## Future-proofing pathology part 2: building a business case for digital pathology

Bethany Jill Williams,1,2 David Bottoms,3 David Clark,4 Darren Treanor1,2

### ABSTRACT

Diagnostic histopathology departments are experiencing unprecedented economic and service pressures, and many institutions are now considering digital pathology as part of the solution. In this document, a follow on to our case for adoption report, we provide information and advice to help departments create their own clear, succinct, individualised business case for the clinical deployment of digital pathology.

### INTRODUCTION

Digital pathology has the potential to revolutionise the way in which pathology services are delivered, and in the current climate, the case for adoption is increasingly compelling. Digital slides are a transformative technology, which will ultimately replace the current standard practice of conventional light microscopy. While the process of whole slide imaging (WSI) adds an additional step to the current laboratory workflow for glass slides, this additional cost is affordable and can be offset by productivity and efficiency gains, direct cost reduction opportunities and cost avoidance opportunities.

In this document, we provide advice on structuring and preparing a salient, succinct business case for digital pathology in your department, based on your own departmental data, and supported by relevant national policy and guidelines. This paper is the follow-up to Future-Proofing Pathology: The Case for Clinical Adoption of Digital Pathology, and provides complementary information on the financial, commercial and management aspects of digital deployment. A template of business case section headings can be found in supplementary appendix A online.

### Structuring the business case

In developing your business case, you should adhere to any local business case templates available in your institution, but the basic outline should include:

- An introduction that describes current pathology processes and digital slide technology in clear, accessible language, suitable for a layperson.
- A compelling description of the need for change within your institution.
- Detail of the scope of investment required, and the principal components of this investment.
- A description of the strategic context of digital pathology, with reference to relevant local, national and international policy and data.
- An economic case, with an options assessment.
- A financial case, including potential cash releasing benefits, cost avoidances.
- Non-financial quality and service improvement benefits.
- A commercial case.
- A management case.
- A succinct and convincing conclusion.

In the following sections, we will provide outline text, data and references to help you populate these parts of your business case.

### WRITING THE INTRODUCTION

The introduction needs to be accessible, and should not presume background knowledge of current or future pathology processes. For example:

In the pathology department, glass slides containing processed and stained human tissue are examined using a conventional light microscope to make diagnoses and direct patient treatment pathways. Conventional light microscopy has been employed to identify microscopic tissue abnormalities for over a century, and this process is the current gold standard technique to provide pathological input into the diagnosis and staging of cancers.

Digital pathology, or WSI, is an evolved technology which adds an extra step to the current workflow for glass slide production.

In digital pathology, digital images of glass slides are acquired in a scanner using high-quality microscope lenses. These ‘whole slide images’ are then stored and transmitted, and can be viewed and annotated by pathologists on computer display screens. The digital slides are readily available within the department, via any networked PC, and have the potential for transmission and sharing within a local, regional, national or international network, as well as being made available for remote and out-of-hours reporting.

WSI systems have been European Conformity marked for primary diagnostic use in Europe for many years, and in spring of 2017, the Food and Drug Administration (FDA) announced approval for marketing of a WSI device for primary diagnosis in the USA. A recent systematic review of the diagnostic accuracy of digital pathology versus conventional light microscopy identified 38 quality validation studies of digital pathology, and found good rates of concordance between digital and light microscopy diagnosis. Various proof-of-concept studies both within and outside of the UK have concluded that digital images are of sufficient quality for primary diagnosis of histological specimens.
COMMUNICATING THE NEED FOR CHANGE

In this section, you need to summarise the current pressures on pathology services, at local, regional and national levels. This can be conveyed by the following bullet points:

