Artificial Intelligence technologies to assist histopathology for prostate cancer diagnosis ID6684

Final Protocol

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Decision problem

People referred with suspected prostate cancer should receive multiparametric magnetic resonance imaging (mpMRI) within a defined timeframe in line with national guidance (NICE, 2026b). Where indicated, this is followed by a core needle biopsy generating digitised images of tissue samples, called whole slide images (WSIs) for review by a histopathologist (NHS England, 2024). However, demand for pathology services is increasing in volume and complexity, while the availability of trained histopathologists is declining (Royal College of Pathologists, 2025). This introduces potential risks to service sustainability, diagnostic timeliness, and patient safety.

The Royal College of Pathologists' position statement on the use of digital technology and of artificial intelligence (AI) recognises growing evidence and interest in the use of AI tools to support pathologists in diagnosis (Royal College of Pathologists, 2023). They highlighted the potential for AI-assisted approaches to transform working models within pathology services, potentially improving care pathways and clinical outcomes.

This assessment will address the decision problem set out in the NICE draft scope for the evaluation of AI technologies to assist histopathology for prostate cancer diagnosis. The purpose of the evaluation is to determine the clinical effectiveness and cost-effectiveness of AI technologies used alongside histopathologist review of digitised WSIs from prostate core needle biopsies, compared with histopathologist review without AI.

No deviations from the published scope are planned.

Table 1 summarises the decision problem to be addressed in this assessment. Further details on each element can be found in the published scope for the assessment.

Table 1. Summary table of the decision problem

Item	Description	EAG comments
Population(s)	Adults who have undergone a core needle biopsy for suspected prostate cancer and are awaiting initial diagnosis	As defined in the scope
Subgroups	People who have had treatment (i.e. chemotherapy, radiotherapy or androgen deprivation therapy) for a previous prostate cancer episode which was considered in remission	Subgroup analysis may be performed if data permits
Intervention(s)	AI technologies assisting histopathology review of digitised WSIs from prostate core biopsies	Technologies (8) to be considered are listed in the scope
Comparators	Histopathologist review of prostate biopsies without the use of AI	As per scope
Setting	NHS histopathology services for prostate cancer diagnosis	Digital pathology infrastructure is a prerequisite
Outcomes eligible for inclusion	Intermediate outcomes (diagnostic accuracy and workflow outcomes) Clinical outcomes Patient-reported and user-reported outcomes Resource use	Outcomes detailed in the scope
Economic analysis	Cost-utility analysis from an NHS and Personal Social Services perspective	

1.1 Objectives

The intended analysis is designed to address the NICE decision problem of whether AI technologies to assist histopathology diagnosis of prostate cancer are a clinically effective and cost-effective use of NHS resources, compared with standard histopathologist review without AI. The analysis will directly address issues highlighted in the final scope, including variability in diagnostic accuracy, pressures

on pathology service capacity, uncertainty regarding clinical and system-level impact, and gaps in the evidence base.

The objectives of this assessment are to:

- critically appraise and synthesise evidence on the clinical effectiveness of AI technologies for assisting histopathology diagnosis of prostate cancer, in line with the NICE scope
- assess the impact of these technologies on diagnostic accuracy, workflow efficiency, clinical outcomes, patient experience, and resource use
- evaluate the cost effectiveness of AI-assisted histopathology compared with standard histopathologist review of digitised WSIs without the use of AI, using decision-analytic modelling where appropriate
- identify key uncertainties in the evidence base to inform NICE committee decision-making

The assessment will address the following research questions:

1. In men undergoing histopathological assessment for suspected or confirmed prostate cancer, how does AI-assisted histopathology compare with standard histopathologist review of digital WSIs in terms of diagnostic accuracy and reliability?
2. What is the impact of AI-assisted histopathology on pathology workflow, reporting efficiency, and service capacity?
3. What evidence is available on clinical outcomes and patient experience associated with AI-assisted histopathology?
4. Is AI-assisted histopathology a cost-effective use of NHS resources compared with standard practice, when reading digital images, and how sensitive are results to key uncertainties?

