

On the Edge of a Digital Pathology Transformation: Views from a Cellular Pathology Laboratory Focus Group

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Abstract

Introduction: Digital pathology has the potential to revolutionize the way clinical diagnoses are made while improving safety and quality. With a few notable exceptions in the UK, few National Health Service (NHS) departments have deployed digital pathology platforms. Thus, in the next few years, many departments are anticipated to undergo the transition to digital pathology. In this period of transition, capturing attitudes and experiences can elucidate issues to be addressed and foster collaboration between NHS Trusts. This study aims to qualitatively ascertain the benefits and challenges of transitioning to digital pathology from the perspectives of pathologists and biomedical scientists in a department about to undergo the transition from diagnostic reporting via traditional microscopy to digital pathology. **Methods:** A focus group discussion was held in the setting of a large NHS teaching hospital's cellular pathology department which was on the brink of transitioning to digital pathology. A set of open questions were developed and posed to a group of pathologists and biomedical scientists in a focus group setting. Notes of the discussion were made along with an audio recording with permission. The discussion was subsequently turned into a series of topic headings and analyzed using content analysis. **Results:** Identified benefits of digital pathology included enhanced collaboration, teaching, cost savings, research, growth of specialty, multidisciplinary teams, and patient-centered care. Barriers to transitioning to digital pathology included standardization, validation, national implementation, storage and backups, training, logistical implementation, cost-effectiveness, privacy, and legality. **Conclusion:** Many benefits of digital pathology were identified, but key barriers need to be addressed in order to fully implement digital pathology on a trust and national level.

Keywords: Artificial intelligence, computational pathology, digital pathology, image analysis, whole-slide imaging

INTRODUCTION

Digital pathology involves the examination and analysis of tissue samples taken from glass slides transferred to digital images using whole-slide imaging technology. Digitalization has the potential to revolutionize the way clinical diagnoses are made and to improve safety and quality.^[1,2] The current workflow in pathology is very manual and has remained largely unchanged for decades. It centers around diagnoses being made by a cellular pathologist via glass slides on a microscope. The change to digital reporting on screens is similar to the changes seen in radiology and imaging around 20 years ago. Once this digital transformation is made, the scanned slide images can be used as the raw material to build algorithms, which can then be tested and implemented in the clinical workflow. Algorithms have the potential to perform some of the tasks already done by pathologists in a potentially more reproducible and labor-saving way. In addition, artificial intelligence (AI)

can allow novel insights into tissue biology that could not previously be evaluated by a human observer.

The UK government published an Industrial Life Sciences Strategy in August 2017.^[3] Histopathology was highlighted in the report as being “ripe for innovation” and “where modern tools should allow digital images to replace the manual approach based on microscopy... and the opportunity to create AI-based algorithms that could provide grading of tumors and prognostic insights that are not currently available through conventional methodology.”

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While in Europe and Canada, several centers have deployed digital pathology for primary diagnosis for a few years. In the UK and USA, uptake and experience has been relatively lower. Simultaneously, there is an increased demand for pathology services due to increased cancer incidence with an aging population, a growing complexity of referrals, and the rise in initiatives to diagnose premalignant changes and early-stage cancer. A recent report by Cancer Research UK^[4] cited a 4.5% year-on-year increase in the number of histopathology requests since 2007–2008, the majority for the investigation of cancer. However, staffing levels have not increased to meet the demand. It is thought that digital pathology could alleviate some staffing and workload issues while improving efficiency. Previous studies have found that a digital workflow released up to 13% of an individual pathologist's time in addition to laboratory technician time.^[5]

Recent quantitative studies have demonstrated a strong interest in digital pathology adoption in the UK and its increased use for pathological diagnoses.^[6] Recently, a surge in interest for the adoption of digital has prompted The Royal College of Pathologists to release guidance on the implementation of digital pathology.^[7] Reporting using a digital approach cannot be assumed to be exactly the same as reporting via microscopy. Visually, there are subtle differences, and these need to be understood via a period of validation, comparing between glass slides and digital images. While few guidelines exist for digital pathology validation at the present time, the College of American Pathologists published guidance in 2013 that has formed the basis of most of the current validation analysis. Key validation studies have been undertaken in breast pathology^[8] and a large-scale study of primary histological diagnoses involving over 3000 cases.^[9] However, more national guidance on validation may be needed as National Health Service (NHS) Trusts transition to digital pathology.

