



TESTING TIMES TO COME? AN EVALUATION OF PATHOLOGY CAPACITY ACROSS THE UK

NOVEMBER 2016

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ABOUT CANCER RESEARCH UK

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LIST OF ACRONYMS

AFC	Agenda for Change (pay bands)
BMS	Biomedical Scientists
B/M	Benign or malignant
CM-Path	Cellular Molecular Pathology initiative
COSD	Cancer Outcomes and Services Dataset
CT	Computed tomography
DNA	Deoxyribose nucleic acid
FOBT	Guaiac Faecal Occult Blood Test
FIT	Quantitative Faecal Immunochemical Test
FTE	Full-time equivalent
GMC	General Medical Council
GP	General Practitioner
H&E	Haematoxylin and eosin stain
HER2	HER2 is a receptor for a particular growth factor made in the body called human epidermal growth factor
HPV	Human papilloma virus
HSCIC	Health and Social Care Information Centre (now known as NHS Digital)
IHC	Immunohistochemistry
IT	Information Technology
MDT	Multidisciplinary Team
MLA	Medical Laboratory Assistant
NLMC	National Laboratory Medicines Catalogue
NCRI	National Cancer Research Institute
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
SIHMDS	Specialist Integrated Haematological Malignancy Diagnostic Services
STPs	Sustainability and Transformation Plans
TWW	Two-week wait
UK	United Kingdom

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EXECUTIVE SUMMARY

Whilst cancer survival is at its highest ever level, our health services are under considerable pressure. Increasing cancer incidence, an ageing population and efforts to improve outcomes means that the demand for cancer diagnostics has never been higher.

There were around 352,000 new cancer diagnoses in the UK in 2013¹ and this is set to increase considerably as we live longer. Indeed, around half of us will be diagnosed with cancer in our lifetime.²

Each country in the UK has their own waiting time targets. All measure how many people begin their treatment for cancer following an urgent referral, and these targets have been consistently missed in recent years. This is indicative of pressures across the pathway – from seeing a specialist, to receiving a test, to getting results, and ultimately commencing treatment.

We know from our previous research that endoscopy and imaging services have been delivering more activity over recent years^{3,4} but they are currently struggling to meet demand – leading to a diagnostic bottleneck and thousands of patients waiting in limbo. Ensuring diagnostic services can cope with future demand is essential if we are to improve outcomes for patients through early diagnosis.

Pathology plays a major role in the diagnosis and treatment of cancer, as well as many other conditions. Pathology is comprised of 19 different disciplines and our research focussed on the most relevant to cancer: cellular pathology (which encompasses both histopathology and cytopathology); blood sciences; and molecular pathology.

Cancer Research UK commissioned this research to understand the pressures facing pathology services across the UK and to identify solutions to address these issues. The work, conducted by 2020 Delivery, involved interviews with 25 different pathology providers, a survey of 11 laboratories and use of centrally collected data.

CURRENT LANDSCAPE

Increased demand for pathology services is due to higher cancer incidence, the growing complexity of referrals and requests, and the introduction of initiatives to increase earlier cancer diagnosis. Cellular pathology, blood sciences and molecular pathology, have all experienced an increase in activity in recent years. Each specialty is also experiencing difficulties in staffing their services.

Based on the number of pathologists currently in training and the age profile of the current workforce, our study found there is likely to be a severe crisis in pathology capacity within the next five to ten years.

CELLULAR PATHOLOGY

Year on year, the amount of histopathology requests received by each laboratory has been going up by around 4.5% on average.⁵ Demand has also increased as requests are increasing in complexity.

However, capacity has not kept up: staffing levels have not increased at the same rate as demand. Staffing estimates suggest that consultant cellular pathologist numbers have increased, but only by 1.2%⁶ to 3%⁷ per year.

In the next five to ten years there will be a shortage of consultant pathologists across all areas of pathology. This will have the largest impact on cellular pathology, as there is a shortfall in the numbers becoming cellular pathology consultants compared to those leaving the profession.

Many organisations have reported staffing shortages. To tackle the difficulty of recruiting at consultant level, there has been some use of skill mix approaches and role expansion, but implementation is varied. Many cellular pathologists have been reducing their other commitments such as training and research. Waiting times in cellular pathology are now starting to increase as a result of the increasing mismatch between staffing capacity and demand.

BLOOD SCIENCES

There has also been an increase in blood sciences activity. However, some processes in blood sciences have been automated, which has meant that the increase in demand has been absorbed by technological developments.

Delivery of blood sciences has changed, as the ratio of medical laboratory assistants to biomedical scientists increase – from 0.34 in 2008-9 to 0.51 in 2014-5.⁸ Vacancies are a problem for blood sciences but not to the same extent as cellular pathology.

MOLECULAR PATHOLOGY

Although demand for molecular testing has increased, capacity in test providers is generally capable of meeting current requests. However, testing activity has increased in recent years and this demand will continue to rise, especially as fewer tests were requested than would be expected from patient eligibility.⁹

It is likely this underutilisation of molecular diagnostic tests was due to a lack of clear commissioning arrangements. NHS England's forthcoming personalised medicine strategy will consider molecular diagnostic commissioning and provision.

RECOMMENDATIONS

Without action taken now to address workforce issues and improve efficiency, waiting times are likely to increase as it will take longer to process and report all requests. This means more people will be left in limbo when they require tests, and it may delay patients' diagnosis and treatment.

Turnaround times will increase to unacceptable levels which could compromise efforts to diagnose cancer earlier. Immediate action is needed to avert a crisis in pathology capacity and ensure we have a service that is fit for the future.

ENSURE PATHOLOGY SERVICES ARE MAXIMISING EFFICIENCY

There are inefficiencies in pathology services that must be reduced. Networking and consolidation of pathology services should continue. This may require upfront investment and should also take place with suitable planning. This has been noted in several reviews by Lord Carter.^{10,11}

Haematology and biochemistry should continue to increase productivity – absorbing the increase in workload through enhanced utilisation of equipment capacity. Long-term plans for staff, equipment and consumables should be made to address growing demand. Time for giving more clinical advice should acknowledge increasing complexity of tests.

Reducing pathology with limited clinical value (e.g. duplicative tests, or those which are not clinically recommended) could potentially reduce demand. This should be thoughtfully used as there is a risk it could undermine efforts to improve earlier diagnosis (and associated increase in referrals). However, reducing unwarranted demand has been recognised through the 'Choosing Wisely'¹² initiative, and could be addressed through analysis of the Atlas of Variation¹³, as well as the Royal College of Pathologists' 'Minimum Retesting Intervals Guidance in Pathology'.¹⁴

RECOMMENDATION 1: NHS England and NHS Improvement should continue to support Sustainability and Transformation Plan footprint areas (STPs) and Trusts to consolidate pathology services, in order to facilitate testing taking place at the appropriate level.

OPTIMISE THE PATHOLOGY WORKFORCE

Delivery of pathology services is currently getting more expensive due to increasing costs for staff overtime and outsourcing. To tackle this, pathology needs to utilise 'skill mix' approaches, where health professionals take on different but complementary roles and activities. However, efficiency and skill mix approaches will only go so far. In the long term, increasing demand means that we will need more pathologists and scientists.

Health Education England may need to explore increasing the provision of training places for pathology, depending on their ongoing review of the cancer workforce. Pathology may need to be included on the curricula in medical schools where pathology is not currently offered.

Another way to boost supply of the pathology workforce is to keep people within the profession for longer. To retain near-retirement consultants, Trusts should encourage them to remain at the organisation, for example by implementing flexible working and home reporting. NHS decision makers should give individual organisations flexibility in order to decide the terms that they arrange with individuals.

RECOMMENDATION 2: Trusts and their pathology departments, supported through guidance from professional bodies and NHS England, should:

1. Ensure biomedical scientists (BMS) are being utilised to cut up specimens where possible, in accordance with 'Principles of Good Practice for Biomedical Scientists Involved in Histopathological Dissection'.¹⁵
2. Explore the role of clinical scientists to support complex diagnostics and research. Clinical scientist input should be recognised in their job plans with backfill provided for existing duties.
3. Develop graduated increase in trainee responsibility and supervised reporting in accordance with the Royal College of Pathologists' guidance on graded responsibility.¹⁶ The Royal College of Pathologists should update and promote their guidance document.
4. Ensure widespread use of BMS reporting following their completion of the Biomedical Scientist reporting programme.

RECOMMENDATION 3: Health Education England should include cellular and molecular pathology within their review of the cancer and related workforce, to enable longer-term workforce planning. The Royal College of Pathologists should continue to run programmes aiming to attract more staff to cellular pathology.

RECOMMENDATION 4: In considering the new consultant contract, the Department of

Health and NHS Employers should consider the impact on near-retirement consultants.

FUTURE-PROOF PATHOLOGY

As more pathologists struggle to meet clinical obligations, many are deprioritising other activities like teaching and research. Without pathologists getting involved, academic input will decline and innovation in treatments and care may make slower progress.

Technology is changing, presenting new opportunities to improve pathology, including ‘digital pathology’.

