NHS England

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The British Association of Urological Surgeons

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BRITISH ASSOCIATION of UROLOGICAL NURSES

GIRFT Urology: Towards Better Diagnosis & Management of Suspected Prostate Cancer

April 2024

GIRFT is part of an aligned set of programmes within NHS England.

Contents

1. Introduction

This guide has been developed to support the implementation of good practice in management of prostate cancer.

Existing evidence and guidance set out in the NICE guidance and NHS England Best practice timed diagnostic pathway for prostate cancer defines aspirational standards for diagnosing, managing and supporting patients with cancer. However, inevitably, there are gaps in such guidelines when it comes to defining how first-class clinical services should function. These are filled by expert professional opinion, typically provided to urology by the British Association of Urological Surgeons (BAUS) and the British Association of Urological Nurses (BAUN).

The 2018 GIRFT national specialty report on urology demonstrated a wide variation in practice across the NHS and highlighted the need for improvement in urological practice in a range of areas. The GIRFT Best Practice Academy aims to identify good practice and provide guidance on service improvement to achieve nationwide compliance with the published intended level of care.

This best practice pathway aims to deliver best patient care. We acknowledge that there are considerable pressures in delivering this consistently, with variation in those pressures, and we hope that the principles and practicalities described here will support multidisciplinary teams across the NHS addressing the challenges in delivering improved outcomes and experiences for patients with prostate cancer.

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2. Delivery checklist

Primary care	• Men can have a PSA after discussion of prostate cancer risk, whether or not they have lower urinary tract symptoms. • When the PSA is raised, use a urine test to exclude infection. • No digital rectal examination is needed if the PSA is raised. • If DRE has been done, and is abnormal, refer to secondary care on an urgent suspected cancer pathway, even if the PSA is within normal limits. • There is no need to repeat a raised PSA unless there are other probable causes of a raised PSA, for example a urinary tract infection or recent catheterisation. • Patients with a PSA > 20ng/ml should always be referred using an urgent suspected cancer pathway regardless of other potential causes. • Do not routinely test PSA in asymptomatic patients aged over 80 years or co-morbid patients.

Secondary care	• Do not repeat the PSA test unless there are other probable causes of a raised PSA, for example a urinary tract infection or recent catheterisation.
	• Patients with a PSA > 20ng/ml should always be accepted for assessment on an urgent suspected cancer pathway regardless of other potential causes.
	• Clinically supported triage can be done by a trained and supported member of the CNS team or an experienced navigator where there is senior clinical input available.
	• Patients who are fit for radical treatment should go direct to multiparametric MRI (mpMRI) without the need for digital rectal examination.
	• Review in clinic before further investigations if:
	  ○ referred with abnormal DRE and normal PSA;
	  ○ patient not likely to be fit for radical treatment.
	• If DRE done in secondary care is considered within normal limits and PSA normal then take off urgent suspected cancer pathway & consider assessment for lower urinary tract symptoms via internal transfer if needed.
	• Secondary care team to discuss the MRI result and next steps with patient as described in Table 2

Biopsy	• Offer local anaesthetic transperineal (LATP) biopsy in an outpatient setting as the default approach. • Plan a biopsy strategy based on the potential management options, considering MRI, PSA and comorbidities. • Target lesions seen on MRI with a maximum of 4 cores. • Consider the RAPID biopsy approach to targeted and systematic biopsy cores. • Do not use routine transperineal 5mm or sector mapping.

Treatment choices

For patients where active surveillance (AS) is a management option:

Cambridge Prognostic Group 1 & 2:

- Active surveillance is the recommended approach.

Cambridge Prognostic Group 3:

- Active surveillance can be considered, particularly for non-MRI visible Gleason 3 + 4.
- Provide shared decision making support and ensure timely review for those patients who want to explore active treatment options.

Patients suitable for all active treatment options:

- Offer timely review (2 – 4 weeks) for consideration of active treatment, ideally in a joint clinic setting.
- When a patient has made a decision for radical radiotherapy with hormone treatment, and all staging is completed, commence hormone treatment promptly.
- Treat patients with > Gleason 4 +3 within one month of diagnosis

Patients diagnosed with metastatic disease:

- Commence hormone therapy on day of biopsy, if not started already on basis of imaging. Arrange further staging and prompt oncology review. Consider for trial eligibility.

Monitoring

Patients on active surveillance:

- Retest PSA 3 monthly in the first year and repeat MRI at 1 year.
- Digital rectal examination is not needed for patients on active surveillance who have an MRI at diagnosis and during follow up.
- Intensity of follow up will vary with the risk stratification of prostate cancer and the level of risk at which treatment will be triggered.

