Engagement report

Topic details

Title of policy or policy statement: Stereotactic ablative radiotherapy (SABR) for the treatment of localised prostate cancer (adults)

Programme of Care: Cancer

Clinical Reference Group: Radiotherapy

URN: 2106

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

2. Background

Prostate cancer is the most common cancer affecting men in the UK, with 50,702 new cases diagnosed in England in 2022 (NPCA, 2023). Where prostate cancer is diagnosed at an early stage where it is localised within the prostate and has not spread to anywhere else in the body, survival is high. Localised prostate cancer can be divided into five risk groups based on how likely it is to spread or grow: very low, low, intermediate (favourable and unfavourable), high and very high (NCCN, 2023). This risk assessment is based on a combination of 3 factors: T staging, the histological aggressiveness of the cancer (Gleason score) and a PSA measurement. These risk categories also play a role in determining the best treatments and overall management plan for patients.

This policy proposition applies to low risk and intermediate risk localised prostate cancer. For low-risk prostate cancer, most patients are offered active surveillance as the preferred management strategy. For intermediate-risk prostate cancer, management options include active surveillance, radical prostatectomy, external beam radiotherapy (EBRT), brachytherapy, or brachytherapy dose escalation in combination with EBRT. When EBRT is used, this is usually given as moderately hypofractionated radiotherapy and uses fraction sizes, larger than 2Gy, delivered over a shorter overall treatment time, for example 60Gy in 20 daily fractions of 3Gy over 4 weeks. Prior to the move to moderately hypofractionated EBRT for these patients' conventional fractionation was used which is delivered as daily (Monday to Friday) radiotherapy at 1.8-2 Gray per fraction for 7-8 weeks.

This policy proposition recommends the use of stereotactic ablative radiotherapy (SABR), also called stereotactic body radiotherapy (SBRT). This a highly targeted and precise radiotherapy technique, which delivers higher overall doses of radiotherapy in a

fewer number of treatments than conventional radiotherapy. SABR is delivered using three, five or eight treatments (or fractions) and usually delivered in an outpatient setting. This means that patients have a shorter treatment time, and less radiotherapy appointments.

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

- The policy proposition underwent a two-week stakeholder testing between the 6th March 2025 and 20th March 2025 with registered stakeholders from:
- The Royal College of Radiologists
- Institute of Physics and Engineers Medicine
- Society and College of Radiographers
- Radiotherapy Clinical Reference Group
- Specialised Cancer Surgery Clinical Reference Group
- Radiotherapy Trials Quality Assurance (RTTQA team)
- Cancer Research UK
- Prostate Cancer UK
- NIHR
- British Uro-oncology Society

Respondents were asked the following consultation questions:

- Do you support the proposal for routine commissioning based on the evidence review and within the criteria set out in the proposal?
- Do you believe that there is any additional information that we should have considered in the evidence review?
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available?
- Do you support the Equality and Health Inequalities Impact Assessment?
- Does the Patient Impact Summary present a true reflection of the patient and carers lived experience of this condition?
- Do you have any further comments on the proposal?
- Please declare any conflict of interests relating to this document or service area.

The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

A 13Q assessment has been completed following stakeholder testing.

The Programme of Care (PoC) has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

The policy received 29 stakeholder responses:

- 9 Clinicians (including 1 Therapeutic Radiographer)
- 2 Patients
- 15 NHS Trusts and/or other service providers
- 2 Charities
- 1 Medical Device Manufacturer

This number, as well as the range of stakeholders represented, this was deemed a very good level of response. All stakeholders supported the policy proposition and felt that this offered patients a positive change.

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Cancer PoC. The following themes were raised during engagement.

Keys themes in feedback	**NHS England Response**
Relevant Evidence	
Most stakeholders agreed that all the relevant evidence had already been identified.	No further action required.
One stakeholder suggested that patient feedback forms from a Cancer Centre should be included.	As the paper is not currently published it cannot be considered as part of the evidence base in line with the published NHS England Methods: National Clinical Policies.
Two stakeholders suggested that fiducial markers should be recommended as per the PACE-B trial protocol.	The use of fiducial markers is not recommended within the policy proposition as there was no evidence that they reduced toxicity. This is outlined on page 5 of the policy proposition under the patient pathway: *"During the PACE-B trial prostatic fiducial markers were recommended but*