With a few notable exceptions in the UK, a limited number of NHS departments have deployed diagnostic digital pathology platforms.^[6] Thus, in the next few years, many departments may undergo the transition to digital pathology. In this period of transition, capturing attitudes and experiences can elucidate issues to be addressed and foster collaboration between Trusts. While previous studies have examined attitudes toward digital pathology quantitatively through surveys,^[6] few studies have qualitatively captured the complexity and variety of attitudes of pathologists and biomedical scientists undergoing the transition. Thus, this study aims to examine in detail the anticipated benefits of digital pathology and the concerns which may impede its implementation. To achieve this, a focus group discussion was held in the setting of a large NHS teaching hospital's cellular pathology department. At the time of the discussion, the department was on the brink of starting the process of becoming a digital pathology department.

METHODS

The focus group discussion was held at Oxford University Hospitals NHS Foundation Trust, one of the largest NHS

teaching trusts in the UK. The Trust employs over 12,000 people, and the Trust's hospitals in Oxford serve an Oxfordshire population of 655,000. In terms of the Trust's Cellular Pathology Department, during 2018, there were approximately 56,000 requests processed in the main department for histopathology. At the time of the focus group, the department was on the brink of transitioning to digital pathology. The department had installed two slide scanners that were capable of digitizing approximately 40% of the workflow and two further scanners were set to arrive in 2019–2020 enabling full digitization. Although the scanners were installed, at this time, there was no live diagnostic reporting or slide scanning, and this would only commence 3 months following this discussion.

A set of 12 open questions [Table 1] were developed by CT and CV and were posed to a focus group of seven participants by a facilitator (CT). Demographic details of the participants are summarized in Table 2. In summary, the group was mixed featuring both biomedical scientists ($n = 3$) and pathologists ($n = 4$) of varying levels of experience and specialization. The biomedical scientists included the general laboratory manager, the quality manager, and the IT manager, all of whom have been heavily involved in the preparation for transition to digital pathology. All the pathologists participating in the focus group were subspecialists due to the nature of the department as a teaching hospital. Two were urological pathologists and one was an hematopathologist. Another breast pathologist was not present at the focus group, but separate comments were sought from this individual as they brought a useful perspective around governance.

A focus group format was used to generate information and qualitative data on collective views and explore the rationale behind those views in depth. Participants in the group interact with each other on a frequent basis and have shared experiences and a familiarity that facilitated discussion. The sampling strategy for those to take part was strategic

Table 1: Focus group questions

What do you anticipate to be the advantages of digital pathology for the trust/for you personally?
What do you anticipate to be the disadvantages of digital pathology for the trust/for you personally?
In considering the transition to digital pathology
What do you think will be easy?
What do you think will be difficult?
How do you plan to train and validate your use of digital pathology?
How might go digital impact on reporting within the region and further afield?
What concerns do you have about the change/technical challenges?
What do you think could improve the transition to digital for you personally?
Do you think the laboratory could or should go fully digital? If so, over what time frame?
How do you think digital pathology will affect trainees?
How do you think it will change cellular pathology in general?
How about academic pathology?/Functioning of MDTs/workforce issues?
MDTs: Multidisciplinary teams

Table 2: Demographics of participants in focus group

Initials of participant	Subspecialty	Years of experience as consultant or registered IBMS/HCPC	Sex	Position
CV	Urological pathology	11	Female	Consultant
SRG	Biomedical scientist and laboratory manager	31	Female	Biomedical scientist
HH	Biomedical scientist and quality manager	24	Female	Biomedical scientist
KW	Biomedical scientist and IT manager	26	Male	Biomedical scientist
LB	Urological pathology	8.5	Female	Consultant
GR	Hematological pathology	1	Female	Consultant
DR	Breast, endocrine pathology, and FNA cytology	21	Male	Consultant

IBMS: Institute of biomedical sciences, HCPC: Health and care professions council, FNA: Fine-needle aspiration

sampling, which is designed to encapsulate a relevant set of experiences in the group. Specifically, we selected the pathologists and biomedical scientists most involved in the digital pathology pilots. All focus group participants were active in the discussion. An open question format was selected in order that no assumptions or preconceptions strongly led the discussions down particular avenues. Notes of the discussion were made along with an audio recording with permission. The discussion was subsequently turned into a transcript. The data were analyzed using content analysis, which is a technique for analyzing qualitative data by reading the transcript and splitting the contents into relevant categories, which are used as topic headings in the results section. Variable analysis was also performed, which involves making inferences about causation or direction and degree of influence based on the apparent association between variables and is included in the discussion section.

