NHS

Engagement Report

Topic details

Title of policy or policy statement:	Stereotactic ablative body radiotherapy (SABR) as a treatment option for adults with locally advanced, inoperable, non-metastatic pancreatic carcinoma
Programme of Care:	Cancer
Clinical Reference Group:	Radiotherapy
URN:	2011

1. Summary

The policy statement proposition recommends the use of stereotactic ablative body radiotherapy (SABR) as a treatment option for adults with locally advanced, inoperable, non-metastatic pancreatic carcinoma (LANPC) where the disease remains localised following ≥3 months of systemic chemotherapy.

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

Pancreatic cancer is a type of cancer that starts in the pancreas, an organ near the stomach and is relatively rare. The most common type of pancreatic cancer, pancreatic ductal adenocarcinoma (PDAC) (https://www.pancreaticcancer.org.uk/information/just-diagnosed-with-pancreatic-cancer/pancreatic-ductal-adenocarcinoma-and-other-exocrine-tumours/). Around 30% of PDAC present as locally advanced, inoperable cancer which has not spread to other parts of the body (known as LANPC).

Treatment of LANPC involves chemotherapy (either combination regimen or gemcitabine monotherapy) given for 3 to 6 months, depending on the chemotherapy regimen. If the disease remains stable following this treatment, patients may be offered chemo-radiotherapy, which involves 28-30 daily radiotherapy treatments, alongside daily oral chemotherapy (capecitabine).

The use of SABR, a highly targeted form of radiotherapy delivered in fewer treatments (hypofractionation) than conventional radiotherapy, as an alternative treatment option to chemoradiotherapy for the treatment of stable disease, means fewer daily hospital visits and, as concurrent daily oral chemotherapy is not required, patients are also spared the side effects of the chemotherapy.

The policy proposition 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.

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 25/5/21 to 08/06/21. 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 body radiotherapy to be available for patients with locally advanced, inoperable, non-metastatic pancreatic carcinoma 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?
- 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 (PoC) Assurance Group.

4. Engagement Results

17 responses were received from a range of stakeholders. These comprised 6 NHS trusts, 3 Hepato-Pancreato-Biliary (HPB) Surgeons, 2 charities, 2 radiotherapy Operational Delivery Networks (ODN), 1 private provider, 1 physicist, 1 radiographer and 1 other individual. Of these 17, 15 supported the proposals whilst 2 others gave muted support for the proposal. 13 of the responders answered and supported Equality and Health Inequalities Impact Assessment and Patient Impact Assessment.

The following points were raised:

- State-of-the-art radiotherapy equipment would be needed across the country to help deliver this technologically advanced treatment;
- A training and quality assurance programme would need to be rolled out to train professionals on delivering SABR to the pancreas;
- Concern that if the commissioning model was moved back to Tariff, that providers would be negatively impacted financially;
- Queries regarding why the dose range stated as 33-40Gy, when the most commonly used regime used in one of the papers was 30Gy in 5 fractions and suggested this be included as an option;
- Concern that the treatment may not be available to everyone if all providers don't offer the treatment;
- A belief that the severity of patient's symptoms and the rapidity of their decline should be better reflected within the Patient Impact Assessment document;
- A query regarding whether a size criteria cut-off should have been included in the inclusion/exclusion criteria.

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
Relevant Evidence	
The dose range quoted in the 2019 Tchlebi systematic review stated that the most common dose fractionation used was 30Gy in 5 fractions, yet the dose range included in the policy was 33-40Gy.	30Gy in 5 Fractions is not considered to be SABR by current standards, this dose is more akin to high dose palliation and used as a COVID-19 mitigation option, either as a bridging (to surgery) or palliative fractionation.
Impact Assessment	
One respondent felt that the severity of patient's symptoms and the rapidity of their decline should be better reflected within the Patient Impact Assessment document. Another however felt that many of the patients affected in the document would experience symptoms at the milder range of those quoted.	PWG recommend no change given only two responses which were conflicting.
Current Patient Pathway	
State-of-the-art radiotherapy equipment would be needed across the country to help deliver this technologically advanced treatment.	SABR is now delivered at the majority of England radiotherapy centres, so access to equipment is not considered to be a particular issue. One stakeholder also commented on the potential use of magnetic resonance linear accelerators (MR LINACs) in the treatment of this indication – this is noted but is considered out of scope at the present time, as magnetic resonance equipment trials are yet to complete.

A training and quality assurance programme would need to be rolled out to train professionals on delivering stereotactic ablative radiotherapy to the pancreas. There were various suggestions about how this may be achieved.	The policy statement requires that all providers must be compliant with Radiotherapy Quality Assurance (RTTQA) for contouring and outlining. This will be included as part of the national rollout of SABR, if the policy statement is approved.
Concern that if the commissioning model was moved back to the Tariff scheme that providers would be negatively impacted financially.	Radiotherapy planning and delivery has been reimbursed through national prices and the SABR package pricing is based on this methodology. This policy statement is cost neutral and in year 1, we are not planning to remove or add funding to provider blocks. We are intending to move to a new basis of payment, continuing with a form of block payment from April 22, whilst a new reimbursement model is developed.
Potential impact on equality and health inequalities	
Concern that the treatment may not be available to everyone if all providers don't offer the treatment.	There is a plan to roll out SABR to ensure geographical equity of access centred around the ODN structure.
Changes/addition to policy	
A query regarding whether a size criteria cut-off should have been included in the inclusion/exclusion criteria	PWG noted the use of size cut off by Suker but consider that the relation of the tumour to critical structures is more critical than a size cut off.

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

Based on the engagement responses no changes have been made to the policy proposition.

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

No.