

The future of pathology services

Briefing

Sasha Karakusevic, Nigel Edwards, Ruth Lewis and Mark Dayan

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What is pathology?

Pathology is the study and diagnosis of disease through the examination of organs, tissues, bodily fluids and whole bodies. The main branches of this broad and complex scientific field are as follows.

- **Haematology:** Haematologists look at disorders of the blood and hematopoietic system. Procedures include sampling and diagnosis of these, stem cell transplant and the formulation and management of chemotherapy products.
- **Histology and cytology** involve close examination of cells under microscopes to help diagnose a range of diseases and cancer. Cytology looks at the function, structure and chemistry of cells themselves. Histology looks at the anatomy of cells within the tissues they comprise.
- **Microbiology and virology** involve the diagnosis, treatment and prevention of infection.
- **Immunology:** Immunologists investigate autoimmune diseases, specialised immunochemistry, and numbers and function of cells of the immune system; many also do *in vitro* testing for allergies, and some are involved in transplantation and immunogenetics.
- **Molecular pathology and genomics:** Molecular pathology studies and diagnoses disease through the examination of molecules within organs, tissues or bodily fluids. It is commonly used in the diagnosis of cancer and infectious diseases. Genomics is a branch of molecular biology that studies the structure, function, evolution and mapping of genomes (the complete set of DNA within a single cell of an organism).
- **Chemical pathology** studies the biochemical basis of disease and uses biochemical tests for screening, diagnosis, prognosis and management of conditions including liver disease, cancer and diabetes. Chemical pathologists are responsible both for patients within hospitals, and for supporting colleagues across the NHS, including in general practice, on using and interpreting tests.

About this report

Attention in the NHS has been focused on integrated care in recent years, but there is rapid and potentially disruptive change happening in other parts of the system, with opportunities to significantly improve services. One such area is the field of pathology. This report draws on a workshop and interviews with a selection of clinical and managerial leaders involved in pathology, as well as a literature scan. It aims to identify the opportunities and emerging trends affecting pathology that boards should be aware of, and to draw out lessons on making improvement happen in different fields.

'The future of...' series

Breaking down the traditional boundaries between primary care, community services and hospitals is vital if health and social care services are to be integrated around the needs of patients and service users. Doing so will require a move away from single institutions towards a systems-based approach organised around networks of care. This briefing is the second in a series by the Nuffield Trust investigating the future of service delivery in various specialisms within the health service.

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Key points

Opportunities and emerging trends

Pathology presents many concrete opportunities in the near future to deliver better and more efficient care. These deserve a place at the top of the agenda of local and national NHS leaders. They are underpinned by rapid technological change, which will also present some challenges.

- A lot has happened since Lord Carter's reviews of how pathology services were organised in 2006 and 2008, but **progress has been patchy. Efficiency can be improved** and at a time of great financial pressure, it must be. In his latest report looking across the NHS, Lord Carter estimates gains of £200 million are still possible. In many areas savings should be reinvested to fund additional activity and achieve the quality improvements that are needed. Indeed, reinvestment could be a powerful motivator for teams to lead improvement in their services.
- **There is considerable scope to improve the effectiveness of existing services.** The National Laboratory Medicine Catalogue (NLMC) will provide an increasingly useful language and standards for testing and reporting. The Royal College of Pathologists has endorsed the 'Choosing Wisely' campaign, which is designed to ensure only the most appropriate and effective investigations are used. Translating these into routine practice will be a substantial and at times difficult undertaking.
- **Working together with other diagnostic disciplines, pathology can make a substantial contribution to the commitment to diagnose cancer within 4 weeks** of a GP referral by 2020. Acute assessment could also be redesigned to provide improved care out of hospital and reduce crowding of hospitals, extending the life of existing infrastructure, which will struggle to cope with expected population increases without major investment.
- Acknowledged **gaps in provision currently exist in the fields of molecular testing and genomics, but rapid progress is beginning.** The 100,000 Genome project has created a network of 13 genomic medical centres. The pace of sample collection is accelerating with several positive results for patients already reported, and the design of this programme has the potential to lead to more rapid and consistent adoption of new technology than any previous initiative.
- **The pace and scale of innovation in the biosciences is significant and developing the sector is seen as a national priority.** Point of care testing carried out at the bedside or nearby to patients is developing quickly, and biosensors developed in other sectors are starting to have applications in health care. Smartphones and the ease of entering the market for apps will expand a parallel consumer market with implications for traditional services.

Making the future happen

Taking advantage of these opportunities and emerging trends will need careful, informed leadership at every level – from boards, clinicians, commissioners and the national leadership of the NHS.

- Trusts that are making most progress have formed networks and joint ventures and are already reporting benefits. But **far greater opportunities exist for systems that want to be ambitious**. Boards should not limit their thinking to achieving efficiency savings: with effective clinical leadership and staff engagement more is possible, but securing benefits will take time and long-term commitment.
- It is not clear that the most effective solutions are found at the level of existing providers so **there is scope for new approaches that consider the whole pathway together with pathology**, and these should be encouraged. Although some existing providers will want to provide services throughout the value chain, many will need to be more selective about what they can achieve.
- With a shift to place-based planning it is possible that **systematic collaboration between sites will deliver greater benefits than consolidation** into larger-scale centres.
- The evolution of genetic services is expected to lead to an integrated network of genomic laboratories, operating to common standards across the country. **Local health and care systems will need to design improvement and governance systems to take account of these developments**. With rapidly developing technology, **contractual frameworks need to be sufficiently flexible** to keep pace with developments and support local approaches to networking.
- Getting the greatest benefit for patients from bioscience and software innovation will require the NHS to play a role not only in evaluating what works, but in **investing in developing models of care that take advantage of what is available**, and new approaches to contracting to encourage innovation.
- There is widespread agreement on the **need for better supported IT that is interoperable so patients and other institutions can easily access data**. The National Laboratory Medicine Catalogue is an important foundation for this work. Effective laboratory information management systems are also critical for the delivery of high-quality, safe pathology services. As the quantity of digital information increases, **the ability to store, retrieve and analyse data will become increasingly important**.
- **None of these changes can be delivered without a highly skilled and effective workforce**. We have identified several concerns about the future, but have not been able to build a comprehensive picture. The Royal College of Pathologists identified that 40% of pathologists are over 55 and most are expected to retire in the next five years. **Training pathways will not generate sufficient people** to replace them, which poses a significant risk to service delivery. Changing technology may make some skills redundant while requiring new ones, but this is unlikely to fully mitigate the risk. **There is a rapidly increasing demand for bio-informaticians and an increasing need for training and education** to allow the wider clinical workforce to keep up with developments in the field.

The real possibilities of delivering substantial improvements make this a good time to focus on pathology. The landscape will be very different in five years' time. Decisions made now will decide between very different trajectories as patients, commissioners and staff work to secure improved outcomes at lower cost.

1. Introduction

Attention in the NHS has been focused on integrated care in recent years, but there is rapid and potentially disruptive change happening in other parts of the system, with opportunities to significantly improve services. One such area is the field of pathology. This report aims to identify the opportunities and emerging trends affecting pathology that boards should be aware of, and to draw out lessons on making improvement happen in different fields.

Overview of methodology

A high-level review of literature was carried out in September 2015. An online search was also undertaken to identify editorial comment and innovative practice. The literature scan was not a comprehensive thematic literature review. It focused on the broad principles and themes in developments across a range of pathology services, rather than looking at developments at the level of individual tests.

We also interviewed 24 individuals with different perspectives of pathology services during autumn 2015, including clinicians and executives from NHS providers and the independent sector, and officials in national bodies.

Lastly, a stakeholder event on 9 December 2015 brought together over 60 key national and local leaders in pathology to explore how the field is changing and to look at the future of laboratory medicine over the next five to ten years.

Further details on approaches used are given in Appendix C.

Why focus on pathology?

For commissioners and trust boards looking across the system, pathology can be less visible than areas that are obviously pulled into the system's goals of joining up care around complex patients and delivering more treatment outside hospital. However, looked at closely, it has a strong case for being made a priority. The place of pathology in many pathways means it influences services across hospitals and in the community. Demand is rising and changing. Above all, it offers clear opportunities for concrete improvement. Two reviews by Lord Carter in 2006 and 2008 identified a broad agenda of ways in which pathology could change to deliver better care for less (Department of Health, 2006; 2008). Yet although real progress has been made, a mapping against these opportunities clearly shows that it has often been partial and patchy. There are still chances for improvement that can and must be seized.

Pathology is a critical component of most care pathways inside and outside hospital

Pathology diagnostic services are a critical component of health care: it has been estimated that 70–80% of all health care decisions affecting diagnosis or treatment involved a pathology investigation (Department of Health, 2006). On average, every

person in England has 14 tests per year analysed by a pathologist (NHS Choices, 2014).

Pathology plays a vital role in ensuring patients get accurate and timely diagnosis and treatment. Diagnostic errors, be they inaccurate results or delays in receiving results, can cause harm through creating delays in care or the wrong treatment provided (Institute of Medicine, 2015). The Institute of Medicine's study into diagnosis in the United States found that about 5% of adult outpatients suffer a delayed or wrong diagnosis; diagnostic errors are implicated in one of every 10 patient deaths and account for up to 17% of hospital adverse events (Institute of Medicine, 1999). It is not clear how replicable these results are and it is important to emphasise most of the errors occur at service interfaces.

Interviewees reported that although the pathology service budget is only 5–6% of total health care spending, the impact pathology has on total expenditure can be much higher due to it being an integral part of most patient pathways. For example, inpatients waiting for test results can result in increases in length of stay, and lack of organisation in pathways can result in multiple consultations if results are not aligned to appointment times and other tests (see Box 1 for a case study example). Another example is the use of point of care testing (POCT) to promote self-care, avoid multiple appointments or to manage patients more effectively by being able to identify the need for earlier intervention.

Box 1: Case study – urine testing in North Devon

North Devon has significantly reduced urine testing in general practice, while still having the same number of abnormal test results – suggesting patients that needed testing were not missed when levels were reduced through standardisation of the patient pathway and the decision to test. This reduction has improved the flow of testing and management of patients as GPs have more time to review results and contact patients that need contacting. For more detail on this and other effectiveness improvements, see Lewis and others (2016).

Recognising the value of pathology in optimising pathway flow and patient care, diagnostic services are increasingly working more closely with clinical teams to develop clinical pathways. This is an expansion of traditional roles and it will take time to develop to ensure pathologists are able to effectively communicate the contribution they can make.

The rethinking of patient pathways offers ultimately greater potential for savings than just focusing on reducing laboratory costs and chasing economies of scale. Pathology services, working across health care with primary and secondary care clinicians to 'optimise' pathways can be effective in reducing variation and unnecessary testing. This is likely to require the development and adoption of standardised testing protocols, benchmarking and behaviour change. There is increasing interest in the value added by pathology. Although some of this is in the control of the laboratories, a significant amount is dependent on the elements of the patient pathway before and after the laboratory test itself. Securing improvement in these areas requires effective relationships between pathologists and other care providers.

Demand is increasing and changing

Recent data from the Keele University Benchmarking Service¹ from 2012–15 found that total demand for blood science tests (chemistry, haematology, immunology and blood transfusion) has grown by around 5% per year; total demand for microbiology requests has grown by around 2% per year; and total demand for cellular pathology requests has stayed broadly the same (Keele University Benchmarking Service, no date).

Although demand has risen, some of this has been accommodated by the introduction of automation into the laboratory, particularly in blood sciences, but increasingly in microbiology and histopathology. This has meant that larger volumes of tests can be processed with many reported in a matter of minutes.

It is not yet clear what the impact of initiatives to diagnose cancer earlier will be or how significant the increase in genomic tests will be. Cancer Research UK has recently commissioned work to answer this question and results will be published soon.

Some interviewees suggested that demand in primary care has increased over recent years, partly due to clinical demand, but also from policy decisions – such as the implementation of the Quality and Outcomes Framework, which has led to additional testing for chronic diseases. The likely rise in demand for more urgent testing with faster turnaround times in primary and community care was also identified by people we interviewed as an issue that needs to be addressed, particularly in relation to preventing hospital admissions and supporting acute and frail patients in the community. It was suggested by interviewees that urgent pathology testing in primary and community care has not been a priority in many areas:

“Community urgent pathology is an unheard-of concept; GPs make decisions on the back of nothing. Point of care testing and new technology may allow us to close the gap.”

Interviewees also reflected that GPs were often skilled at making decisions with limited access to confirmatory diagnostics and that POCT offered a potential option to support diagnosis at the point of care in the community. However, the clinical and business models still need to develop to enable effective use.

Several interviewees reflected that the changes in demand and unintended consequences of policy implementation (such as the Quality and Outcomes Framework) are often more challenging to identify at a local and regional level as provision of pathology services usually resides within individual providers, and there can be a lack of a collective view across a health economy.

Interviewees also expected patient demand to rise. Patients are unlikely to wait for the NHS to embrace new technologies, and although there is a national drive to ‘choose wisely’, it is recognised that there are significant competing pressures from the genomics programme and commercialisation of pathology. This may create a parallel consumer market which may have an impact on demand for NHS services as patients become more aware of what tests and preventative treatments are available. Although there are benefits to this, there are also risks, and the NHS will have to consider how to influence and respond to these developments.

¹ The Keele University Benchmarking Service (KUBS) has been delivering the Pathology Laboratory Benchmarking programme to NHS organisations in the UK for over 20 years, and are the only organisation in the UK to provide such information. This service is peer reviewed and guided by specialty panels in each discipline, all of whom represent professional bodies including the Royal College of Pathologists and Institute for Biomedical Science (IBMS). It has been developed through feedback from its members.

Most interviewees believed demand would continue to grow, particularly due to:

- increasing numbers of patients with chronic diseases
- development of more personalised medicine and preventative medicine; rising patient and clinical expectations
- a shift to increasingly supporting more frail patients in the community.

It will be important to provide rapid, high-quality diagnostics tests by pathology, radiology and other diagnostic disciplines to avoid admission to hospital and the more accurate prescribing of anti-microbials and other treatment.

There are opportunities for service redesign to deliver better, more efficient care. Centralisation and consolidation are always difficult and contentious, and in some fields there is little evidence that they improve results (Imison and others, 2014). However, our event and interviews reflected a relatively wide belief that, in the case of pathology, substantial opportunities for better quality and more efficient care could be obtained by working in networks and reducing the number of sites at which procedures are carried out.

These opportunities were clearly identified by Lord Carter's reviews. The reviews argued for:

- Consolidation of specialist work into centres to assure quality and address professional isolation
- Pathology networks with single management structures, through several trusts working as a consortium, co-ordination by commissioners or outsourcing
- No more than three networks per previous strategic health authority area – in other words, no more than 30 in England.

Experiences since have shown that over a three-to-five-year period, such redesign can deliver savings of 10–20%. The 2016 Carter Review looked at more recent consolidations and concluded that they confirmed that opportunities for improvement existed (Department of Health, 2016).

2. The implications of technological change

Plans to seize the opportunities presented in pathology must be shaped by recognising the exceptional variety and pace of technological change the field is facing. For many drivers of change, the trend can be expected to accelerate in the coming five to ten years.

Preventative and personalised medicine

Over recent years there has been a progressive shift from disease diagnosis and treatment to predictive and preventative medicine and personalised health monitoring. As well as clear indicators of risk of disease, such as defective genes, research at the molecular level (alongside computer algorithms) has also been able to identify associations and implications based on changes in a number of ‘weak’ biomarkers (Wells, 2012).

Recognising this shift, NHS England recently set out the concept of personalised medicine within the NHS, and the underpinning principles and work being undertaken to develop a personalised medicine strategy (NHS England, 2015).

Genomics

Many interviewees discussed the impact of genomics, and stakeholders at a national level suggested that the genomic medical centres (GMCs) could offer a template for consolidating other pathology services. Genomic medical centres have brought about change, drawing organisations and leaders together and creating energy to address interoperability and pool resources and talent. However, comparisons of the GMC model to other pathology services is limited as the centres required relatively small-scale changes within providers, compared to remodelling existing services on a large scale. However, the GMC footprints largely represent natural communities and may be a useful basis for further joint work.

Interviewees from across all perspectives cited the lack of bioinformatics and connectivity as a critical barrier to the field of genomics (and wider pathology services). One interviewee said:

“Sequencing is cheap compared to the informatics needed, we have nothing like the informatics and interpretation capacity required.”