- There is wide recognition that there are severe pressures on National Health Service (NHS) pathology services caused by a number of factors creating ‘a perfect storm’:
  - Increasing cancer-associated workloads associated with larger numbers of elderly patients often presenting with comorbidities. Cancer Research UK data show a 4.5% year-on-year increase in pathology requests.7
  - Greater complexity of cases with increases in the number of slides per case, the number of special stains and markers to be analysed, and the number of data items to be reported as per the minimum data set requirements of the Royal College of Pathologists’ cancer reporting guidelines.
  - A more ‘time sensitive’ culture to ensure patients with cancer are diagnosed and treated in a timely manner. The Independent Cancer Taskforce is proposing that by 2020, 50% of patients referred by general practitioners for cancer checks should have a definitive diagnosis within 2 weeks and 95% within 4 weeks. This is in the face of the evidence that shows waiting times are currently lengthening, with the number of patients waiting for more than 6 weeks for a diagnosis increasing by 17% per year since 2010/2011.7
  - Decreasing numbers of clinical pathologists as a result of a prolonged history of insufficient trainee recruitment into pathology with a resultant lack of applicants for vacant histopathology consultant posts.
  - A shift in the age demographic of the consultant pathologist workforce. The Royal College of Pathologists’ figures have shown that 32% of the current pathologist workforce are >55 years old and are expected to retire within the next 5 years.5
  - Health systems, including the NHS are under severe economic pressures that prevent funding for workforce expansion and limit investment into new technologies unless they are proven to save money.

DESCRIBING THE SCOPE OF INVESTMENT

Here, you need to list and describe all the components of the digital pathology system:

- WSI scanners: Situated within the laboratory, high-throughput automated slide scanners with associated PC workstations scan high volumes of stained microscope slides.
- Workstations with displays: Installed into pathologists' offices, they allow the visualisation of the slide images at high resolution. Dual monitors are sometimes used to allow simultaneous control of workflow/case selection/slide selection and the viewing of the chosen images.
- Information management and technology hardware: The servers (locally or remotely hosted), host the application software described below and may provide short-term storage for the images. A web server can allow image access from any web browser enabled PC connected to the institutional network.
- Pathology slide/case load software: The software manages the clinical case load and the digital slide images. This includes image creation, workload management, slide viewing, slide sharing, clinical annotation and measurements, report generation and case submission. The software also creates and holds audit trails relating to the activities undertaken for each case. Image analysis software can also be applied to slides to improve the effective quantitation of cell markers (eg, HER2 in breast cases).
- Interfaces: To the main laboratory information management system (LIMs) or other electronic patient record systems, pulling information relating to patient cases and providing an ability to push any required results/report information back when the case is complete.
- Archive database storage solution: The size of any archive storage will depend on the final agreed scope of the investment but the system should retain the images for a sufficient period of time to enable audit and case review. Archive storage architectures would need to be agreed with the supplier as would backup/system resilience plans.

SETTING THE STRATEGIC CONTEXT

In this section, you need to summarise the international, national, regional and local strategic contexts for digital pathology, with appropriate references and accurate local data. These are the key points you may want to include:

International

- Worldwide access opportunities: One of the key benefits of digital pathology is the easy access it provides to pathologist expertise. There are numerous areas of the world where access to such expertise is extremely sparse or non-existent. Availability and integration with a digital pathology network would allow substantial clinical benefits for such isolated populations and provide a potential income source for areas where additional pathologist capacity is available or could be created, as has been demonstrated in the USA.8
- Rolling time zone access: In a similar vein, where urgent analysis is required at times when local pathology services are unavailable, a ‘chase the sun’ facility could be put into place where analysis is provided by trusted partners in other time zones across the globe.

