NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Diagnostics consultation document

Transperineal biopsy for diagnosing prostate cancer

The National Institute for Health and Care Excellence (NICE) is producing guidance on using transperineal biopsy in people with suspected prostate cancer in the NHS in England. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the evidence (the diagnostics assessment report and the diagnostics assessment report addendum).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for guidance to the NHS?

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on people with a particular disability or disabilities.

Issue date: February 2022

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on transperineal biopsy in people with suspected prostate cancer. The recommendations in section 1 may change after consultation.

After consultation, the committee will meet again to consider the evidence, this document and comments from the consultation. After considering the comments, the committee will prepare its final recommendations, which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see the diagnostics assessment programme manual.

Key dates:

Closing date for comments: 8 March 2022

Second diagnostics advisory committee meeting: 22 March 2022

1 Recommendations

1.1 Local anaesthetic transperineal (LATP) prostate biopsy using the freehand needle positioning device PrecisionPoint is recommended as an option for diagnosing prostate cancer.

1.2 Although there is considerably less evidence for them, the following freehand needle positioning devices are also recommended as an option:

- EZU-PA3U device
- Trinity Perine Grid
- UA1232 puncture attachment.

They are expected to have similar cancer detection rates and adverse events to PrecisionPoint because they are technically similar.

1.3 Centres are encouraged to take part in the randomised controlled trial of transrectal biopsy compared with LATP biopsy (the TRANSLATE trial, see section 3.7) to help refine clinical practice.

1.4 There is not enough evidence to recommend LATP using a double freehand technique, that is, when a needle is used without a positioning device (for example CamPROBE). Further research is recommended to understand its clinical effectiveness.

Why the committee made these recommendations

Standard prostate biopsy uses local anaesthetic transrectal ultrasound (LA-TRUS). This involves taking samples of prostate tissue by inserting a biopsy needle through the rectal wall via the anus. An alternative is LATP prostate biopsy, which involves inserting the needle through the perineum, the skin area between the anus and the scrotum.

Techniques for LATP biopsy vary. It can be done using a freehand needle positioning device, a grid and stepping device, or using a coaxial needle (double freehand).

The evidence suggests no significant difference in cancer detection rates between LATP biopsy and LA-TRUS biopsy. But it suggests lower rates of infection and sepsis after LATP biopsies. More evidence on their differences will come from the ongoing TRANSLATE trial, which may help refine clinical practice.

All the clinical evidence for freehand needle positioning devices is on the PrecisionPoint device. There is no comparative evidence for the EZU-PA3U, UA1232, or Trinity Perine Grid devices but experts suggest that cancer detection rates and adverse events should be similar between the different freehand devices.

The most likely cost effectiveness estimates for freehand needle positioning devices are within what NICE considers an acceptable use of NHS resources. Therefore LATP biopsy using a freehand needle positioning device is recommended.

There is no comparative evidence on the CamPROBE device, which uses a double freehand technique. Experts said that, because the double freehand technique is different to using the freehand needle positioning devices, it may not have the same cancer detection rates. Cost modelling suggests that double freehand techniques may not be cost effective compared with LA-TRUS biopsy. More research is needed to understand their clinical effectiveness.

2 The diagnostic tests

Clinical need and practice

2.1 Prostate cancer is the most commonly diagnosed cancer in men in the UK (Cancer Research UK). It mainly affects people over 50 and the risk is higher for people of African family background and people with a family history of prostate cancer.

2.2 Prostate cancer can be slow or quickly growing. If it is growing quickly it is more likely to spread so may require treatment, which includes radiotherapy, chemotherapy, surgery or a combination of these.

2.3 NICE's guideline on prostate cancer: diagnosis and management recommends that, after someone is referred to secondary care with suspected clinically localised prostate cancer, they should be offered a multiparametric MRI (mpMRI) test. The results of this MRI should be reported using a 5-point Likert scale. People with a Likert score of 3 or more should be offered a mpMRI-influenced prostate biopsy.