Another area of innovation is molecular pathology. The level of provision of molecular diagnostic tests has recently been audited by NHS England to understand if there are areas where patients are not receiving the requisite level of testing. This should continue. Standardisation of testing could be achieved through the National Laboratory Medicines Catalogue, which is intended to act as the professional reference for all pathology tests approved for use in the UK.

RECOMMENDATION 5: There should be continued support from the NHS, researchers, funders and professional bodies for the CM-Path initiative^a and delivery of the four work streams within its strategy. Workforce initiatives should allow pathologists to spend time on research. The recommendations from ‘Every Patient a Research Patient’¹⁷ should also be implemented to encourage a more positive research environment in the NHS, including investment in academic pathology training posts and chairs.

RECOMMENDATION 6: Departments and Trusts should invest in infrastructure to support digital pathology and businesses/researchers should look at how to make this worthwhile. Sharing results and on-screen examination of histological slides should both be utilised in the short term to enable more efficient, networked services. Electronic requests should also be used.

RECOMMENDATION 7: Molecular pathology should be more involved with the whole diagnostic process for solid tumours (including how molecular pathology results are reported), in a similar way to blood cancer. This should be facilitated through better IT connectivity and closer working between relevant staff groups.

IMPROVE UNDERSTANDING OF PATHOLOGY PROVISION

There is little pathology data currently collected at a national level, which makes understanding activity and capacity more difficult. There must be reliable data to enable effective planning and commissioning of services. This information should be made available for all to use: by government departments and NHS organisations in workforce planning and by charities such as Cancer Research UK in understanding service challenges. The impact on pathology is also often overlooked when changes are made to service provision, such as the introduction of the 28-day Faster Diagnosis Standard.

RECOMMENDATION 8: NHS Trusts should invest in technology so departments can comply with requirements to supply pathology data to the Cancer Outcomes and Services Dataset (COSD). The Royal College of Pathologists should pro-actively collect comprehensive workforce information from departments across the UK.

^a CM-Path aims to support academic cellular molecular pathology in the UK.

See www.ncri.org.uk/initiatives/pathology/

RECOMMENDATION 9: NHS England should ensure all work on diagnostic pathways factors in the impact on pathology. NHS workforce and resourcing plans must ensure pathologists and clinical scientists are involved in the dialogue.

1 BACKGROUND

1.1 CANCER

In the UK cancer incidence rates have increased by 7% over the last decade.¹⁸ In 2014, there were 356,680 new cases of cancer in the UK.¹ Cancer survival has also been increasing – in the last 40 years, 10-year cancer survival in the UK has doubled, increasing from 24% to 50%.¹⁹ It is now expected that 50% of people receiving cancer diagnoses in England and Wales will survive their cancer for at least 10 years.¹⁹ As a result of the increases in cancer incidence and survival, cancer prevalence is increasing faster than 2% per annum. Indeed, research has suggested that there could be up to 5.3 million people in the UK living with cancer by 2040.²⁰ Despite improvements globally in one-year and five-year survival, these measures remain lowest in the UK (and Denmark) for all cancers.²¹ Late diagnosis and sub-optimal access to treatments are two reasons why the UK's performance lags behind other comparable countries. Compared to Australia, Canada and several Scandinavian countries, patients in the UK^b are diagnosed at a later stage for colorectal and lung cancers. In order to improve outcomes for cancer patients, there is a continued need to reduce late diagnosis. The cancer strategy for England estimates that if early diagnosis improvements are implemented, by 2020 there could be almost 11,000 additional patients surviving their cancer for ten years or more.²²

Cancer Research UK has published research on the other main diagnostic modalities - diagnostic imaging⁴ and endoscopy³. Both imaging and endoscopy services have been delivering more activity over recent years, and are currently struggling to meet demand. Looking forward, ensuring our diagnostic services can cope with future demand is essential if we are to improve outcomes for patients through early diagnosis.

This project was commissioned to understand the pressures facing pathology services across the UK and to identify solutions to address these issues, so that pathology services can be prepared for the challenges of the future, and importantly, meet the needs of people with potential cancer symptoms.

1.1.1 PATHOLOGY, AND ITS ROLE IN CANCER SERVICES

Pathology is the study of disease, and has a major role in the diagnosis and treatment of cancer in the UK, as well as many other conditions. Pathology is comprised of 19 different disciplines each with their own qualifying exams.^c These disciplines vary widely in their approach but the uniting theme is that pathologists examine samples (e.g. blood or biopsies) from patients. Work relating to cancer forms a sizeable proportion of pathology activity, with the most relevant disciplines being:

- Cellular pathology (comprised of histopathology and cytopathology)
- Blood sciences
- Molecular pathology

^b In general, data for the UK from the International Cancer Benchmarking Partnership currently relates to England, Wales and Northern Ireland, as Scotland has only recently joined the partnership

^c The 19 specialties of pathology are: Cellular Pathology, Clinical Biochemistry, Genetics and Reproductive Science, Haematology, Histocompatibility and Immunogenetics, Immunology, Microbiology, Molecular Pathology, Neuropathology, Prenatal, Perinatal and Paediatric Pathology, Toxicology, Veterinary Pathology and Virology.

Lord Carter’s review of NHS productivity estimates that £2.5-3 billion is spent on pathology across the English NHS annually.¹¹ Pathology is a core component in 70% of clinical interventions¹⁰, while it accounts for approximately 2.5% of the total budget.²³ In cancer services, having a ‘tissue diagnosis’ made by a cellular pathologist is usually a prerequisite for starting treatment, and any delays in diagnosis can potentially affect the patient’s outcome.

Pathology does not just play a role in the initial cancer diagnosis, but also in prognosis and monitoring. Cellular pathology is also required to establish whether a surgical procedure has been successful by measuring the margins around a tumour excision. Haematology and clinical biochemistry are used to monitor bone marrow and organ function over the course of the disease and during treatment. Microbiology and immunology can be important in managing complications from cancer treatment.

Recent cancer strategies in England, Scotland and Wales make commitments to earlier diagnosis of cancer, and acknowledge the importance of diagnostic capacity to deliver this. However, pathology was not specifically highlighted in the cancer strategy in England²², other than through molecular diagnostics - as flagged in the Royal College of Pathologists’ response to the report.²⁴ There was similarly a focus on molecular pathology in the Scottish cancer strategy²⁵, although pathology was mentioned as part of the remit of Managed Diagnostic Networks. The Welsh cancer delivery plan highlights workforce shortages in pathology and notes the role of the National Pathology Board in continuing to develop capacity in pathology services.

The role of pathology depends on the route to diagnosis and the tumour site. In many cases, the role of pathology is to confirm or rule out a diagnosis of cancer that has been suggested by imaging or endoscopy. Pathology is also important for staging cancer and providing information on the type of cell which has formed the cancer.

1.2 PATHOLOGY DISCIPLINES

In some disciplines in pathology, the analysis of specimens can be automated to a large degree, reducing the need for trained staff and thus reducing costs. However, histopathology, one of the main areas involved in cancer diagnosis, still requires a large amount of manual work, leading to higher costs per test. Table 1, below, gives a good indication of the range of costs per test across different pathology disciplines and highlights the significantly higher cost of histopathology due to the increased level of staff resource involved.

TABLE 1 COST FOR ANALYSING TESTS ACROSS SEVERAL PATHOLOGY DISCIPLINES

Discipline	Median (£)	Min (£)	Max (£)	Test type
Biochemistry	1.00	0.50	2.80	Routine, high volume
Haematology	2.40	1.50	3.70	
Microbiology	6.10	4.00	9.40	
Histopathology	48.10	21.40	73.40	Routine, non-complex

1.2.1 CELLULAR PATHOLOGY

Cellular pathology currently plays the largest role in the diagnosis of cancer. Cellular pathology describes the group of pathology specialties that look at changes in cells and tissues using a microscope to make a diagnosis. They interpret samples and biopsies to confirm whether or not they contain cancerous cells. Their reports provide information on the type of cancer present, its extent in the sample and its likely behaviour (including in some cases its sensitivity to specific forms of treatment).

Cellular pathology includes histopathology and cytopathology. Cellular pathology makes up the largest proportion of the pathology workforce. Cellular pathologists form 45% of the Royal College of Pathologists total membership (1655 histopathologists and 274 cytopathologists (who no longer do general histopathology), out of a total of 4274). The next largest discipline, haematology, accounts for 26% of the College's membership (1123 haematologists).²⁶ However, it must be recognised that not all of those working in pathology will be members of the College, these figures give a snapshot of their membership and that trainees are not included in these figures.

HISTOPATHOLOGY

Histopathology is the study of diseased tissue, for example, breast lumps or specimens of bowel removed because of suspected cancer, including examination under the microscope.

Histopathologists look at tissues and cells removed from patients in the clinic or during an operation. They use a range of scientific methods to assess if a disease is present and what course of action needs to be taken. The tissue is first examined with the naked eye to look for any visible abnormalities and to select pieces to examine in more detail. These small pieces are treated with chemicals so that very thin slices can be cut. The slices are stained to show different parts of the cells and examined under a microscope. The histopathologist tells the patient's doctor what is wrong and often provides information about the correct treatment to give.