National

- The National Cancer Taskforce Strategy’s paper ‘Achieving World-Class outcomes; a strategy for England 2015–20’ highlights a drive towards achieving earlier diagnosis, the need to make investment to deliver a modern, high-quality cancer service, the need to identify and address workforce capacity gaps, the need to increase diagnostic capacity, and the need to support and streamline regional multidisciplinary team meetings and cancer networks.
- Cancer Research UK highlighted the national pressures on clinical pathology services in their recent paper Testing times to come? An evaluation of Pathology capacity across the UK (November 2016)8 identifying the need for institutions to invest into infrastructures to support digital pathology and the role that it can play in allowing clinical pathologists to work more flexibly, reducing the impact of workforce shortages, facilitating the operation of clinical networks and reducing subjectivity.
- A digital pathology system would meet key elements of the National Information Board’s Framework for Action ‘Personalised Health and Care 2020’ especially those relating to improved access, personalised medicine, supporting innovation and getting best use from technology. The paper emphasises the importance of links to molecular and genomic medicine (1000 Genomes Project). It would also support other information management and technology targets such
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as moving towards paperless reporting and maximising the usage of the NHS number.

► The National Advisory Group on Health Information Technology’s paper Making IT work: harnessing the power of health information technology to improve care in England (August 2016)\textsuperscript{10} states clearly that the advisory group believes that trying to achieve the aims of the five year forward view without giving highest priority to digitisation would be a costly and painful mistake. The paper acknowledges that while it is natural to seek a short-term financial return on investment (ROI) from health information technology (IT), experience has shown that short-term ROI is more likely to come in the form of improvements in safety and quality than raw financial terms. Cost savings may take 10 years or more to emerge, since the keys to these gains are reconfiguration of the workforce, local adaptation of digital technologies, and a re-imagining of work processes. The paper concludes that to those who wonder whether the NHS can afford the ambitious to digitise in today’s environment of austerity and a myriad of ongoing challenges, we believe the answer is clear: the one thing the NHS cannot afford to do is to remain a largely non-digital system’.

► The national Chief Clinical Information Officer’s ‘Newcastle Declaration’\textsuperscript{11} states that complete, accurate and timely information fundamentally underpins safe and effective health and social care.

Regional sustainability

► The two Carter reviews of pathology\textsuperscript{12 13} both recommended the formation of networked pathology services and the development of ‘hub and spoke’ collaborations. Digital pathology will assist institutions in the flexible use of clinical expertise in relation to laboratory locations, pathologist offices and multidisciplinary team meeting (MDT) inputs.

► Include local information on regional collaboration initiatives, sustainability and transformation plans, and how they link with digital pathology

Local context

You can use this paragraph as a template, and collect and insert your own data:

► Workload activity for our organisation in 2016 was xxxxxx surgical cases. The projected workload for 2017 is xxxxxx cases. The total number of glass slides reviewed is in the region of xxxxx per annum. Annual activity growth is in the order of xx% per annum. This increase does not take into account the increasing complexity of the workload, and the extended use of immunohistochemical tests. Taking account of these factors, annual workload growth is in the region of xx% per annum. Over 10 years, surgical specimen case load has increased by xx%, with xx% increase in consultant establishment (\textit{figures 1 and 2}). Comparing 2006 with 2016, consultant productivity levels have increased by xx% (\textit{table 1}).

► There is currently insufficient reporting capacity for workload demand. Additional capacity is delivered at a supplementary rate of x per case by employing a locum at a salary of xxxxx per annum.

► Of the xx consultant pathologists employed in the department, xx are in the age range of 56–60 years. In light of staff age demographics, the department will require a robust recruitment strategy to maintain staffing levels over the next few years.

Figure 1 Illustrative departmental workload statistics: workload by case.

► Include local data on any specialty-specific deficits in reporting capacity, for example, gynaepathology, and how networking with other hospitals in the region/allowing for remote reporting by existing staff could prevent reporting backlogs, and so on.

CREATING THE ECONOMIC CASE/OPTIONS ASSESSMENT

This is most easily achieved by considering two options: do nothing or invest in digital pathology (\textit{table 2}). In summary when the two options are compared against the key success factors shown below (see \textit{table 3}), the following scoring is considered valid (scores are provided as low=1 (worst), high=5 (best)).

Financial case

In the current financial climate being experienced by the NHS it is crucial that wherever possible any new system must be cost-neutral at worst and preferably provide a net position of
financial savings for the institution. The costs will vary between institutions based on size, workload, current Consultant workforce relative to establishment, inhouse storage capabilities/commercial storage costs and distances between the consultant offices and the laboratory.