RESULTS

Benefits of transitioning to digital pathology

Collaboration

The participants expressed several anticipated benefits from improved collaboration due to an environment of sharing and openness and an increased referral rate. In addition, the process of validation in each Trust or department could bring enhanced collaboration and discussion with colleagues.

Teaching

Pathology training and undergraduate teaching may benefit from increased access to an archive of digital slides. Currently, the majority of teaching material relies on physical glass slides, which are subject to fading. Trainees may have access to a greater range of cases including small biopsy specimens which ordinarily are not incorporated into glass slide teaching sets due to the potential for loss of material from the tissue block when cutting extra teaching sections. Trainees may also have access to rare cases and small samples which otherwise may not be available. Furthermore, previous studies have demonstrated that digital pathology modules enhance student engagement.^[10]

Cost savings

Cost savings may be achieved by reducing production of glass slide teaching sets, microscopes (purchase and maintenance), turn-around times, and error logs that require investigation.

Research

Academic research may benefit as the reconstitution of old cohorts will not be necessary, there may be a decreased requirement for glass slide storage, and there may be a reduction in samples that are damaged or lost, or that need to be re-cut or re-stained. Digital pathology may also assist with AI research by providing infrastructure to build cohorts.

Growth of specialty

It is anticipated that digital pathology may attract more trainees as potential trainees may be deterred by microscope work. New technology may bring those with an engineering background to the specialty with the possibility of building algorithms. In addition, the field may become more teamwork focused.

Improved multidisciplinary team meetings

Currently, pathologists do not often show slides at multidisciplinary team (MDT) meetings due to lack of time, but, it is sometimes important to do this both for the pathologist and clinicians. Digital pathology may reduce the amount of time it takes to show slides and allow them to be displayed in MDT meetings. In inconclusive cases, it may be important to show specifically what the uncertainty is and how the case was analyzed by the pathologist. In addition, when communicating details about surgical margins, it can be important to visually demonstrate this at the MDT meeting. Thus, digital pathology may foster greater communication between clinicians and pathologists.

Patient-centered care

Patients may have access to their own images and foster greater patient involvement. Pathologists may interact more with patients and increase patient-centered care and generally enhanced communication between doctor and patient.

Barriers in the implementation of digital pathology

Standardization

One of the main concerns raised about the implementation of digital pathology was the difficulties associated with

standardization across departments or NHS Trusts. The variability of reporting on different microscopes, variations in hematoxylin and eosin staining, and discrepancies in protocols across hospitals and Trusts were raised as the main issues.

Validation

The Royal College of Pathologists digital pathology guidelines for validation of reporting^[7] were discussed. Some concerns were raised over less detail in some areas including determining when it might be appropriate to sign out a case on digital versus glass and also what amount of validation is required in terms of Stages 1 and 2.

Concerns were also raised about how to conduct robust validation and whether this should be self-reflective or externally administered, for instance, by a departmental governance committee. The Royal College of Pathologists recommends self-validation with documentation reviewed by an external assessor. Arguments in favor of self-validation were that it is less cumbersome and encourages engagement among pathologists. It involves two stages as follows: Stage 1 validation is a technical process where each pathologist familiarizes himself/herself with the equipment and understanding the pitfalls when comparing the same case digitally versus on glass slides. Stage 2 is a more formal process of making the diagnosis and writing the report and then reviewing at least the highlights of the glass slides to ensure concordance on all diagnostic parameters. The goal of Stage 2 is to build confidence in the switch from glass to digital and continue to understand the differences between them and determine when deferring to glass is necessary. Then, the decision is made to only report from digital images in circumstances that have been validated past in Stage 2.

An argument against the use of self-validation is that external assessment is necessary to ensure that there is an audit trail to demonstrate that a pathologist has made valid decisions about when to defer to glass in difficult areas. However, self-validation could potentially lack transparency and standardization. Although much of postgraduate medical practice relies on reflective practice and self-accreditation, such as continuing professional development (CPD) schemes, it was acknowledged that external validation could introduce a stressful and competitive environment rather than a collaborative one. Thus, it was felt to be important to focus on creating an open culture to improve the self-validation system that has been advocated in published guidance, and in so doing to be mindful of avoiding a process that makes the pathologists feel that they are being tested.