Patients who have had radical treatment:

- PSA test and assessment at 3 months to consider urinary, bowel and sexual function impact.
- Access to specialist input for functional impact at this point or through patient initiated follow up (PIFU) for up to 2 years after treatment.
- PSA monitoring every 6 months for 2 years in secondary care and continued annual testing in primary care where PSA is undetectable, with re-referral to secondary care if PSA becomes detectable.
- Implement electronic PSA tracking and consider postal point-of-care testing, where available, to avoid unnecessary attendances.

3. Prostate pathway

3.1 Faster Diagnosis Standards

New cancer waiting time standards, summarised below, were implemented on 1st October 2023.

Summary	Standard	Performance threshold
28 day 'Referral to diagnosis'	Maximum 28-day wait from receipt of referral to patient being told they have cancer or cancer is definitely excluded.	77%*
Two-month 'Referral to first treatment	Maximum two-month (62-day) wait from urgent GP referral or consultant upgrade to first treatment (including a decision for active surveillance)	85%
One-month 'Decision to treatment'	Maximum one-month (31-day) wait from decision to treat to any cancer treatment for all cancer patients.	96%

* Rising to 80% by March 2026.

Full detail on Faster Diagnosis Standards >

Cancer waiting times monitoring dataset guidance >

3.2 Best practice timed pathways for diagnostics

NHS England has developed best practice timed pathways for diagnostics, including:

- A 14-day pathway for a one-stop clinic using multi-parametric MRI and biopsy by day 7, with MDT and outpatient discussion by day 14.
- A 21-day pathway with diagnosis by day 14 for exceptional circumstances where MRI is contraindicated (e.g. implantable stimulators) or not needed (based on lack of appropriateness for radical treatment).
- A 28-day straight to test pathway using multi-parametric MRI with biopsy planned after MRI.

NHS England best practice timed diagnostic pathways >

3.3 Primary care

Key quality actions:

- Men can have a PSA after discussion of prostate cancer risk, whether or not they have lower urinary tract symptoms.
- When the PSA is raised, use a urine test to exclude infection.
- No digital rectal examination is needed if the PSA is raised.
- If DRE has been done, and is abnormal, refer to secondary care, even if the PSA is within normal limits.
- There is no need to repeat a raised PSA unless there are other probable causes of a raised PSA, for example a urinary tract infection or recent catheterisation.
- Patients with a PSA > 20ng/ml should always be referred regardless of other potential causes.
- Do not routinely test PSA in asymptomatic patients aged over 80 years or co-morbid patients.

PSA referral threshold

The PSA thresholds that are used to determine whether patients are referred for investigation of suspected prostate cancer differ by local area, and in some cases, vary by the presence of symptoms that might indicate prostate cancer, although there is no association between lower urinary tract symptoms and the detection of early prostate cancer. This variation can lead to missed cancers and could be one of the drivers of geographical variation in the proportion of patients who are diagnosed too late to be cured.

The current NICE guidance differs in the PSA threshold for referral depending on whether a patient has lower urinary tract symptoms (where age related thresholds are used, NG12) or whether their primary reason for seeing the GP was concern over prostate cancer risk (where a single PSA threshold is recommended, Prostate Cancer Risk Management Programme). This variation is acknowledged here, and future clarification by NICE is sought as new data are available.

The NICE NG12 guidance for referral of suspected cancer recommends considering PSA and digital rectal examination for men with lower urinary tract symptoms, such as nocturia, urinary frequency, hesitancy, urgency or retention, as well as erectile dysfunction and blood in the urine. Normal PSA levels generally increase as people get older, and the prostate enlarges. NG12 recommends use of an age stratified PSA threshold for symptomatic men. This is based on studies which did not use MRI to assess men with suspected prostate cancer, and acknowledges that the resource implication of a single lower threshold influenced the decision to use an age related threshold.

The Prostate Cancer Risk Management Programme for men aged 50 and over states that those with a PSA of ≥ 3ng/ml or an abnormal digital rectal examination should be referred for secondary care assessment, if they have no symptoms of prostate cancer.

The Prostate Cancer UK risk checker recommends that men consider discussing a PSA test with their GP if they are aged 50, or aged 45 and from with black or mixed black heritage. Black men have double the risk of being diagnosed with prostate cancer (1 in 4) compared to white men, their risk starts at a younger age (from 45) and they have double the risk of death from prostate cancer (1 in 12) compared to white men (1 in 24) Specific information is available for trans and non-binary people, who are advised that their risk may be different.

