NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Transurethral water vapour ablation for benign prostatic hyperplasia**
Name of Specialist Advisor:	Mark Rochester
Specialist Society:	**British Association of urological surgeons (BAUS)**

1 Do you have adequate knowledge of this procedure to provide advice?

☒ **X** Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☐ Yes.

☒ **X** No. If no, please enter any other titles below.

Comments:

I think it is more adequately described as “transurethral convective radiofrequency water vapour thermal therapy”

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☒ **X** Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐**X** No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

This is a urological procedure, it is new though in UK with only a handful of surgeons currently using it.

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐**X** I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

This is a novel minimally invasive BPH treatment which may be an alternative to TURP/ laser prostatectomy or prostatic urethral lift implants for some patients.

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

☐**X** I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

I work patients up for BPH surgery but in our unit we offer prostatic urethral lift for this group of patients and are examining the case for introducing this also

2.3 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 had no involvement in research on this procedure.

☐ Other (please comment)

Comments:
There is only one published RCT with three year data in Urology Gold Journal this month (Nov 17)

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ 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.

X☐ The first in a new class of procedure.

Comments:

Prostate ablation techniques have been described and studied before (eg microwave/needle ablation. The proposed benefit of this is that steam is used to ablate tissue and prevented from damaging tissue other than transitional zone adenoma by the pseudo capsule of that part of the prostate. So it is not new in that it is an ablative technique, but the technology to ablate is novel and worth further study. It appears safe, but longest follow up only 3 years. Symptom score improvement on a par with Urolift/PUL, but not as good as TURP or HOLEP.

3.2 What would be the comparator (standard practice) to this procedure?

TURP or HOLEP is the gold standard. This is a minimally invasive alternative and I would see it vying with prostatic urethral lift implant as a minimialy invasive (less efficacious but with more favourable side effect profile)alternative compared to TURP

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

X☐ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

Only 5 surgeons at present in the UK, limited experience. It is not advocated of course by NICE.

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

   Dysuria, frequency , urgency , haematuria, retention, UTI, poor stream, fever, perineal pain, pelvic pain (Dixon, Urology 2015)

2. Anecdotal adverse events (known from experience)

   N/A

3. Theoretical adverse events

   Urethral stricture, need for retreatment,

4.2 What are the key efficacy outcomes for this procedure?

Durable symptom score (IPSS) improvement and quality of life (QoL) score improvement. Objective results assessed by flow rate (Qmax) improvement and bladder post-void residual volume measurement. Sexual function measured by IIEF

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

Long term efficacy up to 5 years and beyond not yet clear (this is the concern with BPH treatments)

4.4 What training and facilities are needed to do this procedure safely?

The company (Nxthera) provides surgical case observations, simulator training and mentoring to new adopting surgeons. It is easy to learn for an experienced urologist with adequate endoscopic skills

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

McVary/Roehrborn RCT (3 yr data just published, follow up ongoing- McVary, Urology, 2017, PMID 29122620)

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

1. Gupta N, Holland B, Delfino, K, et al. Convective radiofrequency water vapor energy prostate ablation (Rezūm®) effectively treats urinary retention. Abstract ID 17-7241. American Urological Association Annual Meeting 2017, Boston, Massachusetts.

2. Gupta N, Holland B, Dynda D et al. Comparison of convective radiofrequency water vapor energy ablation of prostate (Rezūm®) to MTOPS trial cohort. Abstract ID 17-7218. American Urological Association Annual Meeting 2017, Boston, Massachusetts.

3. Roehrborn CG, Gange SN, Gittelman MC et al. Convective radiofrequency thermal therapy: durable two-year outcomes of a randomized controlled and prospective crossover study to relieve lower urinary tract symptoms due to benign prostatic hyperplasia. Abstract ID 17-2138. American Urological Association Annual Meeting 2017, Boston, Massachusetts.

