbasi S, Cindolo L, Battaglia M, Ditonno P. Minerva Urol Nephrol. 2023 Jun 14. doi: 10.23736/S2724-6051.23.05270-9.
Ejaculatory Function following Transperineal Laser Ablation versus TURP for Benign Prostatic Obstruction: A Randomized Trial. Bertolo R, Iacovelli V, Cipriani C, Carilli M, Vittori M, Antonucci M, Maiorino F, Signoretti M, Petta F, Travaglia S, Panei M, Bove P. BJU Int. 2023 Mar 14. doi: 10.1111/bju.16008
Transperineal Laser ablation for Benign Prostatic Enlargement: A Systematic Review and Pooled Analysis of Pilot Studies. Tafuri A, Panunzio A, De Carlo F, Luperto E, Di Cosmo F, Cavaliere A, Rizzo M, Tian Z, Shakir A, De Mitri R, Porcaro AB, Cerruto MA, Antonelli A, Cormio L, Carrieri G, Karakiewicz PI, Abreu AL, Pagliarulo V. J Clin Med. 2023 Feb 26;12(5):1860.
Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study. Pacella CM, Patelli G, Iapicca G, Manenti G, Perretta T, Ryan CP, Esposito R, Mauri G. Prostate Cancer Prostatic Dis. 2019 Dec 11.

PCa:
Reliable Visualization of the Treatment Effect of Transperineal Focal Laser Ablation in Prostate Cancer Patients by Magnetic Resonance Imaging and Contrast-enhanced Ultrasound Imaging. van Riel LAMJG, van Kollenburg RAA, Freund JE, Almasian M, Jager A, Engelbrecht MRW, Smit RS, Bekers E, Nieuwenhuijzen JA, van Leeuwen PJ, van der Poel H, de Reijke TM, Beerlage HP, Oddens JR, de Bruin DM. European Urology Open Science, Volume 54, August 2023, Pages 72-79
A single-operator experience using EchoLaser SoracteLiteTMfor focal laser ablation of prostate cancer: One more arrow in the quiver for the conservative management of the disease. Meneghetti I, Giardino D, Morganti R, Marino V, Menchini Fabris F, Bartoletti R, Pinzi N. Arch Ital Urol Androl. 2022 Dec 27;94(4):406-412. doi: 10.4081/aiua.2022.4.406. PMID: 36576471.

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

Registry of transperineal laser ablation for treatment of LUTS with use
of the Echolaser device
Sponsor: Amsterdam University Medical Centers, University of Amsterdam, Meibergdreef 9, 1105 AZ, Amsterdam

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

Other considerations

33. 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)?

Approximately 25,000 men in the UK annually

34. 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.

IPSS sores, urine flow rate, IIEF scores

35. 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:

Early
Need for catheterisation, UTI rate, Haematuria, Haematospermia, rectal thermal injury

Late
Need for future bladder outlet procedure, Urethral strictures

Further comments

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

The expanded role in focal therapy for prostate lesions should be explored.

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.

37. Type of interest: *

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

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

NA

39. 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

40. Name: *

Chidi Molokwu

41. Date: *

21/07/2023

View results

Respondent

20 Anonymous

312:01
Time to complete

1. Project Number and Name - (Can be found on email) *

1956 Transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using a ultra-micro invasive approach

Your information

2. Name: *

Samuel Bishara

3. Job title: *

Urology Consultant

4. Organisation: *

Chelsea and Westminster NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

International Continence Society

7. Nominated/ratified by (if applicable):

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

4646439

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

9. 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.

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

    Are you familiar with the procedure/technology?

    I have undergone training in carrying out this procedure

11. 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.

    I am planning to use this technology shortly.
    It is not currently used widely in the NHS but there is a lot if interest in the procedure. The procedure is currently only being carried out by urologists.

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

- [x] 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

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

Yes

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

The procedure is very different to existing procedures as it avoids interfering with the urothelium which reduces the risk of irritative urinary symptoms, strictures, and minimises the need for catheterisation after the procedure

16. 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.

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

The procedure would have the potential to become a major option for patients favouring a minimally invasive approach, which minimises the risk of incontinence, erectile dysfunction and retrograde ejaculation.

Current management

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

The current standard of care is
TURP, holmium laser enucleation
minimally invasive options; Rezum and Urolift

19. 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?

Rezum and Urolift would be the competing minimally invasive options but their mode of delivery is different being transurethral rather than transperineal procedures.