A single PSA threshold of 3ng/ml for men aged 50 – 69 was recommended in the NHS England Timed prostate cancer diagnostic pathway in 2018 and 2022 and the NHS England Clinical Expert Group report in 2019. This report also recommended that men with a PSA of >1.5ng/ml should have a PSA repeated every 2 – 3 years and that a PSA threshold of 5ng/ml could be used as a referral threshold for men over 75.

However, analysis of over 4,000 men on the RAPID pathway (with a single threshold of 3ng/ml) showed that age related cut-offs would have resulted in missed diagnoses of clinically significant cancer in 16% of men, with older men more likely to be disadvantaged.

Despite the growing body of knowledge and modelling on PSA thresholds, this variation across different groups has persisted. There is an opportunity to tackle this variation and modelling based on data across the UK reports that a single national PSA threshold would reduce missed diagnoses of clinically significant cancer by around 11%. An updated review based on data in the MRI era would be valuable for clarification, and NICE have been asked to look at this.

Reducing over investigation and referral

The development of tests and imaging such as PSA and MRI mean that there are now many circumstances where a digital rectal examination (DRE) will not provide any additional value for decision making. While DRE is a quick and safe examination, it is invasive, can be uncomfortable and may deter some men from discussing prostate cancer concerns. Those with a raised PSA who are being referred for further investigation do not need a DRE, which has less predictive value than other tests.

Patients aged over 80 years

Prostate cancer is commonly found on histopathological examination of the prostate in the over 80s, but will not always be clinically significant.

The Academy of Medical Royal Colleges has published best practice guidance on PSA Testing for men aged 80 years and above. The recommendations on testing are:

> *"1.6. In men over 80, PSA testing should be encouraged where there are symptoms suggestive of metastatic prostate cancer (such as bone pain, unintended weight loss and fatigue).*

1.7. In men over 80 without signs of metastatic disease the benefit of PSA testing is uncertain. A PSA test should only be performed in men who want one after an appropriate shared decision-making process [see above]. The potential benefits are greater in those with a life expectancy of more than 10 years."

The recommendations on interpreting test results are:

"1.8. For men ≥80 years of age who have had a PSA test, offer referral via a suspected cancer pathway if:

- *the PSA >20 ng/mL; OR*
- *the PSA >7.5ng/mL AND there are symptoms suggestive of metastatic disease (bone pain and/or fatigue and/or significant unintended weight loss).*

1.9. If the initial PSA test is between 7.5 – 20 ng/L and there are no symptoms suggestive of metastatic disease, repeat PSA ONCE after 6 months in primary care, prior to any secondary care referral.

1.10. When the PSA is repeated, offer referral via the suspected cancer pathway if:

- *either criteria in recommendation 1.8 being met; OR*
- *PSA has increased significantly (more than doubled), and the patient has a performance status of 0 or 1.*

1.11. If patients do not fit the above criteria but concerns remain, seek appropriate support via 'advice and guidance'."

3.4 Secondary care and MRI

Key quality actions:

- Do not repeat the PSA test unless there are other probable causes of a raised PSA, for example a urinary tract infection or recent catheterisation.
- Patients with a PSA > 20ng/ml should always be accepted for assessment on an urgent suspected cancer pathway regardless of other potential causes.
- Clinically supported triage can be done by a trained and supported member of the CNS team or an experienced navigator where there is senior clinical input available.
- Patients who are fit for radical treatment should go direct to multiparametric MRI (mpMRI) without the need for digital rectal examination.
- Review in clinic before further investigations if:
  - referred with abnormal DRE and normal PSA;
  - patient not likely to be fit for radical treatment.
- If DRE done in secondary care is considered within normal limits and PSA normal then take off urgent suspected cancer pathway & consider assessment for lower urinary tract symptoms via internal transfer if needed.
- Secondary care team discuss the MRI result and next steps with patient as described in Table 2

Once referred to secondary care, unnecessary pathway steps should be avoided as these can become the source of delay and inefficient use of capacity.

A second PSA test should not be a requirement for further investigation, except where the patient has had a UTI found at the time of the first raised PSA. Requiring a second test can lead to a delay of between 2 – 6 weeks in a patient's referral, while the second test is being arranged and completed.

Patients who are fit for radical treatment can be sent direct to multi-parametric MRI before biopsy. This reduces delays. However, in many units there is a practice of routinely seeing patients in an outpatient assessment before requesting an MRI. This leads to delays while the MRI is completed and a further assessment is arranged.

Patients who are going to have an MRI do not need to have a DRE as the DRE will not offer any additional diagnostic information or value to the MRI.

When should MRI be used in the pathway?

