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**Needle biopsy of prostate**

Prostate cancer is the second most common cause of cancer death in people assigned male at birth. It is important that cancer pathways give equal access to care across England. Traditionally needle biopsies would have been taken for diagnosis of prostate cancer. However, studies now show that multiparametric magnetic resonance imaging (mpMRI) scans, which produce a detailed picture of the prostate gland, can more accurately detect clinically significant prostate cancer compared to biopsy alone.

The EBI programme proposes clear, evidence-based criteria for use across England. This details who should be referred, how they should be triaged, over what time period, and how they should be managed, including the type of imaging, how to report, the need for biopsy and how this should be performed.

**Clinical overview**

Prostate cancer is the commonest non-cutaneous cancer in people assigned male at birth in the UK and Europe. Approximately 48,500 new cases of prostate cancer are diagnosed within the UK each year. In the UK among people assigned male at birth, prostate cancer is the second most common cause of cancer death.

Prostate biopsy is a minimally invasive procedure where a small sample of prostatic tissue is obtained using a spring-loaded biopsy gun to assess for the presence of cancer. Generally prostatic biopsies are obtained by either a transperineal (TP) or transrectal (TR) route. There are different techniques to perform prostate biopsy – systematic or targeted. Targeted biopsy refers to image-guided biopsy of a specific target/lesion within the prostate, whereas in systematic biopsy the whole prostate is biopsied in a systematic way. Biopsies may be performed under general or local anaesthetic.

**Guidance**

This guidance applies to those 18 years and over.

*Triage or one-stop clinic*

— All patients with suspected prostate cancer, based on clinical examination and/or Prostate Specific Antigen (PSA) level, should be offered urgent clinical triage by a suitable member of the clinical team (within two weeks), preferably via remote triage consultation (either video or telephone). Offer face-to-face consultations where remote consultations are not considered appropriate

— Following initial triage, mpMRI should be considered to enable a fully informed discussion regarding the role of prostate biopsy based on clinical examination, mpMRI findings and other risk factors. One-stop clinics could be considered, where feasible

— In addition to PSA, digital rectal examination and mpMRI findings, other risk factors such as PSA density, should be considered for clinically suspected cases of prostate cancer

*Pre-biopsy mpMRI*

— Offer mpMRI as the first line investigation for people with suspected non-metastatic prostate cancer. mpMRI should not routinely be offered to people with prostate cancer who are not suitable for radical treatment

— Consider omitting a prostate biopsy for people whose mpMRI Likert or Prostate Imaging and Data System (PI-RADS) v2.1 interpretation score is 1 or 2, and the PSA density is less than 0.15, but only after discussing the risks and benefits with the person and reaching a shared decision. If a person opts to have a biopsy, offer a systematic prostate biopsy

— Prostate biopsy should be offered for patients with PSA density >0.15 on mpMRI specified volume assessment, a strong family history of prostate cancer (e.g. multiple relatives at a young age) or an abnormal prostate on examination, even if Likert or PI-RADS v2.1 score is 1 or 2

— Patients with a Likert or PI-RADS v2.1 score of 3 should be considered for prostate biopsy. This should be following consideration of clinical assessment, PSA density and prostate cancer risk factors, and after discussing the risks and benefits with the patient and reaching a shared decision

— Offer prostate biopsy to all patients with a Likert or PI-RADS v2.1 score of 4 or 5, unless otherwise clinically contraindicated.

*Biopsy route and setting*

— Biopsies may be performed by transperineal (TP) or transrectal (TR) routes

— Preferably offer transperineal biopsy under local anaesthetic (LATP) as a first line investigation.

All centres involved in the diagnosis and management of prostate cancer should aim to offer LATP as an option.

If LATP is not appropriate, then offer alternative options such as general anaesthetic transperineal biopsy or local anaesthetic transrectal ultrasound scan (TRUS) biopsy, based on patient specific factors.

The use of general anaesthetic should be minimised. However, indications may include:

— Patient is unable to tolerate biopsy under local anaesthetic

— Biopsy involves multiple entry points — Repeat biopsy (e.g. following an inconclusive result)

— Prostatic anatomical variation

Visible lesions should be targeted. If there is a lesion, both targeted and systematic biopsies should be offered. Target biopsies should be performed initially, followed by systematic biopsies and sent separately for histological analysis.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

**Rationale for recommendation**

Standardised cancer care pathways are required to facilitate equitable access to care. The NHS urgent cancer diagnostic services during COVID-19 (v 2.0) recommends that patients with suspected prostate cancer undergo virtual triage as initial assessment.

Performance of high quality mpMRI before prostate biopsy is important to ensure best outcomes for patients with prostate cancer. The PROMIS (Prostate MRI Imaging Study) demonstrated that mpMRI is a highly sensitive test (93% sensitivity) for the detection of clinically significant prostate cancer if performed before biopsy. In addition, approximately 25% of patients who undergo mpMRI can potentially avoid biopsy. A subsequent cost effectiveness analysis demonstrated that mpMRI prior to prostate biopsy is highly cost effective. The PRECISON (Prostate Evaluation for Clinically Important Disease: Sampling Using Image Guidance or Not?) found that one third of patients who underwent mpMRI did not require prostate biopsy. MpMRI influenced biopsy was significantly better at detecting prostate cancer than transrectal ultrasound (TRUS) biopsy alone, and reduced the detection of clinically insignificant disease. Of note, PRECISON compared MRI guided target biopsy with TRUS (without MRI), and current NHS practice is to perform MRI influenced biopsy, TRUS or transperineal biopsy. As a result of this study, the 2019 European Association of Urology (EUA) and 2019 NICE guideline NG131, now recommend mpMRI as the initial diagnostic test in biopsy naïve patients referred with suspected prostate cancer.

It should be noted that between 11 and 28 of 100 people with a low-risk MRI actually have clinically significant cancer. Shared decision making should be involved in all cases of suspected prostate cancer.

We note that biparametric MRI (bpMRI), which differs from mpMRI – in that dynamic contrast enhanced sequences are not performed – is used in some centres. We recommend the use of mpMRI over bpMRI given current PI-RADS, EUA, NICE and UK Consensus guidelines.

NICE NG131 recommends the reporting of mpMRI using the Likert scale, however, these recommendations also support the use of PI-RADS system, which has been widely adopted around the world. Both systems demonstrate high cancer detection rates – a recent study comparing the clinical validity and utility of the two scoring systems has demonstrated that both result in similar rates of biopsy.

Overall, the Likert scale was superior at detecting clinically significant prostate cancer in expert centres. Authors do comment that PI-RADS may play a valuable role in the reporting of mpMRI, particularly in less experienced centres. It is also worth noting that this study assessed PI-RADS v2.0 and not the most recent v2.1 and there is currently no evidence on how this updated scoring system directly compares to the Likert scale.

We acknowledge that the literature currently is lacking in high quality evidence comparing transrectal versus transperineal prostate biopsy and that this remains an ongoing area of research. High quality research in this area is strongly recommended and to be encouraged. LATP biopsy is associated with a lower risk of post-procedure infection and rectal bleeding. Furthermore, as LATP biopsy may avoid the use of prophylactic antibiotics, this will also facilitate antibiotic stewardship.

There is currently notable variation in practice between NHS trusts offering transperineal versus transrectal biopsy, with an increasing trend towards the utilisation of the transperineal route. Current clinical consensus supports the use of LATP over transrectal biopsy and we therefore recommend this be considered as first line investigation, where feasible.

Also, this guidance aims to standardise practice and reduce variation between NHS trusts. Reducing the proportion of biopsies performed under general anaesthetic would enable more patients to undergo work up for prostate cancer in community based diagnostic hubs, reduce the risks associated with general anaesthetic and improve resource allocation.