Potential patient benefits and impact on the health system

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

The procedure is minimally invasive but has a wider range of suitable patients as is not limited to prostate size less than 100cc. It is a short daycase procedure and patients are typically discharged without a catheter and can be carried out under local anaesthetic.

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

Patients who are wary of the risk of incontinence and erectile dysfunction. Patients who would not tolerate 3 weeks of catheterisation required by Rezum. Does not require any implant like urolift which can rarely dislodge or become the focus of stone formation

22. 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?

The efficacy of the procedure in cohort studies seems very promising though it has not been fully evaluated in randomized studies compared to other procedures. A RCT comparing TPLA to TURP has been published in preprint suggesting IPSS urinary symptoms score and flow rate are similar to TURP at 12 months https://doi.org/10.21203/rs.3.rs-2433606/v1

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

The procedure does not require any change to facilities

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

Training is required through observation and mentorship. The procedure is technically straightforward for anyone experienced in carrying out transperienal biopsies

Safety and efficacy of the procedure/technology

25. 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

bleeding infection pain, failure to improve
theoretical risk of recto urethral fistula. This risk is present in any procedure that applies energy to the prostate ie TURP or Holmium laser enucleation but in TPLA, the energy can confined to the areas of the prostate away from the rectum using image guidance

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

Objective measures of urinary function;
Maximum flow rate
Post void residual u/s
Quality of life in terms of urinary symptoms, erectile function, measured by the following
IPSS score
ICIQ
IIEF-5 questionnaire
SF-12

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

The long term durability of responses is unknown and whether there are prostatic anatomical factors such as intravesical median lobe extension that my limit its effectiveness

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

Not specifically, though its efficacy need to be further evaluated in randomised studies

29. 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

30. 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.

    Polverino P, Bisegna C, Sessa F, Rivetti A, Re ML, Saladino M, Gallo ML, Pecoraro A, Siena G, Cocci A, Gacci M. 9-Emerging opportunities in minimally invasive BPO management: A single center experience with transperineal interstitial laser ablation of the prostate (TPLA). Continence. 2023 Jun 1;6:100607;

    Polverino P, Sessa F, Re ML, Bisegna C, Marzi VL, Gallo ML, Siena G, Rivetti A, Saladino M, Cocci A, Minervini A. 8-Transperineal laser ablation (TPLA) of the prostate with EchoLaser™ system: Assessing the 6-months Trifecta and Pentafecta in a single center cohort. Continence. 2023 Jun 1;6:100606;

    Sessa F, Rivetti A, Polverino P, Lo Re M, Bisegna C, Saladino M, Siena G, Cocci A, Pecoraro A, Campi R, Minervini A, Serni S (2023). Ejaculation preservation in patients with benign prostatic obstruction: The safety and efficacy of transperineal interstitial laser ablation. European Urology. 83. S9. 10.1016/S0302-2838(23)00066-0;

    Bisegna C, Sessa F, Campi R, Rivetti A, Gallo ML, Barzaghi P, Vittori G, Tuccio A, Polverino P, Spatafora P, Cocci A. 7-Preliminary results of transperineal interstitial laser ablation for carefully selected patients with BPH: Is it a safe and feasible outpatient procedure?. Continence. 2022 Jun 1;2:100048;

    Bisegna C, Sessa F, Campi R, Rivetti A, Gallo ML, Barzaghi P, Vittori G, Tuccio A, Polverino P, Spatafora P, Minervini A. Transperineal interstitial Laser Ablation (TPLA) of the prostate for selected patients with benign prostatic obstruction: Step-by-step technique and preliminary findings. In EUROPEAN UROLOGY 2022 Feb 1 (Vol. 81, pp. S1763-S1763)

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

    https://classic.clinicaltrials.gov/ct2/show/NCT03776006

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

    https://doi.org/10.21203/rs.3.rs-2433606/v1

Other considerations

33. 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)?

In a typical DGH 200 per year

34. 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.

Maximum flow rate
Post void residual ultrasound measurement
IPSS questionnaire
ICIQ SF questionnaire
IIEF-5 questionnaire
SF-12 questionnaire

35. 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:

length of hospital stay
use of antibiotics
reoperation rate
re-admission rate
estimated blood loss
duration of urinary catheterisation
failure to void
Clavian Dindo class of complication

Further comments

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

The procedure is a simple extension of carrying out a transperineal biopsy and would be easy to implement.

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.

37. Type of interest: *

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

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

Ideal Medical Solutions provided training for me without cost to myself, including travel and accommodation expenses in June 23.

39. 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

40. Name: *

Samuel Bishara

41. Date: *

26/07/2023