

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

Artificial intelligence (AI) technologies to help detect prostate cancer on MRI: early- use assessment

Guidance development process

NICE HealthTech guidance evaluates digital technologies, diagnostics and medical devices (including artificial intelligence). It provides evidence-based recommendations about how safe and effective these technologies are, and their cost effectiveness. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible treatments. NICE aims to promote innovations that meet the needs of patients and the healthcare system.

This guidance has been developed as early-use HealthTech guidance, for HealthTech products that could address an unmet need in the NHS and need more evidence to support routine use.

NICE is producing this guidance on artificial intelligence (AI) technologies to help detect prostate cancer on MRI 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 consultation with the stakeholders. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the [evidence](#).

The 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?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?
- Is the 2-year evidence generation period sufficient to collect relevant outcomes?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If the committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on AI technologies to help detect prostate cancer on MRI. The recommendations in section 1 may change after consultation.

More details are available in [NICE's HealthTech programme manual](#).

Key dates:

Closing date for comments: 12 November 2026

1 Recommendations

Can be used during the evidence generation period

1.1 Five artificial intelligence (AI) technologies can be used in the NHS during the evidence generation period as options to help detect prostate cancer on MRI. The technologies are:

- AI-Rad Companion Prostate MR
- DeepHealth Prostate
- ProstatID
- Prostate Intelligence
- QP-Prostate.

These technologies can only be used if:

- the evidence outlined in the [evidence generation plan](#) for the technologies is being generated
- they have appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

More research is needed

1.2 More research is needed on the following AI technologies to help detect prostate cancer on MRI before they can be funded by the NHS:

- hProstate
- mdprostate.

What this means in practice

Can be used during the evidence generation period

The AI technologies in recommendation 1.1 can be used as options in the NHS during the evidence generation period (2 years) and paid for using core NHS funding. During this time, more evidence will be collected to address any uncertainties. Companies are responsible for organising funding for evidence generation activities.

After this, NICE will review this guidance and the recommendations may change. This should be taken into account when negotiating the length of contracts and licence costs.

Potential benefits of use in the NHS during the evidence generation period

- **Accuracy and consistency:** the technologies may improve the accuracy and consistency of diagnosis, particularly in centres without specialist expertise. Improving the accuracy of diagnosis could lead to better detection of clinically significant prostate cancer, and fewer unnecessary biopsies and treatment for people with non-clinically significant prostate cancer.
- **Faster diagnosis:** the technologies could reduce the time people with clinically significant prostate cancer spend waiting for a biopsy or diagnosis, by allowing cases of prostate cancer to be prioritised.

Managing the risk of use in the NHS during the evidence generation period

- **Costs:** early results from the economic modelling show that the technologies could be cost effective.
- **Patient safety:** a radiologist always reviews the results produced by the technologies. If using the technologies to prioritise cases of prostate

cancer for review, existing safety-netting protocols can be used to manage deprioritised cases so that cancers are not missed.

- **Equality:** evidence generation could help address potential equality issues by collecting data on how effective the AI technologies are across different groups of people.

More research is needed

There is not enough evidence to support funding the AI technologies in recommendation 1.2 in the NHS.

Access to these technologies should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.

What evidence generation and research is needed

Evidence generation and more research is needed on the following outcomes for the different use cases (including prioritisation for review and biopsy):

- the accuracy of radiologist interpretation of prostate MRI scans (with and without AI assistance), with follow up for people whose MRI scan is assessed as negative for prostate cancer
- number of biopsies done after radiologist interpretation of MRI scans (with and without AI assistance), including the proportions of clinically significant prostate cancer and non-clinically significant prostate cancer that are detected
- impact of the technologies on time spent waiting for biopsy and diagnosis
- impact of the technologies on patient outcomes
- impact of the technologies on radiologist capacity and workflow
- how the level of radiologist experience affects the accuracy of AI-assisted interpretation of prostate MRI scans

- the accuracy of AI-assisted interpretation of prostate MRI scans when used:
 - across different ethnic groups, particularly for people from Black African and Caribbean backgrounds and other groups at higher risk of prostate cancer
 - with different MRI scanner models, protocols and scan parameters
 - for people with altered anatomy, previous pelvic treatment, pelvic metalwork, or significant benign prostatic hyperplasia
 - for people with rare prostate cancers
 - people taking treatments that may affect the appearance of the prostate on MRI (including hormone therapies).

