The Royal College of Pathologists
Pathology: the science behind the cure

Scanning whole slide images with the Ibex Galen AI breast algorithm

Trials on the Ibex Galen AI algorithm are reporting encouraging results.

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Dr David Bailey reports on his Trust's experience with trialling the Ibex Galen AI breast algorithm. Despite Dr Bailey's early reservations around the use of digital pathology and AI, the trial demonstrated undeniable benefits to workload and performance.

Introduction

Northwest Anglia NHS Foundation Trust (NWAFT) serves a population of 850,000 and was formed in 2017 by the merger of Peterborough and Stamford Hospitals and Hinchingbrooke Hospital NHS Trusts. Peterborough City Hospital (PCH) is a district general hospital with around 600 beds, and provides cellular pathology services to the combined Trust. After activity returned to normal post-COVID-19, our workload increased to its current peak of 40,000 histology and 3,000 non-cervical cytology samples. Coronial autopsy numbers reached 1,200 by 2025, servicing Cambridgeshire and south Lincolnshire.

When I arrived at PCH in 2016, the laboratory was staffed by 4 substantive and 2 locum consultants, and 1 trainee. By 2018, these numbers had changed to 4 consultants and 2 trainees, and we struggled to recruit replacements for retirements and the loss of locums.

Digital pathology

During 2015, I was a fairly vocal 'anti-digitalist' and a strong advocate for the retention of glass slides and microscopes that hadn't changed much in over 400 years. The quality of digital images and the speed of software and internet connections were insufficient to convince me that digital

pathology could be as quick as we needed in the context of our excessive workload.

By 2018, however, technology had improved rapidly to the point where the potential benefits were undeniable. Recruitment had also improved. We found ourselves in a position to seriously consider going digital. We piggybacked onto a regional business case and in 2019 were awarded Cancer Alliance funding, which allowed us to purchase the Philips digital pathology system.

During the COVID-19 lockdown in March 2020, our surgical workload reduced to around 25% of normal. Pathologists became medical examiners to free up junior doctors' time, and autopsy activity increased. Then, at the end of April, Philips delivered our digital hardware and software. We took the opportunity to validate the system and went live with digital reporting for all approved samples (excluding screening pathology at that time) in September 2020, just as surgery returned to normal.

Many laboratories struggled to convince pathologists to transition to digital; in Peterborough, there were no such problems. Our excellent and forward-thinking team was very enthusiastic about its introduction, which directly resulted in the recruitment of new consultants and convinced several pathologists not to retire as soon as they might otherwise have done. In keeping with most published data, we are 10–15% faster on digital than glass, in spite of early problems with scanner reliability. We also use the technology to report remotely.

Artificial intelligence

It is no great surprise, therefore, that we embraced the advent of AI algorithms. The Ibex team contacted us in 2023 to ask if we'd be interested in running local validations of their Galen breast and prostate biopsy algorithms. The software was intuitive and easy to use. We negotiated a 3-year licence for the prostate algorithm, which was already in clinical use in multiple centres, by November 2023. In subsequent months, our prostate biopsy turnaround time, previously floundering at over 30 days, improved to 7 days and the outpatient waiting list reduced rapidly.

The breast algorithm had already been clinically validated in Europe and Israel but was only used in the UK in Wales at that time. Ibex planned a large validation study (the DEBORAH trial) to assess its clinical use in the NHS, and NWAFT was invited and agreed to participate. Following a successful bid to the National Institute for Health and Care Research (NIHR) for funding, the trial commenced in July 2024.

The DEBORAH trial of the Ibex Galen breast algorithm

Features of the algorithm

Galen algorithms pre-scan whole slide images and provide separate heat maps for different features. The filters for each feature can be selected from a menu beside the slide image. Pressing the space bar alternately adds and removes the heat map. The AI searches for both malignant and benign features, e.g. in situ or invasive carcinoma, or fibrocystic change. Red heat maps indicate a high level of confidence that the feature is present; green indicates a high level of confidence that it is not, with amber showing an indeterminate result. The filters also have a 'bull's-eye' button that shows the area with the highest level of confidence that the specific feature is present.

Galen breast also shows whether microcalcification or lymphovascular invasion is present – this is where most time savings are realised. The pathologist reviews the whole slide but can focus in on highlighted areas of concern, providing further timesaving. Unlike the prostate algorithm, the breast version does not currently automate tumour grading, but it does highlight different tumour types.

