

The Leeds Guide to Digital Pathology Volume 2

Building a National Digital Pathology Network

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The background of the image is split into two vertical panels. The left panel shows a pink-stained histological section of tissue, likely showing glandular structures. The right panel shows a blue-toned image of a complex electronic circuit board with various traces and components.

NPIC





INTRODUCTION

It's hard to believe how the world has transformed in the three years since the team first published "The Leeds Guide to Digital Pathology" in 2018. The COVID-19 pandemic forced everyone, including the pathology community to rise to new challenges. The flexibility and resilience offered by digital pathology have never seemed more important if we want to future-proof our diagnostic services and ensure we can continue to deliver a high-quality histopathology service in a timely manner. At Leeds, we were fortunate to have completed our initial scanner deployment of Aperio AT2 scanners, from Leica Biosystems, before the pandemic, enabling our pathologists to share images with socially distanced colleagues and trainees in the department, and with clinical colleagues in the "virtual" multidisciplinary team setting. Our laboratory team, in particular, displayed resilience and ingenuity throughout a difficult year, and managed to deploy a new suite of Aperio GT 450 DX scanners in the laboratory with minimal disruption!

In our last volume of "The Leeds Guide to Digital Pathology", we shared insights from our single site deployment. We have a fully subspecialised diagnostic department of 45 consultant cellular/histopathologists, and generate more than 290,000 H&E stained slides per annum. We are committed to improving patient pathways and patient outcomes in our region and beyond. The first step was transitioning to 100% digital scanning of departmental glass slides in November of 2018, when we held a landmark celebration for the department – but our vision for digital pathology has evolved a great deal since then!

The Leeds Digital Pathology team successfully bid to become one of five UK Research and Innovation Centres of Excellence in digital imaging and artificial intelligence (AI), and formed the National Pathology Imaging Co-operative (NPIC).

This ambitious and innovative project has a number of arms including:

- Sharing our knowledge across the North of England and expanding of our clinical diagnostic digital pathology network to digitize the histopathology laboratories at 15 separate NHS hospitals, employing 238 pathologists and providing services for 6 million people living in the North of England. This major deployment will utilise 48 scanners, feeding an estimated 2.4 million images a year to a single vendor neutral archive.
- The formation of two national digital pathology subspecialty hub and spoke networks for paediatric tumours and soft tissue and bone pathology, with fully digitised laboratory hubs at Great Ormond Street Hospital, London and the Royal National Orthopaedic Hospital, Stanmore.
- The creation of a new National Centre for Digital Pathology Education and Training, furnished with state of the art audio-visual facilities, lecture space, training workstations, and a multi-vendor scanning facility.

Our project may have expanded, and we have adopted a new name (NPIC), but our mission remains the same – to develop best practise guidance in digital pathology and AI to share with other organisations, and to champion evidence-based medicine whilst focussing on patient safety and professional standards.

We hope you will find Volume II of the Leeds Guide a useful and interesting resource – we still have a lot of stories, learning points and challenges we want to share!

*Dr Bethany Williams MBBS PhD
Lead for Digital Pathology Training
and Validation, NPIC*

*Dr Darren Treanor, Consultant Pathologist
and Honorary Clinical Associate Professor
Leeds Teaching Hospitals NHS Trust*

CHAPTER 1

The foundation of quality digital diagnosis lies in the laboratory, where biomedical staff work exceptionally hard, often under challenging time constraints.





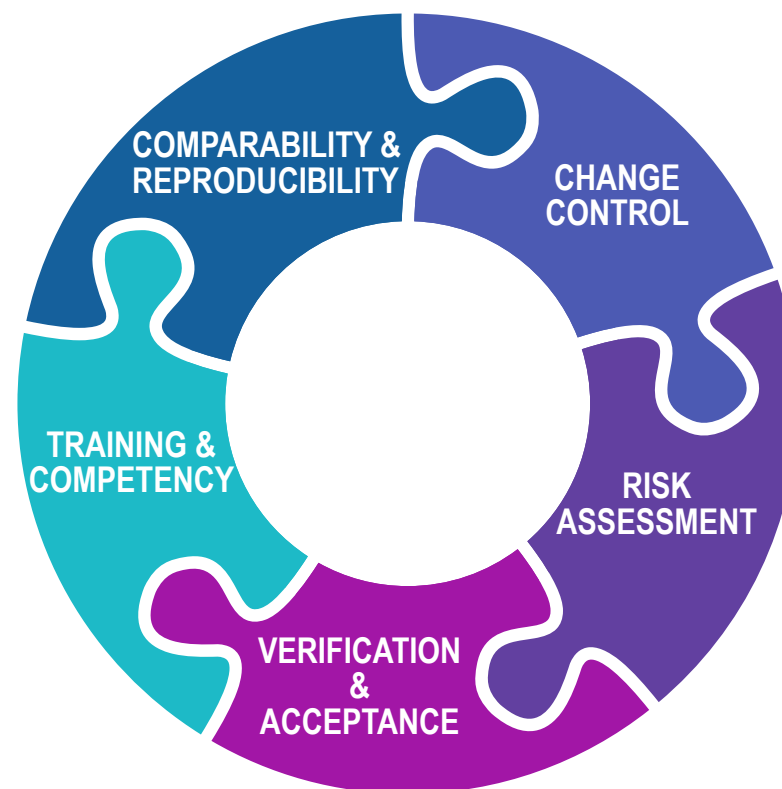
CHAPTER 1 – MAINTAINING QUALITY IN THE LABORATORY

ISO accreditation for digital pathology diagnostic services

The foundation of quality digital diagnosis lies in the laboratory, where biomedical staff work exceptionally hard, often under challenging time constraints. In this section, we will explore some of the key areas pertinent to quality and safety of laboratory digital pathology services, and find out how digitisation has impacted on the laboratory and its staff over the last five years.

Digital pathology deployment in the clinical laboratory represents a massive change management project. Clinical digital pathology is still a relatively novel field, and the deployment and integration of a digital pathology system represents a major departure from standard laboratory operating procedures. In light of this it is important to ensure that laboratory staff can be confident that service quality is at least maintained, or better still, improved. One of the key benchmarks of laboratory quality is ISO-15189 accreditation. At Leeds, we were very proud to pass our first digital pathology UKAS (United Kingdom Accreditation Service) inspection in 2018. We took time to develop protocols and procedures that encompass the examination of hardware and software, calibration of tools and devices, and the training and competence of staff. It was a mammoth task, and we had to assemble much of the evidence base from scratch, and create brand new processes and procedures.

You can find out more about this topic in our publication, “Maintaining Quality Diagnosis with Digital Pathology”, but here is a summary of some of the key points to consider to ensure adequate preparation for an ISO inspection.





Key tips

1. Be prepared! Careful planning in the earliest stages of your deployment can help lay the groundwork for successful inspection and accreditation. Identify key personnel who will be instrumental in delivering core aspects of the accreditation procedure, and compiling necessary evidence.
2. Develop and adhere to a full change control procedure. This should include evidence surrounding the digital deployment proposal, health and safety assessments, validation and verification of equipment, external and internal quality assurance processes, IT user acceptance testing, standard operating procedures and training protocols.
3. Conduct a full health and safety scoping exercise and assessment, considering the equipment, environment and workflows.
4. Provide evidence that scanners and software have been adequately tested for their intended use, and are working in accordance with the manufacturer stated parameters. A simple way to do this, is run internal tests against the manufacturer's installation and verification checklist from when the equipment was initially installed.
5. Demonstrate comparability and reproducibility of images produced by multiple scanners in your deployment by regularly assessing diagnostic quality of a standard set of test slides across your scanners.
6. Produce clear standard operating procedures for all parts of the digital pathology process, alongside training materials and competency checklists for relevant staff.
7. Demonstrate the accuracy of measurements taken using your clinical system using a calibration slide with predefined values, that can assess whether scanned objects are captured to scale. This can be supplemented with an audit of clinically relevant measurements taken by pathologists' using glass and digital versions of the same slide.
8. Ensure you have a standard operating procedures detailing digital slide reporting and validation, and keep accurate records of staff training and validation in this area.
9. Remember that accreditation is an ongoing process, and your digital pathology service must be monitored and improved continuously.



Quality assurance

The key steps to quality assurance of scanned slides are relatively simple, and reinforce existing glass slide quality assurance processes:

Tips for achieving diagnostic quality slides

- Thin sections are important – 3µm is ideal for image capture.
- Sections should be free of folds, creases and bubbles.
- Tissue should be placed centrally, within the scannable margins of the glass slide.
- Slides should be free from overhanging/broken coverslips and excess mountant, all of which can result in damage to the scanner.
- Slides should be clean and dry prior to scanning.
- Ensure scanners are appropriately calibrated and maintained.

Scanners require regular cleaning to prevent build-up of dust and debris both inside the mechanism and on the external casing, which can affect image quality. Fans and vents also require careful cleaning scanners, and machines should be serviced regularly in accordance with vendor guidance. Tasks can be broken down into weekly, monthly and annually depending on the frequency they need to be done.

Daily (Recommended)	<ul style="list-style-type: none"> • Restart the scanner and console (PC) if present • Clean the touchscreen
Weekly	<ul style="list-style-type: none"> • Clean the scanner cover and light source • Clean the slide trays and carousel/loader
Every Six Months	<ul style="list-style-type: none"> • Clean the objective and Koehler • Clear the slide stage tray • Clean the fan filter
When Required	<ul style="list-style-type: none"> • Light Source bulb replacement
Once a year	<ul style="list-style-type: none"> • Schedule annual maintenance visit by vendor

Example of maintenance tasks required and frequency

Calibration should be performed once all weekly maintenance tasks have been completed. Specific settings on the scanners should be checked and calibrated to ensure the scan areas are still accurate, that cameras remain in focus, and that images are to scale.



Quality control in the laboratory

Laboratory quality control is an important step in the histopathology process as it checks that digital slides being signed out of the laboratory are of adequate diagnostic quality.

At digital QC the lab are checking for:

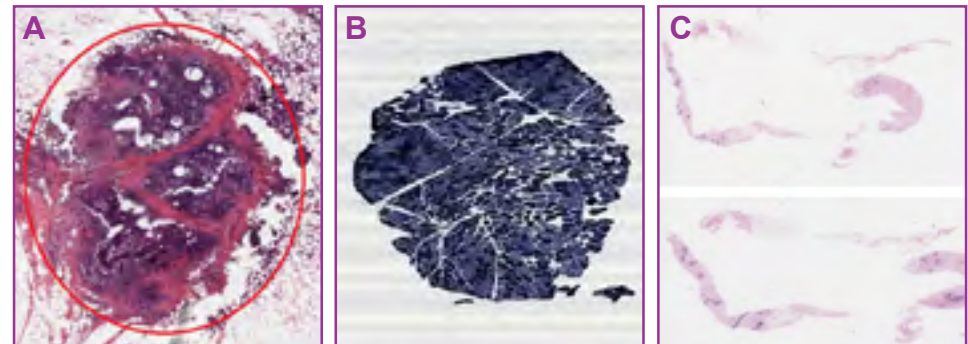
- overall image quality
- gross or focal loss of focus and the reason for this
- are there areas of the image out of focus, and the reason
- areas of missing tissue
- digital artefacts e.g. stitching

The laboratory technicians will also make sure the case has the correct number of images, and patient demographics. Any issues with image quality or the case in general should be dealt with before sending the completed case to the pathologist.

The quality assurance processes listed above should minimise the occurrence of these problems, but quality control processes can help pinpoint issues with individual scanners or scans so these can be addressed.

Using digital images for the full laboratory quality control pathways

Some laboratories check their glass slides for section and staining quality using standard light microscopy before they are sent to pathologists. There is potential for digital image checks to replace this step in the process. Scanners generate a full-slide overview of the slide, which can be compared to the initial tissue block, replacing the physical block and slide check. Recent implementation at Leeds has improved the efficiency of this vital quality control step.



*Examples of slides with quality issues. A) Focal loss of focus
B) Striping artefact C) Missed tissue on scanned image*



Interlaboratory comparisons

As more and more laboratories move towards digital pathology, interlaboratory schemes will become easier to establish. Interlaboratory schemes enable laboratories to compare how their scanners are performing against other laboratories in the network/area. This ensures an element of standardisation across digital pathology in terms of image production and image quality.

Laboratory staffing and training

Ensuring staff are adequately trained and supported to use digital pathology systems safely and confidently is paramount. A two-pronged approach incorporating vendor and local training encapsulate all aspects of digital pathology training for laboratory staff:

Vendor training	Departmental training
Scanner and software operation	Standard operating procedures
Maintenance and calibration	Workflows and processes
Trouble shooting	Reflects competency frameworks for specific roles
Vendor support procedures	

There is potential for digital pathology to assist in tissue recognition courses for biomedical scientists as part of their specialist training. The accessibility of images and the use of shared computers can facilitate this.





PERSONAL PERSPECTIVE
Sarah Caton



“We’ve seen a lot of change in the laboratory since 2015, evolving from a single scanner installation to running a full clinical service, scanning 100% of our glass slides. We’ve implemented next generation scanners – four Aperio GT 450 DX scanners, which have changed the way we work. We have observed an 85% improvement in scanning efficiency compared with our previous scanners, and we have been able to incorporate digital pathology into other workflows including our autosectioner.

One thing I would emphasize, is how important it is to try and keep everyone in the laboratory engaged and involved amidst all the change. There are a lot of people working in the laboratory that have different skill sets and confidence levels with technology, so finding a balance for training and support was challenging. We wanted to make sure everyone was comfortable using digital pathology, but not alienating laboratory staff from the scanners at the same time by overloading them with information and training tasks. Attitudes to digital pathology have also changed amongst laboratory staff. They have discovered that the scanners are easy to use, and the manual steps involved with the scanning workflow have been significantly reduced. This means biomedical scientists have more time to engage in quality control and quality assurance processes elsewhere in the laboratory. They really enjoy creating and checking digital images – it allows biomedical scientists to reconnect with and admire the histology they produce!

Integration and testing are so important to make sure all parties are getting the right information they need. Although we tested everything we could, there were still some issues during go live that we couldn’t predict. Just ensure that you have the right people available during go live that can assist with these issues, in particular, in IT to troubleshoot any issues, as soon as possible.

Making digital pathology part of “business as usual” was one of our key goals when we first deployed a scanner in the laboratory, and it’s great to see it being used routinely as part of the patient pathway. Digital pathology deployment can be one of the most challenging things a lab can go through. There are so many moving parts to it, and it takes a lot of time and effort, but the benefits and the potential digital pathology has for the future of biomedical scientists are worth it!!”

*Sarah Caton
Cellular Pathology Service Manager,
Leeds Teaching Hospitals NHS Trust*

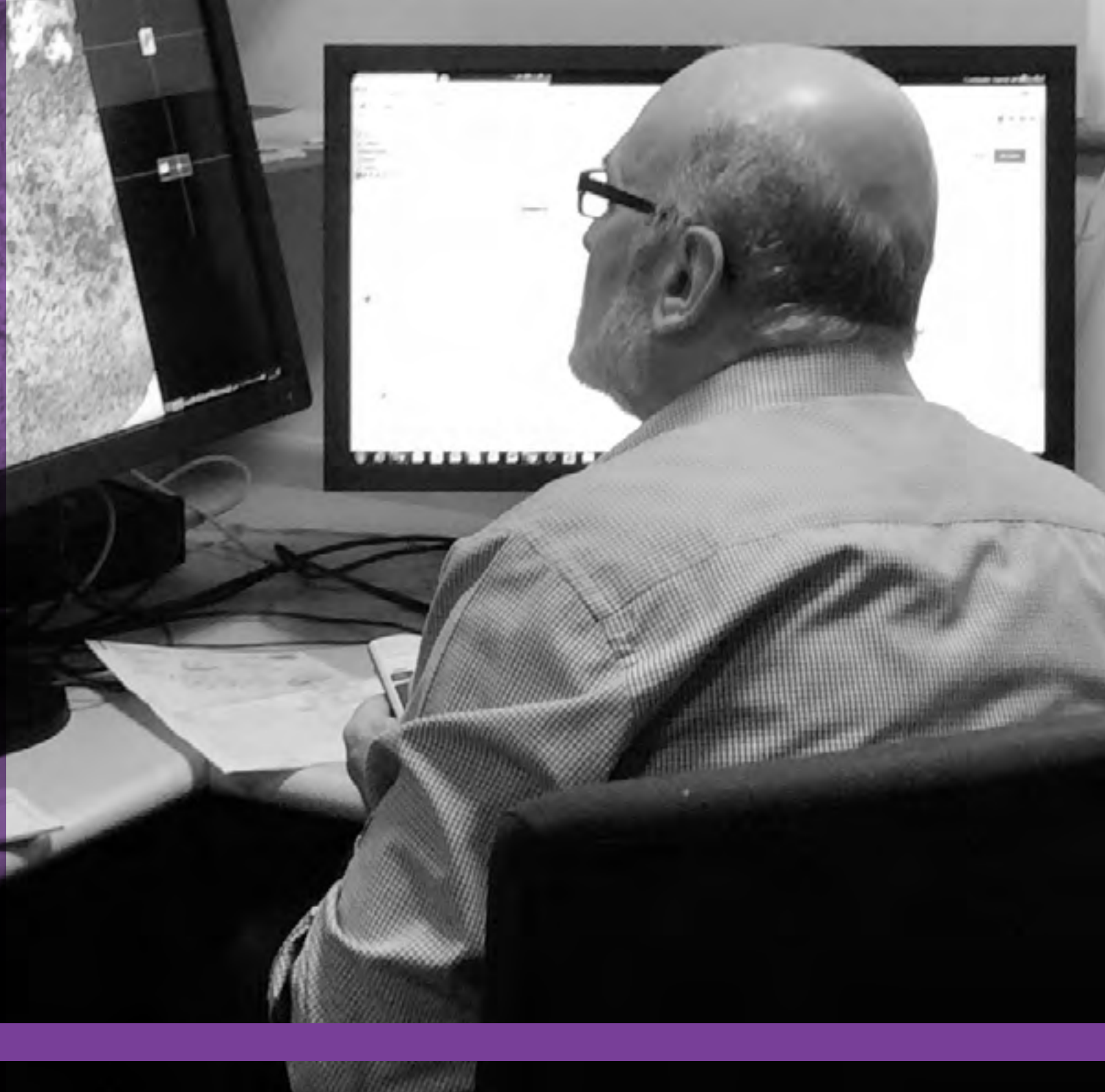


CHAPTER 2

“Digital pathology has improved my turn around time for diagnosis by at least 30 seconds for each slide.

It's very easy and quick to navigate between areas in the same slide and between slides in a case, saving me time and effort navigating through large and complex cases.”

*Dr Azzam Ismail
Consultant Neuropathologist
Leeds Teaching Hospitals NHS Trust*





CHAPTER 2 – DIAGNOSTIC DIGITAL PATHOLOGY: CLINICAL USE

St James University Hospital, Leeds, UK, is a major NHS cancer centre serving a population of 3 million patients, with a fully subspecialised diagnostic histopathology department. We've been integrating digital pathology into our standard clinical workflows over the past 5 years. 100% of histology slides are scanned in the laboratory, and accessible by our consultant and trainee pathologists on medical grade diagnostic workstations.

Our first subspecialties to convert to digital microscopy for primary diagnosis were breast and neuropathology, but they were soon joined by colleagues reporting hepatobiliary, gynaecological, renal and cardiothoracic pathology. Our pathologists have reported a wealth of benefits, including faster reporting of large, multi-slide cases, more efficient “delivery” and transfer of cases between the laboratory and colleague, and less frustration over misplaced or damaged cases.

The COVID-19 pandemic put the pathology service under additional strain and stress, but the use of digital slides allowed our team to continue working through the pandemic. Easy, contact-free sharing of slides for second opinion or case discussion was a great bonus, as was the ability to screen share and train junior pathologists remotely. The benefits of digital pathology weren't just appreciated by members of the pathology team though.

“The ability to view patients' digital breast cancer histology during multi-disciplinary team meetings (tumour boards) has been of massive benefit to the surgical team. Having crucial features such as surgical margins displayed and presented on the big screen helps with clinico-pathological correlation, and aids our decision making. It's also a great educational opportunity for our surgical trainees, who are often unfamiliar with the histological appearance of different tumour types, and how this relates to their clinical presentation.”

