Engagement Report

Topic details

Title of policy or policy statement:	Brachytherapy dose escalation with external beam radiotherapy for intermediate and high-risk localised prostate cancer (adults)
Programme of Care:	Cancer
Clinical Reference Group:	Radiotherapy
URN:	1831

1. Summary

The policy proposition recommends that brachytherapy dose escalation with external beam radiotherapy is made available as a treatment option through routine commissioning for intermediate and high-risk localised prostate cancer.

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

Prostate cancer is the most common cancer affecting men in the UK. Localised prostate cancer is assessed into three groups (low, intermediate and high-risk) depending on how likely the cancer is to spread or return.

There are many treatment options for intermediate or high-risk localised prostate cancer including active surveillance, hormone therapy, surgery and radiotherapy. For people having radical (i.e. curative) radiotherapy for localised prostate cancer, the standard of care in England is to use hypofractionated external beam radiotherapy. The addition of a brachytherapy boost, also known as dose escalation, in combination with external beam radiotherapy enables a higher dose of radiation to be delivered to the prostate.

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 11th January 2021 to 25th January 2021. 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 brachytherapy dose escalation with external beam radiotherapy to be available for intermediate- and high-risk localised prostate cancer (adults) 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.
- The policy also includes a shared decision making (SDM) tool to support patients to decide whether this treatment is right for them.
    - Do you have any comments regarding the relevance and amount of information presented to enable the patient to make a choice?
    - Do you feel the decision-making matrix in the SDM summarises all the key issues to be considered by the patient when making a decision?
    - Do you have any general comments regarding the SDM tools?
- Do you have any further comments on the proposal? If yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'.
- 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 been completed following stakeholder testing.

The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a treatment available which widens the range of treatment options available to patients, 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 11 responses to engagement, of which (i) 3 responses were received from individual clinicians; (ii) 1 response was from Prostate Cancer UK; (iii) 5 responses were submitted on behalf of organisations; and (iv) 2 responses were submitted by Radiotherapy Operational Delivery Networks.

Of the 11 responses received, 10 respondents fully supported the draft policy proposition and 1 respondent did not comment. Furthermore, 9 respondents answered and supported the draft Equality and Health Inequalities Impact Assessment and 7

respondents answered 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:

- Whether the evidence review had considered all relevant published evidence;
- Whether to reflect that urinary flow testing must be completed and results known before treatment;
- Whether High dose-rate brachytherapy (HDR) is the preferred means of boosts;
- Whether a higher dose such as 50.4Gy/28# should be included in the policy for high-risk patients;
- Should consideration be given to radiotherapy organised across centres including travel, which may influence patient choice for HDR boost;
- If the wording in the SDM tool could be revised; it asserts that patient and clinician have agreed radiotherapy and now we consider something new;
- Whether some patients will find the information in the SDM tool too much;
- Whether the decision-making matrix in the SDM summarises should also have considered;

    (i) Possible patient referral and travel to other hospitals to receive HDR brachytherapy
    (ii) Scheduling of external beam radiotherapy (EBRT) and HDR, included in main policy document but not in the SDM matrix
    (iii) adjuvant use of Androgen Deprivation Therapy (ADT)
    (iv) recurrence rates.
    (v) to replace local anaesthetic with spinal SDM
    (vi) A reference to Low dose-rate brachytherapy (LDR) means the patient is radioactive which means that cremation is not possible
    (vii) whether a generalised statement around boosts would be more beneficial rather than complicating this into LDR or HDR boosts.
    (viii) whether the SDM should provide an idea of the absolute frequency of potential side effects.
    (ix) The inclusion of 4.5 weeks of EBRT as an option for HDR brachytherapy boosts as per the clinical commissioning policy.

- Whether there was an opportunity to develop a national tariff for brachytherapy.

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Cancer National Programme of Care (NPoC). The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
Consideration of all published evidence	The papers were reviewed against the original PICO criteria for the evidence review that informed the policy proposal. The three studies that were cited were published after the time frame used for the literature search in the evidence review and two studies did not have a comparator. Therefore no submitted evidence met the criteria.
Inclusion of measures of urinary flow testing	The PWG confirmed that the document includes patient selection based on International Prostate Symptom Score. No change.
HDR preferred over LDR	The PWG confirmed that the evidence review does not identify benefit of HDR over LDR. No change.
Inclusion of 50.4Gy/28# in the policy for high-risk patients	The PWG agrees that until publication of the PIVOTAL boost study results this is not considered to be the standard of care. No change.
Whether some patients will find the information in the SDM tool too much	The PWG considers the information included in the SDM tool is important for patients to make informed choices. It is expected that the treating clinician will discuss the options fully with patients. The SDM tool is considered additional to this. The SDM tool has been developed with Prostate Cancer UK. No change.
SDM tool	
(i) Impact on possible patient referral and travel to other hospitals to receive HDR brachytherapy	The PWG confirmed that this aspect is refenced in the clinical commissioning policy and captured in the SDM tool. No change.

(ii) Scheduling of EBRT and HDR, included in main policy document but not in the SDM matrix	The PWG agreed to update the SDM tool. The sentence "LDR or HDR brachytherapy will be undertaken within 2 to 3 weeks before or after EBRT" has been added to the SDM.
(iii) adjuvant use of Androgen Deprivation Therapy	The PWG agreed that the recommendations relating to specific measures of ADT is out of scope of the clinical commissioning policy. No change.
(iv) recurrence rates.	The PWG confirmed that this is already included in the SDM tool. The evidence review does not support HDR over LDR. No change.
(v) to replace local anaesthetic with spinal	The PWG agreed. This has been amended in the SDM tool.
(vi) A reference to LDR means the patient is radioactive which means that cremation is not possible	The PWG did not consider it appropriate to include in the SDM tool. Additional patient information should be available locally on the implications of treatments using radioactive sources. No change.
(vii) whether a generalised statement around boosts would be more beneficial rather than complicating this into LDR or HDR boosts.	The PWG confirmed that the side effect profiles are different and need to be reflected in the SDM. No change.
(viii) whether the SDM should provide an idea of the absolute frequency of potential side effects.	The PWG confirmed that the SDM should only describes a relative risk compared to standard radiotherapy rather than defining absolute frequency as this varies between publications. No change.

(ix) The inclusion of 4.5 weeks of EBRT as an option for HDR brachytherapy boosts as per the clinical commissioning policy. (x)The SDM tool asserts that patient and clinician have agreed radiotherapy and now we consider something new;	The SDM tool has been amended to reflect all the scheduling options included in the clinical commissioning policy. The PWG confirmed that the SDM tool is only applicable once radiotherapy is the preferred option. No change.
Impact of implementation on workforce and funding issues.	The PWG agreed this was out of scope of the clinical commissioning policy but is noted as a consideration during implementation.

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

No changes have been made to the clinical commissioning policy however, some minor amendments have been made to the SDM tool based on the engagement responses.

PoC Assurance postscript:

At the PoC Assurance meeting a concern was raised relating to the validity of requiring patients to have a life expectancy of 10 years or more to be eligible for the treatment. Following discussion with the policy working group it was confirmed that this is a standard recommendation when considering any radical treatment for prostate cancer since survival benefit from treatment is not seen for some years and therefore treating patients with a short life expectancy is in fact harmful by inducing side effects with no benefit. A link to the European Association of Urology guidelines has now been included in the policy proposition: https://uroweb.org/guideline/prostate-cancer/

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

None.