

Consultation Report

Topic details

Title of policy or policy statement:	Stereotactic ablative radiotherapy (SABR) for patients with metachronous extracranial oligometastatic cancer (all ages)
Programme of Care:	Cancer
Clinical Reference Group:	Radiotherapy
URN:	1908

1. Summary

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

2. Background

Oligometastatic cancer is a form of metastatic cancer. There is no consensus on the definition of oligometastatic cancer, however, the disease is usually confined to a small number of sites in the body (between one to five sites), as opposed to being widespread across the body. This policy is specifically for oligometastatic disease that: (i) develops at least six months after treatment of the primary tumour (metachronous disease); and (ii) is confined to a maximum of three sites of metastases as outlined in the policy proposition.

Treatments for metachronous oligometastatic disease depend on location of the metastases but can include: (i) surgical excision; (ii) RFA; (iii) systemic treatment; and (iv) radiotherapy. The aim of treatment is usually to control symptoms and extend life expectancy.

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.

SABR has been available for the treatment of metachronous oligometastatic cancer 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 be made to this document, and why?

4. Results of consultation

There were 28 responses to public consultation of which: (i) 6 responses were from individual clinicians; (ii) 12 responses were on behalf of radiotherapy service providers; (iii) 2 responses were from radiotherapy networks; (iv) 1 response on behalf of a Cancer Alliance; (v) 1 response from a patient; (vi) 5 responses were from individual members of the public; and (vii) 1 response was the National Radiotherapy Trials Quality Assurance Group.

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

- Respondents noted that although the treatment is not routinely commissioned, it is currently available through 17 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.
- Two respondents queried why the policy was only restricted to 3 sites of metastases when the definition of oligometastatic disease was between 1 to 5 sites of metastases.
- One respondent noted an error in the abbreviation used for radiotherapy quality assurance in the policy proposition.

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 categorised as Level 1, 2 and 3 (see Section 6 below).

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 comment were graded as Level 1 and the policy has been amended:

- **Abbreviation for radiotherapy quality assurance:** this has been amended from RTTQA to RTQA.
- **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 1,500 patients over a three-year period across seventeen 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.

However, as result of the feedback regarding eligible numbers, the clinical criteria in the policy have been reviewed to ensure the eligible patient population driving the eligible patient numbers are clear. The inclusion criteria in the policy proposition have been clarified and these criteria have also been added to the impact assessment confirm the eligible patient criteria driving the patient numbers included in this assessment.

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

- **Number of sites of metastases:** although the clinical definition of oligometastatic disease includes up to five sites of metastases, the clinical criteria in the policy proposition (including the number of sites of metastases that can be treated with SABR, have been developed in line with the available clinical evidence and findings from the SABR CtE programme. The PWG is aware that studies included in the

evidence review did include some studies which treated up to five sites of metastases, however, the CtE programme was restricted to just three sites of metastases. This was discussed by the Specialised Services Clinical Panel when reviewing the policy proposition (see Clinical Panel Report) where it was agreed to align the policy to the CtE eligibility criteria. For this reason, the clinical criteria remain unchanged in the 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 hypofractionated 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.

In the first instance, SABR for the treatment of oligometastatic disease 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.

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

None.

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.