2.4 Prostate biopsies can be targeted, using MRI to identify lesions to take a small number of tissue samples or cores from. Or they can be systematic, taking multiple samples from different regions of the left and right side of the prostate.

2.5 The current standard prostate biopsy is mpMRI-influenced local anaesthetic transrectal ultrasound (LA-TRUS) biopsy or mpMRI-influenced local anaesthetic transperineal (LATP) biopsy. Both routes use a transrectal ultrasound probe inserted into the anus to image the prostate. Both approaches are done in an outpatient setting.

2.6 In a TRUS prostate biopsy, samples of prostate tissue are collected using a biopsy needle inserted through the rectal wall via the anus. The disadvantage of this method is that some people get serious infections, including sepsis, requiring hospital admission and antibiotics. In LATP biopsy, the needle enters the body through the perineum, the skin area between the anus and the scrotum. This could greatly reduce the risk of biopsy-related sepsis compared with a TRUS biopsy, and therefore may reduce hospital admissions and the need for preventative antibiotics.

The interventions

CamPROBE (JEB Technologies)

2.7 The CamPROBE is a cannulated transperineal access system designed specifically for prostate biopsies. It consists of an access needle or cannula with an integrated needle. This needle can be attached to a standard syringe, allowing the device to be inserted and local anaesthetic to be injected at the same time under ultrasound guidance. This removes the need for separate punctures, nerve blocks or sedation. Once the cannula is in position, the integrated needle is removed and standard 18-gauge core-needle biopsies can be taken through the retained cannula. CamPROBE is a disposable, single use device that provides a transperineal biopsy route with only 2 puncture sites. The CamPROBE device does not attach to the ultrasound probe, so it requires a double freehand technique to manually keep the needle in phase with the ultrasound probe. It costs £35.00 and 2 devices per procedure are required. At the time of writing this guidance, CamPROBE does not have a CE mark and is therefore not available on the UK market for clinical use.

EZU-PA3U device (Hitachi Medical Systems)

2.8 The Hitachi EZU-PA3U is a reusable dedicated freehand needle positioning device. It can be attached to either the Hitachi CC41R or the C41L47RP biplane transducer. The needle holder can be positioned on the vertical plane by sliding up or down before securing it into the required position. The needle holder is compatible with 14-gauge or 18-gauge needles. Needle targeting in the transverse plane is achieved by rotating the probe left or right until the needle trajectory is aligned with the lesion or area of interest. It costs £2,000 and is reusable.

PrecisionPoint (BXTAccelyon)

2.9 The PrecisionPoint transperineal access system is a single use freehand needle positioning device that enables freehand LATP prostate biopsies in an outpatient setting. It uses the Perineologic 15-gauge, 7-cm access

needle, which is securely attached to the transrectal ultrasound probe via the PrecisionPoint needle guide. The guide comprises a clip and moving carriage with 5 vertical holes. The integral access needle is aligned with the ultrasound probe, so when the needle is inserted into the perineum it can be seen on the ultrasound image.

The access needle typically requires only 2 entry points: one on the left and one on the right side of the anal verge. The biopsy needle can then be guided and directed to the relevant regions. The company says that the device is compatible with any biplane TRUS or transperineal probe from any ultrasound manufacturer. It costs £200.00 and is a single use device.

SureFire (Delta Surgical)

2.10 SureFire is a disposable freehand needle positioning device. It is designed to be used freehand without a stepper or stabilising device. It consists of a vertical needle guide with separate puncture channels at each of 9 different height settings, and an ultrasound probe clamp. The vertical needle guide can be rotated to reach different areas of the left and right side of the prostate, using the different height puncture channels. It costs £120.00. At the time of writing this guidance, SureFire is not available on the UK market.

Trinity Perine Grid (KOELIS/Kebomed)

2.11 The Koelis Trinity Perine is a reusable freehand needle positioning device grid that attaches to an ultrasound probe for freehand transperineal biopsies under local anaesthetic. It consists of a vertical needle guide with 20 different height settings at 3-mm intervals, and an ultrasound probe clamp. The device is compatible with the Koelis Sidefire Ultrasound probe. It costs £754.40 and can be reprocessed 100 times.

UA1232 puncture attachment (BK Medical)

2.12 The UA1232 metal puncture attachment is designed for transperineal puncture and biopsy. It consists of a freehand needle positioning device

and a mounting ring with a lock screw. The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm suitable for a 14-gauge needle. All parts of the puncture attachment can be sterilised by autoclave or disinfected by immersion in a suitable solution. The device is indicated for use with BK Medical ultrasound probes. It costs £1,400 and is reusable.

The comparators

2.13 The comparators are:

- LA-TRUS prostate biopsy
- LATP prostate biopsy using a grid and stepping device
- general anaesthetic transperineal (GATP) prostate biopsy using a grid and stepping device.

Grid and stepping device-based biopsy approaches require the needle to pass through the perineum multiple times as the needle is passed through different holes in the grid to access different regions of the prostate. The grid is mounted on the stepping device which is also used to hold and position the ultrasound probe.

3 Committee discussion

The diagnostics advisory committee considered evidence on local anaesthetic transperineal (LATP) prostate biopsy, with or without the following freehand needle positioning devices:

- EZU-PA3U (Hitachi)
- PrecisionPoint (BXTAccelyon)
- SureFire Guide (Delta Surgical)
- Trinity Perine Grid (KeboMed)
- UA1232 (BK Medical)
- the double freehand CamPROBE device (JEB Technologies).

Evidence was considered from several sources, including a diagnostics assessment report and an overview of that report. Full details are in the project documents for this guidance.

Risk of infection, possible adverse events, pain and embarrassment are important patient concerns about prostate biopsy

3.1 Patient experts explained the main issues and concerns around prostate biopsy from a patient perspective. These included the importance of getting clear and accurate information about the procedure and possible adverse events. They highlighted risk of infection as a major concern for patients. They were also worried about the severity and duration of side effects such as urinary retention and haematuria. A patient expert explained the importance of receiving early results to reduce the anxiety of waiting for a biopsy result. The committee heard that prostate biopsies using any method can be undignified and embarrassing for patients. Alongside pain, this may be a factor in some patients preferring to have a general anaesthetic. This may be more of an issue for LATP biopsies because patients need to be in a lithotomy position. Patient experts said that unpleasant prostate biopsy experiences can stop people going to any more biopsy appointments.

Clinical effectiveness

The evidence on cancer detection rates is limited and suggests no significant difference between different biopsy methods

3.2 The evidence on cancer detection rates of the different prostate biopsy approaches was limited. The clinical effectiveness review included 23 studies and the strength of evidence was mixed. Six studies were randomised controlled trials (RCTs), but most were observational. Six studies were only available as conference abstracts and 1 (Bojin 2019) was an unpublished slide set. The external assessment group (EAG) said that there was a high risk of reporting bias in these studies because of the limited information that they included. Most studies did not report whether

a prebiopsy multiparametric MRI (mpMRI) had been done and some did not report the number of biopsy cores taken. In studies that did report the number of cores, these varied from around 12 to 24 cores. The committee noted that studies that used an mpMRI image to take targeted biopsy samples and those that took more cores may result in higher cancer detection rates regardless of the biopsy technique used. Eight of the studies used the PrecisionPoint device, 4 used a coaxial needle and 1 used a grid and stepper (for LATP compared with general anaesthetic transperineal [GATP] biopsy). There were 4 single arm studies (1 on CamPROBE and 3 on the UA1232 device). The rest did not report what device was used. There was no comparative evidence on the CamPROBE, EZU-PA3U, UA1232, SureFire or Trinity Perine Grid devices. The committee noted that of the 23 included studies, a single RCT available as a conference abstract was the only study used in the network meta-analysis of cancer detection rates for LATP using a freehand needle positioning device. The committee said that there was limited evidence on cancer detection rates and that caution should be used when interpreting the results. It also noted that the ongoing trial of transrectal compared with LATP biopsy (TRANSLATE; see section 3.7) RCT will provide further evidence on detection rates of clinically significant prostate cancer. The committee concluded that, because there was generally no significant difference between LATP using any method, LATP using a freehand needle positioning device, local anaesthetic transrectal ultrasound (LA-TRUS) or GATP, it could not say if one technique was better than the others.

Cancer detection rates and adverse events are likely to be similar between the different freehand needle positioning devices

3.3 All the comparative clinical evidence for freehand needle positioning devices was on the PrecisionPoint device. However, a clinical expert explained that the different freehand devices were all used in a similar way, with a needle positioning guide that attaches to the ultrasound probe.

This keeps the needle and ultrasound probe in phase during the procedure. The clinical experts said they would not expect significant differences in cancer detection rates and adverse event rates between the devices. No studies directly compare the individual devices so there was no evidence that one performs better than any other. The committee concluded that the clinical effectiveness in terms of cancer detection and adverse events was likely to be similar for all the freehand needle positioning devices, although this was uncertain.

The evidence is not generalisable to double freehand prostate biopsy

3.4 A clinical expert explained that double freehand prostate biopsy approaches should be considered separately to the freehand approach that uses a needle positioning guide. CamPROBE is a double freehand device and therefore is not attached to the ultrasound probe. Clinical experts said that this was a more difficult technique because one hand guides the ultrasound probe while the other guides the needle, and they need to be kept in phase manually. They said that it may be more challenging to target small areas accurately using this technique, and that it takes longer to train someone to the required level of competency. The committee concluded that, because of these differences, double freehand techniques such as CamPROBE cannot be assumed to have the same clinical effectiveness in terms of cancer detection and adverse events as freehand needle positioning devices. Comparative studies of the CamPROBE biopsy device are needed to assess its clinical effectiveness (see section 4.1).

Rates of infection and sepsis are higher for TRUS biopsies than transperineal biopsies

3.5 Clinical experts said sepsis can happen after a prostate biopsy. It is rare but serious, and can result in death. In the EAG's clinical effectiveness review, relatively few studies reported post-biopsy sepsis. In the studies that did report sepsis, it only occurred after LA-TRUS biopsy and not after transperineal biopsy. An analysis of recent hospital episode statistics

(HES) data (from 2017 to 2019) by Tamhankar et al. (2020) showed that there was a difference in rates of infection and sepsis between TRUS biopsies and transperineal biopsies. Rates of infection were 1.50% in people who had a TRUS biopsy and 0.67% for a transperineal biopsy. Similarly, rates of sepsis were higher for TRUS biopsies (1.12%) than for transperineal biopsies (0.42%). The committee concluded that LATP biopsies may reduce the risk of infection and sepsis compared with TRUS biopsies.

There are some differences between LATP and TRUS biopsy approaches

3.6 Clinical experts explained the key differences between LA-TRUS and LATP biopsy approaches. An LA-TRUS biopsy tends to take fewer cores (usually 12), whereas centres that use the Ginsburg protocol for LATP may take 24 cores or more (2 LATP protocols are used in the UK: the RAPID protocol and the Ginsburg technique). However, some centres may also take 12 cores for LATP plus additional targeted cores based on mpMRI results. A clinical expert said that mpMRI may identify anterior lesions of the prostate and these can be more difficult to reach using LA-TRUS biopsy than LATP. However, the committee heard that there was no evidence to assess the clinical effectiveness of the different biopsy approaches in people with anterior lesions. Clinical experts said that LATP may be less tolerable because of the lithotomy position and if numerous skin punctures were needed, when using a grid and stepper for example. LATP biopsies also take slightly longer than TRUS biopsies, particularly when clinicians are training or first start using the technique. However, a clinical expert said that when practitioners are trained equally in the techniques, the difference is minimal. Less experienced clinicians may find it easier to use a grid and stepper. Clinical experts explained that, in a minority of cases, LATP might be contraindicated, for example in people who have had gender reassignment. There are also some patient groups with a higher risk of infection (for example, immunocompromised people) who would prefer LATP because of the lower risk of sepsis with LATP

than LA-TRUS. Clinical experts explained that there is a move towards using LATP nationally and that some centres no longer do TRUS prostate biopsies.

