

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 Scotland
3. Job title or position	██████████
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	<p>Prostate Scotland is a Scottish charity concerned with prostate cancer and disease. We were set up in 2006 to:</p> <ul style="list-style-type: none"> • Provide information about the prostate and its diseases • Increase awareness and improve education, support and provision for prostate issues in Scotland • Influence policy and promote research and treatment developments on prostate issues across Scotland <p>We are the only Scottish charity covering the full range of prostate diseases. We provide a range of information for men and their families and partners, hold events and develop awareness materials about prostate cancer and prostate disease, and provide a range of services to support men with prostate cancer and their families in Scotland. We also undertake research into services and treatments for men with prostate cancer and disease in Scotland. We were involved in the introduction of robotic assisted prostate cancer surgery into the east and west of Scotland- through our successful Blue Horizon Appeal. Over 95% of our funding comes from voluntary sources. Our Board of Trustees is made up of people with experience of prostate disease and experts on cancer and prostate disease in Scotland. We also have a medical and information Committee. This is made up of clinicians from across Scotland treating men with prostate cancer and disease, as well as men living with the condition.</p>

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.)

We gathered the information from a variety of routes including:

- Our Advisory Group which is made up of men with prostate cancer and clinicians from across Scotland treating the disease;
- Comments from members of our prostate cancer research panel, which is made up of men with from across Scotland with prostate cancer;
- Monitoring of enquiries we receive from men with prostate cancer to our information service;
- Our research into Living with Prostate Cancer in Scotland (published in 2020) was based on a survey of men living with prostate cancer in Scotland, as well as a series of focus groups.

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?

Prostate cancer is the most common cancer in men in Scotland, and the second most common cause of cancer death in men. One in ten men in Scotland is at risk of prostate cancer. Prostate cancer now accounts for over a quarter of all cancers in men in Scotland. The most recent figures for Scotland prior to the pandemic show that 4066 men in Scotland were diagnosed with prostate cancer in 2019 and 3394 were diagnosed in 2020. In 2020 1038 men in Scotland died from prostate cancer. For men with early prostate cancer key treatments can be surgery to remove the prostate, radiotherapy, brachytherapy or for some men active surveillance as a management. For men with advanced prostate cancer first line treatment is hormone therapy (and often chemotherapy alongside hormone therapy) and also more recently novel hormone agents. Just over 5% of the male population over the age of 65 has prostate cancer. (See ISD Cancer in Scotland April 2019 Information Services Division, NHS National Services Scotland and PHS Scotland April 2020 and April 2021).

There can be many impacts on men of living with prostate cancer. There can be impacts of the condition, in terms of symptoms such as urinary difficulties, back and pelvic pain, and sometimes for men with advanced prostate cancer bone pain, as well as thinner or brittle bone. Some men with prostate cancer can sometimes have erectile dysfunction/sexual difficulties, or incontinence as a side effect of certain treatments for prostate cancer. A further affect of prostate cancer can be its impact on personal mobility, impacting on both quality of life and also for some men on employment. Some men with prostate cancer can face financial difficulties from being restricted in their employment.

We have carried out research into the situation of men living with prostate cancer in Scotland which has also highlighted the impacts side effects of prostate cancer can have on a patient's life. Worries about cancer progression and death can cause increased mental impacts such as greater anxiety and depression. For example one man in a focus groups said: "I probably went through a bit of depression as well and then just fatigue, horrendous fatigue"

Having a family member with prostate cancer can increase worry and burdens on families/ partners and carers and can cause considerable emotional and mental distress for those close to that person. Our research into the experiences of men of being diagnosed with and living with prostate cancer in Scotland, included the impact of a diagnosis of and of living with prostate cancer men and on their families. In focus groups one patient reflected that "when you think of your wellbeing sometimes it's actually more difficult for the person that's living with somebody having cancer." Another patient told us of how he felt when telling his family about his cancer: "I was told that I had prostate cancer and it was 16 days before I could tell my wife and I was

never in so much mental anguish and turmoil. I can see how people want to end to their lives." Another comment was "From a partners point of view, I know that (the partner) felt (he) wasn't told about the after affects and certainly this has had an effect on our lives..." Such comments and experiences highlight the stress that can be placed on those who live with a person with prostate cancer and the strains it can place on families/partners and relationships.

Living with cancer can also cause considerable disruption to normal family life as decreased mobility can impact on relationships and the ability to work which can cause financial burdens to a patient's family.

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 to be innovative?
 - I. Our consultation has shown an interest in and appetite in Scotland for the availability/option of Focal Therapy/HIFU for eligible men with localised lower/ intermediate risk prostate cancer.
 - II. We have heard from several patients in Scotland, with lower risk prostate cancer who had been advised treatment was necessary for their prostate cancer - and who were interested in the availability of Focal Therapy/HIFU for prostate cancer. For some of these men their interest in HIFU was due to a wish to avoid radical treatments at this stage of their prostate cancer journey- preferring less radical treatments if possible and the potential impact of these. For some other men their interest in focal therapy as a treatment appears to be to also a quality-of-life issue with a wish to try to avoid some of the potential side effects that can arise from some of the radical therapies and in particular concerns about potential incontinence, erectile dysfunction and bowel toxicity.
 - III. We have seen a small, but steady stream of men from across Scotland contact us over the past three years looking for the option of the procedure. Many of these men wished for the availability of Focal Therapy/HIFU in Scotland, rather than having to travel elsewhere in the UK for these treatments
 - IV. Two recent studies have shown that over a 5 and a 7-year period the Failure Free Survival over five years was 88% and overall survival 98% and over seven years Failure Free Survival was 69% (and 68% in patients with intermediate and high-risk prostate cancer). The study by Guillaumier, Peters, Ahmed et al ¹ concluded that 'Focal therapy using HIFU could be offered to select patients with clinically significant nonmetastatic prostate cancer as it is effective in the medium term and has a low probability of urinary and rectal side-effects'. The study by Ahmed and Emberton et al² also concluded that 'Focal high-intensity focused ultrasound treatment to areas of prostate with cancer can provide an alternative to treating the whole prostate. This treatment modality has good medium-term cancer control over 7 years although 10-year data are not yet available'.
 - V. Our Advisory Group which is made up of clinicians and men with prostate cancer felt that the recent research and developments in regard to Focal therapy/HIFU showed that this procedure has the potential to offer an option for the treatment for localised lower risk and intermediate risk prostate cancer through treating individual areas of the prostate, and it should be available where relevant as an option for men in this situation, (though it was also noted that there are not yet 10 year outcomes).
 - VI. In particular it was felt that it is innovative for those men for whom avoidance of potential side- effects issues were of importance, (where such treatment were appropriate/indicated) that Focal therapy/HIFU

should be available as an option for men with lower risk prostate cancer alongside the radical therapies.

¹ Guillaumier S & Peters M, Ahmed H, et al A Multicentre Study of 5-year Outcomes Following Focal Therapy in Treating Clinically Significant Nonmetastatic Prostate Cancer European Journal of Urology 74 February (2018) 422-229 <https://doi.org/10.1016/j.eururo.2018.06.006>

² Ahmed H, & Emberton M et al Cancer Control Outcomes Following Focal Therapy Using High-intensity Focused Ultrasound in 1379 Men with Non-metastatic Prostate Cancer: A Multi-institute 15-year Experience – European Urology Volume 81, Issue 4 April 2022 pages 407- 413

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?

This procedure has the potential for some men those with localised lower /intermediate risk prostate cancer who are eligible for to offer a further choice of treatment – which is a less invasive treatment than radical prostatectomy, and in many cases may offer less side effects than many of the radical treatments. It is a shortish procedure.

Disadvantages of the procedure or operation

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

There are some potential disadvantages of the procedure:

i) Firstly it is limited in its application to mainly to T1 and T2 and is unlikely to be suitable for all men with localised prostate cancer, where their cancer is in more than two places in the prostate, or where the cancer is multifocal;

ii) According to a systematic review of the evidence that between 22 and 29% of men who have been treated with HIFU for prostate cancer have recurrence and progression requiring further treatment ¹

iii) Patients in Scotland told us that a disadvantage is that it is currently unavailable in Scotland necessitating travel and where an out of referral was not available cost for the procedure.

iv) Whilst it is generally has a lower side effect profile than radical treatments the procedure may not be entirely free of side-effects – with between 5-15% of men reporting erectile dysfunction following the procedure ²

¹ Available evidence on HIFU for focal treatment of prostate cancer: a systematic review Bakavicius et al. IBJUInt. braz j urol 48 (2) Mar-Apr 2022 <https://doi.org/10.1590/S1677-5538.IBJU.2021.0091>

². Ahmed H <https://londonprostate.co.uk/areas-of-interest/hifu-treatment-for-prostate-cancer/> accessed 25/07/2022

Patient population
<p>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.</p> <p>The procedure is likely to only be relevant to men with low risk or intermediate risk localised prostate cancer with a Gleason score of 7 or less and with T1 or T2 prostate cancer and often only in one lobe of the prostate. HIFU requires careful case selection of patients but when used for carefully selected patients it can be very effective.</p>
Safety and efficacy
<p>11. What are the uncertainties about how well this procedure works and how safe it is?</p> <p>The current NICE guidelines set out that the procedure raises no major safety concerns- and the recent systematic review¹ also concludes that it appears a safe procedure.</p> <p>The main uncertainties appear to be around the procedures efficacy – with up to 29% of men facing recurrence², and up to 15% erectile dysfunction³. In addition there is a need for larger scale 10 year survival data – currently larger data series mainly only cover 7 years duration.</p> <p>¹ and ² Available evidence on HIFU for focal treatment of prostate cancer: a systematic review Bakavicius et al. IBJUInt. braz j urol 48 (2) Mar-Apr 2022 https://doi.org/10.1590/S1677-5538.IBJU.2021.0091</p> <p>³.Ahmed H https://londonprostate.co.uk/areas-of-interest/hifu-treatment-for-prostate-cancer/ accessed 25/07/2022</p>
Equality
<p>10. Are there any potential equality issues that should be taken into account when considering this topic?</p>
Other issues
<p>11. Are there any other issues that you would like the Committee to consider?</p>
Key messages

12. In no more than 5 bullet points, please summarise the key messages of your submission.

1. Our work and consultation has shown an interest in and appetite for the availability/option of Focal Therapy/HIFU from men eligible men with prostate cancer in Scotland with localised, lower/ intermediate risk prostate cancer.
2. We have seen a small, but steady stream of men with prostate cancer from across Scotland contact us over the past 3-4 years looking for the option of HIFU. Many of these men wished for the availability of Focal Therapy/HIFU in Scotland, rather than having to travel elsewhere in the UK for these treatments.
3. For some of these men their interest in HIFU was due to a wish to avoid radical treatments at this stage of their prostate cancer journey- preferring less radical treatments if possible due to the potential impact of side effects from these.
4. Recent studies have shown that for men receiving HIFU for prostate cancer over a 5 and a 7-year period the Failure Free Survival over five years was 88% and overall survival 98% and over seven years Failure Free Survival was 69% (and 68% in patients with intermediate and high-risk prostate cancer). There is also a need for 10-year data.
5. We believe HIFU should be available, where relevant, as a treatment option for eligible men with localised, lower/intermediate risk prostate cancer. We also believe that there is a need for more information for men with prostate cancer about treatment with HIFU and its advantages, drawbacks/limitations.

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 helen.crosbie@nice.org.uk and ip@nice.org.uk.