Trials have shown that pre-biopsy multi-parametric MRI (mpMRI) is able to:

- Safely reduce the proportion of men with a raised PSA who have a biopsy by at least 25%, with recent data showing that 45% can avoid a biopsy in the RAPID programme.
- Reduce the diagnosis of clinically insignificant cancer and associated need for surveillance.

The proportion of patients who have timely access to an MRI before a biopsy varies significantly by area, likely the result of variation in imaging capacity more generally. However, all patients who are fit for radical treatment should have access to an MRI before biopsy, using a regional imaging network approach if needed.

This information may be updated in 2024 to reflect the findings of the PRIME trial, comparing bi-parametric to multi-parametric MRI in the diagnosis of clinically significant prostate cancer in biopsy-naïve men.

Equivocal MRIs

Where an MRI is equivocal, and a patient has a high PSA density or there are other strong clinical indicators of risk, for example family history particularly of prostate cancer death at an early age, patients should be offered a biopsy.

MRI quality

If the MRI quality is not enough to rule in and rule out significant cancer, consider whether the poor quality is due to patient factors or scanning factors, and whether these can be addressed.

For instance, if poor image quality is due to gas or movement artefact, then a repeat scan may be appropriate. If poor image quality is due to bilateral hip replacements then a further scan is unlikely to be useful, and a biopsy decision should be made on the available information.

PSA density

The PSA density can be calculated from the current PSA and the prostate volume as measured on MRI. It can be helpful as a secondary factor in deciding on biopsies in men with no MRI lesion.

$$\frac{PSA\ ng/ml}{Prostate\ volume\ in\ mls} = PSA\ density$$

Table 1 Use of PSA density at different MRI scores

MRI and PSA density are used to assess the risk of prostate cancer, and the need for a prostate biopsy. Additional factors also affect risk of prostate cancer and can influence the decision by a patient on whether or not to have a biopsy. These factors include age, family history and ethnicity.

The table below shows the risk of Gleason 3 + 4 prostate cancer in men who had an MRI and a biopsy in a UK study of men referred for prostate cancer assessment: [‘Risk stratification of prostate cancer with MRI and prostate-specific antigen density-based tool for personalized decision making.’]

	csPCa prevalence relative to PI-RADS score		csPCa prevalence in the PSA density risk groups					
Total	**ISUP ≥2 Ca prevalence**		**Low (PSA density <0.10)**		**Intermediate-low (PSA density 0.10-0.15)**		**Intermediate-high (PSA density 0.15-0.20)**		**High (PSA density ≥0.20)**	
ALL PI-RADS	623/2055	(30.3%)	65/790	(8.2%)	133/576	(23.1%)	118/269	(43.9%)	307/420	(73.1%)
PI-RADS 1-2	34/1113	(3.1%)	7/602	(1.2%)	9/341	(2.6%)	9/100	(9.0%)	9/70	(12.9%)
PI-RADS 3	36/206	(17.5%)	8/76	(10.5%)	9/63	(14.3%)	10/40	(25.0%)	9/27	(33.3%)
PI-RADS 4-5	553/736	(75.1%)	50/112	(44.6%)	115/172	(66.9%)	99/129	(76.7%)	289/323	(89.5%)

Very low	0%-5% csPCa (below population risk)	No biopsy
Low	5%-10% csPCa (acceptable risk)	No biopsy
Intermediate-low	10%-20% csPCa	Discuss biopsy
Intermediate-high	20%-30% csPCa	Recommend biopsy
High	30%-40% csPCa	Perform biopsy
Very high	>40% csPca	Perform biopsy

Table 2 Patient discussion with MRI Outcomes

Low risk of clinically significant cancer (PI-RADs or Likert 1 and 2) and PSA density < 0.2	• Discharge to primary care with explicit PSA guidance on a threshold for re-referral based on PSA-density for re-referral. (Consider risk factors e.g. family history, ethnicity).
Low risk of clinically significant cancer based on MRI and PSA density (PI-RADS or Likert 3) with PSA density < 0.12	• Inform patient of the low likelihood of clinically significant prostate cancer. • Offer explicit PSA guidance to primary care on a threshold for re-referral based on PSA-density for re-referral. (Consider risk factors e.g. family history, ethnicity). • Follow-up in primary care.
Equivocal MRI (PI-RADS or Likert 3) with PSA density > 0.12 or PiRADS/Likert 1 or 2 with PSA density > 0.2	• Inform patient. • Discuss prostate biopsy – shared decision-making discussion around 10 – 15% risk of clinically significant cancer. • If patient declines biopsy, allow PIFU if they reconsider.
PI-RADs 4 or 5	• Inform patient. • Recommend prostate biopsy due to risk of clinically significant cancer which would benefit from treatment.