The [evidence generation plan](#) gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

Why the committee made these recommendations

If prostate cancer is suspected after initial tests, people have an MRI scan. This is reviewed by a radiologist, who decides whether prostate cancer is likely and whether a biopsy should be offered to confirm this.

These AI technologies can assist with the review of MRI scans, which could potentially allow reviews to be done more accurately and consistently. This may reduce the number of biopsies done in people with non-clinically significant prostate cancer. The technologies may also allow for faster reviews, biopsies and diagnosis for people with clinically significant prostate cancer. This could help address capacity issues in radiology services.

Can be used during the evidence generation period

There are uncertainties and data inconsistencies in the evidence for the clinical effectiveness of these technologies. The early economic modelling results are uncertain, but all 5 technologies could potentially be cost effective.

Real-world evidence is needed to address some of the uncertainties, in particular the impact on NHS workflows if the technologies are used to help prioritise cases for biopsy and radiologist review.

Despite the limited evidence, the risks of using the technologies can be managed because:

- radiologists review all AI-produced results, and
- existing safety-netting procedures can be used to make sure cancers are not missed in cases that are not prioritised for review.

So, these technologies can be used in the NHS during the evidence generation period.

More research is needed

There was no clinical or cost-effectiveness evidence for hProstate and mdprostate, so research is needed on these technologies.

2 Information about the technologies

2.1 This assessment included 7 technologies (AI-Rad Companion Prostate MR, DeepHealth Prostate, hProstate, mdprostate, ProstatID, Prostate Intelligence, and QP-Prostate) that use artificial intelligence (AI) derived, fixed algorithms to help healthcare professionals interpret and report findings from MRI scans of the prostate. These technologies were assessed as aids to healthcare professionals, rather than as replacements for them. All the technologies are used after the MRI scans are done. The technologies can read and segment prostate MR images, identify regions with possible cancer, classify risk and produce summary reports. One technology is currently intended for use for triage (Prostate Intelligence).

2.2 The technologies differ on MR image type compatibility and whether they are cloud based or installed on local systems. All the

technologies are indicated for use in adults, but some specify age ranges.

Table 1 Features of the technologies

Technology (company)	Regulatory status	Deployment options	Image type	Target population
AI-Rad Companion Prostate MR (Siemens Healthineers)	CE Class IIb	Cloud or local	bpMRI and mpMRI	Adults over 21 with suspected prostate cancer
hProstate (Hevi AI)	CE Class IIa	No information	bpMRI	No information
DeepHealth Prostate (DeepHealth)	CE Class IIb	Cloud	bpMRI and mpMRI	Adults with suspected prostate cancer or with a family history of prostate cancer
mdprostate (mediaire)	CE Class IIb	Local (virtual machine or a dedicated server)	bpMRI and mpMRI	People aged 35 to 99 years with suspected prostate cancer
ProstateID (Bot Image)	UKCA Class IIb	Cloud or local	bpMRI and mpMRI	Adults with suspected prostate cancer or with a family history of prostate cancer
Prostate Intelligence (Lucida Medical)	CE Class IIb	Cloud or local	bpMRI and mpMRI	Men aged 21 and over with suspected prostate cancer
QP-Prostate (Quibim)	UKCA Class IIa (CE Class IIb)	Cloud	bpMRI and mpMRI	People over 18 with suspicion of prostate cancer

Abbreviations: bpMRI, biparametric MRI; CE, Conformité Européenne (European Conformity); mpMRI, multiparametric MRI; UKCA, UK Conformity Assessed.

Sustainability

2.3 For information, Carbon Reduction Plans for UK carbon emissions, or a commitment to reducing greenhouse gas emissions and achieving net zero, are published here for each company:

- [DeepHealth carbon reduction plan](#)
- [Lucida Medical net zero commitment and carbon reduction plan](#)
- [Siemens Healthineers net zero commitment](#)
- Bot Image, Quibim, Hevi AI and mediaire did not have a Carbon Reduction Plan for UK carbon emissions or a net zero commitment.

3 Committee discussion

The diagnostics advisory committee considered evidence on artificial intelligence (AI) technologies to help detect prostate cancer on MRI from several sources. This included evidence submitted by Bot Image, DeepHealth, Lucida Medical, Quibim and Siemens Healthineers, a review of clinical and cost evidence by the external assessment group (EAG), and responses from stakeholders. Full details are available in the [project documents for this guidance](#).