- Indicative costs show that for a hospital to install the technology as part of a managed service contract the annual costs to the institution are in the region of £100–£200K dependent on the size of the workload/consultant pool. This includes costings for the proposed information management and technology data storage solution and an interface to the LIMS. The costs would reduce in the event that a region-wide purchase strategy was adopted and further savings may be possible if the purchase of hardware/ peripherals could make use of existing NHS Trust IT suppliers on NHS framework agreements and the sharing of data archives. The supplier could also be contracted to provide a hosted data solution if this was preferred.

- Compensating savings: There are significant savings that will mitigate against these costs and could provide an ROI.

- Funding support: Digital pathology fits well with funds being made available nationally/regionally to support the adoption of digital technologies/innovative working/improved diagnosis and early diagnosis.

- Financial cash-releasing/generating benefits: The first two cash-releasing savings are predicated on the basis that hospitals across the region would be willing to provide diagnostic support to a neighbouring institution due to a shortfall or a lack of specific expertise within its own workforce and that pathologists within the assisting institution have the capacity to undertake the extra work; this would require agreements to be negotiated with regard to overtime/additional sessional payments. Institutions would need to agree on a workload ‘currency’ that takes into account the complexity of work in any exchange/quid pro quo arrangements. Although such an arrangement could generate hospital-to-hospital cross-charges (particularly where there is one-way traffic) they would not be expected to be of the same order as the current locum/send away costs shown below and would significantly reduce the risks. Any income would also remain within the NHS. In particular, the hospital needing the work done would have far greater levels of confidence and knowledge of the professional ability of the regional pathologist undertaking the work.

1. Reduced locum costs: Locum pathologists are still widely used by many NHS Trusts to cover shortfalls in manpower due to retirement/maternity and carer leave, long-term sick leave, and so on. The overall cost of this is substantial (£140 per hour). Improved productivity and utilisation of the existing pathologist workforce using digital pathology, allied with easy transferability of images to trusted colleagues in neighbouring hospitals, should substantially reduce reliance on locum cover.

2. Reduced costs from referring work to commercial laboratory services: Considerable sums (£35 per case) are spent by many NHS Trusts in order to keep abreast of their workloads. The turnaround times of cases outsourced to agencies can be prolonged, given the need for work to be physically transported elsewhere.

3. Potential income generation (potentially £35 per case): Digital slides create the ability for sites to provide remote clinical diagnosis from images generated anywhere, and will open up insourcing opportunities. Pathologists could undertake work for other institutions within the region, and there is also a market nationally and internationally.

4. Transport savings on tissue/slide exchange between institutions/sites (£2–3K per annum): There would be reductions in the logistical costs of relay in slides to reference sites for second/specialist opinions and their subsequent return.

5. Microscope/camera purchase (£20K to 40K per annum): Consultant pathologist microscopes currently cost around £25K each. If cameras are also added this can rise to £30K and height-adjustable benching to provide the appropriate ergonomic posture for microscopy can add further costs. Although they have a long ‘shelf-life’ it has been common practice in many hospitals to provide new consultant pathologist staff with a new microscope to ensure the stock of the department is refreshed. Such regular purchases would no longer be necessary.

6. Reduced archive slide storage/retrieval costs (£2K per annum, £40 per retrieval): Although unlikely to have an impact initially, it is highly likely that costs associated with slide/tissue storage may be avoided in the future. Where these are off-site and commercially supported these costs are not insignificant.

