NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-HTE10089: Artificial intelligence (AI) technologies to help detect prostate cancer on MRI

Final scope

1. Introduction

NICE has selected artificial intelligence (AI) technologies designed to help detect prostate cancer on MRI for HealthTech evaluation.

The technologies will be assessed for early use. Early-use assessment considers HealthTech that could address a national NHS unmet need. It rapidly assesses technologies early in the lifecycle (but that have appropriate regulatory approval for use in the UK) or that have limited use in the NHS and need further evidence to support wider use. Technologies considered for early use can be conditionally recommended for use while further evidence is generated during the evidence generation period. This enables early access to promising new technologies for patients. Conditional recommendations are for a fixed period of time and the technologies will be reassessed for routine use using the evidence generated.

This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the NICE HealthTech programme manual.

2. The condition

Prostate cancer is the most diagnosed cancer in England (NHS England 2025). Every year in England, over 56,000 men are diagnosed with prostate cancer and more than 10,000 die from the disease (Prostate Cancer UK

2025a). The number of new cases is expected to keep rising (Cancer Research UK [CRUK] 2025a).

Early diagnosis of prostate cancer can lead to better outcomes. When diagnosed at the earliest stage, almost all people with prostate cancer survive 5 years or more (NHS England 2023), but only around 53% of people survive 5 years or more when prostate cancer is diagnosed at the latest stage (Office for National Statistics 2019).

3. Current practice

In the NHS, the assessment and diagnosis of prostate cancer follows the:

- NICE guideline on suspected cancer (NG12)
- NICE guideline on prostate cancer (NG131)
- NHS England best practice timed diagnostic pathway for prostate cancer
- GIRFT best practice guidance.

People with suspected prostate cancer are usually seen within the primary care setting first. According to NICE's guideline on suspected cancer, people with suspected prostate cancer should be offered a blood test to check prostate specific antigen (PSA) levels. They may also be offered a digital rectal examination (DRE). According to GIRFT guidance, DRE is not needed in a primary care setting if PSA levels are raised. 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.

If PSA levels are raised or DRE abnormal, NICE's guideline on prostate cancer recommends that people with suspected clinically localised prostate cancer who are able to have radical treatment should be offered multiparametric MRI (mpMRI) as the first line investigation. Prostate MRI is typically done within the secondary care setting. 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 (DCE) imaging. The mpMRI procedure requires a longer appointment time due to the

administration of a contrast agent via an intravenous cannula, and increased scan time.

In most cases, a single qualified radiologist analyses the MR 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 should be offered MRI-influenced prostate biopsy which may be either transrectal or transperineal. The European association of urology prostate cancer guideline (last updated March 2026) suggests that in people with a PI-RADS score of 3, MRI and PSA density results could be combined to help refine the risk of clinically significant prostate cancer and inform whether biopsy is offered. People whose score is 1 or 2 may choose whether to have a prostate biopsy after discussing the risks and benefits of the procedure with a healthcare professional. A prostate biopsy is typically done by a urologist or specialist nurse. For people with a negative biopsy who have an MRI score of 3 or more, NICE NG12 recommends that the possibility of significant disease should be discussed in a multidisciplinary team (MDT) meeting with a view to repeating the prostate biopsy.

People diagnosed with prostate cancer are classified into risk categories based on PSA test results, Gleason score or Grade Group determined by histological analysis of the biopsy, and clinical stage based on imaging. These risk categories help inform treatment options, such as active surveillance, radical prostatectomy and radiotherapy.

According to NHS England guidance on best practice timed pathways for diagnosing prostate cancer, mpMRI and a prostate biopsy (if appropriate) should be done within 9 days from 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 (if appropriate) should be done within 7 days of GP referral.

England has a 28-day target between urgent referrals for suspected cancer and diagnosis, called the Faster Diagnosis Standard (FDS). NHS trusts are

expected to achieve a target of 75% of patients meeting the FDS from October 2021. This target is set to rise to 80% by March 2026 (NHS England 2024).

4. Unmet need

- Demand for prostate MRI has increased due to the adoption of pre-biopsy MRI into the prostate cancer diagnostic pathway. This has increased pressure on radiology teams, whose capacity to read and report scans is already stretched due to workforce shortages (Royal College of Radiologists 2025). This has led to variable and sometimes lengthy report turnaround times, potentially impacting on the timeliness of treatment pathways. From October 2021 to June 2024, only 29% of urological cancer referrals (including prostate cancer) which resulted in a diagnosis of cancer were received within 28 days (CRUK 2025b). With the number of new cases of prostate cancer projected to keep rising (CRUK 2025a), completing the diagnostic process within the 28-day FDS is likely to remain challenging.
- In the UK, prostate MR images are typically reviewed in the order they are acquired, rather than according to the risk of clinically significant prostate cancer. This is because there is no way to prioritise more urgent cases before the scans are reviewed. As a result, people most likely to need a biopsy are not referred in the most timely or efficient manner. This makes meeting FDS targets challenging, because prostate biopsies require time-consuming histological analysis.
- MRI is effective for detecting prostate cancer and can spare people from unnecessary procedures such as biopsies. But the accuracy and consistency of MRI interpretation can vary depending on radiologist expertise, particularly with respect to borderline findings. This issue is compounded by the shortage of specialist uroradiologists in the NHS. Deciding when it is safe to avoid further investigation can be challenging. This uncertainty may potentially lead some clinicians to overestimate the risk of clinically significant cancer to ensure a biopsy is done. Inaccurate

interpretation can lead to unnecessary biopsies and overdiagnosis, as well as missing clinically significant cancers.

- Reporting of prostate MRI is not standardised and differs across centres. This includes differences in how the location of the lesion is communicated to clinicians performing biopsies and the level of detail provided. Miscommunication or unclear prostate MRI reports may lead to missed cancers (due to biopsies being targeted to the wrong area), additional consultations with radiologists, and unnecessary MDT meetings and procedures to clarify findings.

5. The technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. An overview of the key features of each technology is shown in table 1. NICE has not carried out an independent evaluation of these descriptions.

The technologies included in this evaluation use AI algorithms to support the detection of suspected cancer on prostate MRI. All of the technologies can perform segmentation of the prostate images, identification of suspicious regions, risk classification and summary report generation. The technologies use fixed algorithms in clinical settings. They cannot adapt in real time using data from clinical practice. All of the technologies included in the assessment are used after MR images have been acquired. The healthcare professional who reviews the MR images using the software makes the final reporting decision. The technologies do not replace clinical decision making.

All of the technologies are generally compatible across MRI device manufacturers and field strengths commonly used in the NHS. The technologies use MR images in digital imaging and communications in medicine (DICOM) format, which can be stored on the hospital's picture archiving and communications system (PACS). In addition to being able to integrate with the hospital’s PACS, some of the technologies can also be accessed through AI marketplaces, stand-alone web-based services or other

platforms. Some of the technologies can be deployed locally, others are cloud-based, and some offer both options.

Centres may employ the technologies for different purposes according to their specific needs. These may include:

- Improving diagnostic accuracy. The technologies may be used as a decision support tool to increase the accuracy of suspected prostate cancer detection by qualified radiologists. This may help reduce the number of unnecessary biopsies and overdiagnosis, and the number of missed cancers.
- Reducing reporting delays in individuals most likely to require a biopsy, by analysing images upon acquisition and automatically prioritising cases to ensure faster review by qualified radiologists. This may help hospitals meet the 28-day FDS and support more timely treatment.
- Improving the consistency, clarity and applicability of radiology reports to help standardise interpretation of MRI images and the planning of biopsies.
- Reducing the time required for reading and reporting scans by automating some tasks, such as organ segmentation for PSA calculations and biopsy planning. This may help improve workflow efficiency and throughput across the diagnostic pathway.

All the included technologies were available to the NHS at the time of writing this scope or were expected to become available during the assessment period. Three of the AI technologies are currently in use in the NHS (AI-Rad Companion Prostate MR, Prostate Intelligence and QP-Prostate).

Table 1 Features of the technologies

Technology (company)	Regulatory status	Supported MRI images	Local or cloud deployment	Intended user(s)	Intended use	Contraindications and factors affecting performance
AI-Rad Companion Prostate MR (Siemens Healthineers)	CE-marked Class IIb	bpMRI and mpMRI. DCE not included	Cloud or local	Radiologists and clinical IT administrators	To support clinicians read and report prostate MR studies in adults over 21 with suspected prostate cancer	**Factors affecting performance:** image artefacts, metallic implants and incomplete or non-standard MRI protocols.
hProstate (hevi AI)	CE-marked Class IIa	bpMRI	No information	No information	No information	No information
mdprostate (mediaire)	CE-marked Class IIb	DCE images optional	Local (virtual machine or a dedicated server)	Health care professionals and Radiologists	To help radiologists assess prostate MR images in people aged 35 to 99 years with suspected prostate cancer.	**Contraindications:** Prostate volume of less than 5 mL **Factors affecting performance:** people with (partial) prostatectomies or as a result of artefacts (e.g., caused by hip implants)
Prostate Suite (Deep Health) Previously Quantib Prostate	Quantib Prostate is CE-marked Class IIb. ProstateAI undergoing regulatory approval	bpMRI and mpMRI	Cloud	Trained healthcare professionals	To help clinicians detect and characterize prostate cancer lesions using MR imaging data in adults with suspected prostate cancer or with a family history of prostate cancer.	**Factors affecting performance:** image quality and confounding pathology or prior definitive prostate treatments (prostatectomy or radiotherapy).
ProstatID (Bot image)	UKCA-marked Class IIb	mpMRI. Supports bpMRI	Cloud or local	Clinicians qualified to read and	To assist clinicians in the detection, assessment and characterisation of	**Contraindications:** Metallic hip replacements, people who have had a prostatectomy or have received or are

		where image quality is sufficient		interpret prostate MRI studies	prostate abnormalities using MR images from adults with suspected prostate cancer or with a family history of prostate cancer.	currently receiving prostate or cancer treatments. People who have had prostate biopsies within 8-12 weeks, who have used antiandrogens within the past 6 months or luteinizing hormone-releasing hormones within the past 12 months.
Prostate Intelligence (Lucida Medical)	CE-marked Class IIb	bpMRI and mpMRI including DCE	Cloud or local	Radiologists	To support clinicians analyse MRI studies in males aged 21 and over with suspected prostate cancer.	**Contraindications:** People who have had a prostate biopsy within 6 weeks prior to MRI or had substantial prostate or urethral treatment or surgery. Impaired MR image quality, MRI image quality not of diagnostic quality, MRI that does not follow PI-RADS v2.1 scanning protocols, or has been captured using an endo-rectal coil
QP-Prostate (Quibim)	UKCA-marked Class IIa (CE Class IIb)	bpMRI and mpMRI. DCE analysis provided	Cloud	Healthcare professionals	To support health care professionals analyse prostate MRI scans to detect prostate cancer in people over 18 with suspicion of prostate cancer.	**Contraindications:** Paediatric patients, metallic implants affecting MRI quality, people who have had radical prostatectomy or excision of a large portion of the prostate, treatment that directly affects the radiological appearance of the prostatic tissue (e.g., chemotherapy, radiotherapy or brachytherapy in the prostate). Images captured using an endo-rectal coil or that contain artefacts and for whom the radiological interpretation is not possible.

5.1 The place of technologies in the care pathway

This assessment will consider AI technologies used to help detect prostate cancer from prostate MRI studies done for the first-line investigation of people with suspected clinically localised prostate cancer. These technologies would be used as an addition to the current standard of care, rather than as a replacement. All of the technologies included in the assessment are used after MRI acquisition. The qualified radiologist who reviews the MR images using the software makes the final reporting decision.

The evaluation will not consider the use of these technologies for screening in asymptomatic populations, or for active surveillance or monitoring recurrence after treatment.

5.2 Innovative aspects

The AI technologies included in this assessment are able to read prostate MR images, identify and classify abnormalities, and generate reports summarising findings. They may potentially help increase diagnostic accuracy, reduce time to diagnosis, standardise interpretation and reporting, and improve workflow efficiency and throughput.

6. Comparator

The comparator for this assessment is the standard of care, which is review of prostate MRI by a qualified radiologist without the assistance of AI technologies. The reference standard for test accuracy will be determined by the outcome from further investigations.

7. Patient issues and preferences

Waiting for a diagnosis (or for cancer to be ruled out) is likely to be a stressful time and can lead to anxiety and depression, due to the uncertainty of the situation and concerns about potential complications of future treatments and procedures. This could affect family or carers as well as the person awaiting diagnosis. Delays between referral, biopsy, and results may prolong anxiety.

This may be especially distressing in the case of ambiguous or borderline results from investigations.

Some individuals may be worried about overdiagnosis. Detecting slow growing prostate cancers that would never cause harm may still lead to unnecessary biopsies, repeat tests or treatments with lasting complications. On the other hand, some people may be worried about missing cancer or aggressive disease.

Many people feel especially nervous about undergoing a prostate biopsy. This may be due to the invasiveness and intimacy of the procedure, the potential for negative or inconclusive outcomes, and concerns about the severity and duration of complications. As a result, many individuals would prefer to avoid having a biopsy or repeat biopsies. Unpleasant prostate biopsy experiences can also deter people from having additional procedures.