The condition

3.1 Prostate cancer is the most diagnosed cancer in England. In 2023, there were 58,137 new diagnoses of prostate cancer ([NHS England Cancer Registration Statistics, England, 2025](#)). Every year in England, more than 10,000 people die from the disease ([Prostate Cancer UK facts and figures 2026](#)). The number of new cases is expected to keep rising ([Cancer Research Incidence for common cancers 2019, 2021 to 2022](#)).

3.2 Early diagnosis of prostate cancer leads to better outcomes. When diagnosed at the earliest stage, almost all people with prostate cancer survive 5 years or more ([NHS England Cancer Survival in](#)

[England](#)). However, only around 48% of people survive 5 years or more when prostate cancer is diagnosed at the latest stage ([Office for National Statistics Cancer survival in England up to 2017](#)).

Current practice

- 3.3 In the NHS, the assessment and diagnosis of prostate cancer follows the:
- [NICE guideline on suspected cancer](#)
 - [NICE guideline on prostate cancer](#)
 - [NHS England best practice timed diagnostic pathway for prostate cancer](#)
 - [GIRFT prostate cancer best practice guidance](#).
- 3.4 People with suspected prostate cancer are usually first seen in primary care. NICE's guideline on suspected cancer recommends offering people with suspected prostate cancer a blood test to check prostate-specific antigen (PSA) levels. They may also be offered a digital rectal examination (DRE). However, use of DRE is reducing in many centres and is discouraged in a recent [joint statement from the British Association of Urological Surgeons \(BAUS\) and Prostate Cancer UK](#).
- 3.5 If PSA levels are raised or DRE is abnormal, NICE's guideline on prostate cancer recommends multiparametric MRI (mpMRI) as the first-line investigation for suspected clinically localised prostate cancer. Prostate MRI is typically done in secondary care. In some centres, biparametric MRI (bpMRI) is used instead of mpMRI ([Withey et al. 2025](#)). bpMRI differs from mpMRI because it does not include dynamic contrast-enhanced imaging. The appointment for the mpMRI procedure is longer because a contrast agent needs to be given (through an intravenous cannula), and the scan takes longer.

- 3.6 In most cases, a single qualified radiologist analyses the scan images and produces a report on their findings. MRI results are reported using a radiological scoring system, such as the Prostate Imaging Reporting and Data System (PI-RADS) or the 5-point Likert scale. People whose score is 3 or more are offered MRI-influenced prostate biopsy, which may be either transrectal or transperineal. People whose score is 1 or 2 generally choose not to have a biopsy, after discussing the risks and benefits of the procedure with a healthcare professional.
- 3.7 Histological analysis of the biopsy and clinical staging (based on imaging) is used to classify diagnosed prostate cancer into risk categories based on PSA test results, Gleason score or Grade Group. These risk categories help inform treatment options, such as active surveillance, radical prostatectomy and radiotherapy.
- 3.8 According to [NHS England guidance on best practice timed pathways for diagnosing prostate cancer](#), mpMRI and a prostate biopsy should be done within 9 days of GP referral and pathology results reported within 5 days. This is a 14-day turnaround from GP referral to prostate biopsy result. In areas using one-stop diagnostic clinics, mpMRI and biopsy should be done within 7 days of GP referral.

Unmet need

- 3.9 Demand for prostate MRI has increased because pre-biopsy MRI is now part of the prostate cancer diagnostic pathway. This has increased pressure on radiology teams, whose capacity to read and report scans is already stretched because of workforce shortages ([Royal College of Radiologists 2025 article on staff shortages](#)). This is compounded by the shortage of specialist urologists in the NHS. These factors have led to variable and sometimes lengthy report turnaround times, potentially affecting the

timeliness of treatment pathways. From October 2021 to June 2024, only 29% of people with urological cancer (including prostate cancer) were diagnosed within 28 days of GP referral ([Cancer Research UK Faster Diagnosis Standard 2025](#)).