4. Gupta N, Kohler TS, McVary KT et al. Convective radiofrequency water vapor energy ablation (Rezūm®) effectively treats lower urinary tract symptoms due to benign prostatic enlargement regardless of obesity while preserving erectile and ejaculatory function. Abstract ID Pl-01: Best Abstract. American Urological Association Annual Meeting 2017, Boston, Massachusetts.

5. McVary K, Gange, S, et al. Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia with Convective Water Vapor Energy Ablation: Preserved Erectile and Ejaculatory Function. Abstract ID 16-1219. American Urological Association Annual Meeting 2016, San Diego, California.

6. Dixon C, Rijo Cedano E, Pacik D, Vit V, Varga G, Mynderse L, Larson, T. Convective Water Vapor Energy (WAVE) Ablation: Two-Year Results Following Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. Abstract ID 16-5612. American Urological Association Annual Meeting 2016, San Diego, California.

7. McVary K, Roehrborn C, et al. Using the Thermal Energy of Convectively Delivered Water Vapor for the Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia: The Rezūm II Study. Abstract #15-8068. Plenary II Late-Breaking Abstract Session. American Urological Association Annual Meeting 2015, New Orleans, Louisiana.

8. Mynderse L, Hanson D, Robb R, Rijo Cedano E, Pacik D, Vit V, Varga G, Larson T, Dixon C. Rezūm® System Water Vapor Treatment for Benign Prostatic Hyperplasia: Characterization with Magnetic Resonance Imaging and 3D Rendering. Abstract #1890. American Urological Association Annual Meeting 2014, Orlando, Florida.

9. Wagrell L, Tornblom, M. Transurethral Water Vapor Therapy for BPH; A Single Center's Experience Using the Rezūm® System in an Office-based Setting. Abstract #1817. American Urological Association Annual Meeting 2014, Orlando, Florida.

10. Dixon C, Rijo Cedano E, Pacik D, Vit V, Varga G, Mynderse L, Larson, T. Transurethral Water Vapor Therapy for BPH; 1-year Clinical Results of the First-In-Man and Rezūm® I Clinical Trials Using the Rezūm® System. Abstract #1816. American Urological Association Annual Meeting 2014, Orlando, Florida.

11. Wagrell L, Tornblom, M. Transurethral Water Vapor Therapy for BPH; A Single Center's Experience Using the Rezūm® System. Abstract #234. European Association of Urology 2014, Stockholm, Sweden.

12. Mynderse L, Hanson D, Robb R, Rijo Cedano E, Pacik D, Vit V, Varga G, Larson T, Dixon, C. Characterizing Rezūm® System Water Vapor Treatments for Benign Prostatic Hyperplasia with Serial Magnetic Resonance Imaging and 3D Rendering. Abstract #230. European Association of Urology 2014, Stockholm, Sweden.

13. Dixon C, Rijo Cedano E, Pacik D, Vit V, Varga G, Mynderse L, Hanson D, Larson T. Serial MRI and 3D Rendering Following Treatment of BPH Using High Energy Water Vapor Therapy and the Rezūm™ System; Initial Results from the First-In-Man and Rezūm™ 1 Clinical Trials. Journal of Endourology 2013, 27 (s1): A69. Abstract nr MP03-08.

14. Dixon C, Rijo Cedano E, Pacik D, Vit V, Varga G, Mynderse L, Hanson D, Larson T. Transurethral High Energy Water Vapor Therapy for BPH; Initial Clinical Results of the First-In-Man and Rezūm™ 1 Clinical Trials Using the Rezūm™ System. Journal of Endourology 2013, 27 (s1): A340. Abstract nr MP23-13.

15. Dixon C, Rijo Cedano E, Pacik D, Vit V, Varga G, MynderseL, Hanson D, Larson T. Transurethral Water Vapor Therapy for BPH; Initial Clinical Results of the First-In-Man and Rezūm I Pilot Study. Abstract #631. European Association of Urology 2013, Milan, Italy.