One participant stated: *"It is important that we promote a culture of improving the system rather than blaming the individual for discrepancies. So that the question becomes not 'Why did you make that mistake?', but 'How did the system allow you to make that mistake.' It is essential to focus on the system not the individual."*

National implementation

Concerns were raised about how local pilot implementation of digital pathology will transition to a national program. What

will the procedure for this local to national transition be? Which national body will oversee this process? There were feelings that digital pathology lacks a coordinated national implementation strategy and is relying on *ad hoc* pilots and small deployments. The current method of digital pathology implementation involves multiple pilots at different centers and may be more expensive and time intensive than necessary. Participants stressed that national coordination is needed for standardization and cost-saving analyses.

While many national bodies are involved in the process including the National Institute for Health and Care Excellence, the Medicines and Healthcare products Regulatory Agency, Innovate UK, the National Cancer Research Institute Cellular Molecular Pathology Initiative (CM-Path), the Royal College of Pathologists, and NHS England, there has up until now been no general oversight or overarching strategy. However, the Royal College of Pathologists has just published a focused digital pathology strategy to bring together all stakeholders and provide that overarching vision.

Storage and backups

The participants also raised the issue of the role of the glass slides after the transition to digital pathology has taken place. Will glass slides serve as backups to use if the digital archive fails? What are the implications for equipment requirements and cost savings in pathology departments if microscopes continue to be required? It was suggested that most departments will have a hybrid state of digital and glass slides as some samples, such as micrometastases, require viewing on glass slides. One participant commented: *"After the transition to digital has taken place, how will we have backups? What if the digital archive fails and we must resort back to slides?"*

Training

Differences between Trusts and departments in the degree of digital pathology implementation could introduce variation in training among pathologists. Concerns were raised in terms of standardization of a trainee curriculum and whether there should be an aspect of current pathology training that involves digital pathology.

Technical

Issues were also raised about the logistical implementation of digital pathology in a department or Trust in terms of which platforms would be used, what is stored and for how long, who is overseeing the management of the archive, and how it will be funded.

Cost-effectiveness

The participants also emphasized the need to establish measurements for cost-effectiveness, which may require a project manager to oversee baseline measurements and determine the appropriate variables to measure.

Workload

Digital pathology may increase the demand for referrals and second opinions, which may increase the demand on

pathologists at tertiary centers. One participant commented that *“Instant second opinions might increase the demand on tertiary centers and could be undermining to pathologists working elsewhere.”*

Privacy/legality

Legal issues may interfere with the development of digital pathology and the use of AI for algorithms due to privacy data and consent laws, which remain unclear. High-level guidance is needed to determine when consent or lack of an opt-out data research is needed and what types of data can be shared and used for research. These decisions require the involvement of legal teams. While awaiting legal guidance on these issues, Trusts may need to develop risk assessments to capture concerns and in order to provide local guidance in the absence of national guidance specific to digital pathology.

DISCUSSION

This study is one of the only few focus group studies in digital pathology,^[11,12] which has the advantage of exploring the issues and challenges in greater depth compared to quantitative studies. Results from this study can be used as the basis to develop further quantitative surveys as an increasing number of UK departments transition to digital pathology. When teams in other institutions express reservations about digitization, this study can be used to acknowledge that other institutions had similar reservations. In terms of variable analysis in this study, this group, due to the sampling strategy, was composed of enthusiasts and early adopters of digital pathology technology, which could potentially lead to more advantages being identified as themes; however, a number of challenges were also identified. The digital pathology project at this stage had been funded as a capital project, and this meant that financial challenges had a bearing on perceived challenges. We aim to follow up this study with a similar study following digitization to assess whether the challenges and benefits identified were realized or if unpredicted issues or benefits arose.

Since the focus group took place, £50 million of funding has been awarded to create new centers of excellence for digital pathology and imaging using AI medical advances from the Data to Early Diagnosis and Precision Medicine strand of the government's Industrial Strategy Challenge Fund, managed and delivered by UK Research and Innovation (UKRI).^[13] These new digital pathology centers are PathLAKE, a digital pathology consortium led by University Hospitals Coventry and Warwickshire NHS Trust, and also include Oxford, Belfast, Nottingham, the Leeds-led Northern Pathology Imaging Co-operative, and the pan-Scottish Industrial Centre for AI Research in Digital Diagnostics. Each center was awarded funding in partnership with industry, who will make significant in-kind investments.