	there was no evidence this reduced toxicity."
One stakeholder commented that the current evidence does not distinguish between low and high-risk prostate cancer in terms of variables such as tumour length and size of lesion of MRI.	The inclusion criteria of the policy proposition are based on the PACE-B trial which uses the Gleason scoring system and PSA to risk stratify patients. There is no current evidence that assesses clinical outcomes by these variables.
One stakeholder disagreed that patients with Gleason 3+3 should be included in the policy proposition as active surveillance is more appropriate.	Active surveillance is still the treatment option for patients with low risk (Gleason 6 and below, including Gleason 3+3) prostate cancer as outlined in the patient pathway on page 6 of the policy proposition. The National Prostate Cancer Audit found that in 2019-2023, 92% of patients with low risk prostate cancer chose active surveillance. Therefore, it is expected that a minority of low risk patients will refuse surveillance. This policy proposition allows SABR as an option should they refuse or not be suitable for active surveillance.
Policy Proposition	
All stakeholders supported the policy proposition and most noted that the policy would have a positive impact on patients.	No further action required.
Several stakeholders disagreed with the inclusion criteria and noted that it should be broadened to include those who are on androgen deprivation therapy (ADT) and those with a Gleason score of 4+3.	Patients who are on ADT are not included in this policy as in the low and favourable intermediate risk cohort of prostate cancer patients, ADT does not significantly reduce cancer recurrence. Patients who have a Gleason score of 4+3 are considered to have higher risk prostate cancer and are out of scope of the policy. The PACE-B trial did not include patients with Gleason 4+3 and/or on ADT (however the PACE-C trial will further assess this).
Multiple stakeholders commented that clinicians should be able to have	This policy proposition offers eligible patients the option of SABR as an

flexibility regarding the radiotherapy schedule used. This includes how many fractions are given and the dose of radiotherapy given, including the dose of SABR.	alternative to surgery and moderately hypofractionated radiotherapy. Patients are still able to receive other types of radiotherapy (e.g. moderately hypofractionated with 20 fractions). This policy proposition supports the use of SABR, however, patients will still be able to have moderately hypofractionated radiotherapy if they and their clinician wish to do so. For SABR, the dose of 36.25Gy in 5 fractions has been specified in line with evidence from the PACE-B trial and guidelines from the Royal College of Radiologists.
Multiple stakeholders commented that the use of fiducial markers should be considered in the policy to reduce toxicity risk of SABR.	The need for fiducial markers was discussed with the policy working group following December 2024 Clinical Panel. The use of fiducial markers did not reduce toxicity within the PACE-B trial and therefore not a requirement in the policy proposition.
Two stakeholders disagreed that the Radiotherapy Trials Quality Assurance (RTTQA) should not be a requirement in the policy proposition.	Providers must be compliant with RTTQA as this is a new SABR treatment indication. Most radiotherapy centres have already completed or are in the process of completing QA. This approach is to ensure the quality and safety of treatments which are more complex than standard conventional radiotherapy.
Impact Assessment	
All stakeholders agreed with the Equality and Health Impact Assessment (EHIA) and Patient Impact Assessment (PIA).	No further action required.
Current Patient Pathway	
One stakeholder queried as to whether suitability of active surveillance also considered patient choice.	The patient pathway flowchart on page 6 of the policy proposition advises that patients should be referred *"to a clinical oncologist for shared decision making and discussion of treatment options."*

	Shared decision-making should consider patient choice.
Potential impact on equality and health inequalities	
One stakeholder commented that the policy may have a particularly positive impact on patients of working age as there are fewer treatment appointments associated with SABR.	The EHIA was reviewed, and further detail was added to highlight the positive impact the policy may have on patients who are working age.
Changes/addition to policy	
One stakeholder commented that in the 'Epidemiology and needs assessment' section on page 3 of the policy proposition, it is not clear as to what type of radiotherapy the 15,000 patients who received radiotherapy in 2022/2023 had.	On page 3 of the policy proposition under 'Epidemiology and needs assessment,' the following sentence has been amended to: *"In 2022/23, circa 15,000 patients received conventional fractionated and moderately hypofractionated radiotherapy using equivalent external beam radiotherapy regimens"* to highlight the types of radiotherapy patients had.
One stakeholder commented that the wording of the 4th criterion of the inclusion criteria on page 4 of the policy proposition is worded too strongly.	The wording of fourth criterion of the inclusion point was reviewed and has been changed to the following: *"The decision to choose SABR is a result of shared decision making between the patient and clinician acknowledging the potential higher risk of grade 2 genitourinary toxicity after SABR, particularly in the first 1 to 2 years after SABR."*
Several stakeholders commented that escalated doses of radiotherapy may increase the risk of gastrointestinal adverse events and that the use of rectal spacers to mitigate this should be considered.	The PACE-B trial noted that low numbers of patients experienced grade 2 and above gastrointestinal adverse events and no statistically significant difference was found between patients who had SABR compared to those who had control arm radiotherapy. Further detail on this has been added to the shared decision-making tool in Appendix 1 of the policy proposition to support patients in making treatment decisions.

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following change(s) based on the engagement responses has (have) been made to the policy proposition:

- **Policy Proposition:**
  - Page 3: Under 'Epidemiology and needs assessment,' the following sentence has been amended to: *"In 2022/23, circa 15,000 patients received conventional fractionated and moderately hypofractionated radiotherapy using equivalent external beam radiotherapy regimens."*
  - Page 4: The wording of fourth criterion of the inclusion point was changed to the following: *"The decision to choose SABR is a result of shared decision making between the patient and clinician acknowledging the potential higher risk of grade 2 genitourinary toxicity after SABR, particularly in the first 1 to 2 years after SABR."*
  - Page 13/14: The shared decision-making tool in Appendix 1 of the policy proposition has been updated to reflect the gastrointestinal adverse events of SABR and moderately hypofractionated radiotherapy as reported in the PACE-B trial.
- **EHIA:** No amendments made.
- **PIA:** No amendments made.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No