16. Dixon C, Pacik D, Huidobro C, Rijo Cedano E, Mynderse L, Hanson D, Hoey M, Larson T. Preliminary Data Following Treatment with Vapor for BPH: The Rezūm System. Abstract #1476. World Congress of Endourology 2012, Istanbul, Turkey.

17. Dixon C, Huidobro C, Rijo Cedano E, Hoey M, Larson T. Acute Effects in the Human Prostate Following Treatment with High-Calorie Water Vapor (Rezūm). Abstract #0838. World Congress of Endourology 2012, Istanbul, Turkey.

Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

It is being introduced safely, but long term data lacking at present.

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

IPSS &QoL at baseline and 3, 6, 12 month follow up, Flow rate and residual bladder volume measurement at same time points. IIEF questionnaire to monitor sexual side effects

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Infection rate (UTI) catheterisation duration, bleeding, readmission to hospital, failure to void if done for retention, possible worsening of LUTS (as

can happen with PUL), need for further treatment such as TURP/HOLEP, sexual dysfunction (retrograde ejaculation or erectile dysfunction), perineal pain post operatively. Complications as graded by Clavien-Dindo

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

I expect it will mirror the uptake of urolift which has taken off in the last 12 months in the UK and lags behind the US by a year or so. The market there for minimally invasive prostate treatment is large and the number of PULs done is rising exponentially. This device competes for the same patient group but has the claimed advantage of treating patients with enlarged median lobes of prostate

6.2 This procedure, if safe and efficacious, is likely to be carried out in (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.

Comments:
All DGHs manage patients with BPH

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

X☐ Major.

☐ Moderate.

☐ Minor.

Comments:

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Just published papers mentioned above

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

X☐ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	**X** ☐	**YES**
	☐	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	**X** ☐	**YES**
	☐	**NO**
	☐	**YES**

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	X ☐	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	X ☐	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	X ☐	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	X ☐	**NO**
Do you have a **non-personal** interest? The main examples are as follows:		
Fellowships endowed by the healthcare industry	☐	**YES**
	X ☐	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	X ☐	**NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

Worked as a consultant for Neotract.

Engaged in private medical practice in urology

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as **'specific,'** or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as **'non-specific'**. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

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Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Transurethral water vapour ablation for benign prostatic hyperplasia**
Name of Specialist Advisor:	Mark Speakman
Specialist Society:	British Association of urological surgeons (BAUS

1 Do you have adequate knowledge of this procedure to provide advice?

X Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☐ Yes.

X No. If no, please enter any other titles below.

Comments:

1. There is an ability to confuse this title with another LUTS/BPH technique known as Aquablation which uses a high pressure water jet rather than a **heated** water vapour to do a more thorough ablation of the prostate.
2. It is used to treat LUTS (lower urinary tract symptoms) and not BPH (benign prostatic hyperplasia) which is a histological diagnosis. Compare with NICE LUTS/BPH guideline. Ideally title should be …for LUTS but a compromise would be …for LUTS/BPH.

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

X Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

X I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

I have discussed this procedures with American specialists who have carried out the procedure and presented on it as a choice for LUTS/BPH treatment

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

X I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

It is still in the experimental stages for this procedure with very limited trial data so far. In the UK all patients should be involved in clinical trials

2.3 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 had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

McVary et al, J of U 2016, Roehrborn et al J of U June 2017, McVary et al, J Sex Med 2016. 3 good papers but predominantly the same patient group. Early results are good but more data needed.

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ 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.

☐ The first in a new class of procedure.

Comments:

3.2 What would be the comparator (standard practice) to this procedure?

Standard Practice remains the TURP in the UK, although as this is a relatively minimally invasive procedure then comparison with Urolift procedure would seem appropriate – and comparable data collection to this device should be expected.