When MRI is contraindicated for a patient

If MRI is contraindicated, management should be determined by clinical and PSA density thresholds (the PSA density can be calculated by using TRUS to estimate the prostate gland volume.)

CT is not indicated unless and until (1) there is a diagnosis of biopsy proven clinically significant cancer; (2) staging for nodes and visceral metastases has a clinical relevance. In these cases, CT may benefit from concomitant more dedicated imaging such as radionucleotide bone scanning or PSMA PET-CT.

3.5 Biopsy

Key quality actions:

- Offer local anaesthetic transperineal (LATP) biopsy in an outpatient setting as the default approach.
- Plan a biopsy strategy based on the potential management options, considering MRI, PSA and comorbidities.
- Target lesions seen on MRI with a maximum of 4 cores.
- Consider the RAPID biopsy approach to targeted and systematic biopsy cores.
- Do not use routine transperineal 5mm or sector mapping.

When a biopsy should be offered

Biopsy should be offered to patients with an MRI highly suspicious of cancer, or an equivocal MRI but high PSA density. In equivocal cases, other strong clinical indicators of risk, for example, family history and ethnicity can be considered.

Delivering biopsy in the Urological Investigation Unit

Local anaesthetic trans-perineal prostate (LATP) biopsy is now the standard care for prostate cancer diagnosis across the majority of units in England. LATP can be delivered in the Urological Investigation Unit and should take place in a procedure room rather than an operating theatre, with recovery facilities available for those patients requiring it. In many centres, LATP is delivered by advanced or specialist nurses, typically band 7 and above.

Prostate biopsy in the GIRFT guide to Urological Investigation Units >

Planning a biopsy strategy

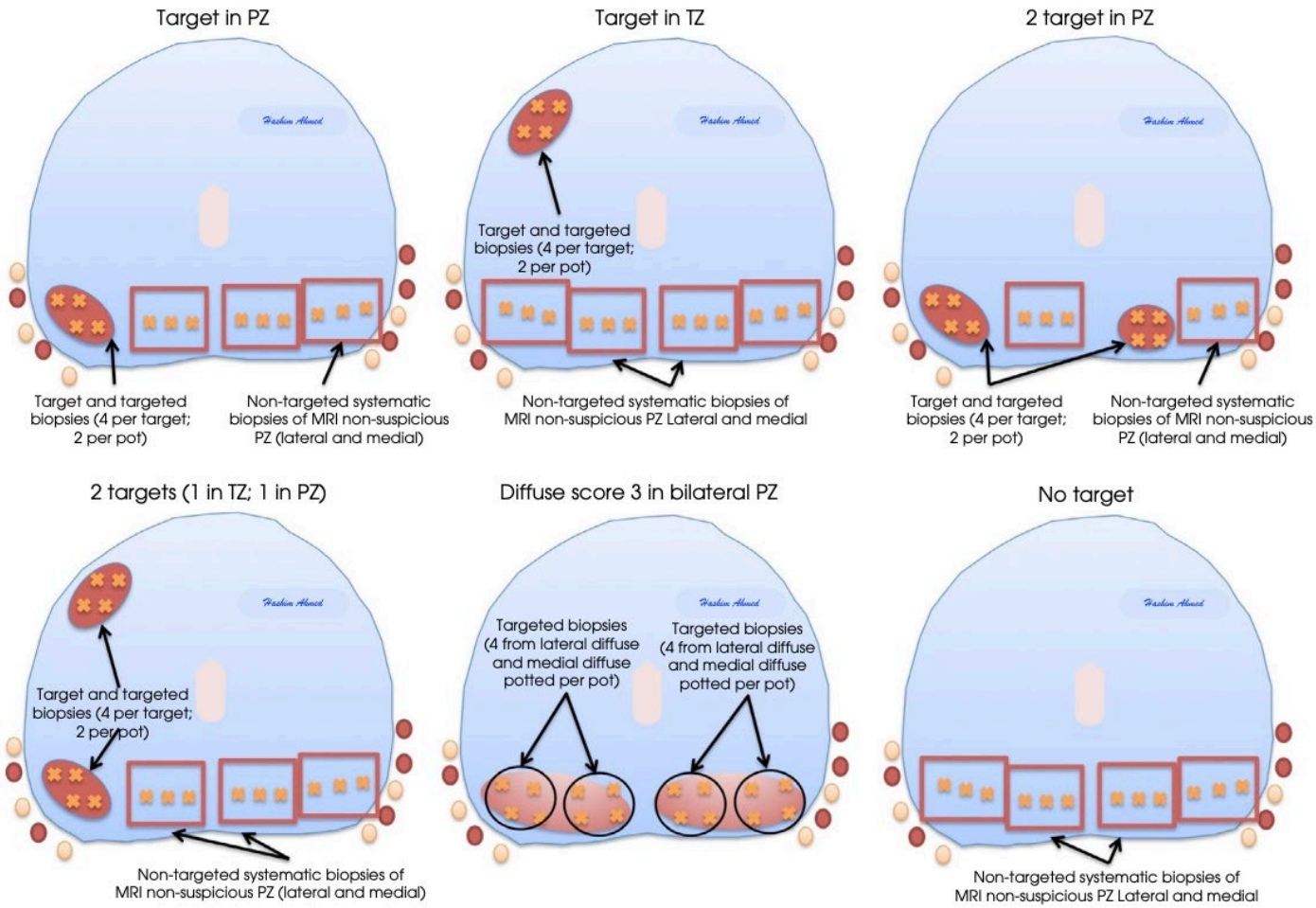
The biopsy strategy should be planned based on the potential management options and considering MRI, PSA and co-morbidities. A poor biopsy strategy can lead to an inefficient use of histopathology capacity, where increased burdens lead to longer diagnostic turnaround times.

Where metastatic disease is evident on imaging, it is usually sufficient to take 3 -4 cores from the most significant prostate lesion on imaging.

Do not use routine transperineal 5mm or sector mapping. Do not routinely sample the transition zone if there are no MRI lesions there, as this is very unlikely to show any clinically significant cancer and increases the risk of urinary retention.

Put samples from any MRI lesions into a separate labelled pot. Report the maximum cancer core length in mm for targets at each location rather than for every core.

Figure 1 Diagram excerpt taken from RAPID pathway



Click to access report of RAPID pathway outcomes in BJU International >

Table 3 Clinic review and discussion of negative biopsy results

	In the case of a negative biopsy following a suspicious MRI, there should be a joint urology and radiology review to decide whether to immediately re-biopsy if it is considered likely the lesion has been missed.
Negative biopsy and suspicious MRI (score 4/5)	Likert or PI-RADS 4/5 with no atrophy or inflammation on biopsy may indicate a 'missed target', so the urology and radiology review may consider re-biopsy or surveillance, such as repeat MRI after 6 – 12 months when inflammation may have settled and the MRI lesion resolved. The joint urology and radiology review can also decide if the level of suspicion on MRI should be regraded.
Negative biopsy and equivocal MRI	In the case of a negative biopsy following an equivocal MRI, the patient should be discharged to their GP, with a PSA threshold for re-referral calculated by a senior clinical member of the team, set at a level of change that would be concerning.

Table 4 Risk stratification of prostate cancer

NICE risk group	NICE criteria	CPG category*	CPG criteria	Risk stratification for treatment	Treatment option
Low-risk disease	Gleason score ≤ 6 *AND* PSA < 10 ng/ml *AND* stages T1-T2a	1	Gleason score 6 (Grade Group 1) *AND* PSA < 10 ng/ml *AND* stages T1-T2*	Lower risk prostate cancer	For men with lower risk prostate cancer recommend active surveillance. Record on FDS as starting active surveillance at the point the patient is informed of diagnosis.
Intermediate-risk disease	Gleason score 7 *OR* PSA 10-20 ng/ml *OR* Stage T2b	2	Gleason score 3 + 4 = 7 (Grade Group 2) *OR* PSA 10-20 ng/ml *AND* stages T1-T2*	Intermediate risk prostate cancer where active surveillance is an option	Most men with Cambridge Prognostic Score 2 & some with CPG 3 will be suitable for active surveillance. Men with ≥ Gleason 3 + 4 should be recorded on FDS as having started active surveillance, whilst also offering discussion of active treatment.
		3	Gleason score 3 + 4 = 7 (Grade Group 2) *AND* PSA 10-20 ng/ml *AND* stages T1-T2* *OR* Gleason score 4 + 3 = 7 (Grade Group 3) *AND* stages T1-T2*	Intermediate risk prostate cancer where active surveillance is not advisable * see note	Offer timely review (2 – 4 weeks) for consideration of radical treatment, in a joint clinic setting where appropriate. Commence hormone therapy in those patients who will require neo-adjuvant treatment as part of their SOC.
High-risk or locally advanced disease	Gleason score 8 – 10 *OR* PSA > 20 ng/ml *OR* Stage ≥T2c	4	*One of:* Gleason score 8 (Grade Group 4) *OR* PSA > 20 ng/ml *OR* Stage T3	Higher risk localised prostate cancer	Offer timely review (2 – 4 weeks) for consideration of radical treatment, in a joint clinic setting where appropriate. Commence hormone therapy in those patients who will require neo-adjuvant treatment as part of their SOC.
		5	*Any combination of:* Gleason score 8 (Grade Group 4) PSA > 20nb/ml or Stage T3 *OR* Gleason score 9-10 (Grade group 5) *OR* Stage T4		