5. What are the main gaps and uncertainties in the current evidence base relevant to NICE decision making?

2. Evidence review methods

This evidence review will follow NICE guidance for health technology evaluations (PMG36) (NICE, 2022). Project-specific methodological considerations are outlined below.

Inclusion criteria

Table 2 outlines the inclusion and exclusion criteria that will be used to determine the eligibility of relevant evidence.

Table 2. Inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Intervention	All AI technologies that assist histopathology review of digitised whole slide images (WSIs) for the initial diagnosis of prostate cancer and meet the following minimum criteria: ✓ they grade detected prostate cancer using the Gleason grading system, ✓ measure tumour length and the proportion of tumour per core, and ✓ either have appropriate regulatory approval and are available to the NHS or are in the process of obtaining approval. Relevant AI technologies include: • Aiforia Clinical Suite for Prostate Cancer (Aiforia) • AIRAProstate (AIRA Matrix Private Limited)	AI tools used for non-prostate indications, or used outside histopathology

	• Deep Dx Prostate (Deep Bio) • HALO Prostate AI (Indica Labs) • Ibex Prostate (formerly known as Galen Prostate) (Ibex Medical Analytics) • Mindpeak Prostate (Mindpeak GmbH) • Paige Prostate Suite (Tempus, formerly known as Paige.AI) • Qai prostate Grade (Qritive)	
Population	Adults who have undergone a core needle biopsy for suspected prostate cancer and are awaiting initial diagnosis	Studies not involving prostate biopsies.
Subgroups	People who have had treatment (i.e., chemotherapy, radiotherapy or androgen deprivation therapy) for a previous prostate cancer episode that was considered in remission.	
Comparators	Histopathologist review of prostate biopsies without the use of AI technologies. The reference standard for test accuracy will be determined by the evidence.	Comparators not relevant to current NHS practice.
Outcomes	Outcome measures for consideration include (as per scope): **Intermediate outcomes** (diagnostic accuracy and workflow outcomes): • diagnostic accuracy (sensitivity, specificity, positive and negative predictive values) • case review time / turnaround time (slide review time, number of cases reviewed per session, time to produce report for the	Outcomes not relevant to the decision problem.

	multidisciplinary team meeting [MDT]) • time to diagnosis (referral to diagnosis, biopsy to MDT) • time to initiate treatment (referral to diagnosis, referral to treatment, MDT to treatment) • concordance between AI and pathologist review • need for / use of additional tests (repeat biopsies / immunochemistry) • need for second pathologist read • effect of acquisition methods on accuracy • proportion of slides not appropriate for AI review and reason for it • adverse events or technical failure • feature-level accuracy • impact on clinical decision making **Clinical outcomes:** • grade of cancer at detection • overall survival • prostate cancer-specific mortality • metastasis-free survival, progression-free survival, distant disease-free survival • adverse effects of treatment, including undertreatment or overtreatment **Patient-reported outcomes:** • health-related quality of life	

	• service user and carer acceptability, views and experience **Other:** • user ease of use or user acceptability **Resource use:** • cost of technology, considering • procurement • implementation • ongoing running costs • IT set up • costs of updates • costs of data storage • cost of training • costs of second reads • costs of repeat interventions (e.g. scans, biopsies) • costs of additional tests (e.g. IHCs) • cost of managing cancer, related to missed cancers or overdiagnosis	
Setting	Histopathology services that use digitised WSIs for prostate cancer diagnosis	Non-healthcare or pre-clinical settings
Economic analysis	The NICE reference case stipulates that the cost-effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.	

	Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be considered. The availability of any managed access arrangement for the intervention will be taken into account.	
Study design	Comparative and non-comparative clinical studies; diagnostic accuracy studies; full economic evaluations	Case reports.
Other considerations	In line with the final scope, the following factors will also be considered: • Guidance will only be issued in accordance with the CE marking • Digital infrastructure supporting digital pathology • Technology validity for the population of interest • Workforce training for the safe and optimal use of AI technologies • Sustainability of using AI technologies in routine clinical practice • Acceptability of AI technologies • The potential impact of AI technologies on optimising treatment and reducing overtreatment.	
Equality considerations	No equality issues were identified. Equality considerations include: **Usability:** specifically, the accessibility and compatibility of technologies with assistive technologies for users with disabilities affecting vision or digital interaction should be considered.	