Many histopathologists are also cytopathologists, as doctors wanting to pursue cytopathology are trained in both areas. Some consultants choose to become specialist cytopathologists, whereas others continue to report other types of specimen. All consultants train as histopathologists in the first instance, and this includes cytopathology training, so all histopathologists are able to practise cytology at the point of qualification.

CYTOPATHOLOGY

Cytopathologists study diseases at a cellular level. Specimens may be bodily fluids or other samples that are placed into a fluid after being taken (such as cervical screening samples using liquid based cytology). Specimens may be smeared onto a glass slide immediately, or be processed and dropped onto a slide to be studied under a light microscope.

The complexity of diagnostic histopathology has increased in recent years due to a number of factors. Firstly early diagnosis of cancer introduces some challenges, as early-stage cancers are smaller and more similar to surrounding tissue, requiring more skill to identify, which may lead to procedures being repeated in order to confirm results.²⁴ Secondly, in addition to the traditional haematoxylin and eosin stain (H&E), a histopathologist may request additional investigations or tests to be performed on the slide. One common form of additional investigation is immunohistochemistry (IHC). In this approach, molecules which target specific tumour markers are used. If the tumour markers are present, the molecules attach to them

and a reaction which indicates this can be observed on the slide. This allows for further prognostic and therapeutic information to be gathered, to identify the tumour type and elucidate treatment options.

As many cytology samples can be obtained with less risk and discomfort than a biopsy (tissue sample), cytology plays an important role in the diagnosis of cancer and other diseases. Cytopathologists study individual cells, groups of cells and background material. Their reports may result in a specific treatment for the patient (such as chemotherapy) or a further diagnostic procedure. For example, by studying the fluid from a pleural effusion (an abnormal collection of fluid around the lungs), a cytopathologist may be able to diagnose a patient with cancer and suggest what tissue it has arisen from.

Cytopathology is also an important part of screening; the detection of early abnormalities in cervical specimens has prevented many deaths from cervical cancer.²⁷ The UK National Screening Committee has recommended that liquid-based cytology should be replaced by testing for Human Papilloma Virus (HPV) as the primary test – which would greatly reduce the amount of cytopathology activity needed. Much of this work is provided by cytoscreeners and biomedical scientists. When implementing this change to cervical screening, one major consideration will be its impact on the cytopathology workforce. In the long term there is likely to be a significant reduction in workload as HPV will be used first in the screening pathway – but this needs to be managed gradually, so that cytopathology services do not entirely disappear whilst there is still a high level of demand.

1.2.2 BLOOD SCIENCES

‘Blood sciences’ is a term which primarily encompasses haematology and clinical biochemistry, but may also include immunology. These disciplines may be combined in the same department, or they may form separate departments.

Haematology is the study and treatment of disorders of the blood cells and bone marrow. Blood sciences involves samples of bodily fluid, most often blood, to identify changes to composition and the presence of particular tumour markers. The Royal College of Pathologists received 1165 responses from haematologists to their most recent workforce survey across the whole of the UK – representing 26% of all pathologists who responded. In England, NHS iView^d suggests there were 735 Full-Time Equivalent (FTE) haematologists in 2014, which is around 29% of the total pathology workforce recorded on iView.

Haematologists have both clinical and laboratory responsibilities, so in this specialty the pathologist who treats people with blood cancer in a clinical setting will be the same person who has examined blood or bone marrow under the microscope.

The major steps in laboratory haematology are automated, with analysers used to process samples. Laboratory haematology is involved in a very large proportion of diagnostics in the NHS and, while many cancer patients will undergo blood testing, only a small percentage of overall haematology is related to cancer. Flow cytometry, which is an essential part of diagnostics and monitoring in haematological malignancy is usually part of laboratory haematology

Clinical biochemistry involves investigating bodily fluids through chemical means to diagnose changes in body chemistry. Tests for certain chemicals may be completed by a chemical

^d NHS iView is an online service that provides aggregated health and social care data to authorised users within the NHS. The service currently includes annual and monthly workforce data.

pathologist (who is trained as a doctor in medicine) or a clinical scientist. As with haematology, a large proportion of clinical biochemistry occurs in areas not related to cancer.

1.2.3 MOLECULAR PATHOLOGY

Molecular pathology assesses cancer at the molecular level, utilising genomic analysis to determine abnormalities in the DNA structure and functionality. Molecular pathology findings will inform prognosis and treatment options. Molecular pathology involves the identification of genetic markers in diseased specimens, and may entail sequencing all or part of the genome of the sample. This has an increasing role in cancer treatment planning as it allows the identification of mutated genes in the cancer and therefore more targeted treatment. Identification of particular tumour markers has been possible for some time through immunohistochemistry, usually seen as an interface between cellular and molecular pathology.

More recent technological developments allow for the sequencing of certain segments or the entirety of the cancer genome – while this has not had much of a role previously in guiding cancer treatment, it is likely to have a greater role in the future.

Delivery arrangements for molecular pathology in each UK nation

England: Molecular pathology tests are completed by specialist laboratories across the country through a 'hub and spoke' model.

Scotland: Nationally commissioned and provided in four labs

Wales: All tests are currently completed by one laboratory – the All Wales Medical Genetics Service in Cardiff.

Northern Ireland: Some molecular pathology tests are completed at a specialist laboratory in Belfast. There are some tests which cannot be completed in Northern Ireland and so samples are sent to England to be completed.

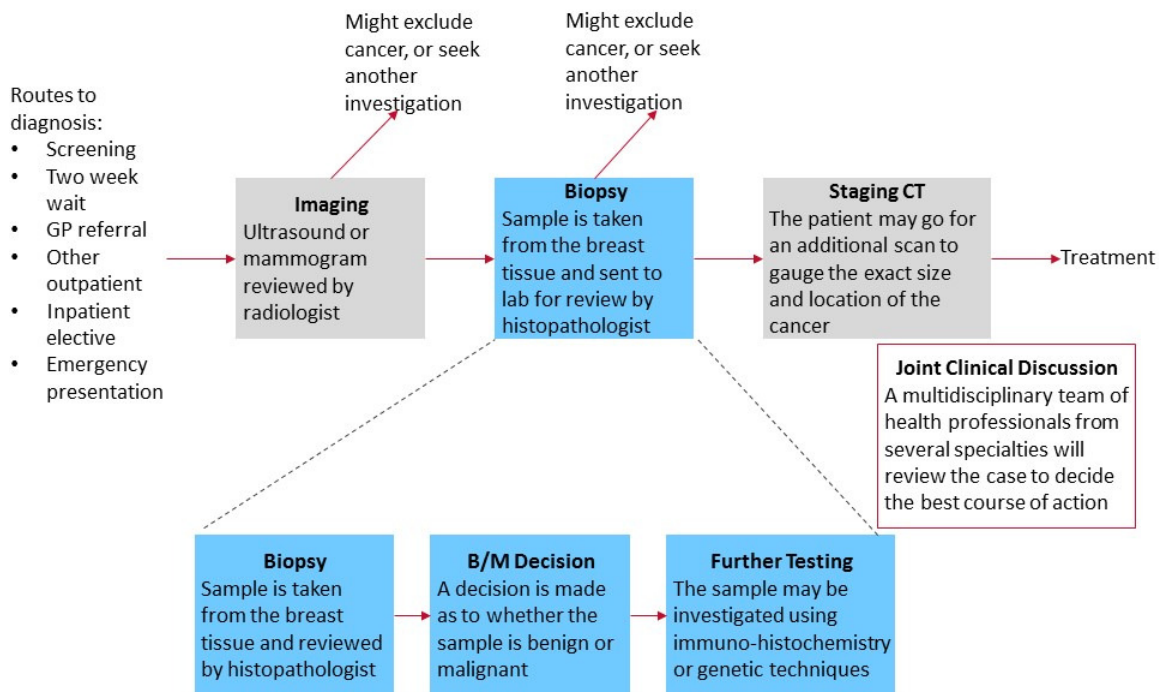
1.3 PATHOLOGY AND DIFFERENT CANCER TYPES

Below are some examples of the roles played by pathology in the diagnosis of different types of cancer. While not all patients will follow these pathways, they are representative of the majority of patients for these cancer types.

1.3.1 BREAST CANCER

Figure 1 shows the different steps and techniques in the diagnosis and staging of breast cancer, and highlights the central roles played by histopathology and immuno-histochemistry.

FIGURE 1 COMMON PATIENT PATHWAY FOR BREAST CANCER



The Breast Screening programme in the UK is provided for asymptomatic women between the ages of 50 and 70. In England, there a study where the age range is being extended to include women between the ages of 47 and 49 and 71 to 73. The trial began in 2009 and eventually is likely to include at least two million women aged 47-49 and one million aged 71-73. This addition of several million more women would lead to increased demand for mammography, and by extension a related (but smaller) increase in histopathology, as within the current breast screening programme, around 4% of women are called back following a mammogram.