Some people may have concerns about data privacy and security when AI is used to analyse images of their prostate, as well as transparency about how the data is used.

8. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

- People with cancer are protected under the Equality Act 2010 from the point of diagnosis. Some people with disabilities may be partially or completely ineligible for MRI. For example, certain medical devices are not MRI-compatible, including some cochlear implants used by people with hearing loss, and some pacemakers or implantable cardioverter defibrillators used by people with heart conditions.
- Prostate cancer mainly affects men over 50, and risk increases with age. The most common age for men to be diagnosed with prostate cancer is between 70 and 74 years (Prostate Cancer UK 2024).

- 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 (Prostate Cancer UK 2024).
- A person can have a prostate but not identify as a man. This includes trans women, non-binary people who were registered male at birth and some intersex people. Prostate cancer can affect trans women, as the prostate is usually not removed during gender-affirming surgery. The risk of developing prostate cancer may be lower in people who take testosterone blockers or anti-androgens, or who have had an orchidectomy, as these treatments reduce testosterone levels (Prostate Cancer UK 2025b).

Disability, sex, age, race and gender reassignment are protected characteristics under the Equality Act (2010).

Additional issues include:

- The risk of metastatic disease at diagnosis is higher in people from more deprived areas, but the risk of developing prostate cancer overall is lower (Dodkins et al 2025).
- Some rural or underserved areas may lack dedicated specialist uroradiologists, or have limited access to prostate MRI.

9. Guidance type

AI technologies to help detect prostate cancer on MRI will be assessed for early use. This approach to guidance development was chosen because:

- the assessed technologies have limited use in the NHS
- clinical experts have advised that robust prospective evidence to support the performance of these technologies in detecting prostate cancer across a range of UK-relevant clinical settings is currently limited
- the technologies have the potential to address a high unmet need in the NHS.

10. Decision problem

The key decision questions for this assessment are:

- Do AI technologies to help detect prostate cancer on MRI have the potential to be a clinically and cost-effective use of NHS resources?
- Are there gaps in the evidence base and what are the key gaps?

Table 1: Decision problem

Type of assessment	Early use
Population	People with suspected clinically localised prostate cancer, undergoing prostate MRI as first-line investigation for initial diagnosis (biopsy naive). Where data permits, the following subgroups may be considered: • People who have prostate bpMRI • People who have prostate mpMRI
Interventions	AI technologies to help detect prostate cancer on prostate MRI, including: • AI-Rad Companion Prostate MR • hProstate • mdprostate • Prostate Health (Quantib Prostate) • ProstatID • Prostate Intelligence (Pi) • QP-Prostate The technologies are used alongside healthcare professionals. The healthcare professional who reviews the MR images using the software makes the final reporting decision.
Comparator	• Review of prostate MRI by a qualified radiologist without the assistance of AI technologies. • Reference standard for test accuracy will be determined by the outcome.
Setting	Specialist centres, district general hospitals and community diagnostic centres.
Outcomes and costs (may include but are not limited to)	Intermediate outcomes: • Measures of diagnostic accuracy at patient and lesion level (clinically significant and clinically insignificant prostate cancer)

	• Accuracy for staging/ risk stratifying prostate cancer • Number of clinically significant prostate cancers detected or missed • Number of clinically insignificant prostate cancers detected • Cancer grade at diagnosis • MRI reading time • Radiology report turnaround time • Time to rule-out, diagnosis and initiation of treatment • Effect of radiologist's level of experience and technical expertise on diagnostic accuracy and reading/reporting time • Number of people having a biopsy or number of biopsy cores taken • Number of people who need repeat MRI • Impact of MRI image quality and scanner (e.g., field strength, age, vendor) • Technical failure rate • Proportion of people excluded for any reason (e.g., due to metallic implants) and reasons for exclusion Clinical outcomes: • Survival • Progression free survival • Adverse events from biopsies and managing prostate cancer Patient-reported outcomes: • Health-related quality of life • Service user and carer acceptability, views, experience and satisfaction Other • Service provider acceptability, views, experience and satisfaction Costs and resource use: • Cost of technology, including integration to PACS (e.g., one-off purchase costs, pay per use, annual subscriptions or site licenses and any additional software required) • Cost of data storage • Cost of training • Cost of biopsies (including any adverse events) • Costs of managing cancer (including any adverse events) • Staff time and cost at different specialisms and levels of pay

Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

11. Other issues for consideration

11.1 Potential implementation issues

The RCR recommends that AI technologies should integrate as seamlessly as possible in reporting (radiology information system [RIS] and PACS) workflows and be user friendly so as not to cause barriers to use (Royal College of Radiologists 2021). The GIRFT Radiology Report highlights that many departments currently struggle to meet minimum IT requirements for a modern radiology service. IT compatibility and capacity issues may be a potential barrier to the implementation of AI software in some NHS Trusts. The cost of implementation may vary between centres, depending on existing IT infrastructure.