	Health inequality issues and equality considerations are reported in the equality and health inequality impact assessment.	

2.1 Search strategy

An Information Specialist will develop a sensitive literature search strategy to identify published peer-reviewed studies. The following sources will be considered:

- **major electronic databases** to identify relevant clinical and cost-effectiveness evidence will be searched, including MEDLINE, Embase, Cochrane Library, Web of Science, NHS Economic Evaluation Database, International HTA Database (INAHTA), Research Papers in Economics, EconLit, and the Cost-Effectiveness Analysis (CEA) registry
- search will focus initially on the **approved technologies** listed in the NICE final scope; search facets defining the population of interest and health care location will be included if required to limit a large amount of literature
- there will be **no restrictions on date or language of publication** at the time of the search
- **reference lists of studies** selected for full-text appraisal will be screened for additional studies
- **ongoing trials** will be identified through searching major clinical trial registries
- **websites** of manufacturers, professional organisations, regulatory bodies and HTA organisations will be searched to identify additional relevant reports
- **information sent from companies and other stakeholders** to NICE, as well as **relevant systematic reviews** identified by the search strategy, will be scrutinised to identify additional relevant studies.
- published and unpublished **studies provided by companies** and other stakeholders will also be considered and included if relevant to the decision problem
- any additional information on potentially relevant studies **provided by the manufacturers of the technologies of interest** will also be considered.

- relevant **clinical guidelines** from NICE, SIGN and INAHTA, particularly for economic modelling. Examples of Medline searches to identify relevant clinical and cost-effectiveness evidence are reported in Appendix 1.
- registry data and real-world evidence signposted by relevant stakeholders or companies, where relevant to the decision problem

All references will be exported to Endnote for recording and deduplication.
Titles and abstracts will be screened against the inclusion criteria. Full-text articles will be obtained for potentially relevant studies.

2.2 Study selection

Titles and abstracts will be screened against the inclusion criteria by a single reviewer, with a second reviewer independently screening a random 20% sample of citations. Full-text articles will be obtained for potentially relevant studies. Study prioritisation may be undertaken where the evidence base is large, focusing on studies most relevant to the NICE decision problem. Any disagreement between reviewers will be resolved by discussion or consultation with a third reviewer or the wider research team. Multiple publications of the same studies will be linked and considered together. For excluded studies, we will document reasons for exclusion. We will illustrate the study selection process using a PRISMA flow diagram. The web-based review management system, Covidence (2024, Melbourne, Australia; available at https://www.covidence.org), will be used to aid study selection and data management, if necessary. When there is a large amount of relevant evidence to present during the assessment stage, we will prioritise, for each technology, the studies or data considered most relevant to the decision problem, following NICE PMG36, particularly to the NHS.

For the review of cost-effectiveness evidence, we will focus on full economic evaluations defined as comparative analyses of costs and outcomes within the framework of cost-utility, cost-effectiveness, cost-benefit, or cost-minimisation analyses. Economic evaluations conducted alongside single effectiveness studies or decision analysis models will also be considered relevant for inclusion.

2.3 Data extraction strategy

Data will be extracted by one reviewer and checked by a second reviewer. We will extract information on study characteristics, population details, description of interventions and comparators (including information on the datasets used to inform AI algorithms), outcomes relevant to the scope, and parameters required for economic modelling. Key clinical and cost-effectiveness findings will be summarised in a tabular format and described narratively. In the case of a large evidence base, we will prioritise evidence according to the decision problem, and particularly to the NHS.

2.4 Quality assessment strategy

Methodological quality of included studies will be appraised in accordance with NICE critical appraisal guidance. Risk of bias in diagnostic accuracy studies will be assessed using QUADAS-2 criteria (Whiting et al., 2011). The reporting quality of economic evaluations will be assessed using the Consolidated Health Economic Evaluation Reporting (CHEERS-AI) checklist, (Elvidge et al., 2024) and the methodological quality of the analytic decision model will be assessed using the ECO-BIAS checklist (Adarkwah et al., 2016). Appraisal methods specific to other study designs will be detailed in the assessment report if such studies are identified.