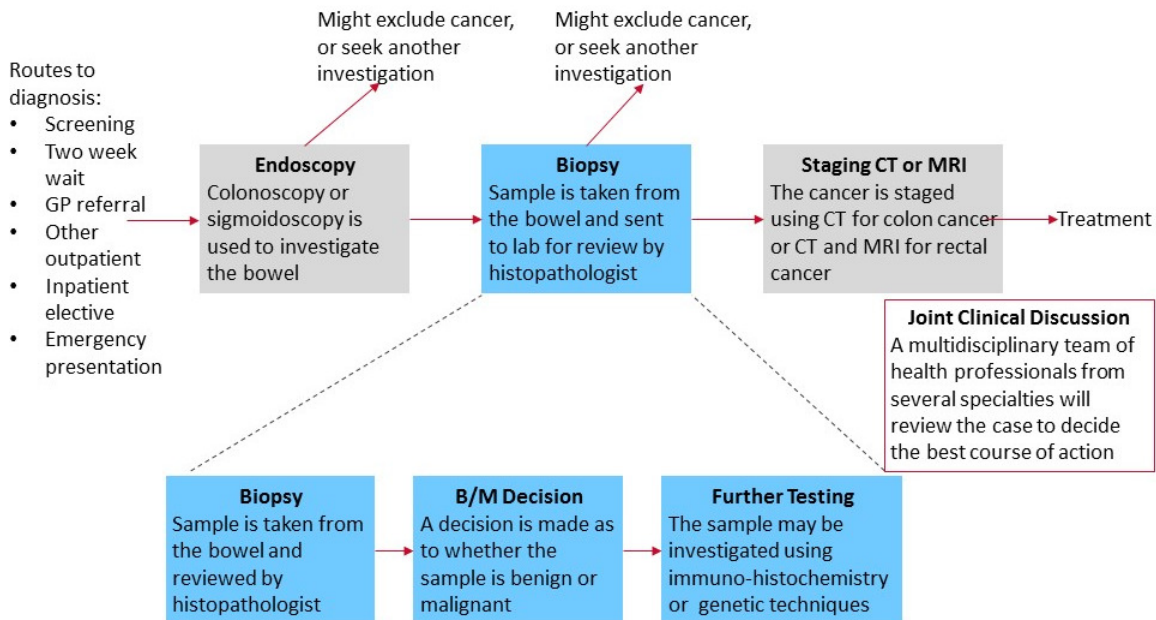
Symptomatic patients undergo a 'triple assessment': physical examination, imaging and biopsy. When identifying and treating this suspected breast cancer, a cellular pathologist reviews the breast biopsy taken from the patient.

Once the diagnosis of breast cancer is made, immunohistochemistry is used to test breast cancer cells to see if they have receptors for the hormones oestrogen or progesterone. Tests are also conducted to identify whether the tumour has receptors for a protein called HER2.. HER2 is a receptor for a particular growth factor made in the body called human epidermal growth factor. Knowing about HER2 receptor status allows more targeted treatment. Other immunohistochemistry and molecular pathology tests may also be used which allow the use of drugs targeted to specific types of breast cancer.

1.3.2 BOWEL CANCER

Figure 2 shows the different steps and techniques in the diagnosis and staging of bowel cancer and highlights the central role of histopathology.

FIGURE 2 COMMON PATIENT PATHWAY FOR BOWEL CANCER



Survival for colorectal cancer has been increasing significantly for patients in England and Wales over the last 40 years. In 1975, 24.4% survived their disease for at least five years. In 2011 it was 58.7%.¹⁹ Earlier diagnosis and improvements in treatment are having a positive impact on survival, although increased incidence and survival is likely to lead to further demand for colorectal cancer services.

The National Bowel Cancer Screening Programme began between 2006 and 2010 in each UK nation (2006 in England, 2007 in Scotland, 2008 in Wales and 2010 in Northern Ireland). It currently uses guaiac Faecal Occult Blood testing (FOBT) to check stool samples for hidden blood traces. Efforts to increase uptake, if successful, will lead to further demand on pathology services.

A new test, the Faecal Immunochemical Test (FIT), will replace FOBT for bowel cancer screening in Scotland in 2017, England in 2018, in Wales in the next few years and, dependent on Government commitment, potentially in Northern Ireland. The new FIT test has been shown to have higher participation rates, and the switch is expected to increase screening uptake by around seven to eight percentage points in England.²⁸ This will increase pathology demand, both as a result of increased initial testing and because positive results lead to further testing.²⁸

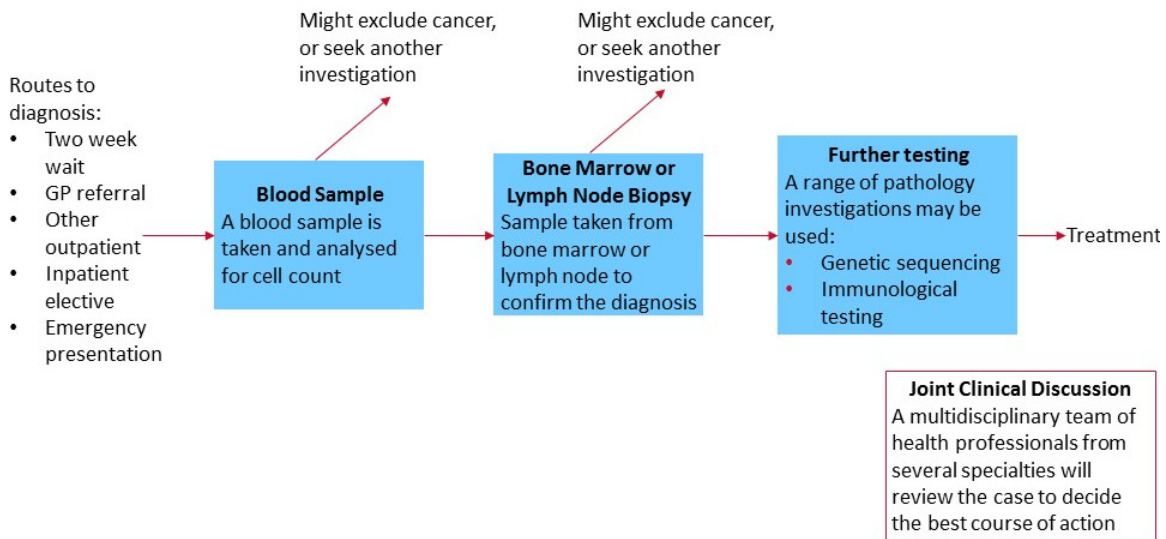
In addition to this, a Bowel Scope Screening Programme began in 2013 in England, involving a one-off flexible sigmoidoscopy examination of the lower bowel for all men and women at age 55; a similar programme is also being piloted in Scotland. Bowel Scope will lead to a significant increase in endoscopy activity and pathology workload as polyps excised must be

reported by histopathologists.^e

1.3.3 LEUKAEMIA

As a cancer of the blood, leukaemia requires input from haematologists to diagnose and stage. There are several forms of leukaemia, but the pathway below shows a generic patient route relevant to the majority of forms:

FIGURE 3 COMMON PATIENT PATHWAY FOR LEUKAEMIA



The patient's blood sample is run through an autoanalyser in order to determine whether the number of different types of cells in the blood is outside of the acceptable range. The cell count is performed by technical staff in a laboratory and interpreted by a haematologist. If the blood count is suggestive of a blood cell cancer a bone marrow or lymph node biopsy is performed. This may be interpreted by a histopathologist specialising in blood cancer or a haematologist to identify the type of cancer. The approach to diagnosis in blood cancers is integrated, with the National Institute for Health and Care Excellence recommending that that diagnostic reporting takes place within Specialist Integrated Haematological Malignancy Diagnostic Services (SIHMDS).²⁹

^e NHS Bowel Cancer Screening Programme stipulates that: 'The laboratory would need two to four nominated consultant histopathologists who participate in the Bowel Cancer Screening Programme External Quality Assurance scheme to report these samples.'

2 INCREASING DEMAND FOR PATHOLOGY

The number of patients being referred to pathology services is increasing. The contributing factors to this increased demand include:

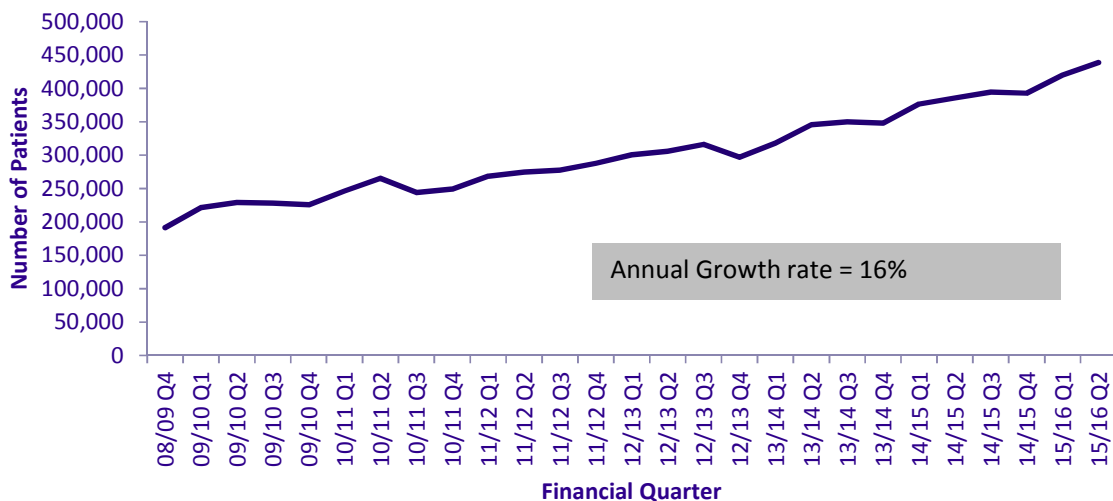
- Increase in population
- Increased cancer incidence, due in part to ageing population
- Increased cancer survival
- Increase in efforts to diagnose cancer earlier
 - Reduction in threshold for referral
 - Changes to diagnostic pathways, such as the introducing of the 28-day 'Faster Diagnosis Standard'
 - Increase in capacity and activity of other diagnostic areas
 - Increase in sensitivity of other tests in diagnostic areas, leading to higher rate of detection of abnormalities
 - Changes in clinical practice, so higher likelihood of pathology being requested.

There are several initiatives across the UK aiming for patients to be diagnosed at an earlier stage. As a result of this, the number of patients being referred for diagnostic investigations has increased.

In England, the number of patients who have been urgently referred by their GP for suspected cancer (on the 'two week wait' (TWW) pathway) has been increasing at 16% on average per year (see

Figure 4) since records began in 2009. Overall there has been a large increase of 60% in the directly age-sex standardised referral rate, increasing from 1904 to 3055 referrals per 100,000 people in the five years from 2009-10. This increase relates to a 71% increase in the number of two week wait referrals, with an additional 642,754 TWW referrals in 2014-15 compared to 2009-10.³⁰

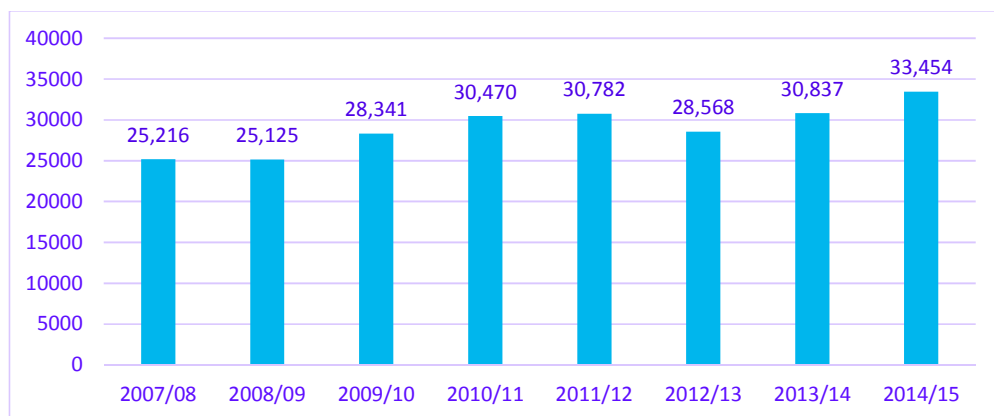
FIGURE 4 NUMBER OF PATIENTS ON THE TWO WEEK WAIT PATHWAY, ENGLAND



This increase must be considered within the context of a lower levels in earlier years. In 2009, TWW referrals made up 28% of referrals; whilst in 2013 this had increased to 34%.³¹ Over the same period there was also a welcome drop in emergency presentation.

Figure 5 shows the average number of requests for histopathology in the laboratories involved in the Keele Benchmarking Service across the UK. A high proportion of histopathology requests are linked to cancer investigations but not all of them. These data show on average an increase in histopathology requests per laboratory of 4.5% per year.

FIGURE 5 HISTOPATHOLOGY AVERAGE TOTAL REQUESTS, UK WIDE



Source: Data from Keele Benchmarking Service, issued May 2016

A number of the pathologists we interviewed had observed increasing risk-aversion among referring clinicians, reporting that tests which previously would not have been requested were now being requested “just to check”. However, the reduction in threshold for referral and drive for earlier diagnosis will inevitably lead to more testing for which there is a lower likelihood of malignancy – this is a necessary part of a movement towards early diagnosis.

2.1 INCREASING COMPLEXITY

In addition to an increase in the number of patients or requests, there has also been an increase in the amount of work required in relation to each patient referred to pathology. There are a number of reasons for this.

Due to changes in clinical practice, more biopsies are being taken from each patient. A good example of this is in routine biopsies of prostate samples. The previous approach to sampling a patient was to take six needle cores from the prostate. The template biopsy approach now involves taking 24 or 36 cores from the patient, thus greatly increasing the amount of material that the histopathologist must report on.

More samples are being taken from each resection specimen, to satisfy an increasing demand for information at MDT meetings and in order to meet the requirements for increasingly comprehensive, evidence-based Royal College of Pathologists datasets. This growth in complexity has been ongoing for many years – a paper from 1992 examined the content of histopathology reports over 50 years, from 1940 to 1990, finding a 337% increase in the number of words in reports and a 273% increase in the number of items of information included in them over this period.³²

In addition to the increased number of biopsy specimens there are now newer tests, which are often required in addition to existing tests rather than replacing them. Immunohistochemistry procedures and in-situ hybridisation have been introduced for a number of tumour markers, for example in lung cancer. This leads to further investigation on the part of the histopathologist, resulting in more time spent processing and reporting per sample. As cancer medicine becomes increasingly personalised, further panels (groups of tests) and investigations will be introduced. As this becomes standard practice the tests may be performed more efficiently, but will further add to demand. Also, the ambiguous morphology of early stage cancers further increases the time taken to report.

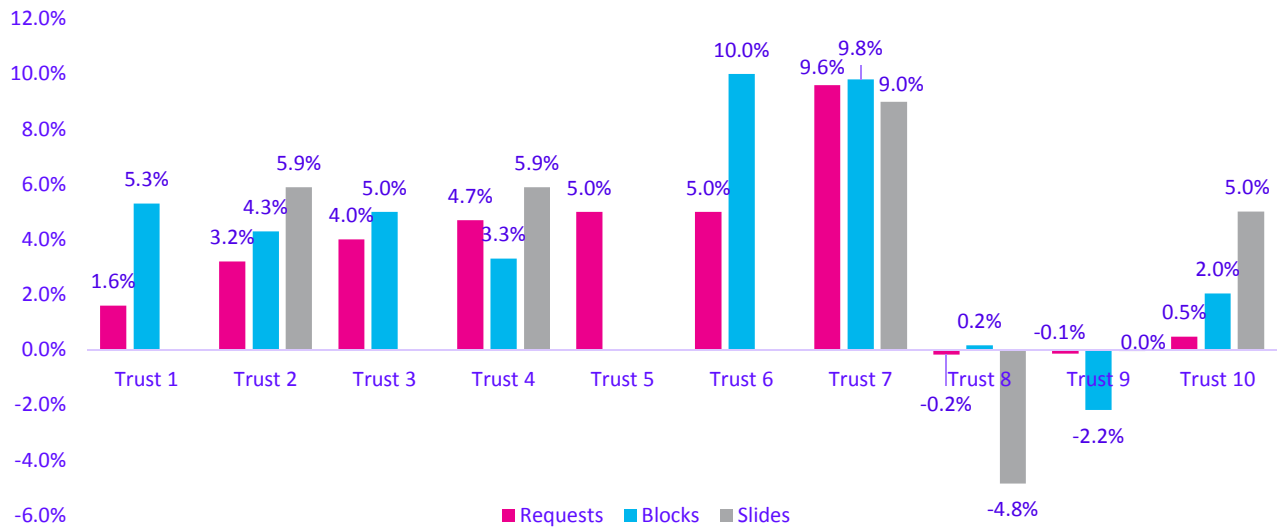
Data relating to complexity are somewhat contradictory, as a mixed picture emerges from different data sources. Quantitative data obtained from laboratories shows that the number of blocks and slides processed has typically grown at a faster rate than the number of requests, as shown in Table 2 and Figure 6. This suggests a greater amount of complexity per patient.

TABLE 2 ANNUAL GROWTH IN CELLULAR PATHOLOGY WORKLOAD ACROSS 10 LABORATORIES

Workload Category	Average Annual Percentage Increase 2009-10 to 2014-15
Requests	3.3%
Blocks	4.2%
Slides	3.5%

Source: Responses to 2020 Delivery quantitative request sent to laboratories interviewed as part of this project,

FIGURE 6 PERCENTAGE CHANGE IN DEMAND FOR CELLULAR PATHOLOGY SERVICES IN LABORATORIES ACROSS THE UK, 2009-10 TO 2014-15



Source: Responses to 2020 Delivery quantitative request sent to laboratories interviewed as part of this project

However, data from Keele Benchmarking Service shows a different picture, indicating that the average number of slides per request has remained steady at approximately six from 2007-08 until 2014-15, as shown in Figure 7.

FIGURE 7 RELATIVE RATIOS OF HISTOPATHOLOGY REQUESTS, BLOCKS AND SLIDES, AVERAGE FOR EACH LABORATORY



Source: Data from Keele Benchmarking Service, issued May 2016

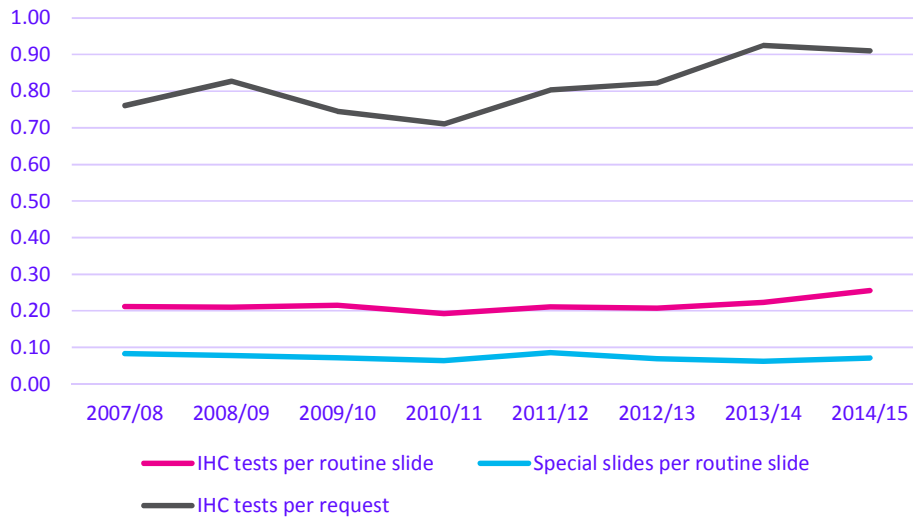
Many pathologists expressed a view that data suggesting a steady workload were unlikely to be comprehensive and may therefore be misleading. They suggested it is more likely that both demand and complexity have increased.

The number of immunohistochemistry investigations per request across the UK has increased

by 20%, from an average of 0.76 in 2007-08 to 0.91 in 2014-15, as shown in Figure 8. This also suggests an increase in complexity.

The amount of immunohistochemistry completed has been increasing more in Scotland. The number of immunohistochemistry investigations per request has increased by 46%, from an average of 0.92 in 2007-08 to 1.34 in 2014-15.³³

FIGURE 8 RELATIVE RATIOS OF HISTOPATHOLOGICAL COMPLEXITY, AVERAGE FOR EACH LABORATORY



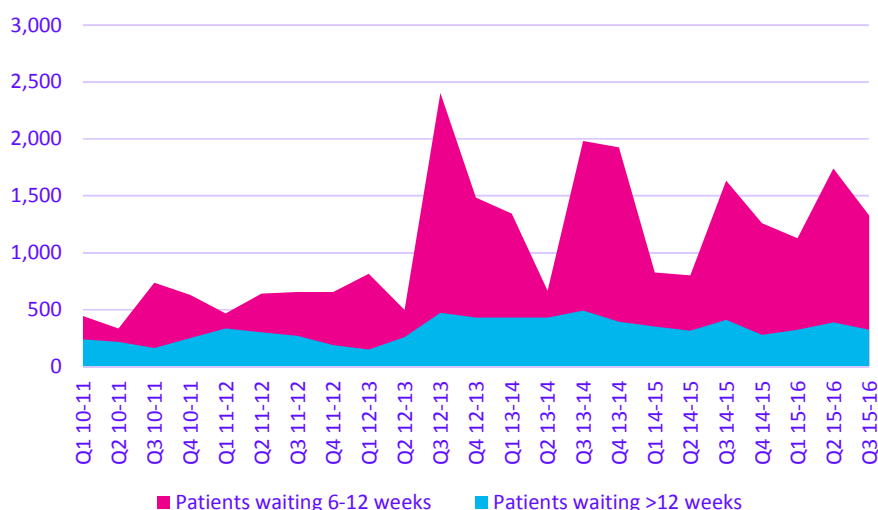
Source: Data from Keele Benchmarking Service, issued May 2016

2.2 TURNAROUND TIMES ARE INCREASING

Despite some improvements in throughput and capacity, increased demand is having a negative impact on turnaround times. This can be seen in the data for England showing the number of patients waiting more than six weeks for diagnostics in pathology, which has been increasing at approximately 17% per year since 2010-11, with significant fluctuation from quarter to quarter, as shown in Figure 9.

It should be noted that these statistics refer to all people waiting for diagnostic tests, not just people with suspected cancer. Whilst these data are not available across the whole of the UK, the activity data for England are indicative of difficulties across the UK.

FIGURE 9 PATIENTS WAITING MORE THAN SIX WEEKS FOR PATHOLOGY DIAGNOSTICS AT QUARTER END



Source: NHS England Quarterly Diagnostic Waiting Times Statistics

While this growth is significant, it is not as dramatic as in imaging or endoscopy as Table 3 below shows:

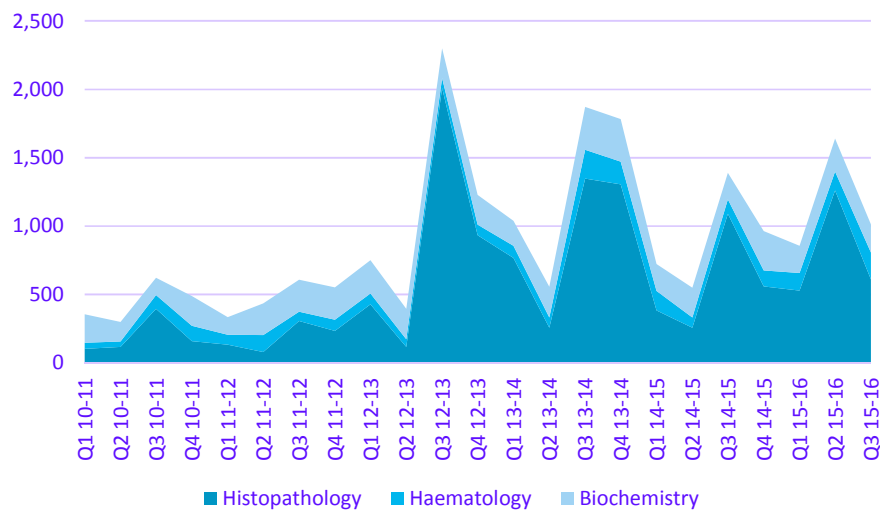
TABLE 3 SNAPSHOT OF NUMBER OF PATIENTS WAITING MORE THAN SIX WEEKS FOR PATHOLOGY, IMAGING AND ENDOSCOPY AT THE END OF QUARTER 3, 2015-16

Diagnostic Area	Patients waiting at end of Q3, 2015-16			Compound Annual Growth Rate, since 2010-11
	Between 6 and 12 weeks	More than 12 weeks	Total (more than 6 weeks)	
Pathology	1,326	324	1,650	16.5%
Imaging	6,673	1,036	7,709	32.8%
Endoscopy	6,534	2,194	8,728	23.0%

Source: NHS England Quarterly Diagnostic Waiting Times Statistics

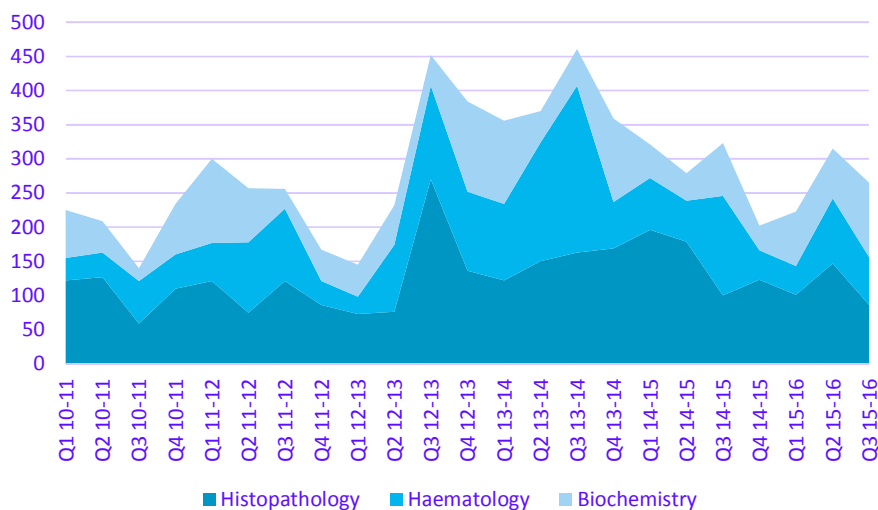
When the figures are broken down by discipline, it is clear that the area under the most significant pressure is histopathology. Figure 10 and Figure 11 show the numbers of patients in England waiting between 6 and 12 weeks, and greater than 12 weeks, for diagnostics in histopathology, haematology and biochemistry.

FIGURE 10 PATIENTS WAITING 6-12 WEEKS FOR PATHOLOGY DIAGNOSTICS AT QUARTER END, BROKEN DOWN BY DISCIPLINE



Source: NHS England Quarterly Diagnostic Waiting Times Statistics

FIGURE 11 PATIENTS WAITING >12 WEEKS FOR PATHOLOGY DIAGNOSTICS AT QUARTER END, BROKEN DOWN BY DISCIPLINE



Source: NHS England Quarterly Diagnostic Waiting Times Statistics

In the latest quarter for which data are available, of the 1,650 pathology patients waiting more than six weeks, 695 were from histopathology, compared with 315 from biochemistry and 268 from haematology. As there are fewer patients referred to histopathology compared to biochemistry and haematology, this figure represents an even greater proportion of histopathology activity.

Backlogs are gradually building up, with some departments using outsourced reporting services in order to keep up with demand.

3 MAXIMISING EFFICIENCY

To enable pathology services to meet growing demand, steps should be taken to ensure they are as productive as possible when using current resource. There are inefficiencies in pathology services that must be reduced. Networking and consolidation of pathology services is one way to increase efficiency.

Haematology and biochemistry have a good track record with regards to increasing efficiency. These services should continue to increase productivity – absorbing the increase in workload through enhanced utilisation of equipment capacity. However, these gains will not continue indefinitely – so thought must be given now to their long-term resource requirements.

Reducing pathology with limited clinical value (e.g. duplicative tests, or those which are not clinically recommended) could potentially reduce demand. This should be thoughtfully considered as there is a risk it could undermine efforts to improve earlier diagnosis.

3.1 PATHOLOGY NETWORKS IN ENGLAND

Pathology networks are already well established in Scotland, Northern Ireland and Wales. However, there is still some way to go in England.

The two Carter reviews into pathology, in 2006 and 2008, both recommended the development and formation of networked pathology services, set up with consolidated specialist services in a core site, with satellite laboratories feeding in.¹⁰ This is often known as the ‘hub and spoke’ approach. Following the initial recommendation in the ‘Report of the Review of NHS Pathology Services in England’,¹⁰ several pathology networks were developed.

The more recent report by Lord Carter into operational productivity in the NHS suggested further consolidation and collaboration between services, stating that “Our further analysis has confirmed that consolidated pathology organisations are the most efficient in the NHS.”¹¹ NHS Improvement has recently indicated to Trusts that they, alongside sustainability and transformation plan leaders, had to show how they will consolidate pathology services and put ‘unsustainable services’ on a secure footing financially.³⁴ Networked pathology services have also been covered more recently in the Nuffield Trust report ‘The Future of Pathology’, which states the aim of locally developed networks as “improving quality and efficiency through: delivering economies of scale through use of large capacity automated systems; faster turn-around times linked to connected IT; centralising workforce; streamlined logistics; centralising skills and expertise.”³⁵

There are different approaches for developing networks: they may be located on an individual site, spread across several locations or outsourcing laboratory provision. These networks have had mixed success. Uptake of this has been varied, with many discussions regarding joint provision not leading to true joint provision of services. The report by the Nuffield Trust cites a wide range of internal and external barriers to developing effective networks.³⁵ The report highlights barriers to achieving consolidation and suggests that successful networks have “emerged locally and moved forward incrementally”. It recommends involvement of clinicians and local understanding to ensure that networks are effective. It also flags that although a network can present efficiency gains, it may need upfront investment and that effectiveness is also an important motivation.

‘The Future of Pathology’ also stated that without change “it will be difficult to maintain an appropriately skilled workforce in many areas of the country.”³⁵ In addition to this, networks

can provide benefits in procurement. It is important for this integration to be driven by pathologists and scientific staff, rather than feeling that it has been forced on the trust staff.

It seems to be widely accepted that consolidation of services will improve efficiency in the blood sciences, where there is a high throughput of tests and extensive automation. As cellular pathology is still largely manual, it is unclear that this discipline would benefit as much from forming part of a networked service, other than providing increased resilience for covering sub-specialties over holiday periods or where recruitment is difficult. An example given in the recent report on NHS productivity relates to a collaboration between Salford Royal and Wrightington, Wigan and Leigh which improved reporting times, workforce profile and delivered savings of 15%¹¹; although there are areas where the effect was not positive, so lessons must be learnt.

As well as continuing to develop improved pathology pathways and processes, we recommend that departments invest in supporting infrastructure, such as voice recognition technology and IT systems. An effective Laboratory Information Management System which communicates across a network can have a significant impact on how the network operates.

RECOMMENDATION: NHS England and NHS Improvement should continue to support Sustainability and Transformation Plan footprint areas (STPs) and trusts to consolidate pathology services, in order to facilitate better quality and increased efficiency. This may require upfront investment and should also take place with suitable planning.

3.2 CONTINUE PRODUCTIVITY GAINS

Haematology and biochemistry have so far been successful in increasing their capacity – they have absorbed the increase in workload through enhanced utilisation of equipment capacity.

The disciplines in blood sciences have so far been able to absorb their increased workload without significant impact on turnaround times. In the short to medium term, they should continue to maximise the efficiency of the service by exploiting the scalability of large automated equipment. The role of BMS and technical staff should continue to be expanded where this can be achieved without an impact on quality.

However this increased productivity will not continue indefinitely and so long-term plans for staff, equipment and consumables should be made to address growing demand. When considering the future for these services more time needs to be factored in, as there is an increased requirement to give more clinical advice as tests have got more complex. Departments should also be aware of expected lifespan of equipment and plan to replace this when required.

3.3 REDUCE PATHOLOGY OF LIMITED CLINICAL VALUE

Reducing pathology with limited clinical value could potentially lead to a reduction in demand, especially if there are significant numbers of duplicated tests or tests which are not clinically useful or recommended. There are likely to be different levels of activity around the country, and there might be some efficiency gains to be made within existing services. To understand the full picture, it might be useful to utilise an 'Atlas of Variation' for diagnostic tests, to show levels of activity, alongside acknowledgement that different populations are likely to have different needs.

For example, higher than average activity might be entirely appropriate due to levels of social deprivation, chronic disease, and a growing older population. Simply describing higher levels

of testing as surplus would be too simplistic.

Reducing duplication and removing unwarranted variation might free up some resources, but this should only be embarked upon after careful analysis. Reducing activity should be examined carefully as there is a risk it could undermine efforts to improve earlier diagnosis (and associated increase in referrals). However, reducing unwarranted demand has been recognised through the 'Choosing Wisely' and 'Right Test, Right Time' efforts. The Royal College of Pathologists' 'Minimum Retesting Intervals Guidance in Pathology' is also useful to tackle duplication.¹⁴

4 OPTIMISING WORKFORCE

While demand for pathology services have been increasing over recent years, the number of staff has not been increasing at the same rate. Growth in the numbers of cellular pathology consultants has been especially low, which is crucial as consultants play an integral role in reporting. Vacancies are widespread, and many 'non-essential' activities are falling by the wayside in order to prioritise the limited time available.

In order to boost capacity, short term solutions include realising the potential of others in the team to take on tasks including dissection and reporting: this may mean BMS or trainees are given extra responsibilities. This skill mix approach must be utilised more comprehensively than it is at the moment.

Efforts to prevent people leaving the profession should also be made. International recruitment could also be explored to address acute shortages which may occur when many current pathologists retire. In the long-term, more medical students must be attracted to cellular and molecular pathology as their specialty.

4.1. CELLULAR PATHOLOGY

Figures from Keele Benchmarking Service provide an approximation for the number of staff working in a laboratory in each discipline. Table 4 show the average number of staff in each laboratory subscribed to the service.

**TABLE 4 AVERAGE NUMBER OF CELLULAR PATHOLOGY STAFF FTE IN A LABORATORY.
(UNCATEGORISED STAFF REMOVED)**

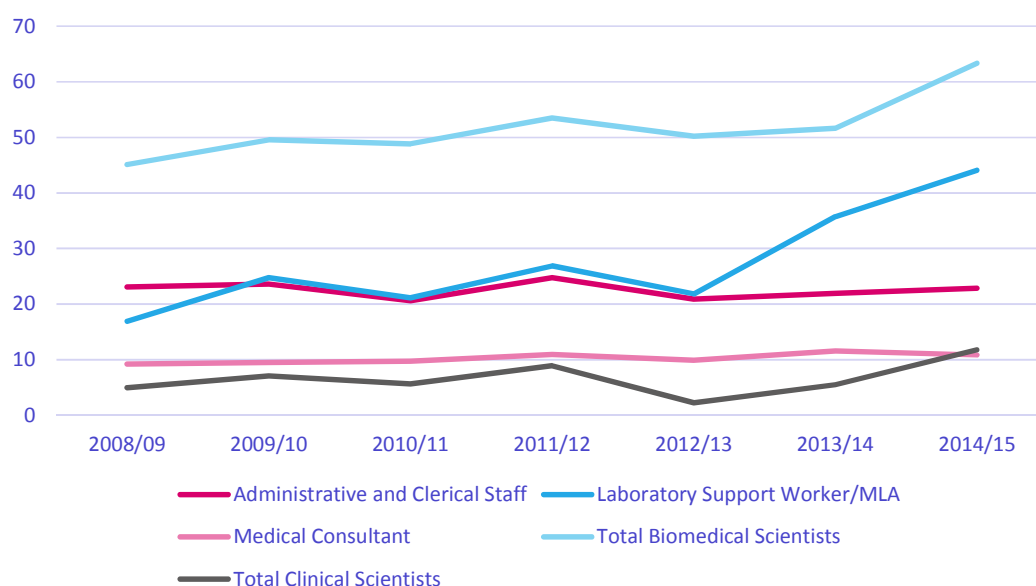
Profession	UK	England	Scotland
Medical consultants	3	2	6
Biomedical scientists	6	1	5
Medical laboratory assistants	17	18	6

Source: Data from Keele Benchmarking Service, issued May 2016

There has been a small increase in the number of medical consultants across the UK, approximately 3% per year from 2007-08 to 2014-15. There has been a greater increase in the number of biomedical scientists (6% per year) and medical laboratory assistants (17% per year).

The NHS iView figures for England also show an increase in FTE consultant histopathologists, albeit at a lower rate than suggested by the figures from the Keele benchmarking data. Data from NHS iView shows an increase of approximately 1.2% per year, which is higher than the overall rate of growth of consultant pathologists at 0.8%.⁶ Further material is included in Appendix D.

FIGURE 12 TOTAL INCREASE IN PATHOLOGY RELATED STAFF (from laboratories subscribing to KEELE BENCHMARKING SERVICE) 2008-9 TO 2014-15



Source: Data from Keele Benchmarking Service, issued May 2016

4.2 BLOOD SCIENCES

According to data from Keele Benchmarking Service, numbers of staff in haematology and biochemistry have not been increasing at the same rate as in molecular diagnostics. Data from the benchmarking service does not provide an accurate picture of medical resource, as the service only captures laboratory time for consultants. For medical staff in blood sciences, this is much lower than in cellular pathology, as this group have a significant clinical commitment which is not measured. As a result, the Medical Consultant entry is not shown for Blood Sciences

The number of laboratory support workers or medical laboratory assistants has been increasing at a rate of approximately 7% per year in haematology across the UK.

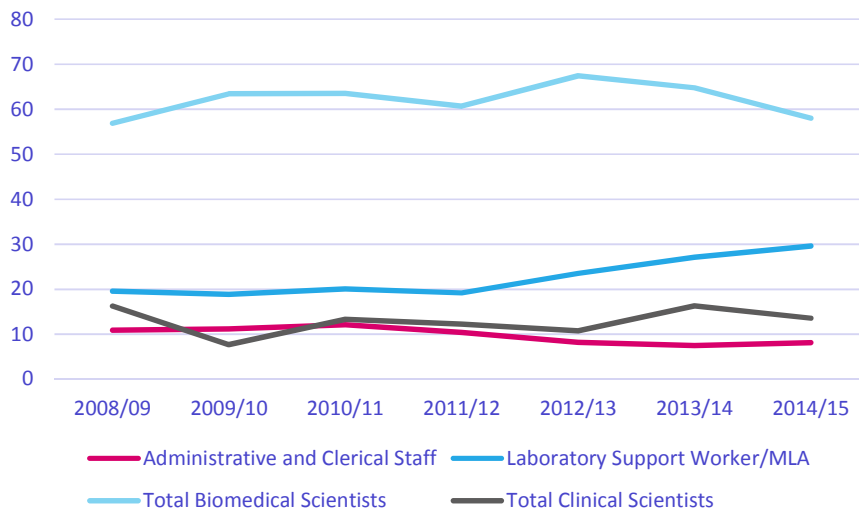
TABLE 5 PERCENTAGE INCREASE PER YEAR OF MEDICAL LABORATORY ASSISTANTS

Profession	UK	England	Scotland
Medical laboratory assistants (haematology)	7	8	Small decrease: likely due to automation (see below)

Source: Data from Keele Benchmarking Service, issued May 2016

The number of biomedical scientists has not been increasing significantly in haematology, which is expected because the increased level of automation in haematology laboratories means that more roles can be performed by technical staff.

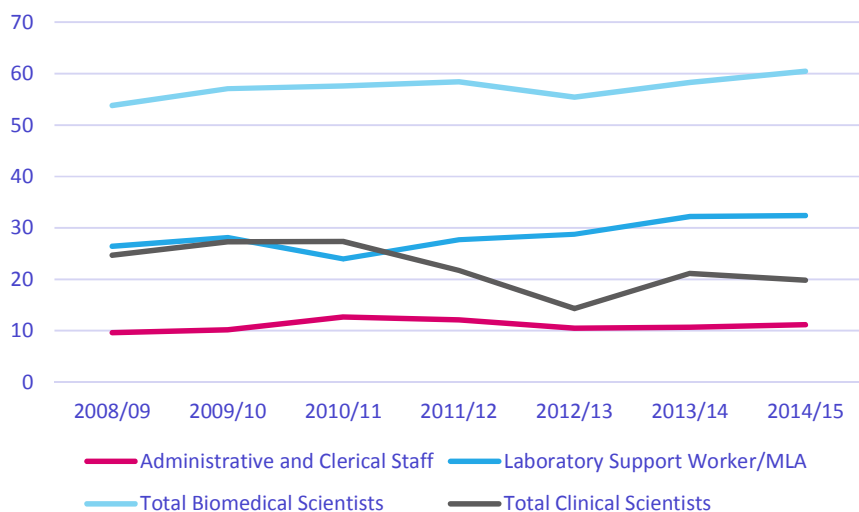
FIGURE 13 AVERAGE HAEMATOLOGY STAFF FTE IN A LABORATORY. UNCATEGORISED STAFF REMOVED



Source: Data from Keele Benchmarking Service, issued May 2016

Staffing in biochemistry has also remained fairly constant over recent years, with a small increase in biomedical scientists and medical laboratory assistants.

FIGURE 14 AVERAGE BIOCHEMISTRY STAFF FTE IN A LABORATORY. UNCATEGORISED STAFF REMOVED



Source: Data from Keele Benchmarking Service, issued May 2016

4.3 CHANGES TO SKILL MIX AND WORKING PRACTICES

There have been a number of skill mix initiatives throughout the various disciplines of pathology which have in part mitigated the increased demand on the service.

4.3.1 CELLULAR PATHOLOGY

Some elements of skill mix have been explored in cellular pathology. Many sites we interviewed were using BMS to dissect specimens – however this is not universal practice,

and consultant input is still required for complex specimens. Medical specialty trainees are required to dissect a certain number of specimens as part of their training.

The flowchart in appendix C shows the overall outline for processing a histopathological sample. This process has two components and different stages in the process require staff of varying levels of qualification. The technical component which can be carried out by laboratory scientific staff, and a number of these stages have become automated, such as processing and staining. Medical Laboratory Assistants (MLAs) or technical staff who are usually Agenda for Change (AFC) Bands 2-4^f, perform certain stages in the process, including loading the processing and staining machines and placing the samples in blocks. These benefit from economies of scale.

The other component is medical, and these stages are mainly carried out by doctors. These include stages such as cut-up and reporting, which require human input and are unlikely to benefit much from scale or digitisation. BMS perform the slide preparation, and are increasingly involved in dissections or cut-up.

Another change to working practices which has been noted in this work is the decrease in protected time for the Supporting Professional Activities in their job plans. They also recounted how, while usually able to attend MDT meetings, pathologists' ability to prepare in advance of these meetings has suffered owing to increased reporting demands.

"Providing support to MDTs puts immense pressure on the service. At the minute we are able to meet this, but at the expense of reporting time. We have to report overtime to make up for this."

- Histopathology clinical lead

"Pathology is clearly under a lot of pressure, and it shows from the support they are able to provide to MDTs. In the past the pathologist had the opportunity to review the reports in advance of our meeting and provide further detail. Now, they are just able to turn up to the meeting, so read the reports in front of them."

- MDT Chair

DISSECTION

In the past, pathologists completed all sample dissections. There is variability in pathologist versus biomedical scientist involvement in dissections. In some cases now, pathologists are only involved in particularly complex dissections, with more straightforward and high-volume dissections being completed by biomedical scientists. Where possible, cut-up should be performed by suitably trained BMS, in order to free pathologists' time for microscopic reporting.

There is wide variation across the UK in the level of BMS cut-up activity, with some laboratories still relying on pathologists for the majority of this work. Demand for medically qualified cellular pathologists is outstripping supply, leading to an increase in backlogs and difficulty recruiting to positions. Due to the current shortfall in suitable candidates applying for training places in this discipline, it is likely that this gap will continue to increase.

While the level of demand is approaching critical levels, it is important to consider how

^f Agenda for Change is the current National Health Service (NHS) grading and pay system for all NHS staff, with the exception of apprentices, doctors, dentists and some senior managers.

capacity could be increased to avoid critical shortages. Biomedical scientist participation in cut-up is varied, and should be expanded where safe and effective. We also recommend expanding the role of clinical scientists in performing dissections, and of medical laboratory assistants in sample processing. The extent to which BMS currently undertake cut-up varies across departments, but they should be utilised for this as much as possible. