Technoleg Iechyd Cymru
Health Technology Wales

# Health Technology Wales (HTW) Guidance 057
# May 2024

## Artificial Intelligence (AI) assisted review of prostate biopsies in the detection and diagnosis of prostate cancer

**HTW Guidance:**

There is insufficient evidence to support the routine adoption of AI-assisted review of prostate biopsies in the detection and diagnosis of prostate cancer.

There is currently limited peer-reviewed evidence on the effectiveness of AI technologies, but that which is available is promising and shows the potential for AI technologies to support pathologists in diagnosing prostate cancer.

Further research is recommended to understand the clinical and cost-effectiveness of the AI systems, as well as their impact on real-world clinical practice. In particular, Health Technology Wales would support the analysis of data from the ongoing pilot project using an AI system for prostate cancer diagnosis in NHS Wales.

## Why did Health Technology Wales (HTW) appraise this topic?

Prostate cancer is the most common cancer in men in the UK, affecting around 2,000 men in Wales each year. Confirmation of the diagnosis involves blood tests, scans and the assessment of biopsy tissue by a pathologist, either under the microscope or using digital review. Artificial Intelligence (AI) technologies have been developed to assist in this assessment, with the aim of improving diagnostic accuracy and reducing case review time. The AI can highlight areas of abnormality to the pathologist and can help assess the Gleason Grade of the biopsy to determine the extent and aggressiveness of the cancer. This information assists in the selection of different treatments.

The topic was submitted to HTW by a company producing AI technology.

**The status of HTW guidance is that NHS Wales should adopt this guidance or justify why it has not been followed. HTW will evaluate the impact of its guidance.**

## Evidence summary

Refer to Evidence Appraisal Report 057 (EAR057) for a full report of the evidence supporting this Guidance.

The review aimed to summarise the published evidence on the clinical and cost effectiveness of the use of AI technologies to assist pathologists in the review of prostate biopsies.

HTW identified one NICE Medtech Innovation Briefing (MIB280), eight primary studies, three ongoing studies and one unpublished report reviewing AI-assisted review of prostate biopsies (AIPB). The technologies identified were Galen Prostate, Paige Prostate, and Deep Dx, all of which are CE marked. Paige Prostate has been used in three NHS Trusts in England in collaboration with the University of Oxford, after being awarded funding from the NHSx AI Health and Care Awards, and Galen Prostate has been introduced across Wales as part of the Welsh Governments Innovation Fund, supported by the Small Business Research Initiative (SBRI) Centre of Excellence. All identified studies compared pathologist review of prostate biopsy slides alone, to AI-assisted review by a pathologist. HTW also performed a meta-analysis using data from four of the studies.

Overall, AI was found to numerically improve the sensitivity of diagnosis, without impacting negatively on specificity, indicating there was a reduction in false negatives with no increase in false positives. There was a slight improvement in inter-observer concordance, indicating pathologists generally agreed on the diagnosis and grading both with and without AI, but the AI did help to improve this numerically. There was high diagnostic intra-observer concordance, meaning pathologists tended to distinguish between cancer and benign tissue well, both with and without AI. Intra-observer grade group concordance was slightly lower, indicating grading can be difficult to determine consistently, even with the use of AI. With the use of AI, there was a reduction in case review time per-slide, per-case and for overall case turnaround time, suggesting AI can result in more efficient biopsy review. There was also a reduction in the ordering of additional tests such as immunohistochemistry, and requests for second review by pathologists with the use of AI.

Experts who reviewed EAR057 noted that AI technologies require integration with local computer and information management systems as well as the support of several teams locally. They also noted that there could be variation in use of the AI due to the level of confidence in using the technology, and the extent to which the AI is used as a first-read, second-read, or concurrent read system.

HTW didn't identify any economic evidence on the AI-assisted review of prostate biopsy. A new economic analysis was developed to estimate the cost-effectiveness of the use of AI technologies with pathologist review as compared to pathologist review alone. The model replicated the cost-effectiveness model built by NICE for Guidance NG131 for the diagnosis and management of prostate cancer, however it was adapted to include an initial decision tree featuring relevant review methods of prostate biopsies. The results of the analysis show that using AI-assistance is expected to increase costs by £207 per patient and provide additional 0.02 quality adjusted life years (QALYs) compared to pathologist review alone. This translates into an incremental cost-effectiveness ratio of £13,278 per QALY, which is below the cost-effectiveness threshold of £20,000 per QALY, and so using AI-assistance is deemed a potentially cost-effective strategy. Results of the probabilistic sensitivity analysis suggest that using AI-assistance has a 69% probability of being cost effective.

The appropriate mechanism for patient engagement was determined and the patient perspective was considered where possible. There were two articles identified which reviewed AIPB, and a patient focus group was hosted by Velindre Cancer Centre to discuss the use of AI in healthcare. The outcomes of this focus group indicated that most patients expected to be

informed when AI would be used, but this should not be too detailed. Patients expected practitioners to retain ultimate responsibility in any final decisions but were hopeful that the introduction of AI would result in quicker and more accurate diagnoses.

