Consultation Report

Topic details

Title of policy or policy statement:	External beam radiotherapy of the prostate for newly diagnosed patients with hormone sensitive prostate cancer presenting with low volume metastatic disease
Programme of Care:	Cancer
Clinical Reference Group:	Radiotherapy
URN:	1901

1. Summary

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

2. Background

Metastatic prostate cancer is a cancer that has spread beyond the prostate gland, most commonly to the bones and lymph nodes. At the point of diagnosis, approximately 18% of all cases of prostate cancer are metastatic. Metastatic prostate cancer can be classified into a low volume (burden) or high volume based on the number of metastases found in the body.

It is not possible to cure metastatic prostate cancer but treatments, such as initial hormone therapy (i.e. androgen deprivation therapy [ADT]) and chemotherapy, can keep it under control, sometimes for several years. These treatments are aimed at extending life expectancy and maintaining a good quality of life.

Radiotherapy has been historically used as a treatment for symptom control at the site of metastatic disease. This policy proposition considers whether external beam radiotherapy (EBRT), a method of delivering radiotherapy, should be offered as an additional treatment to the prostate for people with prostate cancer.

3. Publication of consultation

The policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 9th March to 8th April 2020. Consultation 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 policy proposition 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 inaccurate?
- 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 10 responses to public consultation of which:

- 1 response was from a trust,
- 1 response was from a private provider;
- 1 response was from a charity organisation (Prostate Cancer UK); and
- 7 responses were individual responses (including 1 radiographer, 1 carer, 1 patient and 4 clinicians).

All respondents were supportive of the policy proposition but raised the following:

- Respondents noted that it was important for patients to be fully informed of the all the treatment options and potential side effects of treatment and this should be reflected as part of the patient pathway requirements.
- One respondent suggested that the eligibility criteria for 'low volume metastatic disease' should take account of new technical imaging developments that can more accurately assess metastatic burden.
- One respondent suggested that the policy proposition should include 5 fractions of stereotactic ablative body radiotherapy (SABR) as an alternative treatment with people with a large prostate.
- Comments raised also included the use of SABR radiotherapy and in particular the PACE trial schedule, the impact on eligibility of more accurate imaging modalities, and the methodology used to estimate the number of patients eligible for the treatment per year.

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

5. Has anything been changed in the policy as a result of the consultation?

It was noted and confirmed that:

- The 36Gy in 6 fraction schedule is derived from Level 1 evidence in the STAMPEDE trial which did not show an advantage for a 20 fraction schedule in the patients with low volume metastatic disease. The 6 fraction schedule is considerably more convenient for patients and is therefore recommended in the policy proposition. *Response graded as Level 2.*
- The Widmark study used image guided therapy and conventional linear accelerators (not SABR) and was used as an example of Level 1 evidence showing that large doses/fraction could be safely and effectively given. *Response graded as Level 2.*
- The prescribed dose in the phase 3 PACE trial is considerably higher at 36.25Gy in 5 fractions. There is no evidence to indicate that the use of a SABR dose suggested as 35Gy in 5 fractions, treating daily improves outcome in patients with low volume metastatic disease. Ideally this should be the subject of further clinical trials. *Response graded as Level 4.*
- The STAMPEDE trial has shown there is a statistically significant advantage for both overall and failure free survival for radiotherapy in the pre-specified analysis for the low metastatic burden group of patients. This advantage was not seen in patients with a high burden of metastatic disease. *Response graded as Level 2.*
- The definition of low burden disease is based on clinical trial evidence. Definition 1 within the policy (Burdett et al) has been used to define the eligible population, eligibility and ineligibility as the methodology was well-defined and allowed the maximum number of patients to be included in the meta-analysis. Definition 3 (Parker et al) has been used to define the prevalence of low burden disease only. The policy proposition references Parker et al in the exclusion criteria and for accuracy this reference should be removed. *Response graded as Level 1.*
- Improvements in diagnostic test quality may impact on the number of metastases detected, and further advice and policy review may be required as diagnostic testing evolves. Correlative studies between new imaging techniques and current standard of care bone scan will be required as evidence becomes available and may lead to a review of the definition of low burden disease in the future. *Response graded as Level 4.*
- Ensuring that an informed view of side effects of all treatment options should be described to patients in detail at this stage of disease enabling them to make the choice. *Response graded as Level 2.*

As a result of public consultation, the PWG recommends removal of the reference quoted in the exclusion criteria and a change to the patient pathway section to reflect the importance of clinicians discussing the risks and benefits of the treatment with eligible patients. No other changes are recommended.

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

There are no outstanding concerns arising from the consultation.