

# Clinical Priorities Advisory Group summary report

<b>Agenda item</b>	2.1
<b>Date of Meeting</b>	7 January 2026
<b>Title of the Proposition</b>	Stereotactic ablative radiotherapy (SABR) for the treatment of localised prostate cancer (adults)
<b>Unique Reference Number</b>	2106
<b>Programme of Care</b>	Cancer
<b>Clinical Reference Group</b>	Radiotherapy
<b>Service/treatment status</b>	delegated

## Action requested

Support the adoption of the policy proposition

Recommended its approval as an in year service development.

---

## Summary of the proposition:

Prostate cancer is the most common cancer affecting men in the UK, with 50,702 new cases diagnosed in England in 2022. Prostate cancer is usually slow growing, with most patients being diagnosed with localised prostate cancer, meaning that the cancer has not spread to other areas in the body. Once diagnosed, localised prostate cancer is risk stratified into

groups to help guide management. For patients with low and intermediate risk prostate cancer, this means that the cancer is unlikely to grow or spread for a few years. For these patients, as there is a low risk of disease progression, most patients' will just be closely monitored without the need for treatment, and this is known as active surveillance. For those who are not suitable for active surveillance, patients will either have radiotherapy (usually 20 sessions) or surgery.

This clinical commissioning policy proposition recommends the use of stereotactic ablative radiotherapy (SABR) as an alternative treatment option for patients with low or intermediate risk localised prostate cancer. SABR is a highly targeted and precise radiotherapy technique which delivers high overall doses of radiotherapy, in fewer treatment sessions than conventional radiotherapy. The policy is for adults only in line with the findings from the independent evidence review.

## Clinical Panel recommendation:

The Clinical Panel recommended that the policy proposition progress as a routine commissioning policy.

## Assurances

The committee is asked to receive the following assurance:	
1.	The Deputy Director of Clinical Effectiveness confirms the proposition has completed the appropriate sequence of developmental and governance steps.
2.	The Deputy Director of Cancer Programme confirms the proposition is supported by the following documentation (please tick the box where applicable)
	Draft Clinical Commissioning policy proposition <input checked="" type="checkbox"/>
	Three Paper Evidence Summary <input checked="" type="checkbox"/>
	Public Health Evidence Report <input type="checkbox"/>
	Evidence to Decision Making (EtD) Summary <input checked="" type="checkbox"/>
	Equalities and Health Inequalities Assessment (EHIA) <input checked="" type="checkbox"/>
	Prior Approval Form <input checked="" type="checkbox"/>
	Engagement Report <input checked="" type="checkbox"/>
	13Q Assessment and Patient & Public Voice Assurance <input checked="" type="checkbox"/>
	Clinical Panel Report <input checked="" type="checkbox"/>
	Policy Working Group membership <input checked="" type="checkbox"/>
	Other (please state if required) <input type="checkbox"/>

3.	The Deputy Director of Finance (Specialised Commissioning) confirms that the Impact Assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal.
4.	The Director of Clinical Commissioning (Specialised Commissioning) confirms that the Service and Operational Impact Assessments have been completed.
5.	The Deputy Director of Quality and Nursing (Specialised Commissioning) confirms that the proposed quality indicators have been adequately defined (where applicable).