*Mr Baek Kim, Consultant Breast Oncoplastic Surgeon
St James's University Hospital, Leeds*





Digital Neuropathology

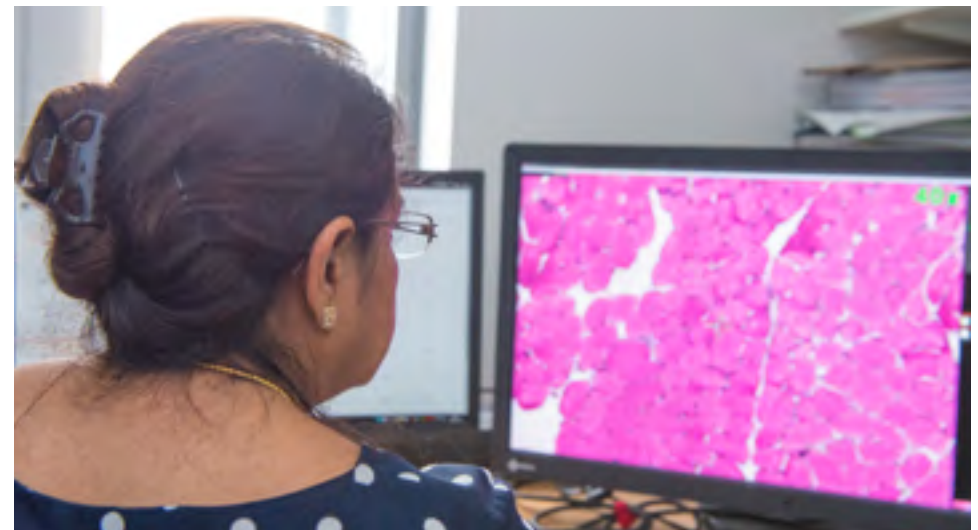
Leeds Teaching Hospitals NHS Trust provides neuropathology and ophthalmic digital pathology in neuropathology services to the West Yorkshire region, encompassing a population of 2.2 million, and includes multidisciplinary team meetings (tumour boards) for adult, young adult and paediatric central nervous system (CNS) tumours, and adult and paediatric neurology. 2 neuropathologists work on site to deliver this crucial diagnostic service.

Neuropathology is a highly subspecialized area of pathological diagnosis, and includes the diagnosis of brain tumours and rare muscle diseases. Only 70 consultants are in this line of work in the UK, and as such, this field is particularly vulnerable with many single or double handed services covering wide geographical areas. A large proportion of CNS tumours, especially in the paediatric population are rare, therefore allowing no one centre to develop reasonable experience and expertise in these unusual entities.

Pathologists need to be able to view and share cases efficiently, which can be difficult using conventional glass slides, which must be transported from the laboratory to the pathologist, between pathologists, and between hospital sites. Given the relatively small number of specialist neuropathologists, these staff may need to be able to work more flexibly in the future. Again, opportunities for collaboration are limited by the physical glass slide medium.

“In addition to clinical diagnosis, I use the digital pathology system for several MDTs, teaching and research. At MDTs, surgeons find it very useful and informative when we are able to zoom in from a brain slice or a large anatomical structure to demonstrate single cell pathology. Equally, whilst teaching junior histopathologists and researchers, the ability to move around the slide with ease and correlate pathological features with adjacent or background normal tissue structures enhances the understanding of pathology tremendously.”

*Dr Aruna Chakrabarty, Consultant Neuropathologist
Leeds Teaching Hospitals NHS Trust*





The digital neuropathology service at Leeds was one of our first pilots in 2018, the success of which has led to a full, 100% digital transformation of the histopathology output at Leeds Teaching Hospitals NHS Trust, covering all specialties and cancer pathways. In 2018, we devised training and validation materials to allow our 2 neuropathologists to learn how to use digital pathology for primary diagnosis and frozen section diagnosis. Since then, our neuropathologists have made all primary diagnoses on digital slides as standard, performed all MDTMs using digital slides, and started to trial remote reporting of digital neuropathology slides whilst working from home. The use of digital slides has resulted in multiple benefits for the neuropathology service:

- Greater efficiency assessing large, multi-slide cases
- Streamlined delivery of diagnostic slides from the laboratory to the reporting pathologist, without loss or damage
- More efficient preparation of cases for multi-disciplinary team meetings (MDTMs)
- More secure, convenient MDTMs, negating the need for physical transport of glass slides between hospital sites
- Easy sharing of cases for second opinion
- Enhanced training and educational opportunities for trainee pathologists
- Increased flexibility of reporting time and location including ability to work from home

“Digital pathology has enormous benefits for surgeons. It enables professional development so we can keep updated in an accessible way as changes are made to pathology classification systems and new technologic advancements. It also offers excellent research possibilities in machine learning/artificial intelligence and real-time intraoperative histological diagnostics.”

Mr Ryan Mathew, Associate Professor and Honorary Consultant Neurosurgeon, University of Leeds and Teaching Hospitals NHS Trust





Validation and Training

In Volume 1, we discussed the training and validation programme for digital pathology which we developed, and was adopted by the Royal College of Pathologists as an example of best practice in digital implementation (summarised below.)

Training phase

Formalized training in use of the digital pathology system

- Safe and efficient use of hardware and software
- Clinical workflow

Validation 1 (V1) Training Set

Training set of up to 20 challenging and informative cases, reflecting the workload of the individual pathologist

Cases are viewed on digital, the pathologist records their assessment, then immediately reviews the glass slides, to allow for direct comparison of digital and glass case representation.

This process allows the pathologist to identify areas of difficulty which can be training targets in the live phase of validation.

Validation 2 (V2) Live reporting

All live diagnoses made on digital slides, with glass slide checks before sign out. All discrepancies documented and reviewed.

The pathologist should view a suitable breadth and depth of cases – average time 2 months, but this can vary depending on the comfort of the pathologist.

Review and sign off

Overall concordance rates between glass and digital diagnosis throughout the validation period are reviewed.

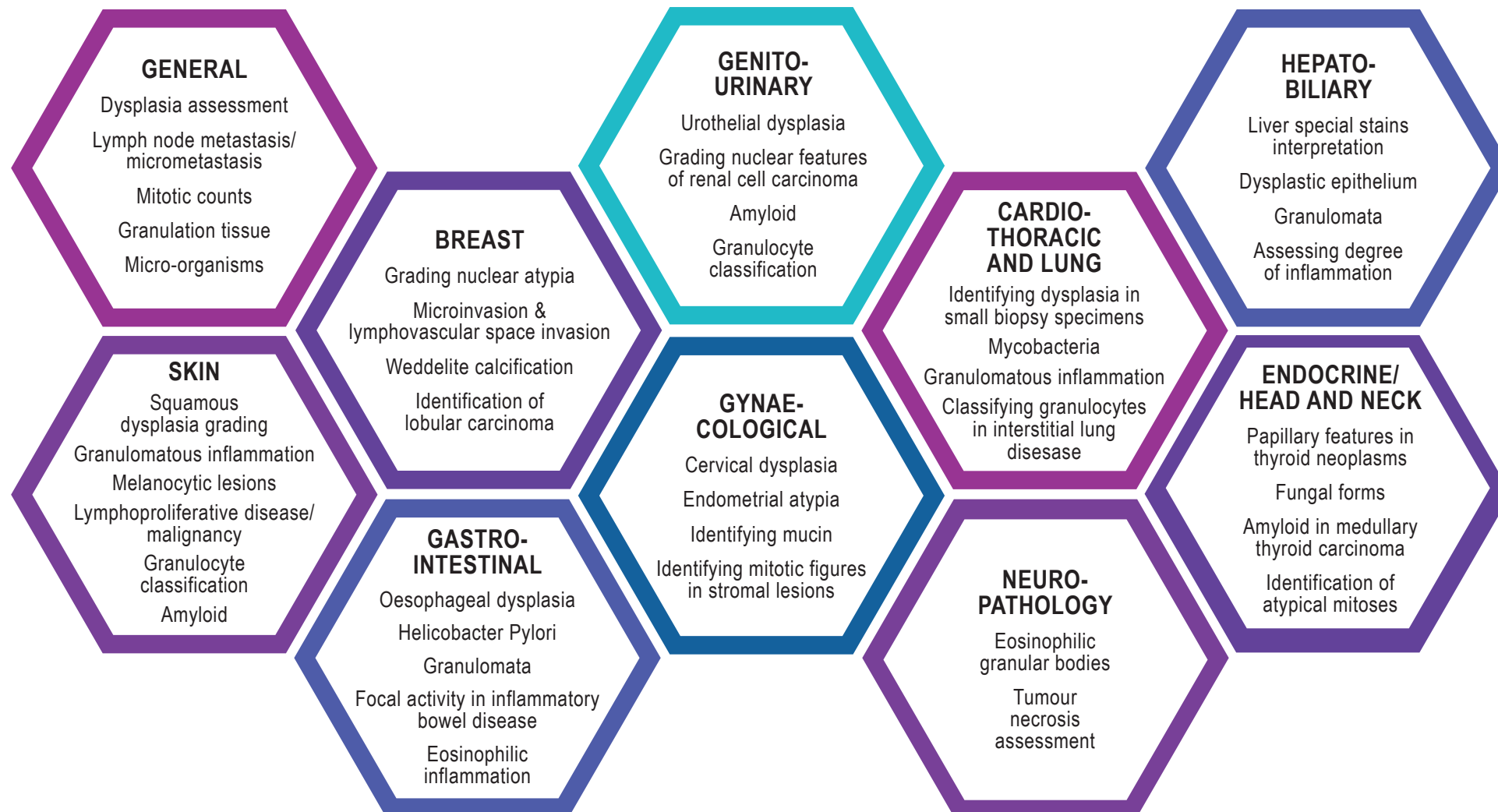
The pathologist defines the scope of their future digital reporting. Any areas they still find challenging on digital should be out of scope, and continue to have glass slide checks. The need for these safety checks can be reviewed over time as the pathologist gains confidence post validation.

The pathologist's validation procedure is certified, and they can make digital primary diagnosis within the defined scope.

The validation process is designed for the individual pathologist – we have noticed that pathologists differ greatly in their attitudes to and comfort with technology, and their attitudes to change and risk. Pathologists should proceed through the validation stages at a pace that suits their individual needs and allows them to develop their skills and confidence comfortably. Utilising this protocol, and our extensive research on the topic of digital versus glass slide diagnosis, we have been able to identify key training targets for different topographies. These entities are all present on the digital slide, but it can take a while for pathologists to become confident in their assessment. On completing their validation procedure, our pathologists are able to make 95-99% of their diagnosis digitally, and this proportion increases with time and experience post validation. We may still have our light microscopes in our rooms, but they are becoming an under-utilised resource!



