Engagement Report

Topic details

Title of policy:	Stereotactic ablative radiotherapy (SABR) for patients with previously irradiated, locally recurrent primary pelvic tumours (All ages).
Programme of Care:	Cancer
Clinical Reference Group:	Radiotherapy
URN:	1909

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.

The policy proposition 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 proposition relates solely to the pelvic tumour group.

Based on the findings of the CtE and an Evidence Review, the policy proposition recommends that SABR should be routinely made available for people with previously irradiated, locally recurrent primary pelvic tumours as a treatment alternative to systemic therapy (e.g. chemotherapy), where curative surgery is not an option or has been declined.

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

Importantly, this policy proposition is one of two that are currently progressing through the policy development process; the other relates to para-aortic tumours and recommends a not for routine commissioning position. 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 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 27 July 2020. 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.

Respondents were asked the following questions:

- Do you support the proposal for stereotactic ablative radiotherapy (SABR) to be available for the treatment of previously irradiated, locally recurrent pelvic tumours through routine commissioning based on the evidence review, CtE report 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?
- 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 (EHIA)?
- 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.

The Programme of Care (PoC) agrees that the policy 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

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

All respondents fully supported the draft policy proposition, the draft Equality Health Impact Assessment and agreed that the Patient Impact Form represented a true reflection of the patient and carers lived experience of this condition.

However, respondents queried the following:

- The scope of the policy, particularly in terms of the link to the CtE and the clinical criteria included in the policy proposition:
    - Whether positive margin disease following exenteration is included in the policy proposal, as these patients were included in the CtE evaluation.

- Whether para-aortic lymph nodes are included in the proposed policy proposition particularly because the CtE findings did not separate out this group as distinct from the pelvic group and because the policy proposition did not contain any data to suggest that para-aortic tumours would respond less favourably to SABR treatment than pelvic disease.

- 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.

- The discontinuation of targeted/ systemic therapy for minimum 14 days before SABR be reviewed.

- Whether evidence relating to prostate re-irradiation, published by Jerecek-Fossa BJR 2018 has been considered.

- The number of centres that would be able to deliver this treatment should the policy be approved.

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
The inclusion of positive margin disease following exenteration	The PWG agrees that the proposed patient pathway diagram should be revised to include the treatment of positive margins as per the commissioning position described in the policy.
Evidence relating to prostate re-irradiation (Jerecek-Fossa BJR 2018) was not included in the Evidence Review.	This policy proposition considers the role of SABR for patients with previously irradiated, locally recurrent pelvic tumours and, as such, prostate cancers are included in the recommended policy position. The Public Health lead for the policy proposition has reviewed the additional evidence cited by the stakeholder and has confirmed that it did not meet the PICO criteria. Please see the Evidence Report.

Clarification is needed as to the distinction made between pelvis and para-aortic nodes as different target sites.	The feedback provided did not appear to take into account that the policy proposition dealt solely with pelvic tumours and that para-aortic tumours were dealt with in a separate policy. In terms of the substantive point raised as to why para-aortic tumours had not been approved to be routinely commissioned, the Clinical Panel concluded that the evidence was insufficient to support making SABR routinely available to treat para-aortic tumours. The rationale for this is set out within the Clinical Panel Reports associated with this policy.
The discontinuation of targeted/ systemic therapy for minimum 14 days before SBRT is not evidence based.	The PWG agrees that the wording should be slightly amended to reflect the individualised care of each patient's specific situation but must be stopped at some point prior to treatment.
Whether the titles of the proposals should be amended to; 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 manage the 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. Spinal re-irradiation is 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.
NHS England intention as to the number of centres able to deliver this form of treatment should the policy be approved	Improving access to modern radiotherapy techniques is a key focus of the NHS Long Term Plan and work is already underway to expand access to SABR where it is clinically appropriate to do so and Trusts have met the necessary quality assurance requirements.

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 to;

a) Include the treatment of positive margins, as per the policy proposition in the proposed patient pathway schema.

b) Reflect flexibility in the timing for discontinuing targeted / systemic treatment prior to SABR.

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

On review of the post stakeholder testing feedback, the Cancer Programme of Care Product Assurance Group considered that there was still a lack of clarity within the policy proposition about what was proposed to be commissioned and what wasn't. Furthermore, that there may be a need to refine the proposed policy title to reflect that the group covered by the commissioning position were those with locally recurrent primary pelvic tumours that had been previously treated with radiation. This is an important distinction because the CtE covered all locally recurrent tumours in the pelvis that had been previously treated with radiation, i.e., both primary and secondary. This distinction would also need to be reflected in the 2016 policy, as secondary pelvic tumours would continue to not be routinely commissioned.