

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Interventional procedures

# Patient Organisation Submission Focal therapy using high-intensity focused ultrasound for localised prostate cancer IP839/2

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

To help you give your views, we have provided this template, and ask if you would like to attend as a patient expert at the bottom of the form. You do not have to answer every question — they are there as prompts. The text boxes will expand as you type, the length of your response should not normally exceed 10 pages.

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

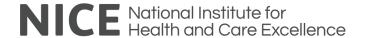


About you	
1. Your name	
2. Name of organisation	Prostate Cancer UK
3. Job title or position	
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	Prostate Cancer UK is a voluntary organisation based in London. It is a registered charity in England and Wales (1005541) and in Scotland (SC039332). Registered company number 02653887.

5. How did you gather the information about the experiences of patients and carers to help your submission?

(For example, information may have been gathered from one to one discussions with colleagues, patients or carers, telephone helplines, focus groups, online forums, published or unpublished research or user-perspective literature.)

Desk research and our own knowledge of the experiences of patients. We have spoken with our specialist nurses about their experience of speaking with patients with regards to this treatment.



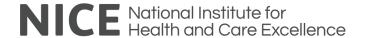
#### Living with the condition

6. What is it like to live with the condition or what do carers experience when caring for someone with the condition?

Patients with prostate cancer report many different symptoms which affect their daily lives. For those with localised disease, most of these symptoms are associated with the side effects from radical treatment, specifically radiotherapy in conjunction with ADT, which is the current standard of care, which causes damage to normal tissue alongside cancerous tissue. Short term side effects from radiation include irritation and inflammation of the bladder and bowel. When side effects are at their peak, patients may find it more difficult to hold urine within their bladder and may experience an overwhelming urge to urinate. The fear of incontinence/leakage can be distressing, and incontinence pads are often needed. Fatigue can also be a result of external beam radiotherapy and can be exacerbated by any anxiety or distress caused by the cancer or its treatment, and/or other issues such as the daily journey for treatment (which can be considerable for those patients in more rural areas, especially in Scotland), or lack of sleep due to an increased need to urinate at night.

Long-term effects can occur months to many years after radiotherapy. Some of the potential long-term side effects of radiation to the prostate include urinary problems that are potentially the result of urethra stricture (often more likely after combined external beam radiotherapy and brachytherapy). Symptoms include urinary retention, weak urinary flow, bowel problems and bowel damage, erectile dysfunction, hip and bone pain and/or weakness. Patients in this position will then have regular PSA checks to determine whether the ADT is working to stave off metastasis. This process can cause a high amount of stress and anxiety in a person as it will not be known whether or when metastasis will happen.

# Advantages of the procedure or operation



7. What do patients (or carers) think the advantages of the procedure or operation are? Why do you consider it be to be innovative?

We know through our nurses team that, anecdotally, this procedure has the propensity to be very popular as we do have men call up to enquire specifically about it and where they might be able to have it. The advantages of this procedure for the men to whom we have spoken, who have had the procedure, include little to no side effects post treatment including urinary issues and erectile dysfunction.

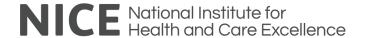
8. Does this procedure have the potential to change the current pathway or patient outcomes? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Prostate Cancer UK believes that this procedure could have the potential to change the current pathway, due to its minimally invasive nature and also its propensity to have fewer side effects post treatment (due to better preservation of surrounding organs and tissue in comparison to radical prostatectomy). Fewer side effects will lead to better outcomes for patients, as maintaining quality of life post treatment is imperative for all patients

#### Disadvantages of the procedure or operation

9. What do patients (or carers) think the disadvantages of the procedure or operation are?

We do not have a patient or carer perspective in this instance, however as an organisation we do know that there isn't substantial evidence as yet to suggest that this modality shows an improved level of failure free survival in comparison to the current standard of care, or indeed other forms of focal therapy. We would welcome more clarity on this as the evidence emerges.



#### Patient population

10. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why.

Patients with specific lower risk disease (who are unsuitable for active surveillance) or specific intermediate disease may be spared some of the side effects of radical treatment if they are treated for focal therapy using HIFU.

With this in mind, Prostate Cancer UK would welcome clarity on the defined patient population who would be eligible for this procedure. For example, consideration needs to be given to those patients who have low risk disease who may get little to no benefit from this procedure, and also those with high-risk disease where more radical therapies would be beneficial.

It should also be noted that there is evidence that suggests treating anterior prostate cancer lesions with focal HIFU may be less effective compared to posterior tumours.

Ref: Huber, P., Afzal, N., Arya, M., Boxler, S., Dudderidge, T., & Emberton, M. et al. (2020). Focal HIFU therapy for anterior compared to posterior prostate cancer lesions. World Journal Of Urology, 39(4), 1115-1119. doi: 10.1007/s00345-020-03297-7

#### Safety and efficacy

11. What are the uncertainties about how well this procedure works and how safe it is?

Retrospective data has been published showing 15-year outcomes for patients treated with focal therapy by HIFU. Seven-year failure free survival was 69% (64–74%). However, we note the absence of randomized control trial evidence comparing failure free survival in HIFU focal therapy to conventional radical therapies.

REF: Reddy, D., Peters, M., Shah, T., van Son, M., Tanaka, M., & Huber, P. et al. (2022). Cancer Control Outcomes Following Focal Therapy Using High-intensity Focused Ultrasound in 1379 Men with Nonmetastatic Prostate Cancer: A Multi-institute 15-year Experience. European Urology, 81(4), 407-413. doi: 10.1016/j.eururo.2022.01.005

#### **Equality**



10. Are there any potential <u>equality issues</u> that should be taken into account when considering this topic?

Many older patients may not be fit enough for treatment with radical prostatectomy and HIFU may provide another alternative treatment for this group of patients.

#### Other issues

11. Are there any other issues that you would like the Committee to consider? n/a

## Key messages

- 12. In no more than 5 bullet points, please summarise the key messages of your submission.
  - 1. A clearly defined patient population is needed for this procedure
  - 2. This procedure could well spare some patients the side effects of radical treatment
  - 3. More evidence is needed which compares failure free survival in HIFU focal therapy to conventional radical therapies

4.

### **Committee meeting**

13. Would you be willing to attend the interventional procedures committee meeting to provide the view from your organisation in person?

yes

Thank you for your time.

Please return your completed submission to <a href="https://energenice.org.uk">helen.crosbie@nice.org.uk</a> and <a href="mailto:ip@nice.org.uk">ip@nice.org.uk</a>.