- 3.10 The AI technologies included in this assessment could allow reviews to be done faster, more accurately and more consistently, and improve workflow efficiency and throughput. Clinical experts, stakeholders and patient organisations stated that the technologies could help with:
- Improving accuracy and consistency in reporting between radiologists: the accuracy and consistency of MRI interpretation can vary depending on the radiologist's level of experience. Prostate MRI reporting is not standardised and differs across centres. Miscommunication or unclear prostate MRI reports may lead to missed cancers (because biopsies are targeted to the wrong area), additional consultations with radiologists, and multidisciplinary team meetings to clarify findings. Improving accuracy and consistency in reporting may reduce the number of unproductive biopsies (biopsies in people with no clinically significant prostate cancer), and therefore overdiagnosis and overtreatment.
 - Prioritising cases for radiologist review or biopsy: prostate MR images are typically reviewed in the order they are acquired. But the technologies could allow them to be reviewed in order of the risk of clinically significant prostate cancer. The technologies could also enable people to get their biopsy quicker by identifying people who are most likely to need an appointment.
 - Improving detection with bpMRI: this would reduce the need for more time-consuming and expensive mpMRI.

Patient considerations

- 3.11 Patient experts and organisations said that people would need reassurance that:
- the technologies perform equally across different groups (for example, people with different prostate anatomies or implants, people with rare prostate cancers, and people from different ethnic backgrounds)
 - final interpretation and reporting will still be accountable to and overseen by qualified healthcare professionals
 - people with suspected prostate cancer will still be involved in decision making
 - using the technologies does not exacerbate health inequalities already caused by lack of access to MRI in some services.

Clinical effectiveness

Evidence base

- 3.12 Twenty studies (covering 5 of the technologies) were included in the clinical evidence review. No eligible studies were identified for mdprostate (mediaire) or hProstate (Hevi AI). Most evidence in the review was from diagnostic accuracy studies looking at use alongside clinician review (as opposed to AI review alone).
- 3.13 The studies were heterogeneous in methodology, patient populations, reference standard and healthcare professional experience and expertise. Only Prostate Intelligence had NHS-based evidence, which was from a single centre. The EAG concluded that it was unclear how applicable the findings for the other technologies were (see [sections 3.23 and 3.24 on generalisability](#)). The EAG rated the risk of bias as moderate to high in all but 1 study. Ratings of unclear or high risk of bias were mainly related to the validity of the reference standard, because some studies used expert radiologist opinion rather than biopsy

and did not use long-term follow up. Some studies also used selective inclusion of participants and made exclusions because of missing data.

Diagnostic accuracy and consistency of AI-assisted MRI interpretation

- 3.14 The committee concluded that the 5 technologies with evidence could potentially improve radiologist accuracy in detecting clinically significant prostate cancer. These technologies had some evidence that showed AI assistance improved sensitivity or specificity for prostate cancer, for some healthcare professionals. For technologies with more than 1 study (AI-Rad, DeepHealth Prostate, and Prostate Intelligence), findings were inconsistent between studies for each technology. There was only 1 study each for ProstatID and QP-Prostate.
- 3.15 The committee noted that one of the potential benefits of using AI is to improve the consistency of prostate cancer detection (see [section 3.10](#)). Studies showed varying results for how accuracy was affected for radiologists with different levels of experience. The EAG noted that this could be related to differences in the definition of 'experience' between studies. The clinical experts suggested that experience should be measured by the number of prostate MRIs reported recently, rather than by years of experience.

Evidence for using AI to prioritise prostate MRIs

- 3.16 The committee noted that prioritising cases for biopsy or for radiologist review was a popular potential use case. But this was only evaluated by 1 real-world study for Prostate Intelligence based in a single NHS centre. The AI was used as a standalone tool to prebook biopsies for people with the highest risk of clinically significant prostate cancer, before being used to assist the radiologist review. The committee noted that the findings were

promising and did not show any evidence of harm, and that there are ongoing UK and NHS-based studies that may support use for prioritisation in the future. At consultation, stakeholders highlighted that technologies could be used in a 'rule-out' scenario, but this assessment only covers use of the technologies to assist radiologist review (as opposed to AI review alone).

Impact on radiologist capacity

- 3.17 The findings on reading time were the only evidence of the impact of the technologies on radiologist capacity. Evidence was available for 3 technologies (AI-Rad, DeepHealth Prostate and QP-Prostate), but the EAG concluded that they had no clear impact. When there were reductions in reading time, these were less than 2 minutes. Based on this evidence, the committee agreed it was unlikely that AI assistance has a meaningful impact on MRI scan reading time. A clinical expert noted that it would be more useful to know what the impact was on the number of cases reviewed per session. Most prostate cancer grows slowly (except for small-cell prostate cancer). Because of this, the committee noted that small time savings in the diagnostic pathway are unlikely to have an impact on clinical outcomes. The clinical experts also noted that any effect is dependent on workflow integration and familiarity with the software. Without this, the technologies could increase reading time and interrupt workflow. The committee concluded that more data is needed on the interaction between radiologists and the technologies, and the impact on workflow and capacity.

Effects of MRI hardware and imaging protocols

- 3.18 There are many variables that can affect the quality of an MR image, including hardware and imaging protocols. Two technologies (DeepHealth Prostate and QP-Prostate) had some evidence comparing performance across images from different scan manufacturers and MRI field strengths. But the EAG said it

was not possible to conclude with certainty if these differences had any impact on AI performance. The clinical experts explained that there is variability between NHS centres in the hardware, software and settings used for MR image acquisition, and noted that AI technologies would need to function across this variability. The committee concluded that it would be useful for studies to be done across a range of settings and to report the technical specifications for scan acquisition. This will make it clearer if the range of hardware and protocols used in the NHS impacts the technologies' performance.

- 3.19 The clinical experts also noted the potential for the technologies to reduce the need for mpMRI (which is more time-consuming and expensive than bpMRI). If the diagnostic accuracy of AI-assisted interpretation of bpMRI scans is comparable with the unassisted interpretation of mpMRI scans, then bpMRI could be used more widely. No technologies had evidence directly comparing AI-assisted bpMRI interpretation and unassisted mpMRI interpretation.

Differences in prostate MRI across groups

- 3.20 In addition to the effects of differences in MRI hardware and imaging protocols (see [section 3.18](#)), the clinical experts advised that interpretation of prostate MRI may be affected by the person's age and ethnicity, and by clinical factors that affect imaging of the prostate.
- 3.21 People from different ethnic backgrounds may have different risks associated with prostate cancer. For example, people from a Black African or Caribbean background are at higher risk of developing prostate cancer, and are also more likely to be diagnosed with prostate cancer at a younger age. The clinical experts advised that this could affect how radiologists interpret MRI, for example

whether they consider a lesion to be benign or malignant. There was no evidence that the technologies performed differently for any ethnic groups. Two unpublished studies for Prostate Intelligence reported that standalone accuracy was similar across different ethnic groups and in people with a family history of prostate cancer, compared with people without. The EAG said it was unclear whether there were important differences between the groups studied for DeepHealth and QP-Prostate. No evidence analysed by ethnicity was available for other technologies. The committee was not confident that these findings demonstrated equal performance across ethnic groups, because the sample sizes were small and confidence intervals were large. The committee concluded that more evidence is needed to establish whether the technologies perform consistently across different ethnic groups.

3.22 The clinical experts highlighted that pelvic anatomy could affect MR image acquisition, and therefore the performance of the technologies in:

- people with altered anatomy, previous pelvic treatment, pelvic metalwork or significant benign prostatic hyperplasia
- people with rare prostate cancers
- people having hormone therapy.

The committee said that studies should collect data on people in these groups to establish how well the technologies work for them. The committee noted it may not be possible to include all these groups because of contraindications for some technologies.

Generalisability to NHS practice

3.23 The committee was uncertain about whether the evidence was generalisable to the NHS. It concluded that the best way to get

evidence that was generalisable to NHS practice was to collect data across a wide range of NHS centres.

- 3.24 Most of the available evidence was in non-UK settings, largely from the US or Europe. The clinical experts said there would be variation in the equipment, MRI protocols, training and demographics in these studies, but there was also wide variation in these factors in the NHS. The committee noted that the prevalence of prostate cancer and clinically significant prostate cancer was often lower in the studies than in the population that would have prostate MRI in the NHS. The clinical experts indicated that it is important to ensure in future studies that the prevalence of clinically significant prostate cancer represents the NHS prostate MRI population. This is needed to establish how well the technologies work for people of different ages, ethnicity and socioeconomic backgrounds. The clinical experts also emphasised that these factors may interact in the way they influence study findings.