Potential Pitfalls



Chapter 2

Diagnostic Digital Pathology: Clinical Use

Chapter 1

Maintaining Quality in the Laboratory

Chapter 3

Home Reporting

Chapter 4

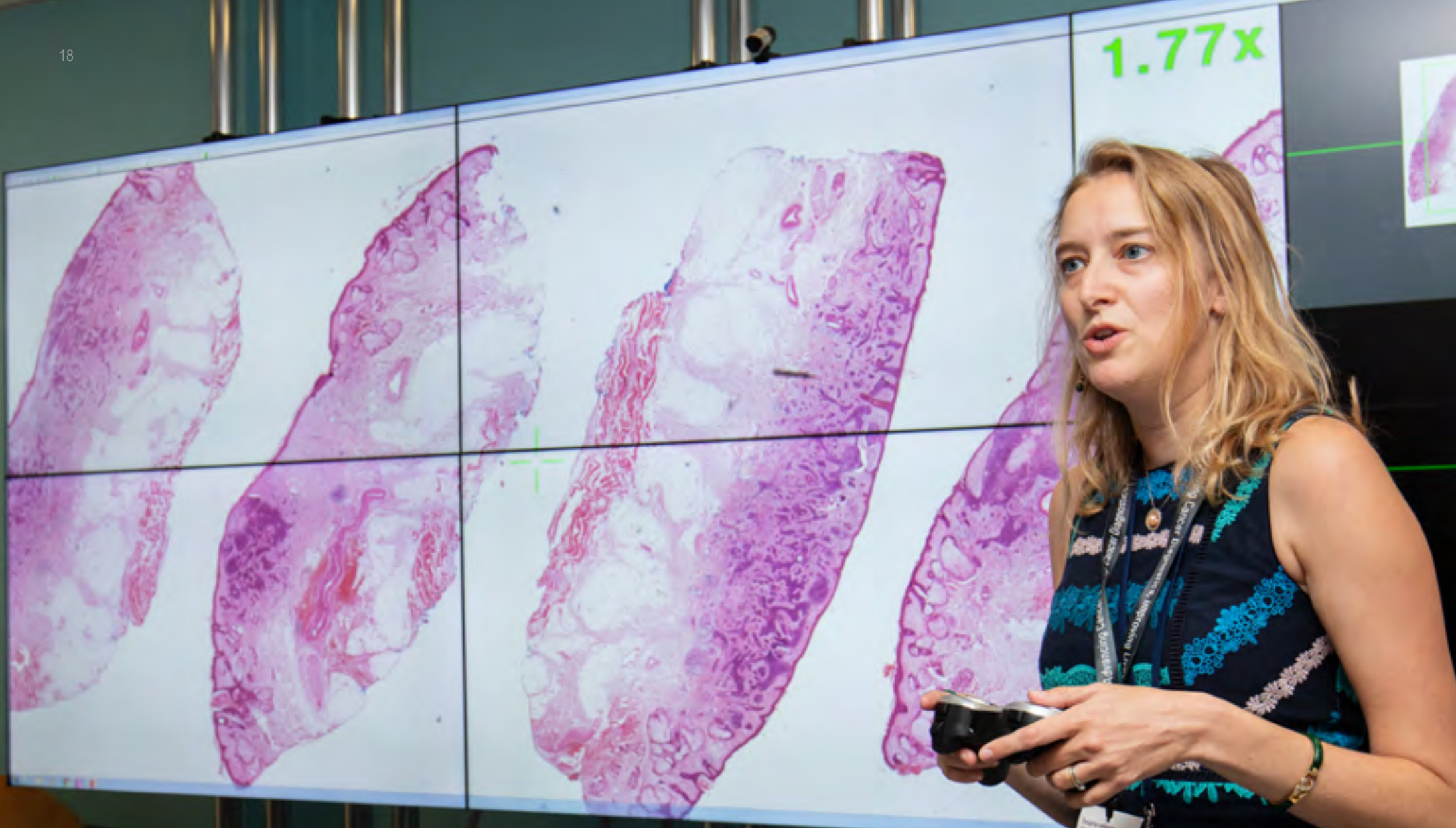
Multisite Digital Pathology Deployment

Chapter 5

Artificial Intelligence

Chapter 6

Patient & Public Involvement & Engagement



PERSONAL PERSPECTIVE
Dr Bethany Williams



“ Writing content for this 2nd volume of the Leeds/NPIC guide to digital pathology has provided a fascinating opportunity to look back on how much the field has progressed since the first instalment! Part of my job involves engaging with pathology professionals across the world, offering advice and disseminating best practise in clinical digital pathology. Five years ago, I would attend a general pathology conference, and have to focus on justifying the need or desire for digitisation of pathology services – there is no need to make that case anymore. Instead of asking “why they should go digital”, pathology departments are asking “how they can start” the process of digitisation! The first volume of The Leeds Guide to Digital Pathology was designed to answer some of the basic questions that need to be addressed when planning a digital deployment. We wanted to share very practical advice that could act as a foundation for other departments to start planning and implementing their own digital pathology services. I am thrilled we are now able to present a second volume to update the world on our project, and share insights into more complex and topical aspects of digital pathology deployment.

Throughout the pandemic, digital pathology has helped our teams stay connected through challenging times, enabling us to continue to deliver quality diagnosis, training and research. Trainee pathologists have been able to screen share digital cases with senior staff for socially distanced, safe, real-time educational feedback. Colleagues have been able to collaborate on difficult cases, and even provide opinions from remote locations or the home environment whilst they have been shielding or isolating. The flexibility of the digital slide has the potential to revolutionise not just the process of clinical diagnosis, but the way entire services are delivered – we really do have the opportunity to redesign the way in which pathologists and departments work. The next big step is seeing how we can incorporate more complex image analysis and AI into standard workflows to improve quality and efficiency of diagnosis. Exciting times are on the horizon!”

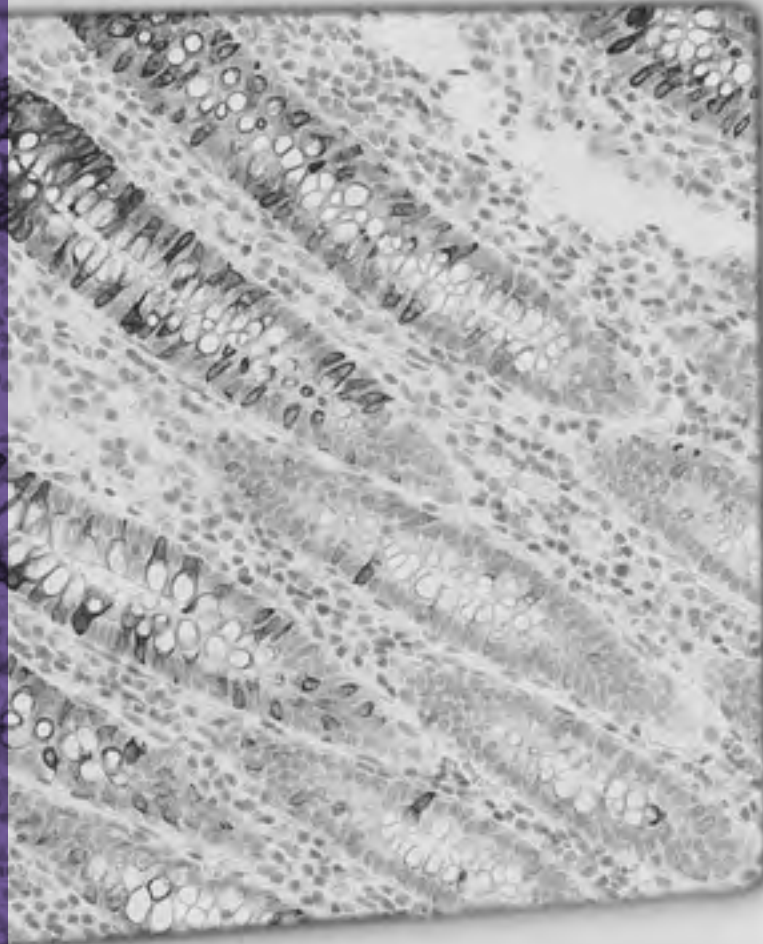
*Dr Bethany Williams, MBBS PhD
Lead for Digital Pathology Training
and Validation, NPIC*



CHAPTER 3

The idea of flexible remote or home reporting of slides has been an attractive proposition for many pathology departments.

Individual pathologists get the opportunity to balance their work and home commitments.



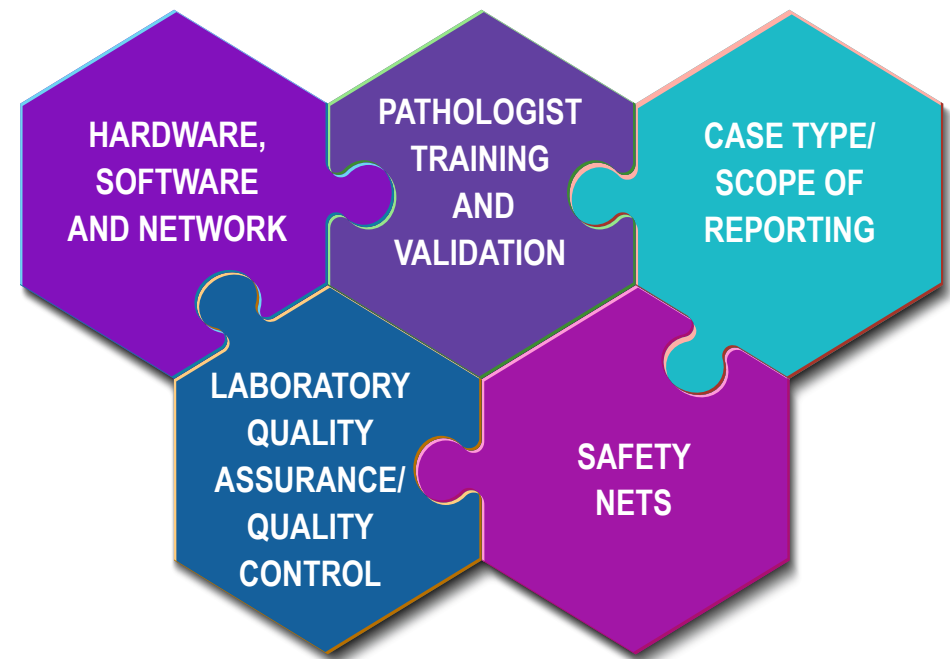


CHAPTER 3 – HOME REPORTING

The global pandemic put pathology departments through unprecedented levels of strain and uncertainty. Team members were required to shield or self-isolate for periods of time, and workload levels fluctuated. The situation prompted many departments to investigate opportunities for home reporting of slides, either glass or digital. Beyond utilisation at times of extreme service pressure, the idea of flexible remote or home reporting of slides has been an attractive proposition for many pathology departments. Individual pathologists get the opportunity to balance their work and home commitments, the needs of those who work less than full time, have medical conditions or carer responsibilities can be supported, and pathologists can be recruited more easily to hard to fill posts in geographically remote or unappealing locations.

Evaluating and balancing risks is a routine part of a pathologist's job – deciding when to get a second opinion or order further work from the laboratory, for example. These same practical principles of risk assessment and risk reduction can be applied to remote use of digital pathology. In light of this, we devised a departmental standard operating procedure outlining how clinical departments can risk-assess home reporting of digital slides in order to safeguard service provision during times of exceptional pressure (e.g. Global pandemics), which forms the basis of the UK Royal College of Pathologists Guidance on this subject.

Before embarking on home reporting, it is valuable to perform a risk assessment taking into account factors including scanning and laboratory processes, the scope of work performed at home, training and validation of pathology consultants, technical considerations including hardware/software and networks, and support and safety nets.





Hardware and network

In hospital settings, primary digital diagnosis is usually performed using workstations with high quality displays (often “medical grade” screens, which are high contrast, high resolution and are calibrated and quality controlled). Food and Drug Administration-approved digital pathology systems include a specified display as part of the system.

There is little evidence as to what the minimum display screen specification should be for home or remote reporting, or how to quality assess home reporting technology. For long-term home reporting, replication of the hospital workstation might be advisable, but for temporary, emergency home reporting, pathologists may need to use home computers or laptops. These may have lower resolution, less contrast and less consistent illumination than departmental equipment, and these factors may contribute to increased difficulty in assessing particular pathological features. Alternatively, some home technology may have higher specification than departmental systems!

The Leeds team have developed a useful tool that can help pathologists working from home to assess the suitability of their home screens for digital slide reporting: a point of use quality assurance tool (POUQA). The test is freely accessible online and challenges the user to identify four letters. Successful identification of the four letters indicates that the user is able to discriminate between subtle differences in colour pertinent to pathological assessment, and that they may be able to use their screen for primary

diagnosis. Our recent data suggests that around 11% of users fail the test, indicating that their display or visual system were not providing sufficient contrast to detect subtle differences in H&E.

Another factor which may impact on the pathologists’ comfort with use of a home reporting system is network capabilities. In hospitals, network capacity is sufficient to support multiple users on high resolution displays, with connections typically in the 100 Mbit/s to 1000Mbit/s range. Remote connections, particularly those running over encrypted “virtual private networks” may be much slower,



The Point of Use Quality Assurance tool. The user is challenged to identify four letters, which change in each instance of use. In this example, XGQY should be visible on the workstation. Access the tool via <https://www.virtualpathology.leeds.ac.uk/research/systems/pouqa/pathology>

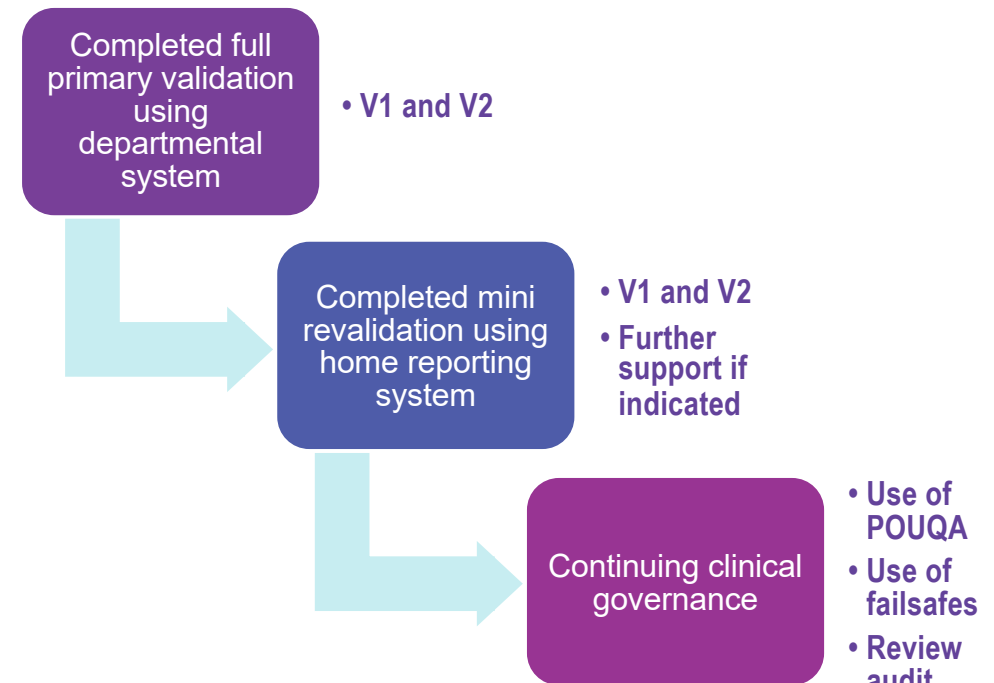


and performance of domestic internal wireless network could reduce the overall speed of the collection, leading to streaming delays and a slower viewing experience. Pathologists intending to report remotely should consider a trial period in which they can measure they can record any streaming difficulties, and measure and log their home connection speeds at times of difficulty.

Pathologist training and validation

One of the most important factors is the individual pathologist's level of digital pathology training, validation and experience. Ideally, for routine home reporting, pathologists should already have completed a full validation programme on the departmental digital pathology system. They can then review their original digital training cases (V1 digital slide sets) from home, using their domestic IT system, and compare the results to their original validation. If they find any cases problematic, they may want to exclude these types of case from the scope of their home reporting, or exercise more caution in their assessments. Use of the POUQA quality assurance tool before each home reporting session should be encouraged, and the need for and scope of home reporting should be reviewed and audited at suitable intervals.

Under emergency circumstances, it may not be possible for pathologists to complete the standard training and validation programme before using the system for home reporting. These pathologists will need access to support including the opportunity to defer diagnosis or refer cases to colleagues.



Scope of home reporting

Certain types of pathological features or scenarios, and certain categories of diagnosis may be more challenging, or pose a greater degree of risk than others when home reporting. In our view, primary digital diagnosis would represent the highest level of clinical risk, with assessment of immunohistochemistry,



secondary review, MDT preparation, etc., potentially presenting less risk. If the pathologist has limited experience of digital slide review, they may find they lack confidence in particular tasks e.g., assessing nuclear features of dysplasia, and identifying mitotic figures. The pathologist will need to risk assess on a case-by-case basis and employ suitable mitigation where required (e.g. Levels, second opinion, deferral to glass, communication of uncertainty to the clinician/surgeon).

Laboratory quality control/quality assurance

Physical separation between the pathologist and the laboratory renders laboratory quality control and quality assurance processes even more important. The main risk would be that tissue might be missed in the scanning process, and not represented on the slide. This can affect very pale slides such as those that are predominantly fatty tissue, or biopsy slides with multiple pieces of tissues. This is more likely to occur when automated tissue detection algorithms are used without additional human QA/QC steps. Risks can be mitigated by ensuring tissue is placed centrally on glass slides, so that it is within the scannable margins of the slide, referring to macroscopic images of glass slides to compare tissue coverage, and default scanning of the entire scannable area of the slide for particularly risky specimens (e.g. Fatty tumours, breast biopsies, smear preparations).





Failsafes

It is important that the pathologist is able to contact the laboratory and colleagues easily. They may consider lowering their threshold for requesting second/consensus opinion from colleagues whilst working remotely.

Depending on their risk assessment of a case, the pathologist may wish to convey this risk to the requesting clinician, either verbally, or within the report. For example:

“This diagnosis was made on a nonclinical system at a remote site, to expedite giving a rapid opinion, but this diagnosis is provisional and will be confirmed on second review on site.”

The ideal scenario – how to report remotely from home

- Initiate discussion with your clinical/departmental lead, and departmental clinical governance/risk management specialists
- Familiarise yourself with local and national guidance on digital pathology e.g. RCPATH guidance, CAP guidance, local standard operating procedures
- Risk assess your proposed home reporting system – record information regarding the specification of your home screen, and check network connection speeds.

- Ideally, you should have completed a full departmental digital pathology validation procedure, and have experience in digital reporting. If not, you should at least have training in use of your digital pathology software, and complete an abbreviated validation exercise, viewing potentially challenging slides from home. This will help you define the scope of your home reporting, and identify scenarios that require failsafes and additional support.
- Ensure you can easily contact the laboratory or colleagues in case of difficulty.
- Incorporate use of the POUQA tool into your daily home reporting schedule.



PERSONAL PERSPECTIVE
Dr Darren Treanor



“Being able to report cases remotely has transformed our ability to offer an on call liver transplant pathology service. Before digital pathology, reporting a biopsy out of hours, was a laborious process that required hours of planning, coordination and travel. Now, we have access to the scanned images, we can log on within minutes of the slide being prepared. Less travel and disruption out of hours is really beneficial for balancing work and family life, and the flexibility of digital means that we have enhanced our service by reporting digitally. We can now report cases one-by-one on demand, rather than waiting to do them all at once, in person.

Having a digital image on screen adds another benefit – I can show the images to the transplant physician live, so they can see the severity of rejection for themselves and understand my pathology report much better. In addition, remote sharing of images with colleagues really helped our liver reporting team stay connected and offer each other diagnostic support under difficult circumstances throughout the pandemic. The use of digital images also allowed us to continue to educate trainee pathologists (residents), and offer real-time feedback on cases using screen sharing – an invaluable tool in an era of social distancing.”

*Dr Darren Treanor
Consultant Pathologist and Honorary Clinical Associate Professor
Leeds Teaching Hospitals NHS Trust*



CHAPTER 4

Single site deployment of digital pathology can offer many benefits to a department in terms of efficiency and quality, but the flexibility and transferability of digital slides can be harnessed for even greater achievements when you start to form digital networks with colleagues and partner institutions.





