Consultation Report

Topic details

Title of policy or policy statement:	Stereotactic Ablative Radiotherapy (SABR) for Hepatocellular Carcinoma (Adults)
Programme of Care:	Cancer
Clinical Reference Group:	Radiotherapy
URN:	1913

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposal.

2. Background

Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer, with approximately 5,000 new cases diagnosed in England per year. There are many available treatment options for HCC including: (i) surgery; (ii) transarterial chemoembolisation or TACE; (iii) radiofrequency ablation (RFA); and/or (iv) systemic cancer treatments.

SABR is a highly targeted form of radiotherapy which treats the tumour with radiation beams from different angles at the same time. The treatment is delivered in a fewer number of treatments (hypofractionation) than conventional radiotherapy. 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.

It is thought that SABR could be an additional treatment option for people with HCC who are unable to have any of the current available treatments. In addition, SABR may also be an alternative treatment option for some people currently eligible for treatment with either RFA or systemic cancer treatments.

SABR has been available for the treatment of HCC through the SABR Commissioning through Evaluation (CtE) programme. This policy has been developed in line with the findings of the CtE programme and a new evidence review. The policy proposition has been subject to stakeholder testing and public consultation in line with the standard Methods.

3. Publication of consultation

The policy was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 10th September 2019 to 10th October 2019. Consultation 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 policy might be recommended.

Respondents were asked the following consultation questions:

- Has all the relevant evidence been taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is accurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to made to this document, and why?

4. Results of consultation

There were 18 responses to public consultation of which: (i) 3 responses were from individual clinicians; (ii) 7 responses were on behalf of radiotherapy service providers; (iii) 2 responses were from radiotherapy networks; (iv) 1 response from a Cancer Alliance; (v) 2 responses from patients; and (vi) 3 responses were from individual members of the public.

All respondents supported the policy proposition, but raised the following concerns:

- Respondents noted that the treatment was currently available through centres who participated in the CtE programme. Respondents felt that the access to the treatment needed to be expanded to more radiotherapy centres and queried how NHS England would look to do this in a fair and equitable way. Furthermore, respondents queried the support that would be available to centres that had not been part of the CtE programme including: (i) peer support; (ii) the role of the Radiotherapy Trials Quality Assurance (RTTQA) team in supporting roll-out; and (iii) the quality assurance (QA) process that would be used.
- Respondents felt that policy proposition represented an expansion of the treatment and therefore did not feel the estimated patient numbers were high enough.
- Respondents felt the financial assessment included in the impact assessment did not accurately reflect the true cost of the delivery of the treatment and felt that the use national tariffs as the reimbursement mechanism required review. Furthermore, respondents felt that additional costs, , relating to radiotherapy quality assurance, were required to roll-out the use of the treatment to other radiotherapy centres, outside of the CtE programme.
- Three respondents queried whether use of SABR as bridge to transplant had been considered as part of this policy proposition.
- One respondent felt that proton beam therapy was an alternative form of radiotherapy for HCC and suggested this also be considered as a treatment option.

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document

- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility

Responses to public consultation have been graded as either Level 2, 3 or 4 (see Section 6).

6. Has anything been changed in the policy as a result of the consultation?

The responses to public consultation have been reviewed by the Policy Working Group (PWG) and the Cancer Programme of Care (PoC).

The following response was graded as Level 2 and therefore no change has been made to the policy proposition as a result of feedback:

- **Eligible patient numbers:** the eligible patient numbers included in the policy documentation represent the best estimate of the potential impact of the policy. However, while the estimated activity plays an important role both in allocating service development monies to Regions and onward to provider contracts, it does not represent a cap on funded activity because activity should be reimbursed on actuals. The basis of the estimate used is recruitment to the SABR CtE programme, because epidemiology data isn't granular enough. The CtE programme recruited approximately 91 patients over a three-year period across seven centres. This figure was used as benchmark and extrapolated for the England population, in line with expert clinical advice from the Policy Working Group. Therefore, the predicted numbers are unchanged in the draft policy proposition.

The following responses were graded as Level 3 and therefore no change has been made to the policy proposition, however, further work will be undertaken by NHS England on the following:

- **Financial impact assessment:** As outlined in the NHS Long Term Plan, work is underway to review the national tariffs for radiotherapy in order to enable more providers to offer hypofrationated radiotherapy and replace equipment. It is anticipated that the costs of providing treatment with SABR would be reviewed as part of this work. However, for the purpose of policy development the impact assessment will be amended to reflect the prices used as part of the SABR CtE programme as an interim arrangement, noting that these costs are subject to review and change, as part of the National Tariff reform for radiotherapy[1].

- **Expanding the number of centres and supporting roll-out**: The NHS Long Term Plan sets a clear commitment to expand access to hypofractionated radiotherapy. In line with NHS England and Improvement's wider commissioning responsibilities, any expansion will need to be equitable. For this reason, further detail has been added to both the Integrated Impact Assessment and the Commissioning Plan that sets out how and when expansion will be managed.

[1] Following Clinical Priorities Advisory Group (CPAG) the average package price for SABR was revised and has been calculated using 19/20 tariffs and 3 fractions per SABR fraction. The revised price per patient and anticipated cost pressure can be found in the final Impact Assessment associated with this policy proposition.

In the first instance, SABR for the treatment of hepatocellular carcinoma will continue to be offered from the centres who participated in the SABR CtE programme. Alongside this, during 2020-21, the first cohort of new providers will undertake to organise their services to comply with service specification and policy requirements and also to complete the necessary QA process. Full implementation across all providers is expected to be completed by March 2022.

The following responses were graded as Level 4 and considered to be outside the scope of the policy proposition:

- **Use of SABR as bridge to transplant**: use of SABR as a bridge to transplant was not considered as part of the original SABR CtE programme and therefore was considered to be outside the scope of this policy proposition.

- **Use of PBT for the treatment of HCC**: this is a different radiotherapy intervention to SABR and therefore outside the scope of this policy proposition. Use of PBT in the treatment of HCC is however covered by another NHS England Clinical Commissioning Policy (NHS England Reference: 1842)

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

None.