Risk of adverse clinical effects

- 3.25 The committee noted that there was no evidence that using AI to assist in detecting prostate cancer on MRI causes harm to patients. The way a technology is used in practice (for example, prioritisation compared with second review) may affect whether all prostate cancer lesions are detected, or whether some are missed. There is also a risk that radiologists may miss incidental findings of other clinically significant pathologies on a prostate MRI scan. The technologies are not designed to detect other cancers. The clinical experts said it was unclear whether the technologies affected healthcare professional detection of incidental findings, because the evidence only focused on detection of prostate cancer. The committee noted that no proposed use cases replace human interpretation. Healthcare professionals would have to be alert for pathology in the prostate and surrounding areas, just as they would

when reviewing scans without AI assistance. The clinical experts also noted that existing safety-netting processes could be adapted to limit the risk that prostate cancer is missed by the technologies, or by the radiologists using them. The committee was also reassured by evidence from an NHS service evaluation of Prostate Intelligence that found an increase in clinically significant prostate cancer detection after implementing AI.

Cost effectiveness

Model structure

3.26 The EAG developed a de novo model to evaluate the potential cost effectiveness of using AI technologies to assist radiologists in detecting prostate cancer on MRI. The EAG did not model use of the technologies for prioritisation, because there was not enough evidence to support this. The population was people with suspected clinically localised prostate cancer who were having MRI as the first-line investigation for initial diagnosis. The model estimated the potential impact of changes in diagnostic accuracy when using the AI technologies to assist a qualified radiologist, compared with radiologist review without AI assistance. It consisted of a short-term decision tree and an exploratory high-level long-term payoff model. The short-term model captured the diagnostic pathway over a 30-day time horizon. The long-term model used payoffs to capture estimated costs of monitoring, treatment or further diagnostic tests, according to short-term diagnostic outcomes over a 10-year time horizon. Treatment costs were applied upfront, and monitoring costs and utility decrements were applied in yearly cycles alongside mortality and utility. Only 5 technologies were included in the model, because no clinical data for the other 2 (hProstate and mdprostate) was available.

Base-case results

- 3.27 The economic analysis found that, when used to assist radiologist review, all 5 technologies had the potential to be cost effective compared with review without AI assistance. But there were scenarios in which all 5 of the technologies were not cost effective. In the base-case results, 3 of 5 technologies were cost effective and 4 showed small quality-adjusted life year (QALY) benefits. Sensitivity analysis showed that the model findings were driven by sensitivity and specificity inputs. The cost of treatment increased if clinically significant prostate cancer was missed on MRI, because the cancer progresses before diagnosis. Costs also increased if clinically insignificant prostate cancer was detected, because of the costs of additional diagnostic procedures and the long-term costs of unnecessary treatments or follow-up tests. So, cost effectiveness was dependent on increasing the diagnosis of clinically significant prostate cancer and reducing the diagnosis of clinically insignificant prostate cancer.
- 3.28 The base case showed a reduction in unproductive biopsies (when no or non-clinically significant cancer is detected) for 4 technologies, and an increase in productive biopsies (when clinically significant prostate cancer is detected) for 4 technologies. While the number of biopsies done did not directly drive the model outcomes, the number of productive and unproductive biopsies done is determined by the sensitivity and specificity of the technology. Increasing either sensitivity or specificity reduces costs. So, reducing the number of unproductive biopsies and increasing the number of productive biopsies is a key potential benefit for these technologies. The committee noted that it would be beneficial for future evidence to demonstrate how this change impacts pressures on biopsy services.
- 3.29 The EAG reported that AI assistance may be more beneficial for less experienced radiologists. The definition of 'experience' was

inconsistent between studies. The EAG did a 2-way sensitivity analysis that represented the effects of radiologist experience on biopsy costs, by increasing specificity with and without AI. This showed that the less experienced the radiologist is, the higher the chance the AI could reduce costs by reducing the number of unproductive biopsies. The committee acknowledged that AI could help less experienced radiologists, but it was uncertain whether this would be realised in practice, given that radiologists would need to become experienced in using the AI to gain benefits from it (see [section 3.17](#)).

Clinical inputs

- 3.30 The committee noted differences for each technology in diagnostic accuracy model inputs for unassisted radiologists. The EAG explained that, despite applying criteria to identify the best-quality evidence that was applicable to the decision question, there was still a high degree of heterogeneity between the studies used for the model inputs. This included differences in how a positive test result was defined, the reference standard used, and the study location and clinical context. The EAG stated that this likely explained the variation for each technology in the accuracy of unassisted radiologists, and the variation in whether accuracy improved or got worse (and by how much) when using AI assistance. The committee agreed that it was not appropriate to compare cost-effectiveness findings between technologies because of these differences.