The other key challenge to genomics is to maintain consistent interpretation of genomic data – it was felt that “it is important to tell [the] truth, but essential to say the same story, we won’t always be able to tell the truth as we don’t know enough”. Knowledge of pathogenetics is rapidly evolving and there is a significant challenge in ensuring a common standard for interpreting results and the cut-off point of

statistically significant pathogenicity: there are likely to be high levels of confusion and interpretation without clear guidelines. This raises ethical issues around responsibilities of reporting and openness which do not seem to have been fully explored. As experts in pathogenesis, pathologists have a key role to play here.

There was often a range of views expressed on genomics and the impact that it will have on service delivery – national leaders present a strong vision of the future of genomics in improving care and within personalised medicine, whereas some clinicians working within local systems report that genomics was a very distant development. Many interviewees believed that there was a stronger need to focus on and not lose sight of existing services in order that they have the impact that is needed and cover seven-day working. Many felt that the genomics programme may create unnecessary clinical and patient demand – particularly where there are existing tests to determine diagnosis. The need to target the genomics resource effectively was raised by several interviewees. It is clear that the expertise needed to do this will take some time to develop – during which time existing testing regimes will continue.

Patients will need to be engaged, educated and become increasingly ‘health literate’ alongside the development of innovations, such as genomics, and increasing testing – ethical debates are likely to arise around consent and how to interpret complex data with long-term impacts on patients. These debates require more time and involvement of patient groups. For example, patient interpretation of genomics is a significant challenge. In particular, defining and communicating levels of pathogenicity and the early stages of interpretation of genomics may risk unnecessary anxiety, treatments and interventions.

There is also a risk of rising inequalities as patients that are more health literate may be more likely to request and access new technologies. In addition, some conditions such as particular types of cancer and rare and complex diseases may obtain more focused attention in light of genomics advancement, which risks skewing finite resources from other diseases or specialities.

POCT and bio-sensing

There are now a wide variety of point of care tests that provide rapid ‘near patient’ results. These may have potential to improve outcomes outside of the hospital by improving prescribing decisions, reducing referrals, improving efficiency of care and decreasing costs. Professional POCT has the potential to deliver results more rapidly, improve speed to diagnosis (which is critical for life-threatening conditions such as sepsis and infection control), accelerate patient management, and assist in targeting treatment (Jones and others, 2013; Bissonnette and Bergeron, 2010; Goldenberg and others, 2014; Moore, 2013; Huang and others, 2013), and could be used in primary care and in remote settings with no laboratory infrastructure (Pai and others, 2012).

Opportunities in specific fields may include the following:

- **Supporting self-care.** For selected and successfully trained patients with long-term conditions, POCT could offer improved quality of life with less travel to clinics and fewer adverse events requiring hospital treatment. Self-care chronic disease management with the use of POCT usually requires a health care contact point (often a nursing team), which may require establishing a new service and workforce

skills around motivational interviews and behavioural change (Heneghan and others, 2006; Connock and others, 2007; Garcia-Alamino, 2010).

- **Changing processes and roles.** Adoption of POCT is often insufficient to achieve benefits; in many cases a change of care process is usually required (St John, 2010). Close working between those undertaking the testing, the laboratory staff and the service lead (to oversee quality assurance) is critical to the success of POCT (Lewandrowski, 2011; Medicines and Healthcare products Regulatory Agency, 2013).
- **Test accuracy and training.** A lack of systems to ensure quality and appropriate use of POCT is a common problem. However, POCT can be successful if tests are performed by trained staff, quality management procedures are followed, and if results are captured to prevent duplication (Stürenburg and Junker, 2009; Goldenberg and others, 2014; Campbell and Fedoriw, 2009). Interviewees outlined the need for pathology to provide oversight and quality assurance to POCT. However, in one case a provider had implemented POCT in multiple hospitals and put in place a support pathology service, the service had not been used much, as nurses undertaking testing and interpreting results did so confidently and accurately.
- **Costs** are also likely to remain an issue within the current contracting context of cost per test, rather than viewing costs across the pathway. POCT does offer the potential of substantial hospital savings through enabling rapid delivery of results, and reduction of costs and lower patient length of stay; most benefits are found when senior clinicians are undertaking POCT (Asha and others, 2014).

POCT in primary care may also prevent onward referral and further testing, so the higher cost of the test may be outweighed by the possible additional use of resources without a rapid diagnosis in primary care. However, there is a lack of robust research to confirm this hypothesis.

Patient travel costs could also potentially be saved if POCT is undertaken in primary care and the patient is not referred on (particularly if very rural) (Laurence, 2010).

A good example of this approach is highlighted by the case of a patient who needs regular transfusions for their condition, has poor venous access and had to travel for almost 2 hours each way for monitoring and transfusion. The laboratory and GP practice worked together to provide a point of care meter, so the patient now only has to travel when a transfusion is needed, significantly improving their life at the same time as making clinic management easier.

POCT is also a growing market, and analysis of current trends in molecular diagnostics points towards developments in micro-fluid dynamics and automated 'lab-on-a-chip' devices, promoting point-of-care diagnostics (Weile and Knabbe, 2009).

Implications for funding and governance

Political prioritisation of personalised medicine and genomics has raised the profile of diagnostics. As well as the genomics programme, other technology innovations are expected to drive service changes.

The best answers regarding what works will come from local experimentation and collaboration across networks. It is critical that business models, education and training and contracting frameworks are allowed to develop to ensure opportunities to improve care and value are not lost.

Regulation and the difficulty in using the NHS as a test site for new diagnostics were cited as barriers to embracing new technologies, such as around bio-sensing, where most innovation is occurring in agriculture and environmental science.

3. Securing consistent care and services

Standardising how care is delivered, assuring quality and reducing variation in when and how procedures are ordered will be key areas of opportunity in the near future.

Standardisation

Variation across all aspects of pathology – such as processes, technology, connectivity, operating practices and workforce – were all cited as barriers to realising efficiencies, releasing capacity, and to effective networking or partnerships with other NHS providers and the independent sector. Equally, innovation must be protected and encouraged: what is required is a systematic approach to learning and improvement at a scale that is effective.

Box 2: Case study – POCT in hospitals

One independent sector provider uses POCT – for haemoglobin, full blood count, glucose, urine and blood gas in intensive care – in over 50 of its hospitals and developed seven consolidated laboratories to support laboratory testing. The consolidation of laboratories required the standardisation of processes and testing. Although challenging, the approach was based on evidence-based standard operating practice and any changes had to be based on evidence.

The National Laboratory Medicine Catalogue (NLMC) aims to reduce some of the level of unnecessary testing through developing standard naming conventions and providing decision support and test evaluation (NHS England, 2014). The Royal College of Pathologists (2015) identifies this as one of its core priorities for the Five Year Forward View period. However, they rightly warn that further investment will be needed to fully implement the programme.

The benefits of standardisation have been broadly recognised across the service. However, clinicians emphasise that although there should be standardisation, there should not be “fossilisation” and that standard operating procedures (SOPs) need to be continually developed in light of experience.

There is increasing recognition of the need to balance the tension to develop local solutions that fit local needs and populations with high levels of standardisation required to ensure reliability of complex diagnostic processes (e.g. genomics, and subsequent tests that come from positive genetic results). The right solution will be very dependent on local context and should be reflected in Sustainability and Transformation Plans (STPs).

Assuring quality

There have been a number of positive steps made towards improving assurance and information regarding pathology services, such as the NHS Atlas of Variation in Diagnostic Services, the National Laboratory Medicine Catalogue and accreditation programmes. NHS England is working to develop quality and performance dashboards. It is important that these tools continue to develop and the resources needed to do this are taken into account.

Although improvements in accreditation and the introduction of performance dashboards are mainly well received, there is concern that there is over reliance on process and input measures such as turn-around time, volumes, access to specialist advice and guidance to interpret results. End-to-end service and patient information standards remain limited in many areas, but are increasingly being discussed in terms of how to develop more effective measures of quality.

There is also a growing recognition at the local level of the value in establishing education programmes to enable the clinical community to keep up to date with developments in pathology. Effective programmes are based on proven improvement methodologies, such as implementing models that replicate the medicines optimisation teams – providing benchmarking, support, education and peer review to reduce variation and to roll out good practice (see Box 3).

Box 3: Case study – using patient stories to address unnecessary testing

Patient stories, widely used in other contexts, work well as a powerful approach to improvement in pathology. Stories can often elicit information that cannot be captured in standard process measures. The story of a patient who had an inappropriate test that was reported outside normal reference ranges and led to 14 additional GP and hospital appointments and further tests has led North Devon to establish a pathology optimisation process – using the same approach as medicines optimisation: ensuring GP leads in each practice; benchmarking; reviewing testing; addressing variation; decommissioning if appropriate; study sessions; and an interface group to discuss issues.