2.5 Methods of synthesis and analysis

For the analysis of diagnostic test accuracy data, we will follow the recommendations of the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy and treat each technology separately (Deeks et al., 2013). Where studies directly compare AI-assisted histopathology with standard assessment without AI on the same or comparable cases, comparative diagnostic accuracy data will be extracted. For each included study, data will be extracted or derived as true positives (TP), false positives (FP), true negatives (TN), and false negatives (FN). Study-level sensitivity and specificity and positive and negative predictive values will be

calculated with 95% confidence intervals. If data are reported for multiple staging thresholds (e.g., based on Gleason scores), these will be reported separately.

Where sufficient data are available, differences in sensitivity and specificity between AI-assisted and standard assessment will be synthesised quantitatively using appropriate hierarchical methods; otherwise, findings will be summarised narratively.

For each specific technology, where studies are judged to be sufficiently clinically and methodologically comparable, pooled estimates of sensitivity and specificity will be generated using a bivariate random-effects model. This approach accounts for both the correlation between sensitivity and specificity and between-study heterogeneity. A hierarchical summary receiver operating characteristic (HSROC) model will be considered to account for variation in diagnostic thresholds. Where appropriate, the area under the curve (AUC) will also be reported. Forest plots of sensitivity and specificity, together with summary receiver operating characteristic plots, will be used to present the findings graphically.

Heterogeneity will be explored through visual inspection of forest plots and ROC space and through subgroup analysis and, where feasible, meta-regression. Separate analyses will be undertaken for different units of analysis, such as patient-level, rater-level and slide-level data, where appropriate. Sensitivity analyses will be conducted excluding studies judged to be at high risk of bias.

Studies reporting relevant data on clinical outcomes, intermediate outcomes or patient experience will be described narratively or synthesised using standard meta-analysis techniques where appropriate.

2.6 The use of supportive AI tools

AI tools such as Copilot (Microsoft, 2024) and Adobe Assistant (Adobe, 2024) will be used solely to support comprehension of complex technical reports, to verify manually extracted data, and to assist with editorial refinement. All analyses, interpretations, and conclusions will be undertaken by the authors. Potential risks associated with the use of AI tools include misinterpretation or oversimplification of technical material, inaccurate or incomplete data extraction, and inappropriate

influence on the interpretation of findings. To mitigate these risks, all use of AI tools will be subject to full human oversight. Reviewers will retain responsibility for study selection, data extraction, and quality assessment; interpretation of the evidence; drafting and approval of all outputs; and the formulation of final decisions and conclusions.

3. Economic analysis methods

The economic evaluation will follow the NICE reference case (NICE, 2022), adopting an NHS and Personal Social Services perspective on costs and expressing outcomes as quality-adjusted life year (QALYs). Costs and benefits will be captured over a lifetime horizon, applying standard discount rates. A decision-analytic model will be developed based on a focused review of models used to support NICE guidance on diagnostic technologies for prostate cancer. The tentative expectation is that the model will be adapted from the economic model developed to support NICE Clinical Guideline NG131 (NICE, 2019b), ensuring methodological continuity while incorporating the specific mechanisms and impacts of AI-assisted histopathology.

3.1 Model development

The model will simulate the diagnostic and treatment pathway for prostate cancer, comparing AI-assisted histopathology with standard pathologist reporting of digitised WSIs. It is anticipated that the diagnostic and disease progression modelling framework used in NG131 will serve as the foundation, with adaptations to incorporate AI impacts on detection rates, pathology grading accuracy, and workflow. A decision tree component will capture the initial diagnostic pathway and outcomes, while long-term disease progression and survival will be represented through a Markov state-transition model.

The model will explicitly simulate the incidence and progression of undiagnosed prostate cancer, using disease states for low-, intermediate- and high-risk localised disease, and further states for progression to metastases. Thus, it will be able to capture survival and quality of life benefits and associated cost-savings if AI

improves diagnostic sensitivity. Conversely, the impacts of any changes to specificity will be modelled through the expected costs and consequences of false positive results. The potential adverse impact of overdiagnosis and overtreatment may be implicitly captured in the model through the cost and utility impact of adverse events associated with treatment that does not prevent progression or extend life in the context of the competing risk of background mortality.