Cost inputs

- 3.31 The committee noted that the cost structures between companies were very different. In particular, the cost of AI-Rad was very low and did not include any set-up or training costs. The cost of the technology was not a key driver of the model outcome for any of the technologies. Threshold analysis was done to explore the

impact of additional unknown costs for AI-Rad, but adding set-up costs in line with other technologies would not have changed the direction of results. The manufacturer for Prostate Intelligence also provided alternative costing, but this did not change the overall model results.

- 3.32 The committee noted that updates to NHS IT infrastructure may be needed to support the use of the technologies. But these costs were not modelled. The EAG stated that it is difficult to assign an appropriate proportion of infrastructure upgrade costs to a specific AI indication, because they may affect multiple services. The committee concluded that it was reasonable not to include the costs of IT infrastructure upgrades.

Assumptions

- 3.33 The committee concluded that the assumptions used in the model were appropriate for an early-use assessment. Future modelling should include more detail on factors that go into biopsy decisions, and on the long-term outcomes after AI-assisted detection of prostate cancer. Some modelling decisions that were queried by stakeholders included:
- assuming that all people with a positive result on MRI and clinically significant prostate cancer would have a biopsy
 - assuming that people with false negative results from MRI would have their cancer detected after 1 year, and that a proportion of people in this group would experience disease progression in this time
 - costs associated with monitoring and treating non-clinically significant prostate cancer
 - the health utility value associated with a biopsy.

The EAG tested these assumptions in sensitivity analyses and

concluded that none would change the model results, which mainly depended on sensitivity and specificity inputs (see [section 3.14](#) and [section 3.27](#)).

Plausibility of cost effectiveness

3.34 The committee noted the degree of heterogeneity and the risk of bias for sensitivity and specificity inputs. For each technology, the results were highly dependent on the difference in accuracy between AI-assisted and unassisted radiologists. If the AI technology increased sensitivity and specificity, it was more likely to be cost effective. The model results were therefore dependent on the source used for the sensitivity and specificity inputs, and the level of uncertainty within that source. The committee discussed:

- diagnostic accuracy ([sections 3.14 and 3.15](#))
- effects of MRI hardware and imaging protocols ([section 3.18](#))
- generalisability of findings to the NHS ([sections 3.23 and 3.24](#))
- clinical inputs ([section 3.30](#)).

Based on the discussions in these areas, the committee concluded that the direction of the model results was not definitive for any technology, but all modelled technologies had potential to be cost effective.

Equity in access to AI technologies

3.35 Patient organisations noted that the potential benefits of AI assistance may be especially important for people seen in remote centres, or centres with backlogs and workforce shortages. At consultation, stakeholders said that restricting use of AI technologies to research could limit evidence generation in populations that are already under-represented in prostate MRI research. This would be a particular issue for people who are seen in centres that have lower levels of specialism and are less

involved in research. The committee recalled that there are many confounding factors that could affect the performance of AI technologies and the radiologists using them (see [sections 3.20 to 3.24](#)). It concluded that the best way to establish the true performance of the technologies would be to collect data across a variety of NHS specialist and non-specialist centres, in different areas of the country. This would ensure that the findings were generalisable to wider NHS practice. A key concern for patients was ensuring that the technologies have evidence of effectiveness across different groups (see [section 3.11](#)). The committee also noted that the clinical risk to patients was manageable (see [section 3.25](#)). So, it concluded that the technologies with some evidence showing potential benefit (AI Rad, DeepHealth Prostate, ProstatID, Prostate Intelligence and QP Prostate) could be used with core NHS funding while further evidence was generated.

Evidence gaps

3.36 The EAG highlighted 10 ongoing studies that could be relevant to the decision question. The committee acknowledged that some of these may be able to address some of the identified evidence gaps, particularly as they include UK and NHS-based studies. The [evidence generation plan](#) includes study design, characteristics and outcomes that are needed for future full assessment of the technologies and their use cases.

4 Committee members and NICE project team

This topic was considered by [NICE's diagnostics advisory committee](#), which is a standing advisory committee of NICE.

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

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.

Chair

Thomas Clutton-Brock

Chair, diagnostics advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Simon Webster, Robbie Pitcher, Louisa Robinson

Technical leads

Jacob Grant

Technical adviser

Catherine Pank

Project manager

Rebecca Albrow

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ISBN: