NICE National Institute for Health and Care Excellence

NICE guidance

Transperineal biopsy for diagnosing prostate cancer

Diagnostics guidance
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www.nice.org.uk/guidance/dg54

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

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 and therefore greater uncertainty of clinical benefit for them, the following freehand needle positioning devices are expected to have similar cancer detection rates and adverse events to those of PrecisionPoint:

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

There are technical differences between them, but they all work in a similar way using the same biopsy technique. So, these devices are recommended as options for diagnosing prostate cancer.

1.3 Centres are encouraged to take part in research and data collection, including the randomised controlled trial of transrectal biopsy compared with LATP biopsy (the TRANSLATE trial; see section 3.8) to help refine clinical practice.

1.4 There is not enough evidence to recommend double freehand LATP prostate biopsy using the CamPROBE device. 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 only (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.

Most of 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 are expected to be similar for the different freehand devices. This is because they all function in a similar way, in that they attach to the ultrasound probe and keep the needle in line with it. The biopsy technique is the same.

The most likely cost-effectiveness estimates for freehand needle positioning devices are within what NICE considers an acceptable use of NHS resources. So, 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, more research is needed to understand the cancer detection rates, adverse events and cost effectiveness.

2 The diagnostic tests

Clinical need and practice

2.1 Prostate cancer is the most commonly diagnosed cancer in men in the 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 and may require treatment, which includes radiotherapy, chemotherapy, surgery or a combination of these.

2.3 The section on assessment and diagnosis in NICE's guideline on prostate cancer 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 an 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

2.7 The CamPROBE (JEB Technologies) is a cannulated transperineal access system designed specifically for prostate biopsies. It consists of a coaxial 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 line with the ultrasound probe. It costs £35, and 2 devices per procedure are required. At the time of writing this guidance, CamPROBE has a CE mark and is available on the UK market for clinical use.

EZU-PA3U device

2.8 The FUJIFILM EZU-PA3U is a reusable dedicated freehand needle positioning device. It can be attached to either the FUJIFILM 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. The company says that a coaxial needle can be used with the device. 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

2.9 The PrecisionPoint transperineal access system (BXTAccelyon) is a 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: 1 on the left and 1 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 and is a single-use device.

SureFire

2.10 SureFire (Delta Surgical) 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 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. At the time of writing this guidance, SureFire was not available on the UK market and therefore was not considered by the committee in decision making.

Trinity Perine Grid

2.11 Trinity Perine (KOELIS/Kebomed) 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. There are 2 Perine Grids (18G and 14G). Each has a different needle gauge range. The 18G is compatible with 17-gauge to 20-gauge needles and the 14G is compatible with 14-gauge to 16-gauge needles. The company says that the Perine Grid can be used

with a coaxial needle such as the BARD TruGuide disposable coaxial needle or equivalent. The device is compatible with the KOELIS Sidefire Ultrasound probe. It costs £754.40 and can be reprocessed 100 times.

UA1232 puncture attachment

2.12 The UA1232 metal puncture attachment (BK Medical) 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. The company says that the choice of needle should be made by the clinician and the needle gauge should be compatible with the guide channel diameter. 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 (FUJIFILM)
- PrecisionPoint (BXTAccelyon)
- SureFire (Delta Surgical)
- Trinity Perine Grid (KOELIS/Kebomed)
- UA1232 (BK Medical).

The diagnostics advisory committee also considered evidence on LATP prostate biopsy with the CamPROBE device (JEB Technologies), which is used with a double freehand technique.

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 side effects, 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 side effects. They highlighted risk of infection as a major concern for patients. Patients were also worried about the severity and duration of side effects such as urinary retention and haematuria. A patient expert explained the importance of getting 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 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 RCT of transrectal compared with LATP biopsy (TRANSLATE; see section 3.8) 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.

The freehand needle positioning devices all work in a similar way using the same biopsy technique

3.3 Clinical experts said that the EZU-PA3U, PrecisionPoint, Trinity Perine Grid and UA1232 freehand needle positioning devices are mechanical devices that, despite some technical differences, all work in a similar way for the user. They attach to the ultrasound probe and align the needle with the probe axis, keeping them in line during the procedure. So, the biopsy technique used with them is considered to be the same. The needles the devices use are indicated for taking biopsy samples through the skin. A clinical expert said that when they moved to using the PrecisionPoint device, there was no difference in the biopsy sample quality. Although the PrecisionPoint device comes with a specific non-coring access needle as part of the kit, the companies for EZU-PA3U, Trinity Perine Grid and UA1232 said that their devices could be used with needles bought separately provided they are compatible with the guide channel diameter. Use of an access needle or a coaxial needle means that generally 4 or fewer punctures of the skin are needed. Other differences between the devices are that:

- PrecisionPoint is a single-use disposable device, whereas the other devices are reusable and need to be sterilised between uses.
- PrecisionPoint can be used with third party ultrasound probes, whereas other devices need to be used with specific ultrasound probes.

The EAG confirmed that the costs associated with sterilisation were included in the economic modelling.

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

3.4 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 all work in a similar way with the same biopsy technique (see section 3.3). The clinical experts said they would not expect significant differences in cancer detection rates and adverse event rates between the devices. No studies directly compared 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 using the CamPROBE device

3.5 A clinical expert explained that double freehand prostate biopsy approaches should be considered separately to the freehand approach that uses a needle positioning guide. They noted that for double freehand, a needle is used without a positioning guide, so 1 hand guides the ultrasound probe while the other guides the needle, and they need to be kept in line manually. CamPROBE is a double freehand device, so it is not attached to the ultrasound probe. There was no evidence comparing CamPROBE with any of the freehand needle positioning devices. The committee concluded that, because of these differences and the lack of evidence, it was uncertain if CamPROBE would have the same clinical effectiveness in terms of cancer detection and adverse events as the 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

3.6 Clinical experts said that 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 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

3.7 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: RAPID and Ginsburg). 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, such as 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

3.8 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 people with a prostate 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 research and data collection, including 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

3.9 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 that:

- 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, so they 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.

There is not enough evidence to determine whether LATP using CamPROBE is a cost-effective use of NHS resources

3.10 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 noted that the relative risks for cancer detection used in the revised base-case model were lower for LATP-other (coaxial needle studies) than for PrecisionPoint and for LA-TRUS. However, confidence intervals were wide and overlapped, so it is uncertain whether one technique is better than another. The committee concluded that it was uncertain if LATP prostate biopsy using a double freehand coaxial needle approach is cost effective. It also recalled that there was no comparative evidence on the CamPROBE double freehand device (section 3.5). The committee therefore concluded that there was not enough evidence to understand the cost effectiveness of LATP using CamPROBE, and more evidence was needed.

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

3.11 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. 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

3.12 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: RAPID and Ginsburg. 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

3.13 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 3.6). Cost-effectiveness modelling suggests that using a freehand needle positioning device for transperineal biopsy has the potential to be cost effective (see section 3.11). The committee therefore concluded that the freehand needle positioning devices 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 3.5).

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 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 tests 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:

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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.

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Frances Nixon
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