7. Reduced financial penalties (£1000 per cancer breach): Avoidance of financial penalties due to cancer breaches relating to delays in obtaining pathological

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**Table 1**  
Annual departmental consultant workforce vacancies 2009–2017

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</thead>
<tbody>
<tr>
<td>Budget WTE</td>
<td>xxx</td>
<td>xxx</td>
<td>xxx</td>
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<td>xxx</td>
<td>xxx</td>
<td>xxx</td>
<td>Xxx</td>
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<tr>
<td>Contracted WTE</td>
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<td>xxx</td>
<td>xxx</td>
<td>xxx</td>
<td>Xxx</td>
<td>xxx</td>
</tr>
<tr>
<td>Vacancy WTE</td>
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</tr>
</tbody>
</table>

WTE, whole time equivalent.
Table 2 Options regarding investment in digital pathology

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Do nothing/do minimum</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Continue to use existing microscopy technologies for all cases, transferring tissues and slides to other specialist centres as and when required. Use the continual development of molecular medicine and genetics to further improve services. In this model, consideration will be given to continuing to deliver the service using light microscopy as the sole technology in an environment where the pressures on the service will continue to follow existing and forecast trends.</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Option 2</th>
<th>Invest in digital imaging for pathology</th>
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<tbody>
<tr>
<td></td>
<td>Procure/lease slide scanners, consultant digital workstations, case management and imaging software to undertake the work currently done using microscopy. The software would be expected to be interfaced to laboratory information systems so that appropriate data can be exchanged safely and securely. A digital image archive is required. In this analysis, a service delivery model will be investigated where certain assumptions are made:</td>
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</table>

- All current pathology slides created within the institution will be scanned, stored and made available to consultant pathologists for their analysis.
- Some scanning capability will be available in at least one of the surrounding hospitals.
- Some viewing capability will be available in at least one of the surrounding institutions.
- Viewing capability would be available from hospital-employed pathologists’ homes.
- A significant proportion of our pathologists and those located in at least one of the surrounding institutions would be willing to undertake a validation process, such that once completed they would then use digital pathology to make primary diagnoses on their case load.
- The pressures on the service will continue to follow existing and forecast trends. |

Table 3 Scoring for options 1 and 2

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Option 1</th>
<th>Option 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service sustainability</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Affordability</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Quality benefits</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Risks</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Total scores</td>
<td>7</td>
<td>15</td>
</tr>
</tbody>
</table>

diagnostic opinion. Insert sample data of the number of breaches in your institution where pathology is likely to have been implicated in delay.

8. Reduced litigation costs: Although cases are rare, where institutions have been prosecuted due to diagnostic error relating to pathology, these have proved to be extremely expensive. Postevent analysis has shown that such cases could often have been avoided had there been improved quality assurance checking, often including a second/specialist opinion. Apart from the financial aspects, the reputational damage to the institution and the pathology departments can also be severe.

9. Earlier diagnosis (£50–£100K minimum): Digital imaging can provide quicker turnaround times for cases that require referral to external institutions for regional MDT review.

Financial, non-cash-releasing benefits (cost avoidance):
1. Time savings for consultant pathologist: There are indicative data suggesting productivity improvements for pathologists when they have adopted digital imaging of between 10% and 15%.14 Specific areas where time is saved relate to immediate availability of slides without need to wait for delivery, faster measurements and annotations and easier preparation and compilation of cases for MDT meetings.

2. Delayed clinical workforce expansion costs: As cancer workloads continue to grow, hospitals need to expand their pathologist workforce and are experiencing recruitment difficulties. Increased productivity of the existing workforce will help offset these pressures. Applied conservatively this might give an expectation that institutions would be able to absorb an additional workload of at least 5%. Consultant annual workload is roughly estimated to be approximately 3000 cases. A 5% increase in capacity would equate to an extra 150 cases per annum per consultant for the region. Theoretically at least this could increase the number of cases that could be examined by the overall existing pathologist workforce of our region by as much as an additional 12 000 cases per annum.

Insert own data here. Xx consultants performing an additional 130 cases each=xxxxx extra cases. An annual workload increase of 3%=xx consultants × xxxx cases per annum × 0.03 workload increase=xxxxx more cases each year.
Therefore nearly xxx years of workload increases could be ‘absorbed’ by the existing workforce, saving approximately £xxxx on workforce expansion costs.