3.2 Model Parameterisation

Model parameterisation will draw on evidence identified through the systematic review supplemented by targeted searches of decision-analytic models used in relevant NICE prostate cancer evaluations, relevant clinical literature, national cost datasets, and elicitation of expert opinion where necessary. Parameters will be defined in accordance with the NICE reference case and with methodological continuity to previous economic models developed to support NICE Guidance on prostate cancer diagnosis and treatment. (NICE, 2019a, NICE, 2023b, NICE, 2023a).

Diagnostic Accuracy Parameters

Diagnostic accuracy inputs (sensitivity and specificity by risk group if applicable) will be derived from the systematic review of studies comparing AI-assisted histopathology with standard reporting. Where possible, pooled estimates will be generated to inform technology-specific inputs for the decision tree component of the model. These inputs will determine the probability of correct and incorrect classification at biopsy, influencing the proportion of cancers detected and the downstream costs and consequences of false negatives, false positives, and misclassification. These diagnostic inputs will form the foundation of the short-term diagnostic module of the model and determine the initial state distribution for the Markov model.

Transition Probabilities for the Markov Model

Transition probabilities governing disease progression and survival will be sourced primarily from previous NICE-supported decision models, including those underpinning NG131 and other related technology appraisals. (NICE, 2019a, NICE, 2023b). These established models represent the natural history of prostate cancer

in a way that is consistent with UK clinical practice. Where updated or more granular evidence is required, supplementary clinical literature, such as long-term cohort studies and trial follow-up data, will be used. Transition probabilities will be associated with appropriate uncertainty distributions for probabilistic sensitivity analysis.

Cost Parameters

Costs included in the model will cover the full diagnostic and treatment pathway and will reflect NHS and Personal Social Services resource use. Cost categories will include:

- Diagnostic costs, covering both standard and AI-enhanced pathology workflows, including biopsy handling, AI processing costs, staff time, and system-level workflow impacts.
- Treatment costs, stratified by cancer risk group and stage, and management strategy (e.g., active surveillance, radical prostatectomy, radiotherapy, systemic therapies for advanced disease).
- Monitoring and follow-up costs, including PSA testing, outpatient consultations, and imaging.
- End-of-life care costs for prostate cancer-related mortality, including palliative care.

The resource use inputs and assumptions required to inform these costs will be identified and validated through a targeted review of previous economic models used in prostate cancer decision-making, ensuring methodological consistency and completeness. Unit costs will be sourced from national datasets such as the NHS National Cost Collection, (NHS England, 2025) PSSRU Unit Costs of Health and Social Care, (Jones et al., 2025) and the British National Formulary (BNF). (NICE, 2026a).

Workflow and AI-Specific cost Impacts

AI-specific parameters will be drawn, where possible, from the systematic review of diagnostic accuracy studies. These may include changes in reporting time, case throughput, reductions in double reading, and redistribution of pathology workforce

effort. This will be supplemented with targeted reviews of published implementation studies and technology assessments, and/or expert elicitation where necessary. Impacts on the need for follow-on tests and subsequent repeat biopsies will also be modelled where evidence supports this. Resource impacts and workload savings will be valued using the NHS costs incurred for relevant staff grades and incorporated as diagnostic-stage cost parameters. Potential cost categories associated with AI implementation include those listed in Table 3.

Table 3 Potential cost impacts associated with AI adoption

Cost Category	Description	Examples / Notes
AI Acquisition costs	Costs to obtain AI systems	Licensing fees; subscriptions
System integration and IT Infrastructure	Integration with digital pathology systems	LIS/LIMS links; network upgrades
Implementation	Costs of adoption	Staff training and ongoing support
Operational costs	Routine per-case AI use costs	Processing fees; maintenance and updates; storage requirements
Workforce and workflow impacts	Changes in pathologist time and throughput	Reduced reporting time; changed roles; reduced need for subsequent tests
Governance and compliance	Regulatory and monitoring costs	QA and monitoring; cybersecurity processes

Notes: IT, Information technology; LIS, laboratory information system; LIMS, laboratory information management system; QA, quality assurance.