This approach led to chronic disease testing levels returning to 2002-era volumes and reductions in unnecessary urine test volumes (40% reduction overall) through working across the health system to develop consensus guidelines and engage with clinicians. Taking out inappropriate urine testing (which would lead to culture growth on asymptomatic patients) meant GP and secondary care workload was reduced as inappropriate follow up, prescribing and admissions were reduced, as well as resulting in reduced patient anxiety and risk.

In one year, around £200,000 saving was made (over a population of 160,000). The commissioners were supportive of the drive to improve the whole pathway and roll out a similar approach for other testing (e.g. full blood counts and liver testing, which can result in inappropriate colonoscopies and ultrasounds).

To support this, the service was temporarily moved onto a block contract, with the aim of creating a contract based on pathology service optimisation and adding value.

There is a developing national architecture for standardisation and quality assurance. However, there is more to do to drive local pathology improvement programmes to achieve efficiencies and support improved flow within care pathways.

Quality improvement is most likely to be driven by understanding the pathway. Locally led pathology optimisation teams that are enabled to review data, analyse workload, patient experience and develop standardised protocols can be a valuable approach to improving the quality and efficiency of pathology services. Benchmarking and education sessions could be used as a platform for behaviour change and improving services.

Unless nationally mandated, structural change, such as the development of further networks, is likely to be driven by the need for investment to renew infrastructure or manage workforce challenges. These are not necessarily positive reasons for change and therefore a more proactive approach is encouraged.

4. Making consolidation work

There exists potential for centralisation of tasks in particular sites to save money and improve performance in pathology. As in all medical specialties, however, this is a difficult and contentious process which can take many forms and must be deployed, handled and supported carefully.

Local networks and barriers facing change

Laboratory consolidation received strong endorsement from the two Carter Reports in 2006 and 2008 (Carter, 2008). Areas have undertaken a variety of approaches to redesigning services, including outsourcing, joint ventures, merging, and networks of different scales. The aims are to improve quality and efficiency through (Porter and Olmsted Teisberg, 2004):

- delivering economies of scale through use of large-capacity automated systems
- faster turn-around times linked to connected IT
- centralising the workforce
- streamlined logistics
- centralising skills and expertise.

Different sub-specialities operate at different scales, and business cases will need to take account of this. Interviewees reported that trust reconfiguration has led to a consolidation of some pathology services; either on one site, or splitting the work due to physical limitations of some laboratories and promoting greater use of automated pathology technologies. See Box 4.

Box 4: Case study – networked model

The implementation of a networked model with an independent sector partner resulted in a 50–60% reduction of workload at two hospital laboratories and an over 20% reduction in turnaround times (James and Truman, 2015).

Interviewees outlined a number of barriers to consolidation of pathology services.

Internal barriers:

- Concern that local relationship with clinicians will be damaged or lost
- Increasing operational complexity that does not add clinical value
- Concern on the part of trust clinicians that removing pathology from the hospital would impact on turnaround times and quality
- Resistance from staff who may lose jobs, have to travel further or relocate

- Trusts can be anxious to ‘lose’ laboratory services due to contracting and funding arrangements
- Higher priorities for trust boards and lack of understanding of the role of pathology.

External/change management barriers:

- Lack of a convenor to lever widescale reconfiguration of services between existing trusts
- Previous “heavy handed” attempts at large-scale consolidation have left apprehension in the system
- Lack of capital for investing in reorganisation costs, such as equipment, estate, transport, training and logistics
- Excessive focus on savings as the driver for change
- Difficulties agreeing how benefits will be equitably shared, particularly when trusts have different starting costs and prices, and poor baseline data
- A lack of trust and poor relationships between neighbouring trusts or independent sector providers
- A lack of managerial and clinical capacity and capability.

These issues affect the prospects for making improvements for patients and ensuring long-term service sustainability. Through our interviews we also heard the following concerns:

- Without change it will be difficult to maintain an appropriately skilled workforce in many areas of the country. This is a particular concern for histopathology but also affects other disciplines.
- Networks appear to be achieving productivity gains of 15–20%, and this opportunity is lost without change.
- Operating at the level of individual trusts, the NHS is failing to secure best value in procurement.

How change is driven

There are competing models of change in pathology. There are top-down models for the genomics programmes, and on the other hand a range of local networks are starting to emerge with increasingly mixed provider models. These local models tend to be based on a pragmatic process of what can be achieved within local situations. The average seems to be two or three trusts working together. Few areas have developed networks on a regional scale or forged clearly structured partnerships with the independent sector, although many have commissioned services for specific diagnostic tests (rather than whole-service transfer).

Interviewees cited uncertainty about the commitment of commissioners, the Department of Health and NHS England to driving forward pathology consolidation. Although policy statements have been broadly supportive of joint ventures,

interviewees felt that the centre had not placed a compulsion on trusts to consolidate their pathology services, and had not pushed them to work with the independent sector. Some interviewees suggested that this had led to joint venture schemes falling by the wayside. However, given that local accountability is vital and that what makes sense nationally does not always translate into locally implementable solutions, this does not necessarily represent failure.

Commissioners have not been the drivers for step-change that some had predicted (and in some cases have abandoned major projects). Although some commissioners have used the fact that close to half of most laboratories work originates in general practice and the threat of removing this prompted change in trusts.

Some interviewees felt that a wider debate over privatisation of frontline services had spilled over into pathology and it has been ‘tainted’ because of this. This may mean some trusts are willing to look at trust-to-trust collaboration, but would not consider a partnership with an independent sector provider.

Box 5: Case study – merged laboratory service with specialised sites

PAWS (Pathology at Wigan and Salford) merged their laboratories and located the main laboratory on one site and blood science testing on the other site. The hospitals are approximately 20 miles apart; tests (including urgent tests) now travel either by hourly couriers (weekday 9am–6pm, weekend 9am–4pm) or as individual samples if they need to be expedited. The journey time between hospitals (and therefore the two laboratories) is 45 minutes. Primary care samples are taken to the local hospital site, processed and then transported if the laboratory analysis is on the other site. There was resistance from local primary care and clinicians in the hospital site that was technically ‘losing’ services to be run in the main laboratory in a hospital 20 miles away; however, the system setup has resulted in better-quality testing for some services, consistent turnaround times and overall positive feedback from clinicians.

Investing in new service models and realising the benefits

Interviewees that had undertaken consolidation highlighted the need for investment to enable efficiencies to be realised, such as: purchasing new equipment; setting up transport infrastructure; and connecting IT and training staff.

One network had £7 million invested in new equipment, IT, logistics and training from a joint venture partner. Other networks have been established within existing resources. The scale of the benefits seems to range from 15–20% savings achieved over 3–5 years. For example, two laboratories on different hospital sites consolidated and saved 17% of costs after an initial investment in a new build, equipment, transport infrastructure and training. Many interviewees believed that the financial pressure that trusts are currently under would lead to discussions to consolidate, but that without the finances to ‘pump-prime’ reconfiguration there were likely to be poor outcomes to these mergers.

On average, it seems to take between 18 months and 2 years from concept to implementation of new service models in pathology, although access to a high level of expertise in laboratory design and mobilisation can deliver service change sooner. In deciding which option to progress, it is important not to create polarised arguments and to accept that not all stakeholders will be happy with the final outcome. Strong clinical leadership, open debate and face-to-face communication are critical, as is clear governance (particularly if networks span multiple organisations) with mechanisms to escalate issues to the right level in the entity and networked organisations.

Although many interviewees recognised the need for more specialised testing to be taken to a larger laboratory to make use of equipment, skills and expertise, in some areas there is resistance to this due to the impact on financial viability with current contracting arrangements.

Interviewees found linking change to improved patient experience and clinical workload is an effective enabler. Financial savings are not usually motivators as any gains are rarely reinvested in the service that made the saving.

As networks are developing, it is increasingly helpful to define the performance standards necessary to support clinical decision making rather than to assume that faster is always better. See Box 6 for a case study.