3. Reduced travel costs: The technology provides consultant pathologists with the ability to work at a distance from their laboratories/MDT meeting venues. This could include agile home-working (to cover future 7-day working initiatives) and satellite site working (for MDT attendances). These costs are not substantial in relative terms to the other specified savings.

4. Delayed laboratory workforce expansion: Considerable laboratory staff time is undertaken to support current ways of working that could be significantly reduced if digital imaging were adopted. These are as follows: case assembly, case retrieval, case filing, packing and unpacking dispatched slides, time spent chasing missing/overdue slides, time re-cutting/re-staining lost/damaged slides, time delivering slides to consultants. Assuming a similar 5% efficiency by the consultants for deferment of additional recruitment for x years would create cost-avoidance savings of approximately £xxxx per annum.

Quality benefits
Digital pathology offers numerous and evolving opportunities to improve patient safety, pathology workflow, service quality and workforce factors, and these benefits are appreciated at multiple levels, by the patient, the pathologist, the institution and the wider network in which that institution operates. These benefits have been discussed at length in part 1 of Future Proofing Pathology: the case for digital pathology.1

Direct patient benefits include faster turnaround times for diagnosis, improved access to secondary and expert opinion, and safer, more robust identification of patient specimens and reports. Benefits for the pathologist include safer, more efficient
workflows, closer collaboration with colleagues and the opportunity
for flexible and remote working. The institution can benefit from
leaner workload allocation, paperless reporting, enhanced
recruitment and retention, improved training and education,
more efficient workflows and faster turnaround times for cancer
specimens. The regional network stands to benefit from pooling
of reporting expertise and capacity, increased collaboration,
workforce flexibility, and faster, safer MDT referral pathways.
The innate flexibility of digital reporting also supports opportu-
nities for laboratory consolidation and reorganisation of services.
In addition to promoting internal sustainability, digital pathology
also offers commercial income-generating opportunities.

Figures 2 and 3 from Future Proofing Pathology Part 1,15 provide
a useful summary of the broad benefits of digital pathology.

Constraints
In this section, you need to consider the most pressing existing
and potential constraints on your plans for digital deployment.
These may include the following points:

IT network speeds and capacity: Fast interhospital network
transfer is necessary.

Physical space in the laboratory: To accommodate scanners.

Physical space in pathologists’ offices: To accommodate an
additional viewing screen.

Digital imaging is not appropriate for all slides: Cytology
samples or specific cases requiring polarisation or fluores-
cence examination are not yet easily accommodated on a high
throughput scanner. However, such scanners are now becoming
available as separate entities if required.

User familiarisation: It will take a while for pathologists to
become familiar with diagnosis using the digital pathology
system. The Royal College of Pathologists’ 2017 guidelines for
digital pathology recommend an individual validation procedure
for each pathologist engaging in primary digital diagnosis, and
detail an approach that provides early exposure to live digital
reporting, while retaining a safety net of glass prior to sign out) is recommended for a
dual diagnosis, focused on specimens relevant to their daily work. Dual
reporting (primary diagnosis on digital slides, with immediate
reconciliation with glass prior to sign out) is recommended for a
suitable time period, to ensure adequate exposure and identifi-
cation of additional training needs, or workflow safety nets.15 16

Regulatory approval for primary diagnosis with digital
imaging: The Royal College of Pathologists has published guide-
lines on the safe adoption and progression of digital pathology
for clinical diagnosis.15 Recent acceptance of the first digital
pathology system for primary diagnosis by the FDA in the USA
should help provide additional confidence levels and further
momentum.17 It is anticipated that changes in recommendations
relating to the retention of slides and tissues will be forthcoming
at some future date and these could further add to the cost
 savings of moving to digital pathology.

Scanner throughput: For larger laboratories more than one
scanner will be required. Additional and failover scanners are
included in the business case costs.