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

X Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments: Only 5 UK centres involved in the trials

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

Infection, bleeding, post operative retention, prolonged catheter usage

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

Potential for thermal damage to the bladder urethra and rectum – thorough training needed to make it safe

4.2 What are the key efficacy outcomes for this procedure?

Flow rate improvement, Symptom and QoL improvement, no adverse impact on erectile or ejaculatory function

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

Still limited trial data – although limited data are certainly promising.

4.4 What training and facilities are needed to do this procedure safely?

Device training – ideally in the model of the Urolift implementation with a good simulator

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

See Paper references above from the states where it has FDA approval.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please

do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

McVary et al, J of U 2016, Roehrborn et al J of U June 2017, McVary et al, J Sex Med 2016.

Abstracts from the AUA meeting 2017 in Boston in J.Urol

PNFBA-01 CONVECTIVE RADIOFREQUENCY WATER VAPOR ENERGY ABLATION (REZUM®) EFFECTIVELY TREATS LOWER URINARY TRACT SYMPTOMS DUE TO BENIGN PROSTATIC ENLARGEMENT REGARDLESS OF OBESITY WHILE PRESERVING ERECTILE AND EJACULATORY FUNCTION
Nikhil Gupta, Tobias Köhler, Kevin McVary
The Journal of Urology, Vol. 197, Issue 4, e609
Published in issue: April 2017

PD27-02 COMPARISON OF CONVECTIVE RADIOFREQUENCY WATER VAPOR ENERGY ABLATION OF PROSTATE (REZUM®) TO MTOPS TRIAL COHORT
Nikhil Gupta, Bradley Holland, Danuta Dynda, Tobias Köhler, Kevin McVary
The Journal of Urology, Vol. 197, Issue 4, e511
Published in issue: April 2017

MP27-20 CONVECTIVE RADIOFREQUENCY WATER VAPOR ENERGY PROSTATE ABLATION (REZUM®) EFFECTIVELY TREATS URINARY RETENTION
Nikhil Gupta, Bradley Holland, Kristin Delfino, Danuta Dynda, J. Randolf Beahrs, Lennart Wagrell, Ahmed El-Zawahry, Tobias Köhler, and others
The Journal of Urology, Vol. 197, Issue 4, e337
Published in issue: April 2017

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

Just more data and local experience required

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

Patient group needs to be selected as suitable for surgical intervention based on symptom scores and flow rate.
A urodynamic study in men with proven bladder outlet obstruction is needed to confirm that it relieves obstruction.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

IPSS Symptom and QoL improvement. Erectile and ejaculatory function.
Consideration of an index such as ‘BPH-6’

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Important to confirm lack of thermal damage to adjacent structures and potential strictures to 1 year
Infection rate and duration of post-operative catheterisation to 30 days

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

Potentially quickly as it is a day case or even outpatient procedure. Will depend a lot on the disposable costs of the device (and to a lesser extent the capital cost)

6.2 This procedure, if safe and efficacious, is likely to be carried out in (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.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

X Moderate.

☐ Minor.

Comments:

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

X I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	X	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	**X**	**YES**
	☐	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	X	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	X	**NO**

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Investments – any funds that include investments in the healthcare industry	☐	**YES**
	X	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	X	**NO**
Do you have a **non-personal** interest? The main examples are as follows:		
Fellowships endowed by the healthcare industry	☐	**YES**
	X	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	X	**NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:
Fee paid for – a single speaker meeting for Astellas in April 2017 (EAU)
Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as **'specific,'** or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as **'non-specific'**. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Transurethral water vapour ablation for benign prostatic hyperplasia**
Name of Specialist Advisor:	Bhaskar Somani
Specialist Society:	British Association of urological surgeons (BAUS)

1 Do you have adequate knowledge of this procedure to provide advice?

☑ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☑ Yes.

☐ No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☑ Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☑ I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments: I HAVE DONE A REVIEW PAPER ON IT AND FULLY AWARE OF THE PROCEDURE

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

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☑ I take part in patient selection or refer patients for this procedure regularly.

Comments: WE REGULARLY SELECT PATIENTS FOR BPH TREATMENT

2.3 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 had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ 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.