To achieve greater acceptance of digitization, our department aims to lead by example and demonstrate with real-world experience how to implement digitization and what the benefits can be. A detailed roadmap for adoption has recently

been published by some members of the focus group.^[14] We believe that demonstrating the benefits of digital pathology will lead to greater adoption, rather than enforced implementation of these technologies. In order to increase uptake, we propose that the barriers to uptake are removed as much as possible. For instance, setting a national strategy stating that the use of such technologies is a priority, and then business cases can be written with reference to such a strategy. More funding needs to be obtained for key issues such as the ongoing costs of image storage and more guidance could be provided as to how this is best achieved by which medium (e.g., cloud based, tape storage, or servers).

The barriers to digital pathology implementation identified in the focus group included some lack of clarity over validation, lack of strategy for national implementation, storage/backups and technical IT issues, lack of strategy over training, how to demonstrate cost-effectiveness, workload (increased numbers of referrals), and privacy/legality issues regarding the use of images for other purposes such as research. The department in which the focus group was held is part of PathLAKE digital pathology consortium. As such, we aim to address some of the barriers by sharing our experiences and providing a template that others can follow during the roll out of digital pathology deployment. Despite this, we still have uncertainty over some of the issues such as how to store, backup, and maintain long-term slide archives where the volume of data is greater than the capacity of most hospital IT departments and also how the storage will be funded. Additional issues related to IT infrastructure, interoperability, and integration with common laboratory information management systems (LIMS) will need to be addressed. In the UK, NHS Improvement suggested the creation of 29 such networks in 2017.^[15] While several Trusts have adopted single LIMS in the UK, such as those in Wales^[16] and Dorset,^[17] it is essential that more Trusts adopt common IT systems across laboratories to aid the implementation of digital pathology. It is likely that integration between the IMS and LIMS did not arise as an issue in our focus group as our Trust has an in-house built LIMS system which enables such integration, and this was a planned step in the deployment.

Other issues require the relevant national bodies to lead the approach, such as training and implementation strategies. Members of our team are involved with such bodies and are helping set these national policies. To address concerns about standardization and the potential variation in terms of different technology platforms and equipment across various hospitals (such as scanners and reporting screens), it will be important to work on the interoperability of systems such that images can be shared and file formats are as open source as possible. For future algorithm building, tools must be developed that can be re-calibrated as needed to work on all of the different platforms. A framework should be created that enables standardization of processes and standard operating procedures (SOPs) across sites, which will allow for the use of different technologies.

In terms of the next steps, issues with image storage can be addressed by working with solution providers to determine reference architecture for such archives and write the costs into business cases to make them sustainable. Furthermore, it will be important to work with vendors in the setting of PathLAKE to provide robust evidence for cost-effectiveness. Increased discussion and feedback to those writing the UK Royal College of Pathologists' digital pathology validation process is essential especially from pathologists with limited experience in digital pathology. Other issues may also require intervention at a national level, and our group will feed into relevant committees, such as the Royal College of Pathology Digital Pathology Working Group.

In terms of national implementation, we propose that multiple pilots are created across a number of centers in the UK and then detailed findings from these pilots are collated to create a set of national guidelines and cost-effectiveness analysis. This approach was used in the NHS Cervical Screening Programme^[18-20] and could be adopted for digital pathology. There are now three digital innovation centers, at least in part focusing on digital pathology funded by Innovate UK/UKRI, and these centers are working together to lead the way in setting standards. Finally, departments undergoing transition to digital may benefit from lessons learned at other institutions with several years of experience deploying digital pathology, such as centers in Spain, the Netherlands, and Sweden.

CONCLUSION

Potential benefits of digital pathology include enhanced collaboration, improved teaching, cost savings, research facilitation, growth of specialty, improved MDTs, and enhanced patient-centered care. However, key barriers need to be addressed in order to fully implement digital pathology on a local and national level and to realize these potential benefits. Barriers to transitioning to digital pathology include standardization, validation, national implementation, storage and back-up of data, training, logistical implementation, cost-effectiveness, privacy, and legality.

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Conflicts of interest

There are no conflicts of interest.

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