Engagement Report

Topic details

Title of policy or policy statement:	Stereotactic ablative body radiotherapy for patients with localised, non-metastatic, renal cancer who are medically unfit for surgery (adults) [2332]
Programme of Care:	Cancer
Clinical Reference Group:	Radiotherapy
URN:	2332

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

Renal cancer, also called renal cell carcinoma or primary kidney cancer, is a malignancy that originates in the lining of the proximal convoluted tubule of the kidney. Once localised renal cancer has been confirmed by the appropriate imaging, biopsies are usually performed to confirm the diagnosis.

Tumour Node Metastasis (TNM) staging system (CRUK, 2020):

T – describes the size and extent of the tumour from 1 (tumour less than 7cm) to 4 (involving adjacent structures)

N – describes the presence of involved lymph nodes from 0 (none) to 1 (present)

M – describes whether the cancer has metastasised from 0 (non-metastatic) to 1 (metastatic)

Renal cancer is strongly associated with age, with the highest incidence rates in patients between 85-89 years (CRUK, 2023). Each year around a third (34%) of all new kidney cancer cases in the UK are diagnosed in people aged 75 years and over (CRUK, 2023). Additional risk factors include smoking and obesity.

Patients with localised, non-metastatic renal cancer will be discussed at a specialist renal multi-disciplinary team (MDT) meeting (which may form part of a uro-oncology MDT), where a decision is made about treatment.

The European Association of Urology recommends in the elderly and/or comorbid patients with small renal masses (≤4cm, T1a) and limited life expectancy, active

surveillance, radio-frequency ablation and cryoablation can be offered (Ljungberg et al, 2015). This is supported by Getting It Right First Time (GIRFT, 2023).

However, T1b, N0, M0 renal cancers, compared with T1a, N0, M0 renal cancers, are faster growing and more aggressive, with a higher risk of complications from local disease progression, such as bleeding and pain, and a higher risk of progression to metastatic disease (Volpe et al, 2018; Touma et al, 2019). Active surveillance is not recommended in patients with T1b, N0, M0 renal cancers, and these patients should be assessed for suitability for active treatments (Ljungberg et al, 2015; GIRFT, 2023).

As per current NICE guidance, partial nephrectomy is considered the standard of care for stage I renal cancer (stage I includes T1a (≤4cm) and T1b (>4cm but ≤7cm), N0, M0 cancers), for patients with bilateral cancers, solitary kidneys, or renal impairment (NICE, 2006). If partial nephrectomy is not possible, radical nephrectomy is considered (NICE, 2005). These procedures are major surgical undertakings and require significant inpatient stay, sometimes needing high dependency unit support.

NICE have not approved ablative procedures for these patients. Therefore, there are currently no alternative treatment options available for patients with T1b, N0, M0 renal cancers who are medically unfit for surgery until the development of metastatic disease, for which there is no curative treatment.

Standard treatment upon development of metastases is lifelong treatment with costly systemic anti-cancer treatments (EUA, 2023; NCCN, 2023). These patients, typically elderly and with comorbidities, may not be fit for systemic anti-cancer treatments on development of metastatic disease.

Stereotactic ablative radiotherapy (SABR), also called stereotactic body radiotherapy (SBRT) is a highly targeted and precise radiotherapy technique, which delivers higher overall doses of radiotherapy in a fewer number of treatments (hypofractionation) than conventional radiotherapy. SABR is delivered using one, three, five or eight treatments (or fractions) and usually delivered in an outpatient setting. The aim of treatment with SABR is to ensure that the tumour receives a high dose of radiation whilst the tissues close to the tumour receive a lower dose of radiation sparing the surrounding healthy normal tissues and reducing the risk of side effects. SABR has been used as a non-surgical intervention with curative intent in many cancer settings, such as hepatocellular carcinoma, for many years.

Renal cancer was historically considered radioresistant when treated with conventional radiotherapy, and for this reason radiotherapy has been used mainly to treat metastases with a palliative intent. SABR, compared to conventional radiotherapy, uses a higher dose per fraction with a higher biological effect that can overcome this perceived radio-resistance. This clinical commissioning policy proposition recommends the use of SABR as a treatment option for adults with localised, non-metastatic T1b, N0, M0 renal cancer who are medically unfit for surgery.

3. Engagement

The policy proposition underwent a two-week stakeholder testing between 29th October and 12th November 2025 with registered stakeholders from the Radiotherapy Clinical Reference Group and relevant patient charities.