CHAPTER 4 – MULTISITE DIGITAL PATHOLOGY DEPLOYMENT AND NATIONAL NETWORKS

Considerations for a multisite deployment

Single site deployment of digital pathology can offer many benefits to a department in terms of efficiency and quality, but the flexibility and transferability of digital slides can be harnessed for even greater achievements when you start to form digital networks with colleagues and partner institutions.

One of the most exciting (and challenging!) projects we have embarked upon is the deployment of our regional digital pathology network in the North of England. Histopathologists in adjacent District General Hospitals (Community Hospitals) refer many cases for central review, either for specialist opinion or central MDT review. It can take as long as 10 days for these referrals to reach our central site.

The ability to refer these digitally, rather than sending glass slides via post or courier, saves time and money, ensures slides are not damaged, and enables patients to receive their final results more quickly. It also creates the potential of collaborative diagnosis that is simply not possible with standard light microscopy, such as two pathologists in different locations in the network, reviewing the same digital slide simultaneously. The ability for a pathologist to instantly view digital slides produced elsewhere in the network will also allow more flexibility in cover for staff shortages and longer-term workload planning.

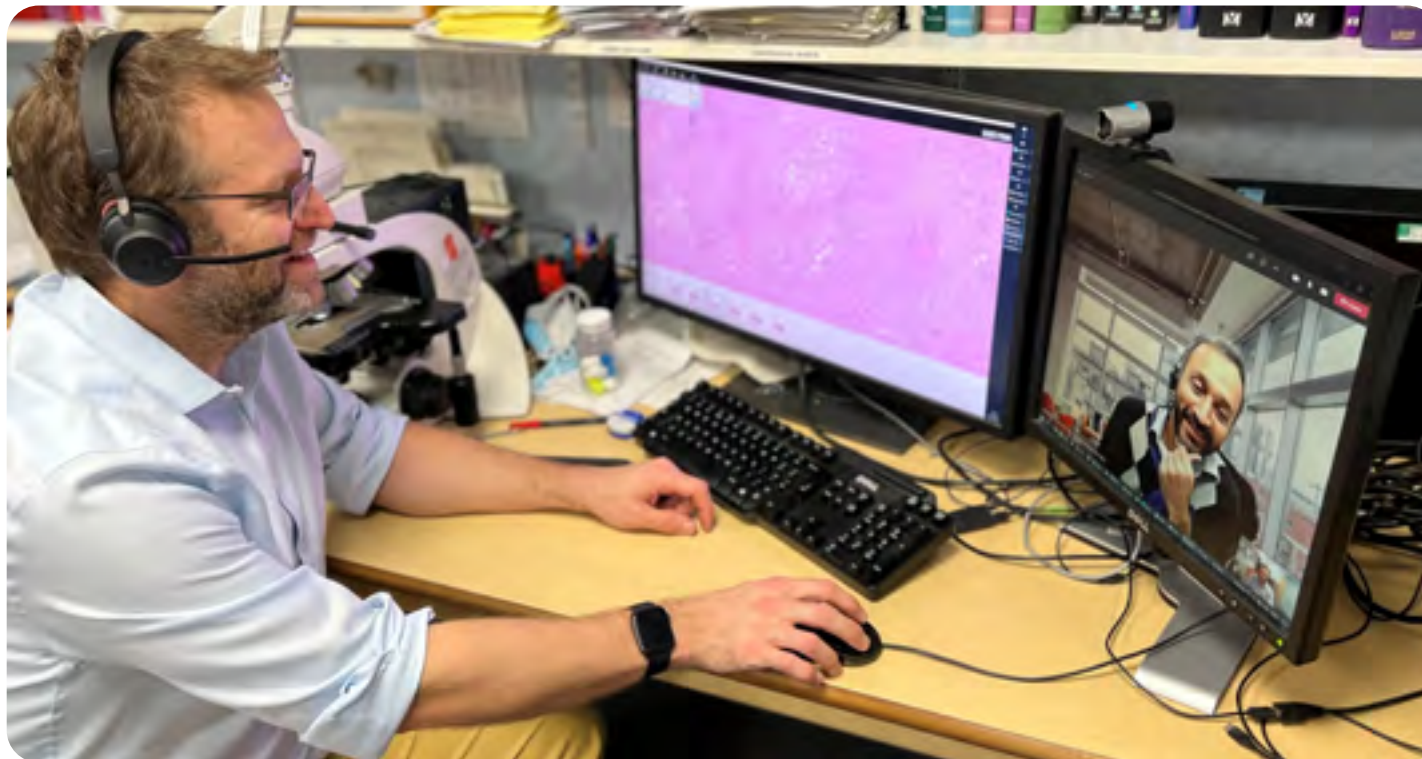
Connecting sites will help us ensure the safe and efficient transfer of pathology cases, between sites, to speed up patient pathways. In addition, sharing a network will allow us to collaborate more closely on quality in our clinical, academic and educational endeavours.



Stakeholder Engagement

Implementing a digital pathology network across multiple clinical sites can prove challenging, requiring the co-ordination and co-operation of IT teams, pathologists and laboratory staff to ensure a steady transition to digital as “business as usual”. Managing the competing expectations and ambitions

of these key stakeholders is essential to success, as is allocating sufficient time to gain the necessary local governance approvals. The key to working collaboratively across programmes is to ensure dependencies and timeframes are understood, and that programmes are aligned at the highest levels of governance and reporting structures.



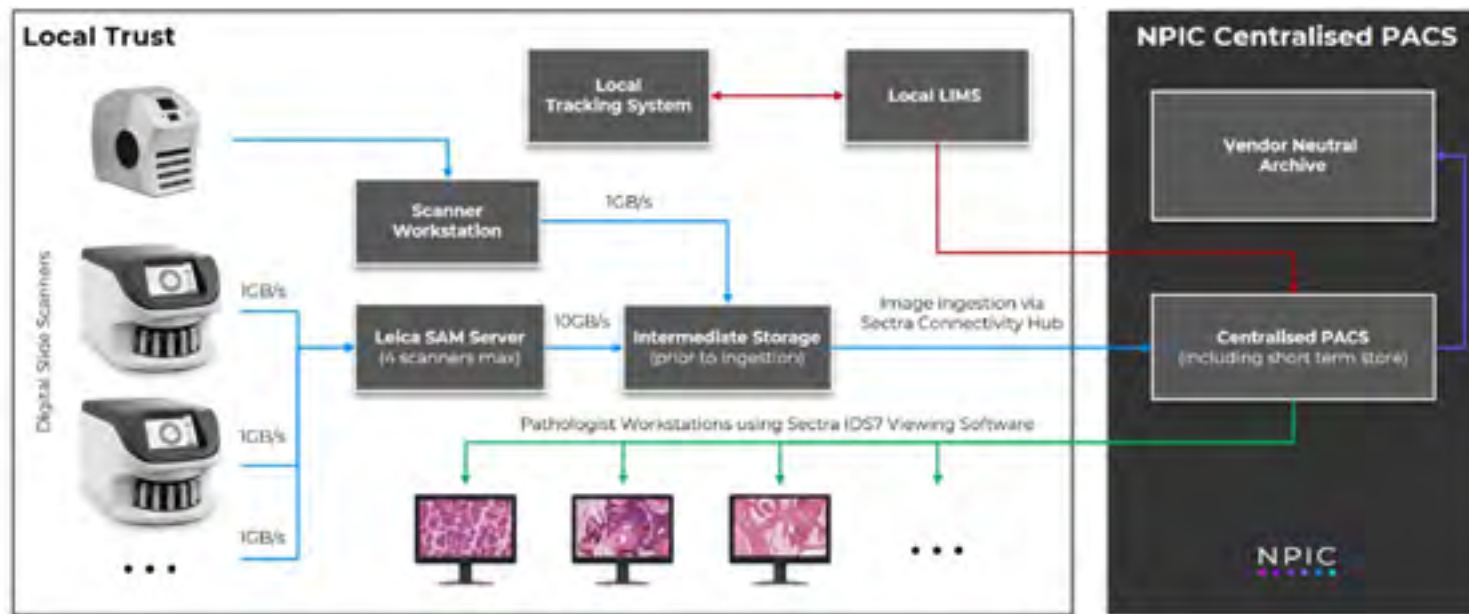


Infrastructure Management

At NPIC, we decided to implement a PACS versus a digital pathology management system. The size and scale of deployment across multiple hospitals, regions and NHS organisational footprints mean that a more sophisticated solution is required to enable the complex integration across multiple systems to be delivered and also to provide a robust enterprise-level solution. NPIC will be supporting over 200 pathologists at sites across the country, generating nearly 10,000 whole slide images per day. This is an

enormous scale, and our pathologists and biomedical scientists need a solution that they can rely on.

Rather than follow the traditional model of deploying in every hospital separately, we also opted for a national vendor neutral archive (VNA). Significant cost savings can be realised by delivering a single infrastructure and storage solution, removing the need and cost of duplicating servers





and storage at each site. A centralised solution also reduces the staffing and maintenance overheads, facilitates the sharing of cases, helps to standardise workflows and supports the various scanner suppliers deliver a digital solution across software platforms.

NPIC will work with a technical solution partner to deliver a high availability, scalable solution. The sheer volume of storage and scalability required for an ambitious digital pathology deployment provides local NHS IT departments with significant challenges and the pace of technological advances mean working with experts in the field is a must, so the latest architectures and infrastructures are available.

There are significant upfront costs associated with deploying digital pathology, but the ongoing sustainability and maintenance costs should not be underestimated. The various components needed for a successful deployment will need ongoing maintenance and support, and some of the major costs around sustainability will sit with the PACS system and ongoing storage. These costs can be considerable and should be factored in whilst planning a clinical deployment.

Interoperability

At NPIC we have placed a strong emphasis on standards and interoperability. We are utilising slide scanners and software from multiple different industry

partners; the ability for these different systems to write to, and read from, a common file type is of paramount importance, ensuring scalability and 'future-proofing' of the project. We have, therefore, stated that compliance with the DICOM Standard is an entry criterion to the NPIC project. This standard is well established in radiology and is rapidly developing in digital pathology. At NPIC we are also involved in the ongoing development of this standard, through membership of the DICOM Digital Pathology Working Group and DICOM Standards Committee. The complete benefits are to be quantified, having DICOM as a standard is essential for the industry to move forward.