Note: Where higher risk features are present including Gleason 4 + 3, cribriform and intraductal pathology, or larger tumour volume seen on MRI or biopsy.

*** CPG categories do not use sub-categories of stage T2.**

3.6 Staging of prostate cancer

Staging is needed for those diagnosed with Gleason 4 + 3 disease or higher. By default, this should be a bone scan and CT scan of the chest, abdomen and pelvis. Where PSMA PET is available, discuss local capacity and demand and consider the following priorities:

- Radiorecurrent disease.
- High-risk disease suitable for radical treatment with no obvious metastases on MRI:
    - PSA ≥ 20
    - T3
    - Gleason 4 + 3.
- Ga-PSMA-11, F-PSMA-1007 and F-DCFPyl PSMA are available in the UK and are broadly equivalent.
- Take care not to allow excessive wait for PSMA-PET to delay radical treatment when CT and bone scan are available sooner.

3.7 Treatment choices

Key quality actions:

For patients where active surveillance (AS) is a management option:
Cambridge Prognostic Group 1 & 2:

- Active surveillance is the recommended approach.

Cambridge Prognostic Group 3:

- Active surveillance can be considered, particularly for non-MRI visible Gleason 3 + 4.
- Provide shared decision making support and ensure timely review for those patients who want to explore active treatment options.

Patients suitable for all active treatment options:

- Offer timely review (2 – 4 weeks) for consideration of active treatment, ideally in a joint clinic setting.
- Treat patients with ≥ Gleason 4 + 3 disease within one month of diagnosis
- When a patient has made a decision for radical radiotherapy with hormone treatment, and all staging is completed, commence hormone treatment promptly.

Patients diagnosed with metastatic disease:

- Commence hormone therapy on day of biopsy, if not started already on basis of imaging. Arrange further staging and prompt oncology review. Consider for trial eligibility.

A significant proportion of patients will meet the criteria for active surveillance without needing an immediate decision for treatment. These patients should be reassured that it is safe for them to take time to explore their active treatment options. The 62-day ‘referral to first treatment’ clock is stopped at this point. Any subsequent decision for treatment would be monitored by the 31-day ‘decision to treatment’ standard.

3.8 Monitoring

Key quality actions:

Patients on active surveillance:

- Retest PSA 3 monthly in the first year and repeat MRI at 1 year.
- Digital rectal examination is not needed for patients on active surveillance who have an MRI at diagnosis and during follow up.
- Intensity of follow up will vary with the risk stratification of prostate cancer and the level of risk at which treatment will be triggered.

Patients who have had radical treatment:

- PSA test and assessment at 3 months to consider urinary, bowel and sexual function impact.
- Access to specialist input for functional impact at this point or through patient initiated follow up (PIFU) for up to 2 years after treatment.
- PSA monitoring every 6 months for 2 years in secondary care and continued annual testing in primary care where PSA is undetectable, with re-referral to secondary care if PSA becomes detectable.
- Implement electronic PSA tracking and consider postal point-of-care testing, where available, to avoid unnecessary attendances.

Many patients have a significant functional impact from radical treatment, which is not always addressed. These patients should have access to specialist input to mitigate functional impact for urinary, bowel and sexual function.

Remote PSA monitoring should be used where possible to minimise inconvenience to patients and avoid unnecessary in person visits with the treatment team. Postal point-of-care (POC) tests can be used to reduce attendance at community or GP sites.

There are several options available for electronic PSA tracking technology for ongoing surveillance of patients.

Read a case study on remote monitoring with digital access for patients with stable cancer >

Example digital PSA tracker patient information leaflet >

Calculation of PSA density and re-referral PSA threshold

When considering an equivocal MRI or the biopsy is negative for cancer:

Calculating the current PSA density	Calculating a PSA referral threshold
$\frac{PSA\ ng/ml}{Prostate\ volume\ in\ mls} = Current\ PSA\ density$	$Prostate\ volume\ in\ mls\ \times\ threshold\ density = PSA\ \ ng/ml\ threshold$

A raised PSA density is a risk factor for significant cancer, with a higher PSA density representing greater risk of clinically significant prostate cancer.