Comments:

3.2 What would be the comparator (standard practice) to this procedure?

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☑ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events
DIFFICULTY IN CONTROLLING BLEEDING

4.2 What are the key efficacy outcomes for this procedure?
HIGH SPEED RESECTION
PRESERVATION OF SEXUAL FUNCTION

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?
CURRENTLY NOT USED IN - URINARY RETENTION,
ACTIVE INFECTION,
ABNORMAL RENAL FUNCTION

4.4 What training and facilities are needed to do this procedure safely?
AQUABEAM CONSOLE, TRAINING
ABILITY TO DO TRUS

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.
WATER TRIAL

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).
AUA 2017

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?
LONG TERM DATA LACKING
POTENTIALLY UNSUITABLE FOR PATENTS WITH
- URINARY RETENTION, MEDIAN LOBE

5 Audit Criteria
Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

FLOW RATE, IPSS, IIEF

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure: INCOTINENCE, EJACULATORY/ERECTILE PROBLEMS, BLEEDING, INFECTION

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread? ONCE SAFETY AND EFFICACY IS PROVEN, THE UPTAKE IS LIKELY TO INCREASE

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ 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.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☑ Major.

☐ Moderate.

☐ Minor.

Comments:

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☑ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

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Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐ **YES** ☑ **NO**
Fee-paid work – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice**	☐ **YES** ☑ **NO**

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry

☐ **YES**
☑ **NO**

Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences

☐ **YES**
☑ **NO**

Investments – any funds that include investments in the healthcare industry

☐ **YES**
☑ **NO**

Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?

☐ **YES**
☑ **NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry

☐ **YES**
☑ **NO**

Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts

☐ **YES**
☑ **NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Transurethral water vapour ablation for benign prostatic hyperplasia**
Name of Specialist Advisor:	Professor Richard Hindley
Specialist Society:	British Association of Urological Surgeons (BAUS)

1 Do you have adequate knowledge of this procedure to provide advice?

x Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

x Yes.

☐ No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

x Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☐ I have done this procedure at least once.

x I do this procedure regularly.

Comments:

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

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 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 had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

x 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.

Comments:

This treatment is novel to the UK but there is 3 year US data.

3.2 What would be the comparator (standard practice) to this procedure?

This would be TURP or PVP/HoLEP, or indeed any of the newer minimally invasive treatments such as Urolift

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

x Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

There are currently only 3 NHS Hospitals that have undertaken this procedure with fewer than 100 cases performed in the UK to date

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

Reference: McVary et al, Journal of Urology 2016; Vol 195, 1529-1538

Incidence of AEs (taken fron table 5 in the above publication) in the first 3 months

- serious adverse events – 6.6% (5.1% related and 1.5% unrelated)
- All non-serious AEs – 43.4%
    - Dysuria 16.9%
    - Gross Haematuria 11.8%
    - Urinary Urgency 5.9%
    - Reduced ejaculatory volume 2.9%
    - Retention of urine 3.7%
    - UTI suspected 3.7%
    - UTI proven 2.9%
    - Pain or discomfort 2.9%

2. Anecdotal adverse events (known from experience)

Secondary haemorrhage (haematuria) requiring readmission and return to theatre

3. Theoretical adverse events

Prostatic infection/abscess

4.2 What are the key efficacy outcomes for this procedure?

Improvement in urinary symptoms as measured by IPSS, IIEF5 and QoL questionnaires and confirmed by objective improvement in flow rate parameters. It is an attractive option for men as it can be performed quickly (20 minutes) as a daycase and is unlikely to upset sexual function which can be a concern with standard options.

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

There are uncertainties about the population of men most likely to benefit – most of the data is for men with moderate and severe symptoms with a gland volume between 30-80mls. In men with larger glands and in higher risk patients further evaluation is required.