In addition to image format standardisation, the NPIC program is also deploying tools to facilitate standardised pathology reporting. Pathologists in the UK report cancer resections using the Royal College of Pathologists minimum datasets, a well-developed method to ensure the correct information is recorded to determine treatment, and used in national data gathering efforts to understand the incidence and outcomes of cancer (the NHS Cancer Outcomes Services Dataset). The NPIC uses the mTuitive xPert tool to capture minimum cancer datasets across its hospital labs. This simple software tool plugs into the laboratory information system, allowing datasets of varying complexity to be recorded in human-readable and machine-analysable formats. The availability of this structured and highly granular information will be of great assistance in developing and evaluating artificial intelligence tools in the future.



We are optimistic that our networked deployment plans will allow us to optimise our use of digital images in clinical diagnosis, research and development and allow us to bring benefit to even more patients across the region, and beyond.

NPIC National Specialist Networks

One of the most exciting benefits of digital pathology is the ability to enable enhanced collaboration between professionals and institutions and remove geographical barriers to effective clinical networking. In light of this, NPIC is currently planning and implementing two national networks to help pathologists connect for quality in clinical diagnosis and research in two key areas – soft tissue and bone, and paediatric tumour pathology. These networks will allow for expedited sharing of images for primary and secondary opinions, and the collection of images for cutting-edge research and development opportunities, including the development of artificial intelligence tools. In addition, the networks could help reinvigorate recruitment of skilled and motivated junior doctors to specialist sarcoma and paediatric pathology roles, allowing trainee pathologists optimised access to quality training materials, and inspiring the next generation of experts!

Soft tissue and bone network

Sarcoma assessment and diagnosis represents one of the most challenging fields in histopathology, encompassing many rare entities. It's also an area with

one of the highest re-diagnosis rates (as much as 25%), and second opinions. Therefore, expert assessments are vital in ensuring that patients receive an accurate diagnosis and the most appropriate new therapies.

As part of our plans, the pathology department at the Royal National Orthopaedic Hospital (RNOH), in London, is being fully digitised, and will be linked with seven other soft tissue sites across England, enabling 50 specialist soft tissue and bone pathologists to share images for diagnosis, research and educational/training purposes. Tumour slides will also be scanned retrospectively, for sequencing and linkage with the UK 100,000 Genomes Project from Genomics England.

National Paediatric Tumour Network

Our paediatric tumour network will fully digitise the world-renowned Great Ormond Street Hospital (GOSH) for Children in London, and create a digital network linking the 19 principle treatment centres for paediatric cancer in England, allowing 70 pathologists to share images to improve clinical outcomes.

GREAT ORMOND STREET HOSPITAL FOR CHILDREN



PERSONAL PERSPECTIVE
Prof Neil Sebire



“Paediatric pathology is a shortage specialty dealing in rare diagnoses, many of which require specialist opinions and management.

The move to digital pathology at GOSH has several benefits including improved workflow management, easier multi centre multidisciplinary team meetings, improved support for teaching and research of rare specimens and opportunities for moves towards decision support including artificial intelligence.

The main short-term benefit of a national network of paediatric pathology specialist is the ability to rapidly request and undertake specialist 2nd opinion reporting, and to support departments which may be under-staffed, through

workflow management and remote reporting. In addition, this would support the large number of research studies which require specialist expert review.

The long-term goal of digital pathology is the ability to embed clinical decision support and artificial intelligence tools. Ultimately this would allow rapid and accurate triaging across all departments, and improved accuracy in reproducibility of a range of diagnostic indices, which will allow the identification of previously unknown pathophysiological associations.”

*Prof Neil Sebire
Professor of Pathology at UCL
Great Ormond Street Hospital Institute of Child Health*



CHAPTER 5

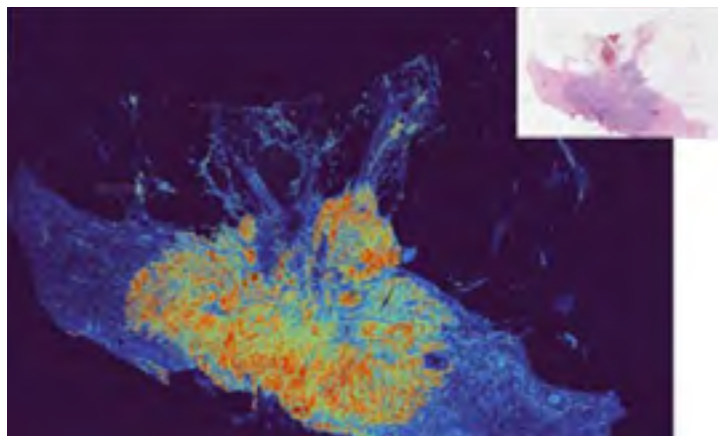
In this role, AI acts as a “junior partner” to the pathologist, taking over simple but time-consuming tasks and allowing the human pathologist more time to devote to more complex interpretation and clinicopathological correlation.





CHAPTER 5 – ARTIFICIAL INTELLIGENCE

One of the most exciting (and challenging!) benefits enabled by digitisation of glass slides is the development and implementation of pathology AI tools. Simple image analysis can already be used to aid the pathologist in repetitive, onerous tasks such as counting mitotic figures, assessing immunohistochemistry, screening large quantities of tissue for possible abnormality, and measuring and quantifying diagnostically significant features. In this role, AI acts as a “junior partner” to the pathologist, taking over simple but time-consuming tasks and allowing the human pathologist more time to devote to more complex interpretation and clinicopathological correlation. Artificial intelligence also reduces inter- and intra- observation, allowing for more reproducible and accurate classification, grading and staging of tumours.



Output from an AI tool trained to detect invasive breast cancer. The original H&E image is visible top right; the markup image uses a heatmap to indicate the probability of cancer across the breast tissue, from blue (benign) to red (cancer).

Potential use cases for AI

1. Quality control checks of slides in the laboratory prior to being released to the pathologist streamlining the specimen pathway
2. Triage of cases if there is a reporting backlog to highlight to the pathologist which cases are more likely to have a malignant diagnosis and therefore should be prioritised for reporting
3. Providing second reads for cases, particularly in areas in which we know there can be small foci of significant abnormalities at risk of being missed, resulting in reduced diagnostic errors
4. Independent reporting of specimens that are histologically normal
5. Assistance in the quantification of a variety of parameters that pathologists routinely assess that are subject to observer variation
6. Discovery of cellular features and tumour characteristics that we currently don't appreciate, and which could be important prognostically or could provide insights into targeted therapy
7. Automated reflex testing of cases based on H&E review (e.g. for cancer biomarkers or assistive immunohistochemistry)



Development of AI tools for use in routine clinical diagnostics starts with establishing the “ground truth”. For pathology applications, this requires detailed annotation of whole slide images by multiple pathologists to determine the classification of heterogeneous tissue into discrete cohorts. This can be a detailed and time-consuming task, but is an essential step as definition of the ground truth sets the foundations from which the AI tool will learn from.

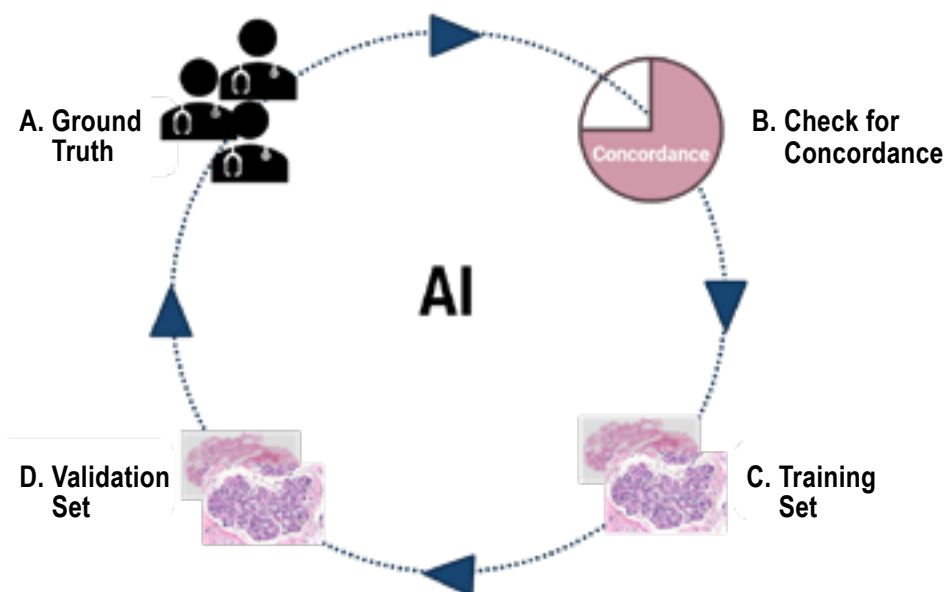
Pathologists’ engagement and input are critical at this stage in the development process. The amount of pathologists’ time required for annotating slides to establish ground truth should not be underestimated, and careful consideration should be given to scheduling sufficient time for both routine clinical responsibilities and ground truth slide annotation.

	<i>Image A</i> Routine Diagnostic Annotations	<i>Image B</i> Ground Truth Annotations
Time to annotate:	1 minute	45 – 60 minutes
Annotation Complexity:	Line	Free Hand
Data Captured on Digital Image:	Length	Classification (multiple)

Annotation of whole side images. Image A shows annotations typically used in routine diagnostics. Image B shows the typical level of detail and annotation complexity required when establishing ground truth.



Once the ground truth is established, development of AI tools is an iterative process of 4 main steps as shown below.



In the future, more sophisticated applications of AI trained on large cohorts of patients could see us using the tool to predict prognosis or response to treatment for individual patients, acting as a powerful digital biomarker, and reducing or triggering ancillary testing.

Whilst clinical AI is in its infancy, the majority of applications introduced into real world workflows in the short term are likely to retain the “human in the loop”, whereby a pathologist exercises their professional judgement, and oversees and modifies the output of the algorithm.

It will be a big, combined effort to get AI working in the clinic. The quality and consistency of images will come central stage, as differences in sectioning, staining and scanning could affect the outputs of image analysis performed with artificial intelligence. The role of the lab in ensuring this quality will be central.