## Evidence Review Summary

**In the Population what is the clinical effectiveness and safety of the Intervention compared with Comparator?**

Outcome	Evidence statement
<b>Clinical effectiveness</b>	
<b>Critical outcomes</b>	
<b>Biochemical or clinical failure (BCF) event-free rate / failure free survival</b>  <b>Certainty of evidence:</b>  Not assessed for 3 paper summaries	<p>BCF was reported in two of the three papers included in the summary.</p> <p>Van As et al (pre-print; PACE-B RCT) reported that at a median follow-up of 74.0 months (IQR 64.8 to 86.3) of patients with prostate cancer of low or intermediate risk, 26 biochemical failure events had occurred in the SABR group (n=433) compared to 36 events in the CRT group (n=441). A total of 10 participants in the SABR group commenced androgen deprivation therapy (ADT) compared to 19 in the CRT group (hazard ratio (HR) 0.55, 95% CI 0.26 to 1.20, p-value not reported).</p> <p>Van As et al (pre-print; PACE-B RCT) also reported that the five-year BCF event free-rates were 95.8% (95% CI 93.3% to 97.4%) for SABR and 94.6% (95% CI 91.9% to 96.4%) for CRT (absolute group difference 1.43%, 90% CI -0.60% to 2.78%, p-value not reported). SABR was shown to be non-inferior to CRT for patients with prostate cancer with low or intermediate risk (HR 0.73, 90% CI 0.48 to 1.12, p=0.004). A test for superiority was not significant (p=0.22). Competing risks analysis indicated no evidence of a statistically significant difference in BCF event-free rates between treatment groups (p=0.18).</p> <p>Widmark et al (2019; HYPO-RT-PC) reported that after median 5.0 years follow-up (IQR 3.1 to 7.0 years) of patients with intermediate to high risk prostate cancer, 100 BCF events occurred in the ultra-hypofractionation group (n=589) and 102 events in the CRT group</p>

	<p>(n=591; p-value not reported). Failure-free survival at five years was 84% (95% CI 80% to 87%) in the ultra-hypofractionation group and 84% (95% CI 80% to 87%) in the CRT group; there was no evidence of a statistically significant difference between the groups (HR 1.002, 95% CI 0.760 to 1.320, p=0.99). Ultra-hypofractionation radiotherapy was found to be non-inferior to CRT (adjusted HR 1.002, 95% CI 0.758 to 1.325, p-value not reported).</p> <p>One included paper reported no statistically significant difference in biochemical or clinical failure at a median 74.0 months follow-up between patients with low or intermediate risk prostate cancer treated with SABR (n=443) compared to patients treated with CRT (n=441) (BCF event-free rates: 95.8% vs 94.6%); non-inferiority was demonstrated. A second included paper reported no statistically significant difference in biochemical or clinical failure at median five year follow-up between patients with intermediate to high risk prostate cancer treated with ultra-hypofractionation radiotherapy (n=589) compared to patients treated with CRT (n=591) (BCF events: 100 vs 102); ultra-hypofractionation radiotherapy was demonstrated to be non-inferior to CRT.</p>
<p><b>Overall survival</b></p> <p><b>Certainty of evidence:</b></p> <p>Not assessed for 3 paper summaries</p>	<p>Overall survival was reported in two of the three papers included in the summary.</p> <p>Van As et al (pre-print; PACE-B RCT) reported that for men with prostate cancer with low or intermediate risk, 46/433 (10.6%) patients in the SABR group and 33/441 (7.5%) patients in the CRT group had died at a median 74.0 months follow-up (IQR 64.8 to 86.3 months); there was no evidence of a statistically significant difference in overall survival between treatment groups (HR 1.41, 95% CI 0.90 to 2.20, p-value not reported). Four deaths were due to prostate cancer and 28 to other cancers; this was not described by treatment group.</p> <p>Widmark et al (2019; HYPO-RT-PC) reported five year overall survival rates for patients with intermediate to high risk prostate cancer, demonstrating no evidence of a statistically significant difference in overall survival between treatment groups (ultra-hypofractionation: n=589, CRT: n=591; HR 1.11, 95% CI 0.73 to 1.69, p-value not reported). Overall survival at five years in the ultra-hypofractionation group was 94% (95% CI 92% to 96%) and 96% (95% CI 95% to 98%) in the CRT group. During the follow-up period a total of 19 patients died due to prostate cancer (n=8 in the ultra-hypofractionation group and n=11 in the CRT group) and 70 patients died due to other causes (n=35 in both groups).</p> <p>One included paper reported no statistically significant difference in overall survival at median 74.0 months follow-up between patients with low or intermediate risk prostate cancer treated with SABR (n=443) compared to patients treated with CRT (n=441). A second included</p>