## Appraisal Panel considerations

- The Appraisal Panel heard from experts that AI systems will never replace pathologists since they are intended only to provide assistance. However, it was noted that if the technology reduces the time taken for pathologists to review slides, then this could help in reducing the backlog of urgent cases that have been increasing since the COVID-19 pandemic. Experts noted that the AI systems can reduce the intensity of the mental effort required, allowing pathologists to concentrate on reviewing slides for longer periods of time.
- The Appraisal Panel discussed the ongoing pilot of the Galen Prostate system in Wales, which has funding confirmed for another 12 months. They heard from experts involved in the pilot that the technology has been successfully integrated into hospital IT systems. Experts noted that AI systems have standardised forms for the pathology report which aids integration with other systems, such as cancer informatics systems. However, challenges have been encountered in terms of storage of the images, and this is currently being investigated by the NHS executive.
- The Appraisal Panel heard from experts that the Wales pilot has shown that AI assistance has improved the confidence of pathologists and aids in the grading of cancer. Experts suggested that this could ease workload burden and aid in the retention of highly valuable pathologists.
- The Appraisal Panel considered the evidence on the clinical effectiveness of AI-assisted review of prostate biopsy and agreed that is currently limited. It was noted that most of the current evidence base includes studies that were undertaken retrospectively rather than prospectively, limiting the strength of the conclusions that can be drawn. Furthermore, while the evidence suggests numerical improvements in diagnostic accuracy using AI-assistance, the impact of the technology on clinical outcomes, case review times and the number of re-biopsies required, is less certain.
- The Appraisal Panel noted the findings of the meta-analysis conducted by the HTW team, which showed that the diagnostic accuracy of the systems was similar when including and excluding non-peer reviewed data. As such, the value of further evidence may be to confirm the validity of that currently available evidence on diagnostic accuracy as well as aid in developing comparative data on other clinical outcomes.
- The Appraisal Panel queried whether existing studies had been conducted only on slides that were of good quality, and whether a real-world scenario could have differing results using AI-assistance. Experts confirmed that it is the scanning process that would particularly need to be of good quality, rather than the slides themselves.
- The Appraisal Panel considered the results of the economic analysis undertaken by HTW and agreed that AI-assisted prostate biopsy pathologist review has the potential to be cost-effective compared to pathologist review alone. However, concerns were expressed about the impact and implications of limited peer-reviewed clinical evidence on the economic analysis. The HTW health economist confirmed that when using evidence from the Paige Prostate systems alone, where evidence is strongest, the system still proved to be cost-effective.
- Experts highlighted that even a small additional cost per-patient can prove difficult to fund at a national level. However, it was noted that implementation costs are relatively low in Wales

due to the presence of a single laboratory information management system, resulting in a less complex AI set-up. The integration costs of the Galen Prostate system in Wales have already been covered as part of the pilot project.

- The Appraisal Panel expressed concerns that the level of evidence is not currently sufficient to support the routine adoption of AI systems to aid in the diagnosis of prostate cancer, whilst acknowledging that this is often the case with newer technologies. However, the Panel were supportive of the accumulation of further evidence in the field and acknowledged that the direction of the current evidence is promising and encouraging.
- It was noted by the Appraisal Panel that further prospective studies are currently on-going nationally and that the manufacturers appear eager to conduct further research. Given the ongoing pilot study in Wales, the panel recommend that data from this project be gathered to provide valuable 'real-world' data and experience.

## Responsibilities for consideration of this Guidance

Health Technology Wales (HTW) was established by Ministerial recommendation[1,2] to support a strategic, national approach to the identification, appraisal and adoption of non-medicine health technologies into health and care settings. The HTW Appraisal Panel comprises senior representation from all Welsh boards with delegated authority to produce guidance 'from NHS Wales, for NHS Wales'. The status of HTW guidance is 'adopt or justify'. There is an expectation from Welsh Government that HTW guidance is implemented with adoption regularly audited by HTW.[3]

The guidance in this document is intended to assist Welsh care system decision makers to make evidence-informed decisions when determining the place of health technologies and thereby improve the quality of care services.

The content of this HTW guidance was based upon the evidence and factors available at the time of publication. An international evidence base was reviewed and external topic experts and HTW committee members consulted to contextualise available evidence to Wales. Readers are asked to consider the generalisability of the evidence reviewed to NHS Wales and that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. It is acknowledged that evidence constitutes only one of the sources needed for decision making and planning.

This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

No part of this guidance may be used without the whole of the guidance being quoted in full. This guidance represents the view of HTW at the date noted. HTW guidance is not routinely updated. It may, however, be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the guidance given.

Standard operating procedures outlining HTW's evidence review methods and framework for producing its guidance are available from the HTW website.

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Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by HTW's Assessment Group. However, reviewers had no role in authorship or editorial control and the views expressed are those of Health Technology Wales.

Chair, Health Technology Wales Appraisal Panel

1. National Assembly for Wales, Health and Social Care Committee. Access to medical technologies in Wales. December 2014.
2. Response to Recommendations from the Health & Social Care Committee: Inquiry into Access to Medical Technologies in Wales. February 2015.
3. Gething, V. Letter to all Health Board Chairs re Funding for Sacral Nerve Stimulation in Wales. VG_01655_17. September 2017.