Box 6: Case study – Increasing efficiency and GP engagement

North Devon laboratory staff worked with GPs and primary healthcare professionals to improve the effectiveness of pathology. GP engagement was based on reducing patient anxiety, always asking ‘did I deliver what the patient needed?’ and reducing GP workload through ‘decluttering’ the workload associated with review of unnecessary testing results. This approach also aims to reduce the unintended consequences of unnecessary testing and reduce variation. There has been a high level of engagement by GPs and a roll out of the approach through a growing network, due to effective and visible clinical leadership, as well as clear messaging on the benefits of improving the patient experience and primary care workload.

Joint ventures with the independent sector

Some trusts have undertaken joint ventures with an independent sector partner to provide the necessary capital investment (and also to bring in expertise to drive down purchasing costs) and process redesign capability.

Interviewees suggested that there can be a degree of naivety and lack of understanding in the NHS about how the commercial sector works. They may not have entered into a joint venture before (or not with a commercial partner). They may not realise what companies expect (e.g. indemnity against unexpected costs from using very old buildings). They may not provide what is expected of them in terms of data for companies to base a tender on. Data can be incorrect, out of date and without warranty. Trusts may also want to offer shorter contracts than commercial operators would like. To achieve a return on investment a company may need at least 10 years with the prospect of a five-year extension due to the long expected life of many of the assets involved.

In addition, the length of time before intention turns to operational activity can be an issue for both parties – as well as the number of aborted tenders that companies invested significant time in developing. This should become less of an issue if trusts build on the expertise that now exists and prepare effectively.

Successful collaborations build on recognition that everyone is in it for the long term and some things cannot be rushed. Good relationships with clinicians and managers at all the hospital sites are important, and clinical leaders are seen to be crucial. Examples of positive clinical engagement include:

- pathology committees which are run by clinicians
- performance data being shared with clinicians
- mechanisms for them to request new tests to be added to the menu – “It has to look and feel to consultants like a joined-up service”
- access to international knowledge and expertise, which can also be helpful for accelerating learning.

Many joint ventures do not affect the employment of pathologists, who generally remain with their trusts. However, laboratory scientists and support staff usually transfer to the new venture. They often have concerns about change and relocation if it is deemed necessary, although some view the transfer positively due to the expanded role and opportunities for career development.

Lessons for the future

Services that have successfully networked and consolidated often emerged locally and moved forward incrementally. It was noted that “networking and consolidation has been incremental, step by step”, recognising that areas “start from very different places with different local contexts.”

There appears to have been a shift from the Carter recommendations to more organic ‘bottom-up’ consolidation, with services coming together either due to hospital mergers or for specific requirements for change (such as the need for investment):

“Collaboration not consolidation may be the answer – working together for mutual benefit, rather than one trust taking charge and taking all the benefits.”

Clinicians need to be deeply involved in the process of change, particularly in managing expectations, facilitating staff engagement, proactively working to standardise approaches and realise benefits. They should chair the quality meetings, provide oversight and be embedded in staff consultation exercises.

A key challenge was identified over the issue of maintaining local clinician-to-clinician conversations that facilitate behaviour change and optimised pathology pathways where there is a move to consolidated larger service units. These may deliver economies of scale but also introduce other, less helpful, dynamics:

“Few people think places like us (small laboratories in smaller hospitals) have anything to offer, they view us as an expensive vanity project. We do look expensive on metrics that are narrowly defined, but we have created teams for ‘optimisation’ on

clinical effectiveness, variation and engagement – reducing admissions, length of stay and testing.”

The aim should be “designing for demand” – analysing levels of clinical and patient need and building a responsive service for the system. This should also take into account the role of pathology in working with the service to support behaviour change to standardised approaches to testing and defining when testing is needed. It was noted that the “use of diagnostics should be based on symptoms and support decision making; not a fishing exercise to find possible problems where there are none.”

Small locality teams may enable:

- more effective relationships with clinicians
- improved clinical decision making through being active participants in multidisciplinary team-based care
- the development of innovative models of diagnosis across primary and secondary care.

It is important that the approach to procurement is aligned with the vision and strategic objectives for change to ensure the process delivers the best solution for the local community. Careful and thorough preparation combined with an understanding of the area are likely to lead to better outcomes.

5. Workforce and digital technology: what's needed for the future?

A sustainable future for pathology rests on its workforce of skilled doctors, scientists and technicians. Achieving the potential improvements to their fullest extent will mean carefully developing, nurturing and planning for these staff. Additionally, overcoming limitations in information technology that are crucial for enabling effective communication is critically important.

The pathology workforce is highly capable, but priorities for development are clear

Many of Lord Carter's 2008 recommendations and conclusions regarding the workforce still stand – particularly in relation to ensuring it has the capabilities and flexibility to meet future workload.

The rapidly changing environment will put additional demands on pathologists and their colleagues, which they must be numerous and properly skilled enough to address. Pathologists have an important role in quality assurance that will expand with increasing test complexity. They will also play a larger role in working with the wider clinical team. The digital transfer of images and information potentially increases the size of networks they have access to. Although there are potential benefits, there are also a number of risks and it is clear more work is needed to understand the implications for role design.

Meanwhile, with the expansion of the number of diagnostic tests available, GPs and hospital clinicians routinely experience uncertainty and challenges in ordering and interpreting diagnostic laboratory tests (Burke, 2003; Hickner, 2014). It is likely that they will need increasing amounts of support from pathologists, scientists and technicians in choosing tests and interpreting laboratory results, as well as support in new models of testing, such as POCT (Plebani, 2002; Bossuyt and others, 2007).

Despite the above, the Royal College of Pathologists reports that 40% of its members are over 55, with half of those planning to retire in the next five years. Currently, only one in four chemical pathology training posts is being filled (Royal College of Pathologists, 2015a). The new target of a cancer diagnosis within four weeks of a GP consultation appears to place even more demand on this limited supply.

Patients are becoming more aware and educated regarding the available tests and increasingly want to understand what is being tested, what that test might find and what the result might mean (Gutmann, 2003), which will lead to changes in how consultations need to be delivered to maximise benefit for the patients.

Issues with the planning and deployment of the workforce also remain. There appears to be an imbalance between what would be the most effective use of workforce across regions and what is possible due to the lack of planning and overview of the workforce beyond the very local level. In terms of service redesign, staff turnover can become a key issue as soon as the change of location and/or employer is mooted. The NHS Atlas of Variation in Diagnostic Services also found differences in the profile of the workforce, and services doing similar work with different skill mixes (Public Health England, 2013).

Developing the workforce of the future

Interviewees cited a high level of pragmatism (often using innovative workforce redesign) in the approach to workforce management, where local changes resulted from problems or gaps in particular sections of the organisation workforce.

The workforce models emerging at local levels need to be captured and linked to national career pathways and education programmes to ensure the future workforce is flexible and equipped to deliver pathology services in the future. National and regional organisations are likely to provide increasing focus to long-term workforce planning and development. Careful consideration is needed to ensure career pathways are clear and promote personal growth and that gaps in service are addressed across regions.

It is increasingly recognised that a cross-discipline and flexible skill-mix approach is needed for future workforce models to meet gaps in skills and expertise. The retention and development of biomedical scientists was viewed as essential, as was the need to train pathologists to cover a broader remit and number of sub-specialities. However, alongside the need for increasing knowledge, there is also a trend for increasing specialisation that needs to be taken into account.

Locally, there is a need to recognise and plan for the service change impact on staff – particularly if relocation is required, which can lead to shortages in some teams within the pathology service. Many areas that have undertaken new service models have taken the time to re-grade and review the skill mix. This can release savings in the long term, but should also emphasise the relevance of training and development, as well as provision of a clearer career structure with opportunities to progress.

Information technology – connectivity and shared records

Connectivity and IT reliability are critical challenges that need to be addressed, not only across organisations, but in linking all tests together (including patient testing and POCT) to create a full diagnostic picture of the individual patient.

Some commentators estimate that around 25–40% of testing is unnecessary, due to previous test results not being available through unconnected information systems and variation in medical practice (Department of Health, 2006; Furness, 2011). However, there are often poor systems in place to monitor unnecessary testing or provide opportunities for learning and feedback to ordering clinicians. Testing ‘just in case’ can add to this variation – this is thought to be particularly true when the test is viewed as being of negligible cost, but where it can subsequently lead to further testing (generating ‘failure demand’).

The Atlas also found inconsistency of coding in both transmitting and receiving systems, which can create risks to interpretation and barriers to population-level use of data (Public Health England, 2013). Information generated through laboratory tests could be a powerful data resource exploited for clinical research, health monitoring and health care needs assessment – particularly if they are linked to related clinical and demographic information. However, the widespread variation in systems and processes and lack of connectivity is a significant barrier.