Health State Utilities

Health state utility values will be assigned to each prostate cancer health state in the model. Utilities will be derived from focused literature reviews, prioritising sources and studies aligned with the NICE reference case, using validated instruments such as the EQ-5D, with valuations using UK general population preference-based tariffs. Where necessary, disutilities for biopsy- and treatment-related adverse effects (e.g., infections, urinary, bowel, and sexual dysfunction) will also be included.

3.3 Analysis and Reporting of Results

For each technology, the base-case analysis will estimate incremental costs, QALYs, and the ICER for AI-assisted histopathology review versus unassisted histopathologist review of digitised WSIs. Where appropriate, full incremental analyses will also be presented. Probabilistic sensitivity analysis will be used to

characterise parameter uncertainty, with results presented using cost-effectiveness scatterplots and acceptability curves. Deterministic sensitivity and scenario analyses will explore key drivers of cost-effectiveness, such as AI cost, diagnostic accuracy, workflow effects, and disease prevalence. Reporting of results will follow CHEERS-AI reporting standards (Elvidge et al., 2024).

3.4 Gap analysis

The development, parameterisation, and analysis of the economic model will provide insight into the robustness of the available evidence underpinning the required structural assumptions and parameter inputs. This assessment will inform a narrative synthesis of the key strengths and limitations of the current evidence base for NICE decision-making. Evidence gaps that would benefit from further research will also be identified. Where appropriate, value-of-information analyses may be undertaken to help prioritise areas for future research.

4. Handling information from the companies and other stakeholders

All data submitted by the companies in evidence and information requests by NICE, or data submitted by other stakeholders, will be considered by the EAG if received by **31/05/2026**. Information arriving after this date will not be considered. If the data included in the information provided meets the inclusion criteria for the review, they will be extracted and quality assessed following the procedures outlined in this protocol. The EAG may seek clarification or additional information from companies and other stakeholders where necessary. All correspondence between the EAG and companies will happen through NICE.

Any ‘commercial in confidence’ data provided by a company and specified as such will be highlighted in blue and underlined in the assessment report. Any ‘academic in confidence’ data provided by a company, and specified as such, will be highlighted in yellow and underlined in the assessment report. If confidential information is included in the economic model, the EAG will provide a copy of the model with ‘dummy variable values’ for the confidential values (using non-confidential values).

5. Competing interests of authors

The authors have no competing interests to disclose.

6. References

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Appendix A: Draft search strategy

1. Prostate/ or prostat*.ti,kw.

2. exp Prostatic Neoplasms/

3. (prostat* adj4 (neoplas* or cancer* or carcinoma* or adenocarcinom* or tumo?r* or malignan* or metasta*)).tw,kf.

4. or/1-3

5. exp Biopsy/ or biops*.tw,kf.

6. (whole* adj2 slide*).tw,kf.

7. ((histolog* or histopatholog* or patholog*) adj3 imag*).tw,kf.

8. ((digital or digiti?e* or virtual) adj3 (patholog* or histolog* or histopatholog* or slide*)).tw,kf.

9. (automat* adj3 detect*).tw,kf.

10. or/5-9

11. Artificial Intelligence/

12. ((artificial or machine or computer or augment*) adj2 intelligen*).tw,kf.

13. exp Machine Learning/

14. ((machine or transfer or deep or hierarch* or computer) adj2 learn*).tw,kf.

15. Neural Networks, Computer/

16. ((neural or convolut*) adj2 network*).tw,kf.

17. Diagnosis, Computer-Assisted/

18. Image Interpretation, Computer-Assisted/

19. ((computer or machine or AI) adj2 (aid* or assist* or support*)).tw,kf.

20. or/11-19

21. 4 and 10 and 20

22. (aiforia or aira or "cells-IA" or "deep bio" or optrascan or paige or tempus or indica or ibex or qritive or virasoft).af.

23. 21 and 22