	<p>paper reported no statistically significant difference in five year overall survival rate between patients with intermediate to high risk prostate cancer treated with ultra-hypofractionation radiotherapy (n=589) compared to patients treated with CRT (n=591).</p>
<p><b>Cumulative incidence of prostate cancer death</b></p> <p><b>Certainty of evidence:</b> Not assessed for 3 paper summaries</p>	<p>Cumulative incidence of prostate cancer death was reported in one of the three papers included in the summary.</p> <p>Widmark et al (2019; HYPO-RT-PC) reported that there was no statistically significant difference in the cumulative incidence of prostate cancer death at five years in patients with intermediate to high risk prostate cancer. This was 2% (95% CI 1% to 4%) in the ultra-hypofractionation group (n=589) and &lt;1% (95% CI 0% to 1%) in the CRT group (n=591) (p=0.46).</p> <p>One included paper reported no statistically significant difference in the cumulative incidence of prostate cancer death at five years in patients with intermediate to high risk prostate cancer treated with ultra-hypofractionation therapy (n=589) compared to patients treated with CRT (n=591).</p>
<p><b>Erectile dysfunction</b></p> <p><b>Certainty of evidence:</b> Not assessed for 3 paper summaries</p>	<p>Erectile dysfunction was reported in two of the three papers included in the summary.</p> <p>Van As et al (pre-print; PACE-B RCT) reported erectile dysfunction for men with prostate cancer with low or intermediate risk using the Common Terminology Criteria for Adverse Events (CTCAE v4.03, grade <math>\geq 2</math>). There was no evidence of a statistically significant difference between the groups in erectile dysfunction symptoms at five years follow-up (SABR: 78/296 (26.4%); CRT: 86/296 (29.1%); p=0.46).</p> <p>Widmark et al (2019; HYPO-RT-PC) reported no evidence of a statistically significant difference in erectile dysfunction symptoms<sup>3</sup> between patients with intermediate to high risk prostate cancer that received ultra-hypofractionation radiotherapy (baseline n=507, 10 years n=21) compared to CRT (baseline n=506, 10 years n=20) at any timepoint between baseline and 10 years follow-up (approximate range of erectile dysfunction scores<sup>4</sup>: ultra-hypofractionation: 30% to 90%; CRT: 35% to 85%).</p> <p>One included paper reported no statistically significant difference in erectile dysfunction symptoms at five years follow-up between patients with low or intermediate risk prostate cancer treated with SABR (n=296) compared to patients treated with CRT (n=296). A second included paper reported no statistically significant difference in erectile dysfunction symptoms at any timepoint between baseline and 10 years follow-up between patients with intermediate to high risk</p>

	prostate cancer treated with ultra-hypofractionation radiotherapy (baseline n=507, 10 years n=21) compared to patients treated with CRT (baseline n=506, 10 years n=20).
<b>Safety</b>	
<p><b>Serious adverse events</b></p> <p><b>Certainty of evidence:</b> Not assessed for 3 paper summaries</p>	<p>Serious adverse events were reported in one of the three papers included in the summary.</p> <p>Van As et al (pre-print; PACE-B RCT) reported serious adverse events for men with prostate cancer with low or intermediate risk using the Common Terminology Criteria for Adverse Events (CTCAE v4.03). Six participants (1.3%) in the SABR group (n=443) and six participants (1.4%) in the CRT group (n=441) reported treatment related serious adverse events at five years follow-up.</p> <p>One included paper reported the same number of treatment related serious adverse events (six) in patients with low or intermediate risk prostate cancer treated with SABR (n=443) or CRT (n=441) at five years follow-up.</p>
<p><b>Genitourinary (GU) toxicity</b></p> <p><b>Certainty of evidence:</b> Not assessed for 3 paper summaries</p>	<p>GU toxicity was reported in all three of the papers included in the summary.</p> <p>Tree et al (2022; PACE-B RCT) reported the proportion of patients with prostate cancer with low or intermediate risk with GU toxicity (grade <math>\geq 2</math>) at two years follow-up using both the Common Terminology Criteria for Adverse Events (CTCAE v4.03) and the Radiation Therapy Oncology Group (RTOG) assessment tool. RTOG GU toxicity was reported in 3% of the SABR group (13/384; 95% CI 1.9% to 5.9%) and 2% of the CRT group (8/381; 95% CI 1.0% to 4.3%) (absolute difference: 1.3%, 95% CI -1.3% to 4.0%, p=0.39, non-significant difference). There was evidence of a statistically significant higher CTCAE GU toxicity at 24 months in the SABR group (47/414, 12%) compared to the CRT group (25/430, 7%) (absolute difference 5.7%, 95% CI 1.6% to 9.8%, p=0.010).</p> <p>Tree et al (2022; PACE-B RCT) also reported evidence of a statistically significant difference in cumulative incidence of GU toxicity at two years using both CTCAE criteria and the RTOG tool. Cumulative incidence rates using the RTOG tool were 18.3% for patients that received SABR (n=414, 75 events; 95% CI 14.9% to 22.4%) and 10.6% for patients that received CRT (n=430, 45 events; 95% CI 8.0% to 14.0%; HR 1.80, 95% CI 1.25 to 2.61, p=0.0015). Cumulative incidence rates using the CTCAE criteria were 32.3% for patients that received SABR (132 events; 95% CI 28.0% to 37.0%) and 19.8% of patients that received CRT (84 events; 95% CI 16.3% to 23.9%; HR 1.73, 95% CI 1.32 to 2.28, p=0.0001).</p>