Lack of industry standards formats: In the event that there
were to be adoption of differing commercial solutions across the
region this could cause problems as there is as yet no industry
standard image format approved by regulators. Therefore the use
of differing systems at differing hospitals could restrict interop-
erative sharing of images. However, there are vendor-agnostic
middleware suppliers that can provide viewers solutions that will
cope with a variety of commercially specific image formats if
required, although this would probably add an extra layer of
costs. Suppliers are likely to have to comply with Digital Imaging
and COmmunication in Medicine (DICOM)-type standards or
provide DICOM wrappers in the near future and many already
do.

Lack of pump-prime investment funding: The adoption of
picture archive and communication system was nationally
funded and led to immediate savings because of plain films being
unnecessary. There is no such underpinning national funding for
pathology and slide storage would still be required in the short
term at least while the digital pathology community reviews
storage requirements. However, the financial analysis within this
business case shows that the investment would be self-funding
within the term of an initial contract period, if savings are met.

Existing information management and technology road maps
and strategies: Any adoption of this technology will need to
accommodate data storage requirements for short-term and
longer-term archive access with backup resilience as appro-
priate. Some strategies can however be adopted to reduce overall
storage requirements, for example, by only retaining selected
images once reported. This is provided the other cases have glass
slides so that repeat digital image scanning and analysis can be
undertaken should a review of archived cases is needed at some
point in the future. These capacity requirements must dovetail
into existing institutional IM&T investment programmes, and
close liaison with hospital chief information officers and their
forums is essential.

Productivity reductions during ‘transition’: While the work-
force undertakes the necessary training and validation through
dual reporting, consultants will be less productive. Leeds
Teaching Hospitals NHS Trust found an approximate 10% in-
creased workload for pathologists undertaking validation.15 16

The Royal College of Pathologists’ new guidelines for digital
pathology recommend an individual validation for each pathol-
ognist that intends to use digital pathology for primary diag-
nosis, focused on specimens relevant to their daily work. Dual
reporting (primary diagnosis on digital slides, with immediate
reconciliation with glass prior to sign out) is recommended for a
suitable time period, to ensure adequate exposure and identifi-
cation of additional training needs, or workflow safety nets.15 16

Ergonomic impact: More time would be spent at computer
workstations—where such workstations have not been ergo-
nomically assessed this might add to occupational health issues
relating to posture. There are views that the posture for pathol-
ologists spending many hours at the microscope is far worse18 and
pathologists are ‘locked’ into a viewing position when using a
microscope whereas digital pathology allows far greater posture
mobility and flexibility. Other environmental factors will need
 to be assessed and optimised for digital workstations, such as
lighting, to ensure that lighting levels are consistent and do not
interfere with the ability to read images. Depending on the types
of monitors used for primary diagnosis, blackout blinds and
controlled artificial light sources may need to be used.

THE COMMERCIAL CASE
Your summary of the commercial case for digital pathology may
include the following points:

► Spin-off technologies further contribute to solutions on
 offer including computer assisted scoring of marker-posi-
tive cells (eg, HER2), image storage/archive solutions, image
compression, versatile handheld peripheral devices for
consultants while reviewing images and bioinformatics and
‘big data’ analysis.

► Higher profile IM&T suppliers to the NHS have already
recognised the role that digital pathology has to play and
have formed commercial partnerships with both scanner, software and biomarker suppliers to offer complete solutions and support services to healthcare providers integrated into other key IM&T systems (eg, laboratory information system, electronic patient record).

- Such partnerships can also extend to encompass broader imaging access and storage solutions such as image exchange portals and vendor neutral archives where pathology images could be stored alongside other image types and formats (radiology, medical photography, electroencephalogram/ECG traces, etc).
- As a result, for healthcare providers who are able to obtain investment funding there is no shortage of suppliers available to respond and an increased likelihood that some of the suppliers will already be providing services to them for other aspects of their existing IM&T services.
- NHS procurement agencies are all now well aware of the desire of pathology departments to purchase digital imaging capabilities. They have an understanding of the requirement and are inviting suppliers to become part of NHS framework agreements which can provide prospective buyers with rapid access to a cohort of ‘trusted’ IM&T partners who can quickly be taken through a competitive tendering process.
- Procurements in the UK, although initially focussed specifically on NHS Trusts, are increasingly becoming multitrust level as institutions form collaboratives as part of sustainability and transformation plans (STPs).
- As pathology services have increasingly turned to managed service contracts for their equipment provision it is highly likely that this ‘new’ technology will be embraced in a similar way to create more effective use of finance and link into solution refreshment as contractual periods approach their end points.