4.4 What training and facilities are needed to do this procedure safely?

The use of a simulator is invaluable having understood the technique and undertaken the necessary reading. Training courses are now underway and opportunities exist to visit those centres offering Rezum. The procedure needs to be performed in an operating theatre ideally in a daycase setting.

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

We are keeping a prospective registry of all cases undertaken. There are plans to create a web based registry to allow all involved centres to upload data for each case.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

We have submitted an abstract to BAUS last week on the first 67 cases and have presented a smaller case series of our initial experience in the first 31 patients at the south Thames Regional Urology day on the 16th November 2017.

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

No controversy. Teaching of the procedure to new users is Consultant lead. We ran a masterclass in Basingstoke on the 30th Nov. We know that this improves men's symptoms and appears to do so with minimal upset with regards to sexual function. I am keen to evaluate the ranges of gland volumes that are suitable and the rate of major AEs post procedure. It is a very time efficient procedure so in theory large numbers could be performed every day if taken on by the NHS across the country.

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

We are undertaking a prospective audit at the present time. We think an initial series of a minimum of 60-80 is satisfactory.
Improvement in PROM's and measures to include flow rates and post void residuals.
Focus on sexual questionnaires to include ejaculatory function.
Proportion of patients treated under LA/sedation compared with GA and discharged home the same day. Cost benefit analysis would be important. Numbers for this would depend on outcome measures selected.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

Early outcome data at 3, 6 and 12 months to include patient satisfaction PROM's - IPSS, IIEF5, Ejaculatory function (MSHQ)plus objective measures to include flow rate parameters (Qmax), Post void residual, with recording of any adverse events (using Clavian-Dindo) and rates of readmission as well as reoperation rates. 3 year data is now available from the US but the durability of this technique in the longer term is also important and warrants further evaluation. Measurement of prostate volume pre and post treatment calculated by ultrasound is also preferable.

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Bleeding complications usually occur within the first 6 weeks. Measure of readmission rates in the first 3 months as well as need for any further interventions
EARLY Adverse outcomes – first 4-6 weeks (common to all prostate BPH interventions) include haematuria, dysuria, urinary frequency and urgency, UTI and epididymitis, retention and re-catheterisation. Complications will also include retrograde ejaculation and erectile dysfunction, which may be apparent usually after 3 months.
LONGER term adverse events might include urinary incontinence and stricture formation as a result of instrumentation.

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

Rapid growth is likely given the ease of performing this procedure and the short time taken for each procedure. This is an interstitial treatment and provided the complication rate is acceptably low this will disseminate quickly.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (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.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

x Major.

☐ Moderate.

☐ Minor.

Comments:
With rising pressures on inpatient beds any procedure that reliably offers a same day discharge with short stays is very attractive. Furthermore, it's safety with regards to maintaining sexual function is clear and so is an attractive option to men who are sexually active. It's cost-effectiveness needs to be evaluated in the UK.

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Gupta et al Abstract presented at AUA 2017 – suggests it may also have a useful role in men with retention of urine (catheterised as a result of BPH). We have included some men in retention in our UK case series.

(Convective Radiofrequency Water Vapor Energy Prostate Ablation (Rezūm ®) Effectively Treats Urinary Retention)

8 Data protection and conflicts of interest

All data is securely held.

No conflicts.

I have received payments for teaching and proctoring of Greenlight PVP (Boston Scientific) and Rezum water vapour therapy (NxThera/Kebomed).

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

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Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	x	**YES**
	☐	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	☐	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	x	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	x	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	x	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	x	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐	**YES**
	x	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	x	**NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:
As mentioned I have received occasional payments for teaching and proctoring of Rezum (the subject of this guidance) and Greenlight PVP (another treatment for BPH).
I am also being paid by AXA PPP to help redesign their prostate cancer pathway for insured patients. I have also received payments from a US Company Sonacare Medical for teaching and proctoring of an ablative therapy for prostate cancer treatment (HIFU).

Thank you very much for your help.

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as **'specific,'** or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as **'non-specific'**. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.