Interviewees strongly felt that there would be an increasing need for robust and reliable IT connectivity and informatics capabilities in pathology. They felt that this requires standardisation in order to share results, benchmark performance, use secondary data, exploit digital technologies in histopathology, and so on.

“Regardless of the service delivery model (central, local, independent or public), data sharing is critical. The ability to analyse data collaboratively is essential.”

Alongside connectivity of data sets, interviewees also outlined the need for clear (or standardised) interpretation of results and patient ownership of their records – including test results – arguing that this is critical for enabling personalised medicine and self-care of chronic diseases.

Very few laboratory information management systems are fully connected to patient records. One study linking testing to electronic health records found that laboratory tests reduced by 18% per week per hospitalisation (Zlabek and others, 2011). Connected systems also offer the opportunity to speed up patient pathways: for example, one study found that computer order entry reduced laboratory turnaround times by 54.5%, from 142 to 65 minutes (Steele and DeBrow, 2008). Decision support may also be effective for monitoring therapy, particularly using laboratory test reminders (Pearson and others, 2009).

What does this mean for the future?

Comparability and standardisation of data is needed in order to improve management and, more crucially, to realise the benefits of big data. The National Information Board and the Health and Social Care Information Centre are focused on developing national data standards for pathology and promoting interoperability and transparency which aims to create a strong information platform for analysis and data sharing.

Commissioning – collaboration and a focus on the service as a whole

At a national level, NHS England is working to explore a range of developments and levers to improve pathology services:

- consolidation of (non-urgent) testing
- training and development of staff
- data transparency and standardisation
- way that new tests in pathology can be used more effectively
- standard contracts for equipment services and instant access

- national standards – these may prompt an executive-level focus on diagnostics and, within this, pathology services.

Approaches to the commissioning of pathology at a local level are variable. One of the key barriers outlined by interviewees to developing new service models was the opaque underpinning contracting mechanisms, which are mainly based on payment according to number of transactions, rather than what is ultimately delivered to patients and other parts of the NHS. In some cases this damages relationships and creates a sense of mistrust between stakeholders, with a sense that they are competing for funding won through doing more. This can be a powerful barrier to improvement.

Commissioners are driving consolidation in some areas, but not necessarily in ways that are felt to be helpful in developing a networked approach underpinned with positive working relationships between organisations. Commissioning can be tactical and short term, and can leave stranded costs (i.e. investments that may become redundant) in the acute sector. There is a need for a detailed analysis of commissioning to ensure payment incentivises improvements in the care pathway (especially improvements that result in less testing). Tariffs must both adequately reimburse providers, while at the same time encouraging innovation and models that anticipate future needs.

At a local level, the potential for established NHS pathology services to lose the work they are given by GPs in some areas has led to thinking about different ways to arrange services. Having primary care activity remain in the service can be vital for ensuring a consistent patient record and making new models financially viable and resilient. There is a need for detailed analysis of the impact of changing service and contracting models, including recognising the long tail of laboratory work – the high-cost complex work that is often subsidised by the lower-cost, high-volume work.

What does this mean for the future?

Interviewees felt that there was a need to focus on end-to-end pathology pathways, as opposed to tests in isolation. Most interviewees recognised that the cost per test will become less relevant, particularly where the unit cost is low. This raises challenges for systems as they seek to deliver the ‘Carter’ benchmarks at the same time as improving effectiveness: sophisticated measures of what this means in practice are needed.

Ensuring that pathology commissioning supports whole-system pathway improvement is critical. Since this usually leads to reductions in test volumes, which can result in pathology budget cuts if viewed narrowly, it is critical to be able to have mature service-level conversations between commissioners and providers and internally within providers, at the service-line level. This allows a balanced approach to dealing with the loss of income, improved effectiveness of pathways and whole-system costs and benefits.

For service redesign and effective commissioning, it is essential to address the vested interest and competition of acute trusts due to models of contracting as well as poor relationships beyond pathology services. Even if the pathology services in an area work well together, there can be wider organisational barriers due to poor relationships between trusts and/or commissioners that prevent services networking – commissioners have a role to play here in convening and working through relationship issues.

Conclusion

We have identified case studies demonstrating both efficiency gains and improvements in effectiveness. Both of these are required in order to secure the full potential of benefits for patients. Productivity depends on laboratories being as efficient as possible while pathologists have the time and resources to work with clinical teams and patients to ensure the right tests are undertaken at the right time and that appropriate action follows. This requires ongoing training and development for the wider clinical community as well as effective information and informatics support.

Commissioners are likely to achieve the greatest system benefits by creating a framework that enables local providers to work together to improve pathways rather than by simply directly commissioning tests. To date, the majority of trusts developing business cases for investment have recognised the need to work beyond traditional boundaries. They have been locally led, with strong clinical and executive leadership. Not all networks have involved private sector investment. In some cases we heard that this accelerated improvement, but this is by no means a universal view – and private involvement is not a prerequisite for making major steps forward.

In parallel, the development of genomic laboratory networks is underway at a national level. It is expected that these networks will align closely with the genomic medical centres and support the implementation of latest generation testing to a national standard.

These parallel local and national processes must be handled carefully by trust boards, commissioners and policy makers. Trusts need to ensure they achieve the benefits of local networking while also being aligned to the national programme. Policy makers, for their part, need to make sure they are sensitive to local considerations and do not block progress. Commissioners need to take a long-term strategic view of the model they wish to support. Recognising this is likely to shape the overall provider landscape over the long term.

The latest Carter report will allow local systems to determine the most appropriate solution, provided that benchmarks are achieved. This is sensible as long as these are properly constructed. Applied well, this could encourage collaboration to ensure individual hospitals are not left out. There is a real risk of putting too much stress on efficiency as a goal at the expense of effectiveness, which tends to be more of a motivating aim for clinicians. But this is a lesser risk than the risk of doing nothing: local systems can and should address it by keeping quality improvement visible.

The bioscience sector is seen as critical to the future economic health of the country, and innovation is underway across the sector. The parallel development of new business models and interoperable information systems that maximise the potential gains from analytics are critical to putting ideas into action. Owing to the level of regulation in health care, proof of concept work is often undertaken in other sectors, and many companies seek to develop consumer markets for the same reasons. This is likely to lead to new challenges to current models of care, particularly for biosensors and POCT.

Providers need to understand what is happening to maximise the opportunities that may exist and minimise the threats.

Despite pathology being one of the most automated areas of health care, the workforce remains critical. Our work has identified significant concern about the future with few clear answers regarding how services will be maintained over the medium to long term. The most successful providers in the future are likely to be those that create careers that people want and that deliver high-quality services for their customers.

Now is a good time for boards to review their approach to pathology as one of the key diagnostic disciplines. Strategies that go well beyond delivering efficiency savings are essential if providers are to deliver the full value of what pathology can offer to service transformation.

Appendix A:

The branches of pathology

This appendix provides brief summaries of major branches of pathology as a discipline. It should be noted that the historic discipline-specific boundaries have also begun to contract, with the concept of blood science-based models also becoming common (Royal College of Pathologists, 2015b).

Haematology

Haematology is the diagnosis and clinical management of disorders of the blood (including constituents such as white blood cells, red blood cells, and platelets) and the tissues and organs comprising the hematopoietic system.

Common procedures and interventions include:

- formulating chemotherapy protocols and managing their delivery
- managing stem cell transplants
- providing advice on haematology laboratory results
- sampling bone marrow and interpreting the morphology
- performing diagnostic lumbar punctures and giving intra-thecal chemotherapy.

Histology and cytology

The study of cellular structure and function is called cytology, while the study of cells and tissues in an organism is called histology. By looking at the way that the cells are arranged, how they have developed and how they are functioning, it is possible to determine whether a patient has a disease, inflammation, a cancer or a non-cancerous growth.

Histology is the study of the structure of the cells, tissues, organs and organ systems. These studies are performed by examining cells and tissues. Tissue and cells are removed during surgical procedures in theatres, outpatient clinics, GP clinics or at post-mortem examination. Very thin shavings of the tissue are dyed different colours, allowing the cells to be examined under the microscope.

Cytology is the study of structure, function and chemistry of cells. Body fluids naturally contain cells, and cells can also be scraped from the surface of tissues. These cells can be collected and transferred onto glass slides where they are dyed and examined under the microscope for abnormalities.