Tree et al (2022; PACE-B RCT) also reported the most frequently reported GU toxicity to be increased urinary frequency; this peaked at 15 months in the SABR group (30/315, 10% and nine months in the CRT group (18/404, 5%). The same paper also reported a higher proportion of patients who had a *“minimally clinically important difference in urinary incontinence in the SABR group than in the CRT group (p=0.011) and in the urinary irritative-obstruction in the SABR group than in the CRT (p=0.012).”*

Van As et al (pre-print; PACE-B RCT) reported the proportion of patients with prostate cancer with low or intermediate risk with GU toxicity (grade  $\geq 2$ ) at five years follow-up using both the CTCAE and RTOG assessment tool. CTCAE GU toxicity was reported in 8.7% of the SABR group (31/355) and 6.7% of the CRT group (24/357; p=0.32, non-significant difference); RTOG GU toxicity was reported in 7.3% (SABR, 26/355) and 4.5% (CRT, 16/357) of the treatment groups (p=0.11, non-significant difference). There was evidence of a statistically significant difference in cumulative incidence for GU toxicity at any time to five years reported using the RTOG tool, with 26.9% of patients that received SABR (95% CI 22.8% to 31.5%) and 18.3% of patients that received CRT reporting toxicity (95% CI 14.8% to 22.5%; HR 1.59 (1.18 to 2.12), p<0.001).

Van As et al (pre-print; PACE-B RCT) also reported no statistically significant difference between treatment groups at five years follow-up in urinary incontinence (median EPIC<sup>5</sup> urinary incontinence score, SABR: n=355, 96.9, IQR 73.0 to 100; CRT: n=357, 100, IQR 79.3 to 100; p=0.45) or urinary obstruction (median EPIC urinary obstruction score, SABR: 93.8, IQR 81.3 to 100; CRT: 93.8, IQR 81.3 to 100; no p-value reported). Van As et al (pre-print; PACE-B RCT) reported no statistically significant difference between treatment groups at five years in sexual subdomain scores (p=0.87; no further results presented).

Widmark et al (2019; HYPO-RT-PC) reported that patients with intermediate to high risk prostate cancer in the ultra-hypofractionation group reported statistically significantly higher levels of acute urinary symptoms<sup>6</sup> at the end of radiotherapy (treatment end: ultra-hypofractionation, n=439; CRT, n=464; p=0.0066; three months follow-up: ultra-hypofractionation, n=330; CRT, n=336; p=0.018) and at one-year follow-up (ultra-hypofractionation, n=425; CRT, n=427; p=0.0036) when compared to patients receiving CRT (ultra-hypofractionation mean score at one-year: 2.06, 95% CI 1.82 to 2.30; CRT mean score at one-year: 1.58, 95% CI 1.37 to 1.78; p=0.0036). At all other follow-up timepoints (baseline to 10 years follow-up) there was no statistically significant difference between the groups in urinary symptom reporting.

