

Engagement Report

Topic details

Title of policy statement:	Stereotactic ablative radiotherapy (SABR) for patients with previously irradiated, locally recurrent para-aortic tumours (All ages).
Programme of Care:	Cancer
Clinical Reference Group:	Radiotherapy
URN:	1918

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

Stereotactic ablative radiotherapy (SABR) is a highly targeted form of radiotherapy which typically involves treating cancers with fewer fractions using a higher dose of radiation.

This policy statement has been developed following the completion of a Commissioning through Evaluation (CtE) programme relating to SABR to treat pelvic, spinal and para-aortic tumours previously treated with radiotherapy. While the scope of the CtE was broader and included indications that are anatomically close, this policy statement relates solely to the para-aortic group.

Tumours that occur in the para-aortic area which is a group of lymph nodes that lie in front of the lumbar vertebral bodies near the aorta in the abdomen, are predominately a result of cancer spreading from other sites of the body such as the breast and prostate.

Initial treatment options for para-aortic tumours includes a combination of different treatments including surgery, chemotherapy and radiotherapy. Further treatment with more conventional forms of radiotherapy is commonly avoided to reduce the risk of damage to healthy tissue and nearby organs which will often have received exposure to radiation as part of the initial treatment. The CtE was designed to evaluate if SABR could be used to treat locally recurrent and previously irradiated para-aortic tumours.

In developing the policy statement proposition, both the CtE findings and an Evidence Review were taken into consideration.

This policy statement has been developed by a Policy Working Group established in line with standard processes and involved clinical members, Public Health England and patient and public voice representatives.

Importantly, this policy statement is one of two that are currently progressing through the policy development process; the other relates to pelvic tumours and recommends that SABR should be routinely commissioned. Should both policies be approved, work will be undertaken to update an existing [policy](#), published in 2016, to reflect the new commissioning position. Collectively, these three policies will address all three clinical indications covered by the CtE.

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 was sent for stakeholder testing for 2 weeks from 8 July 2020 to 22 July 2020. 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.

Respondents were asked the following questions:

- Do you support the proposal for stereotactic ablative radiotherapy (SABR) for the treatment of previously irradiated, locally recurrent para-aortic tumours will not be routinely commissioned based on the evidence review, Commissioning through Evaluation (CtE) report and 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?
- Do you believe that there are any potential negative impacts on patient care as a result of making this treatment option available?
- Do you have any further comments on the proposal?
- 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?
- Please declare any conflict of interests relating to this document or service area.

A 13Q assessment has not been completed following stakeholder testing as this is a policy statement, which means that the full process of policy production has been abridged: a full independent evidence review has not been conducted; and public consultation has not been undertaken. This decision has been assured by the Cancer Programme of Care Assurance Group.

4. Engagement Results

There were three responses to engagement, of which; (i) one response was from an individual member of the public; and (ii) two responses were submitted on behalf of NHS provider organisations.

All respondents fully supported the draft Equality Health Impact Assessment (EHIA), however of the 3 responses received, one respondent did not support the draft policy statement proposition and did not agree that the Patient Impact Form represented a true reflection of the patient and carers lived experience of this condition.

The following specific queries were raised:

- Whether para-aortic lymph nodes are included in the proposed pelvic reirradiation policy proposition (1909) particularly because:
 - The CtE findings did not separate out this group as distinct from the pelvic group;
 - The policy proposition did not contain any data to suggest that para-aortic tumours would respond less favourably to SABR treatment than pelvic disease; and
 - There are no other treatment options for patients.
- As the CtE findings did not separate out the para-aortic group as distinct from the pelvic group, the stakeholder also suggested that the policies should be re-named as follows: (i) SABR for pelvic and abdominal reirradiation (nodal and soft tissue); and (ii) SABR for spinal reirradiation.
- Whether the policy could be amended to include spinal reirradiation as the data demonstrates good local control and overall survival although the number of patients treated within the commissioning through evaluation programme are small.
- A provider organisation queried the data used to derive the policy which refers to spinal, not para-aortic reirradiation and therefore the conclusion not to support para-aortic reirradiation is unjustified.

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
Clarification is needed as to the distinction made between pelvis and para-aortic nodes as different target sites.	<p>Policy proposition 1909 focuses solely on the role of SABR reirradiation of pelvic tumours and does not include para-aortic lymph nodes, as these are in the abdomen and not the pelvis.</p> <p>The Clinical Panel report sets out the rationale for not making SABR available to treat para-aortic tumours – in summary, too few patients were recruited to the CtE and the Evidence Review found no evidence in relation to para-aortic tumours.</p>
Whether the titles of the proposals should be amended to; <ul style="list-style-type: none"> a) SABR for pelvic and abdominal reirradiation (nodal and soft tissue) b) SABR for spinal reirradiation 	As stated within the Background section, the policy approach to managing all three re-irradiation indications included within the CtE has been agreed with the Clinical Panel, i.e., to separate pelvic and para aortic, because the latter is not supported for routine commissioning. Furthermore,

	<p>spinal re-irradiation is already covered in the 2016 policy and the commissioning position has not changed, i.e., it will continue to not be routinely commissioned. This decision was made by the Clinical Panel following a review of the CtE findings and the Evidence Review.</p>
<p>This proposal should be rewritten as spinal reirradiation and supported based on the CtE findings of Local Control and Overall Survival.</p>	<p>This is outside the scope of this policy statement, which relates to para-aortic tumours.</p> <p>Spinal re-irradiation is the subject of a separate clinical commissioning policy, published in 2016. The Clinical Panel reviewed the Evidence Review and CtE findings and concluded that there was insufficient evidence to warrant amending the 2016 policy position on spinal re-irradiation (See the Clinical Panel reports).</p>
<p>The data used to derive the recommendation for this policy proposal refers to spinal, not para-aortic reirradiation</p>	<p>The para-aortic policy statement proposition doesn't contain any reference to spinal re-irradiation.</p> <p>It is possible that the respondent if referring to the fact that both this policy statement proposition and policy proposition 1909 relating to pelvic re-irradiation, are supported by a single Evidence Review and CtE evaluation report and so there are references throughout both documents to clinical indications other than para-aortic tumours. Furthermore, the Evidence Review did not identify any evidence relating para-aortic tumours, hence the focus in this document on spinal and pelvic re-irradiation. Similarly, the CtE evaluation report focusses largely on spinal and pelvic re-irradiation because very few patients with para-aortic tumours were recruited.</p>

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

As a result of stakeholder testing the policy proposition has been amended and the reference to the heart as an organ at risk (OAR) for para-aortic radiotherapy has been removed.

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

None.