Data security is essential when deploying AI technologies in prostate MRI, as they require access to patient data, introducing challenges around confidentiality, integrity, and governance. Consideration should be made to issues such as data ownership and custodianship, risks of re-identification of depersonalised data, unauthorised access and system vulnerabilities, and consent and data sharing. The location of data storage and processing (e.g., on-site or cloud-based), and the security measures employed, are key to these concerns.

Procurement and pricing structures may differ between the technologies, with different pricing options such as one-off payment or subscription models. Any additional bespoke company software may also be a potential barrier to

implementation and may increase the risk of vendor lock-in. Also, the availability (and potential cost) of software updates should be considered.

Some AI algorithms function as “black boxes”, producing outputs without providing a transparent explanation on how the decision was made. This lack of transparency can undermine confidence in their reliability and raises important issues around informed consent, accountability, and medico-legal liability (for example, in cases where an AI technology fails to detect cancer). According to experts, components such as risk scores and heat maps may be helpful for understanding AI outputs and are most useful when integrated into PACS.

11.2 Training and operator issues

Experts noted that there is a learning curve to using these technologies effectively. AI technologies may impact on training and lead to potential over-reliance on AI, which may erode clinical expertise.

11.3 Software updates and long-term monitoring

The technologies may have periodic updates and upgraded versions with new functionality may become available. These updates may have an impact on the technology’s performance. This means that evidence based on earlier versions of the software may not accurately reflect the effectiveness of the current versions. Evidence on older versions should be examined to see if it is relevant to the decision question.

Experts highlighted the importance of monitoring AI technologies after they have been deployed in real-world settings, to detect any performance drift that might arise from software updates, changes in MRI protocols or the emergence of bias in specific sub-populations due to overfitting on narrow or non-representative datasets. The RCR has published guidance on post-deployment monitoring and safety reporting of AI medical imaging devices in clinical practice.

11.4 Ongoing studies

The PARADIGM study, led by researchers at University College London, is a prospective, international, multicentre study designed to evaluate whether AI is non-inferior to radiologists in the diagnosis of clinically significant prostate cancer on MRI.

A single-centre study in the USA is currently recruiting participants to compare the interpretation of prostate MRI images in people with suspected prostate cancer by a radiologist alone, a radiologist aided by AI (AI-Rad Companion Prostate MR), and AI alone.

11.5 Generalisability issues

Generalisability issues with the use of AI technologies in prostate MRI may arise if the software has been developed and validated using data from populations in which particular groups have been underrepresented, such as:

- people from a Black African or Caribbean background
- people with family history of prostate cancer or higher risk due to genetic predisposition
- younger people (aged 40 or below)
- people with atypical anatomy, prior pelvic treatments, pelvic metalwork or conditions such as significant benign prostatic hyperplasia or prostatitis.

The technologies may perform differently in these groups than available data suggests. The generalisability of data used to train AI models should be considered.

NICE team

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Appendix C: Glossary

AI	Artificial intelligence
bpMRI	Biparametric MRI. An MRI study that incorporates T2-weighted and diffusion-weighted imaging but does not include dynamic contrast-enhanced (DCE) imaging.
CE	Conformité Européenne
CRUK	Cancer Research UK
DCE	Dynamic contrast-enhanced
DRE	Digital rectal examination
DICOM	Digital Imaging and Communications in Medicine.
FDS	Faster Diagnosis Standard
ICD	Implantable cardioverter defibrillator
MDT	Multidisciplinary team
mpMRI	Multiparametric MRI. An MRI study that incorporates anatomical and functional information about the prostate. The minimum functional information includes T2-weighted and diffusion-weighted imaging as well as administration of a contrast agent to acquire dynamic contrast-enhanced (DCE) imaging.
MR	Magnetic resonance
MRI	Magnetic resonance imaging
PACS	Picture archiving and communications system
Pi	Prostate Intelligence
PI-RADS	Prostate Imaging Reporting and Data System
PSA	Prostate-specific antigen
PSA density (PSAD)	PSA level divided by prostate size. Usually reported in nanogram/ml/ml
RCR	Royal College of Radiologists
RIS	Radiology information system
T	Tesla