Microbiology and virology

Medical microbiology and virology involve the diagnosis, treatment and prevention of the spread of infection in hospitals and the community. Both are laboratory-based, but contribute to clinical infection management.

Immunology

Immunologists investigate autoimmune diseases, specialised immunochemistry, and numbers and function of cells of the immune system. Many also carry out in vitro testing for allergies, and some are involved in transplantation and immunogenetics.

Immunology services often cover several hospitals or even a region, as some of the tests are relatively uncommon, and a large population is needed to generate the workload so that tests are done frequently enough to maintain expertise.

Molecular pathology and genomics

The discipline of molecular pathology studies and diagnoses disease by examining molecules within organs, tissues or bodily fluids. It shares some aspects of practice with both anatomic pathology and clinical pathology and is sometimes considered a 'crossover' discipline.

Molecular pathology is commonly used in diagnosis of cancer and infectious diseases. Genomics is a branch of molecular biology that studies the structure, function, evolution and mapping of genomes (the complete set of DNA within a single cell of an organism).

Techniques include: quantitative polymerase chain reaction (qPCR); multiplex PCR; DNA microarray; in situ hybridisation; DNA sequencing; antibody-based immunofluorescence tissue assays; molecular profiling of pathogens; and analysis of bacterial genes for antimicrobial resistance.

Molecular diagnostics and biomarker discoveries in oncology have led to the development of novel drug targets and new treatment strategies. The standard of care for patients with advanced-stage cancers has shifted to one that targets the molecular profile of the tumour. Molecular pathology has recently led to individual targeted cancer treatment for the treatment of five diseases: chronic myeloid leukaemia; colon, breast and lung cancer; and melanoma (Kalia, 2015).

Chemical pathology

Chemical pathology studies the biochemical basis of disease and the use of biochemical tests for screening, diagnosis, prognosis and management. Chemical pathologists will typically work with general practitioners, nurses and hospital doctors to provide advice on which tests to use and how to interpret the results of the tests when investigating patients. This commonly includes a wide range of conditions such as liver disease, kidney disease, high cholesterol, cancer, diabetes and hormone imbalances.

Chemical pathologists also usually have direct responsibility for patients in outpatient clinics and on the hospital wards. In these settings, chemical pathologists diagnose and treat a wide range of metabolic disorders such as high cholesterol, diabetes, hormone imbalances, kidney stones, bone disease and nutrition imbalances.

Appendix B: Progress since the 2006 and 2008 Carter reports

The Carter findings and recommendations from 2008 cited below are an amalgamation of recommendations and key statements. Despite progress in many areas, these comments and recommendations are still largely relevant and are yet to be fully addressed (Department of Health, 2008). The recommendations given by Carter in the report have been re-worded slightly in light of NHS reorganisations, such as the abolition of strategic health authorities and the development of NHS England.

Table A1: Progress since the 2006 and 2008 Carter reports

Carter finding and recommendation	Where are we now?
<p>Assuring quality</p> <ul style="list-style-type: none"> – Objective and measurable quality standards should be developed for pathology services, from sample request to delivery of interpreted result. – Accreditation process should be reviewed so that it inspects against the quality standards (once developed). – Pathology service providers (and, in future, consolidated networks) should be subject to mandatory accreditation by an organisation independent of the providers and the professions. – All providers of pathology services (including providers of point-of-care testing) should be required to participate in clinical audit and other clinical governance activities. – Nationally led formulation of proposals for ensuring that more information is made available to service users about the quality and safety of services. 	<ul style="list-style-type: none"> – There have been a number of positive steps made towards improving assurance and information regarding pathology services, such as the NHS Atlas of Variation in Diagnostic Services and the National Laboratory Medicine Catalogue. NHS England is developing a quality and performance dashboard. – The Clinical Pathology Accreditation service has transferred to the UK Accreditation Service. – There is some innovation in the development of patient-centred measures, e.g. in North Devon. There is also considerable work underway to support the 100,000 genome project.
<p>Standardisation</p> <p>Ensure that a pathology ‘formulary’, equivalent to that used in medicines, is introduced.</p>	<ul style="list-style-type: none"> – Standardisation from the National Laboratory Medicine Catalogue aims to develop standard naming conventions and provide decision support and test evaluation. – Some providers have formed networks and implemented standard operating practices.

Table A1: Progress since the 2006 and 2008 Carter reports

Carter finding and recommendation	Where are we now?
<p>Connectivity and IT</p> <p>IT connectivity should be put in place for NHS pathology services as a matter of priority.</p>	<ul style="list-style-type: none"> – The National Information Board and Health and Social Care Information Centre are developing national data standards for pathology and promoting interoperability. – Connectivity and IT reliability are critical challenges that need to be addressed not only across organisations, but in linking all tests together (including patient and point of care testing) to create a full diagnostic picture of the individual patient. – The National Information Board roadmaps highlighted the need for interoperability and data sharing. – Genomic medical centres have provided a focus to drive the interoperability agenda and promotion of standardisation for comparability and extracting the value of data.
<p>Commissioning</p> <ul style="list-style-type: none"> – Commissioners have the main potential to drive change. Because pathology is central to the delivery of responsive and high-quality NHS services, over time we envisage commissioners becoming increasingly involved with, and expert in, the commissioning of community-based and specialist pathology services. – A national clinical director for pathology should be appointed, working in partnership with a national commercial director for pathology. – Proposals for the reform of NHS pathology services should be reflected in the Operating Framework for the NHS in England. – Based on national guidance and support, commissioners should take the lead with providers (existing and, where known, potential) in drawing up cost-effective plans for implementation of recommendations. – Develop a tariff for community-based and specialist pathology. – Determine the coverage and format of benchmarking data to be collected from all pathology providers, and procure the collection of such data. – Develop commissioning guidance as a matter of priority. – Consider the development of model contracts for pathology. 	<ul style="list-style-type: none"> – In many areas there is an absence of strong commissioning in pathology. Most innovation appears to be being driven by providers. – National commissioning for genomic testing is under consideration but the process has slipped.

Table A1: Progress since the 2006 and 2008 Carter reports

Carter finding and recommendation	Where are we now?
<p>Service redesign</p> <p>There is a strong case for consolidation of pathology to improve quality, patient safety and efficiency.</p> <p>Specialist services should be consolidated through referral to specialist testing centres to assure quality and to address professional isolation.</p> <p>Pathology networks should be developed: each consolidated network should have a single integrated management structure, including a clinical director and commercial director, who would provide clear leadership and accountability. Governance and accountability arrangements for these networks might be as follows:</p> <ul style="list-style-type: none"> – A consortium arrangement where provider trusts agree to cede responsibility for the provision of their pathology services to the consortium, which then manages the combined service in accordance with a service-level agreement with the trusts. In some areas, implementation of these new structures for pathology would be led by NHS trusts. – A commissioning arrangement, where commissioners employ the network manager and pathology director to work with the provider trusts and other potential providers, again in accordance with a service-level agreement/legally binding contract. – A contracted-out model where service provision is outsourced to another organisation, either wholly to the independent sector or via a joint venture. <p>Overall, the expected number of networks should not exceed three networks per previous strategic health authority (SHA) area; indeed, a single network might cover one or more of the previous SHA areas.</p>	<p>Areas have undertaken a variety of approaches to redesigning services, including: outsourcing; joint ventures; merging; and networks of different scales (although the average seems to be two or three trusts working together).</p> <p>There are thought to have been twenty mergers involving NHS trusts and foundation trusts from early 2010 to mid-2015 (Collins, 2015), and around half the acute hospitals in England were involved in a reconfiguration during the late 1990s and early 2000s (Gaynor and others, 2012). These mergers have led to a consolidation of many pathology services (i.e. laboratories that are now under the same trust structure); either on one site, or splitting the work due to physical limitations of some laboratories and promoting higher use of automated pathology technologies.</p> <p>Service redesign seems to take 18 months to 2 years to implement. The scale of the benefits seems to range from 10–20% savings achieved over 3–5 years.</p> <p>Some of the mergers in laboratories across trusts arose from commissioners driving efficiency savings and wanting to rebalance the costs of primary care testing compared to secondary care testing.</p> <p>Very few areas have developed regional/larger networks or forged clearly structured partnerships with the independent sector, although many have commissioned services on a service line basis.</p> <p>The Carter recommendations were dependent on a series of organisational interactions and architecture that were subsequently abolished. With the re-organisation there was also a loss of organisational memory, drive and the relationships that underpinned consolidation of pathology services. The lack of overarching regional architecture to bring organisations to the negotiating table and monitor progress and change control has resulted in a diversity of localised approaches being adopted.</p>

