

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Focal therapy using high-intensity focused ultrasound for localised prostate cancer

Symptoms of localised prostate cancer may include difficulties in passing urine, although many people do not have symptoms at the time of diagnosis. This procedure uses high-intensity focused ultrasound to heat up and destroy only the areas of the prostate with cancer (focal therapy). The aim is to destroy the cancer while reducing damage to healthy prostate tissue. This can reduce the risk of side effects (such as loss of bladder control and sexual function) that can happen when the whole prostate gland is treated.

NICE is looking at focal therapy using high-intensity focused ultrasound for localised prostate cancer. This is a review of NICE's interventional procedures guidance on focal therapy using high-intensity focused ultrasound for localised prostate cancer.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

**This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.**

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 17 November 2022

Target date for publication of guidance: April 2023

## 1 Draft recommendations

1.1 Evidence on the safety of focal therapy using high-intensity focused ultrasound for localised prostate cancer is adequate. Evidence on its efficacy is limited. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out [what special arrangements mean on the NICE interventional procedures guidance page](#).

1.2 Clinicians wanting to do high-intensity focused ultrasound for localised prostate cancer should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear written information to support [shared decision making](#), including [NICE's information for the public](#).
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into [NICE's interventional procedure outcomes audit tool](#) (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

- 1.4 Patient selection should be done by a multidisciplinary team.
- 1.5 Further research could include registry data or randomised trials. It should include details of patient selection, including size and classification of tumour, technique used and long-term outcomes including quality of life.

## **2 The condition, current treatments and procedure**

### **The condition**

- 2.1 Prostate cancer causes the prostate to enlarge, this may result in symptoms such as difficulty in urinating and frequent urination. Localised prostate cancer is confined to the prostate and has not spread to nearby tissues or to other parts of the body.

### **Current treatments**

- 2.2 Decisions on treatment are based on imaging, tumour staging, risk assessment, and prostate-specific antigen levels. For some people, localised prostate cancer grows slowly or not at all, and treatment may not be necessary. In such cases, watchful waiting or active surveillance strategies may be appropriate. If treatment is needed, several options are available. These include radical treatments (such as radical prostatectomy, external beam radiotherapy, and radical brachytherapy), focal treatments (such as focal high-intensity focused ultrasound [HIFU], focal cryoablation, irreversible electroporation, focal laser ablation, and focal brachytherapy), and adjunctive treatments (such as chemotherapy and androgen deprivation therapy).

### **The procedure**

- 2.3 Imaging and biopsy mapping are used to confirm that the tumour is suitable for focal therapy and to show its precise location. With the

person under spinal or general anaesthesia, the bladder is catheterised using a urethral or supra-pubic catheter and the HIFU probe is inserted transrectally. Ultrasound imaging guidance is used to position the probe and to monitor the procedure. Pulses of HIFU are directed at the targeted part of the prostate, inducing tumour necrosis by a thermal effect, and causing cavitation (which can be visualised by ultrasound to assess the adequacy of treatment) until satisfactory ablation of the target area is judged to have occurred. This procedure differs from standard whole-gland HIFU in that only some of the prostate is treated. Transurethral resection of the prostate may be done at the same time as focal HIFU to reduce urinary symptoms.

### **3 Committee considerations**

#### **The evidence**

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 3 systematic reviews, 2 registry analyses, 1 propensity score weighted study, 1 retrospective case series, and 1 retrospective cohort study. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: overall survival, recurrence-free survival, metastasis-free survival, improvement in quality of life, and need for subsequent intervention.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, rectal damage, incontinence and loss of sexual function.

- 3.4 Three hundred and seven commentaries from people who have had this procedure were discussed by the committee. The committee also discussed 2 submissions from patient organisations.

### **Committee comments**

- 3.5 There is more than 1 device available for this procedure and the technology is evolving.

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Chair, interventional procedures advisory committee

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