Respondents were asked the following consultation questions:

- Do you support the proposal for stereotactic ablative body radiotherapy for patients with localised, non-metastatic, renal cancer who are medically unfit for surgery (adults) through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- 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? If so, please give details.
- Do you have any further comments on the proposal?
- Do you support the Equality and Health Inequalities Impact Assessment (EHIA)?
- Does the Patient Impact Assessment (PIA) present a true reflection of the patient and carers lived experience of this condition?
- Do you have any potential conflict of interest relating to this document or service area?

The comments have then been shared with the Policy Working Group (PWG) 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.

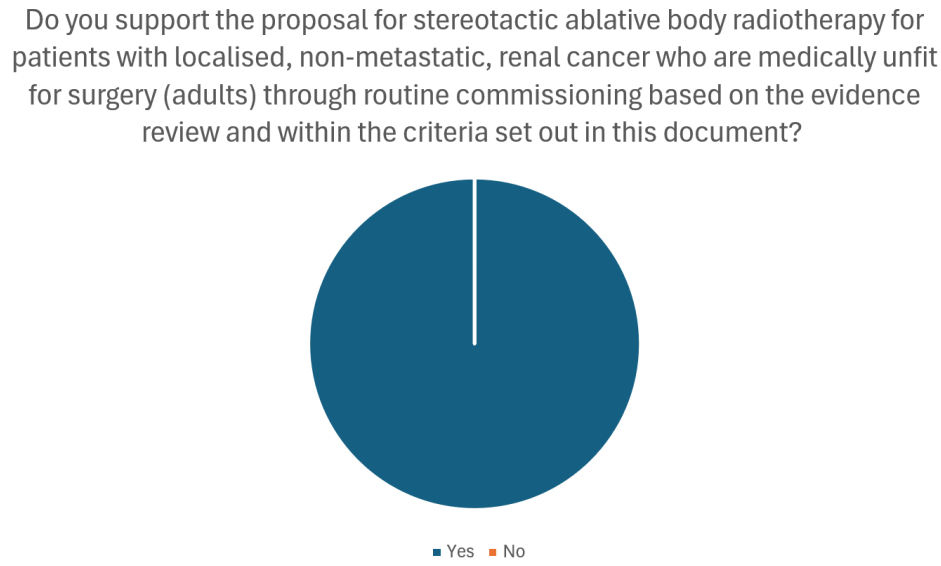
The Programme of Care (PoC) has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation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

4. Engagement Results

Number stakeholders responded: 51

2 patients, 1 academic, 1 clinical scientist, 4 radiographers, 1 charity, 1 professional membership organisation and 41 clinicians.

This was deemed to be a significant stakeholder response. The majority of stakeholders agreed with the policy proposition and felt this offered patients a positive change.



5. How has feedback been considered?

Responses to engagement have been reviewed by the PWG and the Cancer PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Support for proposal	
All respondents supported the proposal citing potential cost savings, efficacy and alternatives to those presently ineligible for current interventions. Two respondents suggested broadening the scope of the present policy proposal either to include those medically fit for surgery or with T1a or T3 disease.	As part of the policy development process, cost effectiveness is carried out in the evidence review however, none of the papers shared any evidence. Further, the policy proposition is currently in the process of financial modelling which aids in rationalising the cost of treatment. During the PICO stage of the policy development process, the PWG focused on the population with the greatest evidence base for use of SABR in renal cancer, opting for individuals are T1 and those medically unfit for surgery. Individuals with ≥ stage II and those who are medically fit for surgery are therefore out of scope of this policy proposition. Presently the majority of evidence is with T1b, therefore those with T1a (≤4cm), N0, M0 renal tumour are presently excluded from the policy proposition. This policy proposition will be reviewed when information, including new evidence is T1a, is received which

	indicates that the policy proposition requires revision.
Evidence review	
The majority of respondents supported the evidence review. Some respondents cited the inclusion of the FASTTRACK II clinical trial as well as Huang et al (2025) to be included in the final review. Others cited Tan et al. (2024) and Ali et al. (2024)	Though not featured in the original evidence review, whilst assessing the clinical effectiveness of the intervention within the policy proposition, Clinical Panel members were made aware of the FASTTRACK II clinical trial as well as Huang et al (2025) publications and took into consideration their findings when agreeing to proceed with the policy proposition. Though the PWG recognise that this is an innovative field with new publications frequently, Tan et al. (2024) and Ali et al. (2024) were out of scope of the initial PICO due to time of publications. Further evidence, such as Huang et al, have been presented to Panel to further reinforce the efficacy of this intervention with randomised control trials being chosen over lower GRADE studies such as case series.
Impacts on patient care	
All respondents agreed that the policy proposal would have a positive impact on patient care.	No further action taken.

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

Nil.

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

Nil.