Table A1: Progress since the 2006 and 2008 Carter reports

Carter finding and recommendation	Where are we now?
<p>Workforce</p> <ul style="list-style-type: none"> – The pathology practitioner of the future, as a member of the multidisciplinary team, must ensure that the investigation(s) which contribute most to the diagnosis and/or treatment of the individual are undertaken. Through this role, the practitioner can improve health outcomes as well as value for money. – Advances will have a major impact on pathology services. Investment will be needed to provide and undertake these complex investigations, and practitioners will require new skills to perform them. <p>The NHS pathology workforce should be reformed in the following ways:</p> <ul style="list-style-type: none"> – Skill mix: There is scope for better alignment of skills with functions, including the grading of functions, as well as for more broadly based skills to enable staff to work more easily across and between the different disciplines. Provision to enable the future workforce to be reskilled so that they can take on new roles will help to ensure the supply of skilled staff necessary to guarantee continuity of service for the future. – Succession planning: provision needs to be made for maintaining specialist pathology and managerial expertise, for example through good succession-planning arrangements. – Education and training: education and training must be geared to the needs of the service, and should reflect the appropriate skill mix. Services that are more responsive will require a different, more outward-looking approach in future. In addition, the consolidation of services will require effective management of the end-to-end service; this in turn means making available to pathologists more training in clinical leadership and for pathology managers training in business management. – Workforce planning: where there is a clear vision of what pathology services should look like in the future, there should also be a workforce plan (numbers, skills, grades). A migration programme could then be devised, taking account of the age profile of the existing workforce, recruitment and retention rates and skill mix. It would be important to ensure that effective arrangements for relocation and redeployment were in place. Workforce planning for consolidated pathology services should help all providers – whether from the public or independent sector – to make effective contractual arrangements for reducing reliance on costly on-call arrangements. 	<ul style="list-style-type: none"> – There is a high level of pragmatism for workforce management, where local changes have resulted from problems or gaps in particular sections of the organisation workforce. There appears to be an imbalance between what would be the most effective use of workforce across regions and what is possible due to the lack of planning and overview of the workforce beyond the very local level. – NHS England is working with Health Education England to identify the education and training needed to prepare the workforce for the future. – Many local areas have redesigned their workforce, often alongside the development of their network. Some new roles have developed within the networks, although there is a lack of standardisation of roles which can mean training pathways may not be scalable/transferrable to other areas.

Table A1: Progress since the 2006 and 2008 Carter reports

Carter finding and recommendation	Where are we now?
<p>Innovation</p> <ul style="list-style-type: none"> – Technological advances are speeding up the shift towards better health outcomes delivered through personalised medicine. This trend will create demand for more molecular-based investigations, and will therefore increase pathology activity and service costs. – Through more complex investigations (genomics, metabolomics, proteomics), a profile of the chemical composition of an individual's body can be produced, making it possible to identify the disease(s) to which each individual has particular susceptibility and to detect such disease(s) in pre-symptomatic form – even to predict the onset of disease. At the same time, treatment can be personalised, enabling the efficacy of the intervention to be optimised for each individual. – Priority should be given to ensuring that pathology services are made more responsive to users' requirements, and, in particular, that phlebotomy and sample collection services should be made more accessible and convenient for service users. 	<ul style="list-style-type: none"> – Political prioritisation of personalised medicine and genomics has raised the profile of diagnostics. NHS England recently set out the concept of personalised medicine within the NHS, and the underpinning principles and work being undertaken to develop a personalised medicine strategy. – Genomic medical centres have produced change, bringing organisations and leaders together and creating the energy to address interoperability, pool resources and talent, and support improving efficiency and quality. – POCT is a growing market and analysis of current trends in molecular diagnostics points towards developments in micro-fluid dynamics and automated lab-on-a-chip devices, promoting point-of-care diagnostics. However, regulation and the difficulty in using the NHS as a test-site for new diagnostics remains a barrier to embracing new technologies.

Appendix C: Research methods

Research for this paper was undertaken over the autumn and winter of 2015, consisting of the following elements.

A high-level review of literature

The literature review was undertaken during September 2015. This included a library scan of articles drawn from key words in relation to pathology service. An online search was also undertaken to identify editorial comment and innovative practice. The literature scan was not a comprehensive thematic literature review. The scan focused on the broad principles and themes in relation to pathology services; it did not look in detail at the future direction of individual tests or branches of pathology, but rather sought to identify the future direction of travel that is likely to be able to be extrapolated to a number of diagnostic tests.

It should be noted that there is a paucity of research focused on pathology service models and workforce. While there are numerous editorial reviews, many studies are limited in that they are not systematic reviews or randomised trials, lack a comparative group, lack clear definitions, lack robust cost-effectiveness analysis, and lack longitudinal evaluation. Due to these limitations, insights from the literature scan were used as a platform to set out key themes and provide a basis for reflection and discussion during interviews with key stakeholders and at the event on 9 December 2015.

Interviews with key stakeholders

The review interviewed 24 four individuals with differing perspectives of pathology services during autumn 2015. Interviewees were drawn from across national organisations, NHS providers and the independent sector, as well as clinicians from across primary and secondary care. Interviewees were selected based on identification by national organisations and internal intelligence of the Nuffield Trust.

Stakeholder event

An event was held on 9 December 2015 to explore how pathology is changing and what the future of laboratory medicine might be over the next 5–10 years. The event brought together over 60 key national and local leaders in pathology and participants from across the NHS, independent sector and technology developers. The event was hosted by the Nuffield Trust in partnership with the Association of Independent Pathology Providers. More details can be found at: <http://www.nuffieldtrust.org.uk/talks/future-pathology> .

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About the authors

Sasha Karakusevic joined the Nuffield Trust in October 2015 as a Visiting Senior Fellow to work on health systems, with a particular interest in new technology, diagnostics and system design. Sasha started his career in dentistry and maxillofacial surgery. Early in his career he became very interested in service improvement and health system design, focusing on the systems and processes that drive innovation and improvement. He played a major role in shaping the South Devon Integrated Care Network. He has operated at Director level in the NHS since 2001 and has wide experience of using information to drive improvement and on aspects of patient flow. Sasha has worked with colleagues in a wide variety of countries exploring how to make health systems work better. Sasha has a BSc and BDS from the University of Manchester and an MBA from Imperial College London.

Nigel Edwards is Chief Executive at the Nuffield Trust. Prior to becoming Chief Executive in 2014, Nigel was an expert advisor with KPMG's Global Centre of Excellence for Health and Life Sciences and a Senior Fellow at The King's Fund. Nigel was Policy Director of the NHS Confederation for 11 years and has a wealth of experience in health and social care. He joined the organisation from a role as Director of the London Health Economics Consortium at the London School of Hygiene and Tropical Medicine, where he remains an honorary visiting professor. Nigel has a strong interest in new models of service delivery and a practical focus on what is happening at the front line as well as a wealth of experience in wider health care policy in the UK and internationally. Nigel is a well-known media commentator, often in the spotlight debating key policy issues.

Ruth Lewis is a Research Associate at the Nuffield Trust and a freelance researcher, providing project management, research and stakeholder management expertise. Ruth has worked within the NHS and has provided research expertise to the Prime Minister's Delivery Unit, the Department of Health, Public Health England and individual hospital trusts. Ruth has a first class Bachelor of Science (Hons) degree Biological in Sciences from the University of Exeter and a master's degree in Health Care Management from the University of Birmingham.

Mark Dayan is a Policy and Public Affairs Analyst at the Nuffield Trust. He works across the Policy and Communications teams. Mark is responsible for developing consultation responses and briefings for stakeholders and the media alongside research leads, applying the Nuffield Trust's cutting-edge research to inform major decisions in health and social care policy. Mark also assists in research projects and external commissions. Before joining the Trust, Mark gained experience in policy roles for the New Local Government Network and the Scottish Civil Service. He is a graduate of the University of Oxford and has an MSc in Philosophy and Public Policy from the London School of Economics.

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59 New Cavendish Street
London W1G 7LP
Telephone: 020 7631 8450
Facsimile: 020 7631 8451
Email: info@nuffieldtrust.org.uk

 www.nuffieldtrust.org.uk