Participation in the ongoing TRANSLATE RCT is encouraged to generate further evidence to help refine clinical practice

3.7 The ongoing TRANSLATE RCT will provide further comparative evidence on LA-TRUS biopsy and LATP biopsy using a freehand needle positioning device. The trial aims to recruit 1,042 men over 15 months from 9 NHS hospitals in the UK. The protocol says that an average of around 12 systematic biopsy cores will be taken, depending on prostate size, with an additional 4 target biopsy cores for each significant lesion seen on prebiopsy MRI. The primary outcome is detection rates of clinically significant prostate cancer. Secondary outcomes include rates of infection, health related quality of life, patient reported tolerability of the procedure, patient reported biopsy-related complications, number of subsequent prostate biopsy procedures, cost effectiveness, and histological parameters. The trial will last for 31 months and is expected to end in October 2023. The committee concluded that centres should be encouraged to participate in the TRANSLATE RCT to generate more evidence to help understand the effects of differences between the LATP and LA-TRUS biopsy approaches and refine clinical practice.

Cost effectiveness

The committee prefers the new assumptions used in the EAG's revised analysis

3.8 The committee considered the original and revised base case analyses and noted that in the revised analysis the key differences with the largest effect on the incremental cost effectiveness ratios (ICERs) were:

- studies that used spinal anaesthesia were excluded

- overnight hospitalisation data from the Berry et al. (2020) study was excluded.

A clinical expert said that studies that used spinal anaesthesia were more closely aligned with general anaesthetic approaches and so could not be used to assess LATP. A clinical expert explained that the Berry et al. (2020) study used older data from when transperineal biopsy was frequently done under general anaesthetic and more cores were taken. Overnight stays after this type of biopsy were more common, but this does not reflect current clinical practice. Clinical experts agreed that excluding the spinal anaesthesia studies and the Berry et al. overnight stay data was appropriate, and the committee concluded that it preferred the EAG's revised base case.

LATP using a double freehand coaxial needle technique does not appear to be a cost effective use of NHS resources

3.9 In the analysis in which most studies did LATP prostate biopsy using a double freehand coaxial needle (LATP-other), this group was dominated by LA-TRUS in most analyses. ICERs for PrecisionPoint compared with LA-TRUS were generally cost effective at below £30,000 per quality-adjusted life year (QALY) gained. This was driven by cancer detection rates. The clinical experts said that studies that used a coaxial needle approach may have lower cancer detection rates because it is a more difficult technique. They said that therefore it is not appropriate to pool freehand data with double freehand coaxial needle data because they did not expect the clinical effectiveness to be the same (see section 3.4). The committee concluded that LATP using a double freehand coaxial needle technique did not appear to be cost effective, but this was very uncertain and more evidence was needed.

Using the cost of the PrecisionPoint device in a scenario analysis increases the ICERs

3.10 The EAG did a scenario analysis using the PrecisionPoint device cost instead of an average cost of all the freehand devices. In this scenario the ICER for LATP using PrecisionPoint compared with LA-TRUS remained below £20,000 per QALY gained for people having a first biopsy, but was higher than £30,000 per QALY gained in people having a repeat biopsy. However, clinical experts explained that the proportion of people having a first biopsy is much greater than the proportion of people having a repeat biopsy. The EAG did not model alternative scenarios using the costs of the other freehand devices but the committee noted that the PrecisionPoint device was the most expensive device. The committee concluded therefore that all the freehand needle positioning devices, including PrecisionPoint, had the potential to be cost effective in first and repeat biopsies.