	<p>One included paper reported a statistically significantly higher genitourinary (GU) toxicity at two years follow-up in patients treated with SABR (n=384) compared to patients treated with CRT (n=381) for prostate cancer with low or intermediate risk. Two included papers (reporting on the same RCT: PACE-B) reported a statistically significant higher cumulative GU toxicity in patients treated with SABR compared to patients treated with CRT for low or intermediate risk prostate cancer (at two (SABR, n=414; CRT, n=430) to five (SABR, n=355; CRT, n=357) years follow-up). A third included paper reported a statistically significant higher GU toxicity at three months (ultra-hypofractionation, n=330; CRT, n=336) and one year (ultra-hypofractionation, n=425; CRT, n=427) follow-up in patients with intermediate to high risk prostate cancer treated with ultra-hypofractionation radiotherapy compared to patients treated with CRT. No significant differences between the treatment groups were seen at other time points.</p>
<p><b>Gastrointestinal (GI) toxicity</b></p> <p><b>Certainty of evidence:</b></p> <p>Not assessed for 3 paper summaries</p>	<p>GI toxicity was reported in all three of the papers included in the summary.</p> <p>Tree et al (2022; PACE-B RCT) reported the proportion of patients with prostate cancer with low or intermediate risk with GI toxicity (grade <math>\geq 2</math>) at two years follow-up using both the CTCAE and the RTOG assessment tool; there was no statistically significant difference between the groups at 24 months follow-up when using either tool. RTOG GI toxicity was reported in 2% (SABR: 6/384; 95% CI 0.1% to 3.5%) and 3% (CRT: 11/382; 95% CI 1.5% to 5.3%) of the treatment groups (absolute difference: -1.3%, 95% CI -3.9% to 1.1%, p=0.32). Using the CTCAE criteria, GI toxicity was 3% and 4% at 24 months in the SABR group and the CRT group, respectively (SABR: 13/414; CRT: 16/430; absolute difference -0.8%, 95% CI -3.8% to 2.2%, p=0.70).</p> <p>Tree et al (2022; PACE-B RCT) also reported no evidence of a statistically significant difference in cumulative GI toxicity rates at two years using both CTCAE criteria and the RTOG tool. Cumulative incidence rates using the RTOG tool were 7.8% for patients that received SABR (n=384, 32 events; 95% CI 5.6% to 10.9%) and 8.1% in patients that received CRT (n=382, 34 events; 95% CI 5.8% to 11.1%; HR 0.98, 95% CI 0.60 to 1.58, p=0.92). Cumulative incidence rates using the CTCAE criteria were 12.5% for patients that received SABR (n=384, 51 events; 95% CI 9.6% to 16.1%) and 12.3% for patients that received CRT (n=382, 52 events; 95% CI 9.5% to 15.8%; HR 1.02, 95% CI 0.70 to 1.51, p=0.91).</p> <p>Van As et al (pre-print; PACE-B RCT) reported the proportion of patients with prostate cancer with low or intermediate risk with GI toxicity (grade <math>\geq 2</math>) at five years follow-up using both the CTCAE and the RTOG assessment tool. CTCAE GI toxicity was reported in 2.5%</p>



	<p>of the SABR group (9/355) and 1.7% of the CRT group (6/357; <math>p=0.43</math>, non-significant difference); RTOG GI toxicity was reported in 0.8% (SABR, 3/354) and 0.3% (1/355) of the population (<math>p=0.37</math>, non-significant difference). There was no evidence of a statistically significant difference in the cumulative incidence for GI toxicity at any time to five years when reported using the RTOG tool, with 10.7% of patients that received SABR (95% CI 8.1% to 14.2%) and 10.2% of patients that received CRT reporting toxicity (95% CI 7.7% to 13.5%; HR 1.03, 95% CI 0.68 to 1.56, <math>p=0.94</math>). There was no statistically significant difference between treatment groups in bowel symptoms (median EPIC bowel subdomain scores, SABR: 100, IQR 87.5 to 100; CRT: 95.8, IQR 87.5 to 100; <math>p=0.10</math>) at five years follow-up.</p> <p>Widmark et al (2019; HYPO-RT-PC) reported that patients with intermediate to high risk prostate cancer treated with ultra-hypofractionation radiotherapy (<math>n=569</math>) reported statistically significantly higher levels of acute bowel symptoms<sup>7</sup> at the end of radiotherapy (treatment end: ultra-hypofractionation, <math>n=440</math>; CRT, <math>n=463</math>; <math>p&lt;0.0001</math>) and at the eight-year follow-up (ultra-hypofractionation, <math>n=73</math>; CRT, <math>n=61</math>; <math>p=0.035</math>) when compared to patients treated with CRT (<math>n=578</math>). At all other follow-up timepoints (baseline to 10 years follow-up) there was no statistically significant difference between the groups in bowel symptom reporting.</p> <p>Two included papers (reporting on the same RCT: PACE-B) reported no statistically significant difference between SABR and CRT for incidence and cumulative incidence of gastrointestinal (GI) toxicity for patients with low or intermediate risk prostate cancer at two (SABR, <math>n=384</math>; CRT <math>n=382</math>) and five years (SABR, <math>n=354</math>; CRT, <math>n=355</math>) follow-up. A third included paper reported a statistically significant higher GI toxicity (immediately following radiotherapy (ultra-hypofractionation, <math>n=440</math>; CRT, <math>n=463</math>) and at eight-year follow-up (ultra-hypofractionation, <math>n=73</math>; CRT, <math>n=61</math>) in patients with intermediate to high risk prostate cancer treated with ultra-hypofractionation radiotherapy compared to patients treated with CRT.</p>
--	---

## Patient Impact assessment

<b>Patient Impact Summary</b>
<p><b>The condition has the following impacts on the patient's everyday life:</b></p> <ul style="list-style-type: none"><li>• <b>mobility:</b> Patients have no problems in walking about</li><li>• <b>ability to provide self-care:</b> Patients have no problems in washing or dressing</li></ul>

- **undertaking usual activities:** Patients have no problems in doing their usual activities
- **experience of pain/discomfort:** Patients have no pain or discomfort
- **experience of anxiety/depression:** Patients may be moderately anxious or depressed

**Further details of impact upon patients:**

People with a diagnosis of low and favourable intermediate risk localised prostate cancer often have anxiety associated with a cancer diagnosis. This anxiety is exacerbated by the heavy treatment burden. Currently, patients will have to attend 20 outpatient sessions to receive radiotherapy. This can be a huge burden in terms of time, as well as costs associated with traveling and taking the time away from work and families. This especially impacts patients who have far to travel, who have a disability that makes travelling difficult, those from a poorer socioeconomic background and those that are self-employed.

**Further details of impact upon carers:**

Carers of patients will have similar experiences. They will also have the physical and psychological burden and anxiety of the uncertainty of looking after someone living with cancer. Carers also will experience the burden of time and cost commitments of attending frequently for radiotherapy appointments.

## Considerations

Equality and Health Inequalities Impact Assessment (EHIA)	
Summary of any potential impacts of the proposal	Prostate cancer is the most common cancer affecting people men. This policy proposition offers SABR as an alternative treatment compared to EBRT and is anticipated to have a positive impact on service users. SABR provides radiotherapy in a shorter treatment time requiring fewer sessions of radiotherapy compared to EBRT and fewer visits to hospital compared with EBRT, which is considered to result in a positive impact on all protected characteristics. There are no anticipated negative impacts on any protected characteristics.
13Q Assessment	
PPVAG outcome	No consultation required
Were PPVAG assured of the level of stakeholder testing?	The group confirmed that it is fully assured with how this has been tested with stakeholders



## Rare Disease Advisory Group

Not Applicable

## Pharmaceutical

Not Applicable

## National Programme of Care

Cancer Programme of Care

The proposal received the full support of the Cancer Programme of Care on 12<sup>th</sup> August 2025.