THE MANAGEMENT CASE

Your management case may include the following:

- Once procurement is complete the implementation timescales and resources required will very much depend on the scope of the investment (ie, single Trust/Multi Trust) and the number and scale of IT systems that require interfacing.
- The installation of the scanner(s) into the laboratories and the workstations into the consultants’ offices and MDT rooms is fairly straightforward provided there is the necessary space and utilities provision (power, uninterruptable power supply, network points).
- The interconnectivity of multisite deployments will require significant liaison between hospital network managers and Information Governance/Caldicott Guardian leads. These staff are vital to ensure that images and image information relayed between organisations are both secure and appropriate. The connectivity itself should not be difficult to achieve but engaging the right hospital representatives to understand the requirement and agree the correct processes can be time-consuming.
- Interface development, testing and going live are often the most time-consuming and error-prone elements of an implementation and therefore planning/testing should commence early with the parties concerned.
- The implementation of digital WSI scanning and its use for MDT review, primary diagnosis and reporting has significant implications for workflow and resource utilisation through the whole of the pathology pathway and therefore it is crucial that the working processes are subjected to lean/six-sigma-type analysis in the earliest stages of the implementation. This should help to ensure that departments make best use of the technology and maximise benefits realisation by cutting out ‘wasted’ resource and ensuring that savings are delivered in terms of both time and finance.
- The technology may be disruptive during its implementation. Some consultant pathologists are keen to adopt digital pathology as part of their day-to-day working and willing to undergo the necessary validation processes that will be required as part of the transformation of their working. Others however will be less certain and may be less adept at or willing to move to such a technology. It is clear too that digital image review is not currently seen to be appropriate for all types of tissues/cancers and therefore it is inevitable that adoption of the new technology will need to be undertaken in a carefully planned and staged/phased process with clear timelines and targets.
- It is crucial that the requirements for clinical validation (and the dual reporting overhead that this requires) are included in the resource planning for the implementation.
- For full adoption it is most likely that implementation will be phased over a 2-year to 3-year period and at the end of that time there would still be the requirement for microscopy for some tissues and specialisms (ie, a mixed economy is forecast for the foreseeable future as technology stands, based on the broad range of tissues and cancers currently reviewed in most institutions).

CONCLUSION

Digital pathology can provide considerable economic and quality benefits to the examination of tissues for pathology purposes. While the technology is not yet able to accommodate all facets of diagnostic reporting, considerable strides have been made and the technology is now ready for adoption into mainstream pathology. The technology will continue to progress and as it develops further this will only broaden the scope of its benefits.

It is believed that in financial terms the system can be cost-effective through improvements in productivity of the service as a whole and in the impact it can have on both care pathways and therapeutics.

When this is married to quality benefits, the creation of flexible working capabilities for pathologists, risk reductions and the support it can provide for service sustainability of the business case is robust. Furthermore the adoption of a system that allows facilitated sharing of pathology images can be an enabler for pathology collaborations and consolidations where these are required.

We hope you have found this discussion, and the illustrations of how to populate the sections of your business case for digital pathology helpful and informative, and would encourage the reader to use parts of this document in their own business case submissions.

Take home messages

- Digital Pathology is going to hold a pivotal role in the transformation of pathology services in the near future.
- It is important that individual departments can create a succinct and salient business case.
- A successful business case will need to include local data, as well as demonstrating awareness of relevant wider regional/national strategy and policies.
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