Clinical trial phases

The trial was undertaken by 5 centres (NWAFT, Cambridge, Birmingham, Nottingham and Betsi Cadwaladr) and included 2 phases. Pre-trial practice at NWAFT included double reporting of all breast biopsies including an initial H&E slide review, ordering of immunostains as necessary, and a second review once these were received.

Phase 1 lasted 3 months, with the AI providing a second read: a pathologist examined the digital images, formulated a report and then compared findings against the AI. There was no human second read unless there was disagreement with the AI opinion.

Phase 2 lasted 9 months, during which time the AI performed a first read and ordered ancillary tests, including receptors or myoepithelial markers, according to a pre-defined scheme. The AI didn't assess the ancillary stains; these were passed to the pathologist with the H&E slide so they could assess the case in 1 pass (unless additional stains were required).

AI governance

Governance arrangements for disagreements between AI and pathologist were implemented. If opinions conflicted, the case was arbitrated by 1 or more additional local pathologists; if consensus could not be reached, an external specialist opinion was sought. Very few cases required arbitration.

Over the whole trial, the AI reviewed 9,143 biopsies. The subsequent health economics data and patient feedback (including patient views on the ethics of using AI in the diagnostic process) are being analysed before submission for publication.

Performance impact

Table 1: Performance of the Ibex Galen algorithm.

Feature	Sensitivity	Specificity	PPV	NPV
Benign vs malignant	100%	99.6%	99.4%	100%
Invasive carcinoma	99.7%	99.7%	99.4%	99.9%
Ductal carincoma in-situ	96.8%	99.9%	99.0%	99.9%

Turnaround time at NWAFT remained static at 6 days; however, this was despite a 16% increase in workload over the course of the trial, with 1,429 biopsies being examined.

Locally, we saw a 79% decrease in the use of immunostaining for benign biopsies, an overall 11% reduction in immunostaining and a £12,000 reduction in processing and reporting costs for all cases (reduced by £9.51 per patient).

Following phase 2 completion, I worked with Ibex to increase the sophistication of the immuno pre-ordering scheme; during the trial, 25% of biopsies needed additional immunostains after the AI's initial output. That number has reduced to <5% following post-trial modifications.

We subsequently introduced a similar scheme for prostate biopsies. Having previously performed immunostaining on all cases, selective pre-ordering by the AI has resulted in a 75% reduction, saving over £50,000 per annum.

Conclusions

As a result of implementing digital pathology and 2 sample-specific AI algorithms, we manage our workload with 80% of the RCPath-recommended level of consultant staffing, with additional Cancer Alliance-funded overtime and a dedicated team of laboratory and administrative staff.

The 2025 RCPath workforce census found that 97% of histopathology laboratories report insufficient staff to meet current workload and clinical needs. As chair of the Histopathology College Advisory Training Team and subsequently as Director of Training in the early 2010s, I lobbied to increase training posts at every opportunity, but without success. Despite training numbers being increased recently, NHS England insisted on only providing the standard 50% of salary. Many local Trusts are disinclined to fund the shortfall, resulting in potential posts remaining fallow. A suggestion that the number of new posts could be halved to allow full central funding of each was rejected. In the absence of any significant upturn in trainee and consultant numbers, technology such as AI becomes even more essential to help bridge the gap.

We must work to reduce the time taken to develop new algorithms and approve them for clinical use. Investment can be extremely difficult to source, but the digital and diagnostics capability funding streams available to pathology networks should provide most laboratories with the opportunity to engage with new models of working in the coming years.

There are philosophical, ethical and regulatory aspects to the use of artificial intelligence. So far, these are insufficiently addressed to allow its ubiquitous use in the diagnostic pathway. The DEBORAH trial included a public and patient involvement arm – it will be interesting to see their feedback.

Getting It Right First Time is about to start looking into the use of autonomous AI in cellular pathology; most of the technology is nowhere near ready for this step and can only be used as a decision support tool. Given the speed of change, however, this is unlikely to be the case for long.

Complications aside, having digital pathology and AI available makes work at NWAFT more enjoyable; nobody likes it when the scanners or the link to the AI servers go down. Although I regularly use a microscope for cytology, I miss the technology when it's not available.

Meet the author

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