The PSA density threshold for re-referral will usually be between 0.12 and 0.15, where the lower value might be used in younger patients. Clinicians in secondary care should determine the appropriate threshold for a patient, which will be influenced by:

- Current PSA density
- Biopsy or MRI findings
- Comorbidities
- Age and ethnicity
- Family history

Include a re-referral PSA threshold in the discharge letter to the patient and GP. Recommend a repeat PSA no more than once per year. Do not offer repeat MRI at the same PSA and do not offer PSA monitoring in secondary care.

Where the PSA density is > 0.12 for an MRI score 3, or 0.2 for an MRI score of 1 or 2 , but the patient prefers to repeat PSA at one year rather than have a biopsy, allow PIFU if the patient reconsiders and chooses to have a biopsy.

Example

Calculating the PSA density in a patient with a PSA of 4 ng/ml and a prostate volume of 60ml.

$$\frac{PSA\ ng/ml}{Prostate\ volume\ in\ mls} = Current\ PSA\ density$$

$$\frac{4}{60} = \mathbf{0.07}$$

The patient's current PSA density is 0.07 ng/ml.

The PSA density threshold for re-referral of this patient, based on their age and comorbidities, should be 0.12.

$$Prostate\ volume\ in\ mls\ \times\ 0.12\ =\ PSA\ \ ng/ml$$

$$60\ \times\ 0.12\ =\ \mathbf{7.2}$$

The PSA threshold for re-referral that should be communicated to the patient and GP as a PSA of 7.2 ng/ml.

4. Further information

Recommended document	Author	Overview
Guidance, advice and quality standards on prostate cancer	NICE	The NICE guidance hub for prostate cancer links to all available NICE products on prostate cancer and also lists products in development.
Best practice timed pathway for prostate cancer	NHS England	The Best practice timed pathway has been developed to support meeting the Faster Diagnosis Standards. The guidance sets out a 2-day straight to test pathway, a 21-day pathway where MRI is not required or contra-indicated and a 14-day one-stop clinic pathway using mpMRI.
Consensus statement on best practice in active surveillance for men with prostate cancer	Prostate Cancer UK	30 consensus statements on active surveillance developed by an expert reference group based on literature review, data from UK urology departments and patient surveys.
PRIME trial (expected April 2024)	PRIME Trial Group	The PRIME trial has been established to compare biparametric to multiparametric MRI in the diagnosis of clinically significant prostate cancer in biopsy-naïve men. Results from this trial are anticipated in 2024 and may inform revision of this document. Further details are available from the trial's protocol registration.
Predict Prostate	Endorsed by NICE	This webtool allows input of clinical parameters to predict survival and side effects for surgery, radiotherapy and active surveillance
Risk stratification of prostate cancer with MRI and prostate-specific antigen density-based tool for personalized decision making	Tristan Barrett, Ishwariya Rejendran, Kang-Lung Lee, Liness Thavaraja	Article published in the British Journal of Radiology testing proposed MRI focused and risk-adapted biopsy decision models on a real-world dataset. Excerpts used for Table 1 in this document.
Lifetime risk of being diagnosed with, or dying from, prostate cancer by major ethnic group in England 2008-2010	Lloyd T, Hounsome L, Mehay A, Mee S, Verne J, Cooper A	Risk analysis from this paper published in BMC medicine are used in section 3.3. on page 7, regarding the increased risks to black men.
PROCESS cohort study	PROCESS study group	A cohort study investigating the pathways to diagnosis for black men and white men in the UK, used to inform content on risks in section 3.3 on page 7.
The rapid assessment for prostate imaging and diagnosis (RAPID) prostate cancer diagnostic pathway	David Eldred-Evans et al.	Article published in the BJU International reporting outcomes within the RAPID pathway, standardising delivery of pre-biopsy multiparametric resonance imaging (MRI) and transperineal biopsy. Excerpt used for Figure 1 in this document.
Risk stratification for prostate cancer management: value of the Cambridge Prognostic Group classification for assessing treatment allocation	M. G. Parry et al.	Article published in BMC Medicine in May 2020 setting out CPG classification as a predictor of prostate cancer-specific mortality. Excerpt used for Table 4 in this document.
Prostate cancer: Knowing your options tool	East of England Cancer Alliance	This website allows input of PSA, Gleason grade and T stage to look at potential treatment options
Track My PSA	TrackMyPSA	Shared as an example. This web tool was designed by the urology services at Addenbrookes to support online PSA Tracking.

5. Contributors

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