As a pathology community, we need to make sure AI is introduced into diagnostic workflows safely and responsibly. Our staff will need to be confident in the capabilities and limitations of individual AI tools. At NPIC, our pathologists are working alongside software developers and data scientists to provide clinical expertise that can guide the creation of practical, user-friendly applications that can be implemented in hospital settings. Dr Rebecca Millican-Slater, a consultant breast histopathologist at St James University Hospital, Leeds is currently working on a project to create a breast cancer tool that can aid in diagnosis.



PERSONAL PERSPECTIVE
Dr Rebecca Millican-Slater



“The digitisation of glass slides in routine pathology practice allows for the development, validation and routine use of AI algorithms to assist in the assessment and reporting of pathology specimens.

Specifically, with regards to breast pathology, there is the potential that AI-based image analysis could assist in the detection of a tumour in breast tissue and lymph nodes, the determination of tumour grade, the quantification of biomarker expression, the prediction of response to neoadjuvant chemotherapy, and as a replacement for multigene assays.

When starting out with an AI project, it is important for AI developers to interact closely with relevant pathologists to ensure that the tool they are trying to develop has clinical utility and that the data they use to train their tool is robust. For AI algorithms which are assessing features we currently don't appreciate so can't be trained by annotations or by pathologist assessment of the tissue, datasets with survival data or genomic changes will be needed.”

*Dr Rebecca Millican-Slater
Consultant Breast Pathologist
St James's University Hospital*



CHAPTER 6

At NPIC, we are committed to putting the patient and public at the front and centre of our endeavours.

As our programme has expanded, we have sought to involve members of the public to allow us to understand their perspectives, interests and concerns, and challenge our assumptions.





CHAPTER 6 – PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT

Digital pathology is a technology which we believe pathology departments will find invaluable in the quest to maintain and improve services, but it is important not to lose sight of the effects of digitisation on individual patients. At NPIC, we are committed to putting the patient and public at the front and centre of our endeavours. Our original deployment and clinician training protocols have all been pathologist led, and was designed with a focus on patient safety. As our programme has expanded, we have sought to involve members of the public effectively and authentically in our work, and recruited an active Patient and Public Advisory Group (PPAG) to allow us to understand public perspectives, interests and concerns, and challenge our assumptions. Regular meetings between the senior NPIC team and the PPAG allow us to co-create public engagement materials, including our website (<https://npic.ac.uk>), where you can keep up to date with our work, and public and professionals can learn more about our aims and projects.

We asked one of our PPAG members, Pete Wheatstone, if he could share his thoughts on the key benefits and challenges of digital pathology and AI, and the importance of the patient and the public voice in medical technology projects.

“The Patient and Public Advisory Group (PPAG) meets regularly and is a forum for patients and the public from diverse communities to meet and discuss topics that are most relevant to all aspects of the provision of a modern digital enabled pathology service. This service is developing artificial intelligence based tools for now and the future to improve health and reduce inequity of the outcomes of care services.

I am particularly pleased to be involved with the PPAG and the wider NPIC team who are strong supporters of authentic public involvement in all aspects of their work. Public feedback is helping to influence and design the way services are governed, organised and provided to make sure they are as accessible and as effective as possible for patients, no matter what their individual needs may be.”

*Graham Prestwich
Chair NPIC PPAG*





Peter Wheatstone
NPIC PPAG Member

“Like most of the members of the NPIC Patient and Public

Advisory Group (PPAG), I recognise that I survived my personal cancer journey entirely due to my GP and other Healthcare Professionals. For myself, and most patients, the journey was one of much anxiety and uncertainty, punctuated by numerous tests that provided ‘indications’ to help guide any intended surgery. However, what patients desperately seek during that journey is greater certainty and hope.

The pathology report represented the first ‘solid stake in the ground’ which revealed the definitive nature and extent of my cancer providing much of the evidence necessary to formulate any post-surgery treatment.

That was back in 2014, where I was in the hands of trusted experts using their eyes, hands and experience. Now patients are confronted with additional terminology such as ‘digital’, ‘data’ and ‘artificial intelligence’, to name just three. For most of us, we have no significant frame of reference to help us truly understand these terms and especially within the context of health data. We fall back on the only references that we are aware of such as newspaper articles, the internet and movies which generally have negative connotations.

Whilst the many benefits that arise from digital pathology are well documented, including within this guide, what do patients know of these and have they been clearly expressed in language which is understandable to them and which resonate with them?

From my point of view, there are some key initial areas to address with patients:



- The perception that information held as data is less secure than as a paper record. Patients also have concerns about, who has access to it and purposes for which it might be used beyond their direct and immediate care
- Understanding that digital pathology is about looking at a patient's tissue scanned into pictures on a computer rather looking at thin slices of a patient's tissue through microscope and the benefits of this
- Understanding that the automation that digital pathology enables is capable of working 24 hours a day, every day so the information from the pathology report and treatment options can be provided to the patient much more quickly
- The reassurance that use of 'artificial intelligence' is a decision support mechanism to aid pathologists in interpreting the nature of the cancer

Much public and patient reassurance is needed to address public mistrust and uncertainty in the areas of digital diagnosis and artificial intelligence. This partly arises from a lack of understandable and relevant information provided to patients when compared with negative connotations provided by press headlines and the movie industry.

This has to be positively addressed when communicating with patients. The relative vacuum must be filled to build and maintain patient and public trust through greater transparency. Whilst much patient concern may be misplaced, it must not be ignored and has to be positively addressed by communicating with patients.

Patients and the public groups, such as the NPIC PPAG, can help with these challenges as we can bring to bear not only our healthcare lived experience but also our lived experiences from our careers and interests outside of the health sector. The challenges faced in these areas are not unique to the health sector and there must not be reluctance to learn from other sectors. As patients, we understand from first-hand experience, what the doubts and uncertainties are (whether logical or emotional, remembering that emotional responses tend to be stronger than logic), the language to use and the patients' perceptions of relevance to themselves of explanations and reassurance offered.

Better still we want to help you! ”

Peter Wheatstone

NPIC





FINAL THOUGHTS

The last 5 years have been challenging and rewarding ones! Our single scanner deployment and breast digitisation pilot has grown to a 100% departmental digitisation at Leeds, a regional network deployment serving 6 million people in the North of England, and two national cancer networks. When we first started our digital pathology workshops in 2016, people were asking, “*why should I go digital,*” whereas today, the focus has shifted to, “*I want to go digital, how do I do it?*” We are eager to see how the lessons we first learned in Leeds can be applied to other sites to help them realise the same benefits, and trying to anticipate the questions the pathology community wants answering next.

The creation of a national vendor neutral digital pathology archive has the potential to transform the way in which pathology professionals work and collaborate. Advances in scanning and storage technology are bringing the future forwards, enabling the project to gain momentum, but the key factor that has enabled change is the human factor. We hope this publication has spotlighted some of the talented and dedicated people who have worked together to deliver this transformation – biomedical scientists, pathologists, IT and informatics staff, managers, researchers, patient and public advisory group members and clinicians.

We hope you have enjoyed this update from the NPIC team – you can find links and references for our extensive resources on digital pathology related topics at the end of this document. It been very exciting to hear back from some of our workshop attendees, and those that have followed our work at Leeds, and learn

about their deployments and successes. We hope to be able to start running courses, at our brand-new National Centre for Training and Education shortly, and being able to welcome you back on-site post COVID-19 restrictions.

From the very beginning, we have seen the importance of sharing our knowledge, our experience, our successes, and our “lessons learned” – it is this openness in the digital pathology community that will help ensure we all continue to adapt to a changing world, and adopt ever evolving imaging technology whilst maintaining the highest standards of patient care and professional service.



Dr Darren Treanor, Consultant Pathologist and Honorary Clinical Associate Professor Leeds Teaching Hospitals NHS Trust

Dr Bethany Williams MBBS PhD Lead for Digital Pathology Training and Validation, NPIC



FURTHER RESOURCES

To find out more about the National Pathology Imaging Co-Operative, and keep up to date with our activities, visit our website: <https://npic.ac.uk/>

To explore the case for digital pathology adoption, view our paper:

Williams BJ, Bottoms D, Treanor D

Future-proofing pathology: the case for clinical adoption of digital pathology
Journal of Clinical Pathology 2017;70:1010-1018.

For advice on how to build a business case for digital pathology, view this guide:

Williams BJ, Bottoms D, Clark D, et al

Future-proofing pathology part 2: building a business case for digital pathology
Journal of Clinical Pathology 2019;72:198-205.

To find out more about digital:glass slide diagnostic concordance, you can read:

Williams BJ, DaCosta P, Goacher E, Treanor D. A Systematic Analysis of Discordant Diagnoses in Digital Pathology Compared With Light Microscopy. Arch Pathol Lab Med. 2017 Dec;141(12):1712-1718.

For detailed information on our breast and neuropathology digital pilots, view these papers:

Williams BJ, Hanby A, Millican-Slater R, Nijhawan A, Verghese E, Treanor D. Digital pathology for the primary diagnosis of breast histopathological specimens: an innovative validation and concordance study on digital pathology validation and training. Histopathology. 2018 Mar;72(4):662-671.

Williams BJ, Ismail A, Chakrabarty A, Treanor D. Clinical digital neuropathology: experience and observations from a departmental digital pathology training programme, validation and deployment. J Clin Pathol. 2021 Jul;74(7):456-461.

For more specific information about use of digital images for assessing cancer screening programme specimens:

Williams, B, Hanby, A, Millican-Slater, R, Verghese, E, Nijhawan, A, Wilson, I, Besusparis, J, Clark, D, Snead, D, Rakha, E & Treanor, D. (2020) Histopathology 76, 968– 975.



For practical advice on how to prepare your laboratory for ISO15189 accreditation of digital pathology services:

Williams BJ, Knowles C, Treanor D. Maintaining quality diagnosis with digital pathology: a practical guide to ISO 15189 accreditation. *J Clin Pathol*. 2019 Oct;72(10):663-668.

For practical advice on how to prepare pathologists for digital pathology:

Williams BJ, Treanor D. Practical guide to training and validation for primary diagnosis with digital pathology. *J Clin Pathol*. 2020 Jul;73(7):418-422.

For information on how to risk assess home reporting of digital slides, view:

Williams BJ, Brettle D, Aslam M, et al. Guidance for Remote Reporting of Digital Pathology Slides During Periods of Exceptional Service Pressure: An Emergency Response from the UK Royal College of Pathologists. *J Pathol Inform*. 2020;11:12. Published 2020 Apr 17. doi:10.4103/jpi.jpi_23_20.



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