Histopathology costs may be overestimated in the revised model

3.11 The EAG's model results were very sensitive to changes in the number of cores taken during the biopsy. It said that this was because of the histopathology cost per core. In the revised base case a higher histopathology cost was used, increasing from £107.50 for 12 cores in the original model to £438.96 for 12 cores in the revised model. The EAG explained that this had little effect on the base case ICERs because the histopathology costs cancel each other out when it is assumed that 12 cores are taken for each biopsy approach. However, if the number of cores differs between biopsy approaches, then there is a bigger effect on the results. The committee noted that the incremental QALYs were very small, which made the ICERs sensitive to changes in cost. Increasing the number of cores from 12 to 24 for LATP biopsy resulted in a very large increase in the ICERs, taking the results above what is generally considered to be cost effective by NICE. A clinical expert said that the average number of cores taken by a centre depended on which LATP

biopsy protocol it used. Two LATP protocols are used in the UK: the RAPID protocol and the Ginsburg technique. Centres using the RAPID protocol take around 12 to 15 cores, whereas centres using the Ginsburg protocol take 24 or more. A clinical expert explained that the model may have overestimated the likely increase in histopathology costs in the 24 core scenario, because increasing from 12 to 24 cores increases histopathology costs only minimally. Histopathology costs only increase substantially if more than 24 cores needed analysing. The committee concluded that the histopathology costs are likely to be overestimated in the revised base case, and that moving from 12 to 24 cores is unlikely to have a substantial effect on the ICERs.

The freehand needle positioning devices have the potential to be cost effective and are recommended as an option for LATP biopsy

3.12 The committee noted that in most analyses, freehand needle positioning devices were cost effective, with ICERs well below £20,000 per QALY gained. Although there was some uncertainty in the model results around cancer detection rates and biopsy costs (see section 3.2), there was no evidence to suggest that LATP biopsy using a freehand needle positioning device was any less effective than LA-TRUS biopsy. The ongoing TRANSLATE study will provide comparative data that may help reduce this uncertainty. The reduced rates of infection and sepsis were an important benefit of LATP biopsy (see section 3.5). Cost effectiveness modelling suggests that using a freehand needle positioning device for transperineal biopsy is more cost effective than other methods such as the double freehand coaxial needle technique (see section 3.9). The committee therefore concluded that the freehand needle positioning devices have the potential to be cost effective and should be recommended as an option for LATP biopsy.

4 Recommendations for further research

4.1 Further comparative clinical effectiveness evidence on the CamPROBE biopsy device is recommended to understand how double freehand prostate biopsy approaches compare with transrectal ultrasound biopsy or transperineal biopsy using freehand needle positioning devices (see section 3.4).

4.2 A patient experience study is recommended to better understand tolerability of local anaesthetic prostate biopsy, what aspects of the procedure may cause patients embarrassment, and how this could be reduced to increase uptake.

4.3 Further research is recommended to understand how the number of biopsy cores taken during local anaesthetic transperineal (LATP) prostate biopsy varies across centres and how this affects prostate biopsy histopathology costs.

5 Implementation

NICE intends to develop tools, in association with relevant stakeholders, to help organisations put this guidance into practice.

In addition NICE will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be considered by the NICE Medical Technologies Evaluation Programme research facilitation team for developing specific research study protocols as appropriate. NICE will also incorporate the research recommendations in section 4 into its guidance research recommendations database and highlight these recommendations to public research bodies.

6 Review

NICE reviews the evidence 3 years after publication to ensure that any relevant new evidence is identified. However, NICE may review and update the guidance at any time if significant new evidence becomes available.

Mark Kroese

Chair, diagnostics advisory committee

February 2022

7 Diagnostics advisory committee members and NICE project team

Committee members

This topic was considered by the diagnostics advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the test to be assessed. If it is considered there is a conflict of interest, the member is excluded from participating further in that assessment.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Additional specialist committee members took part in the discussions for this topic:

Specialist committee members

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NICE project team

Each diagnostics assessment is assigned to a team consisting of a technical analyst (who acts as the topic lead), a technical adviser and a project manager.

Simon Webster

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ISBN: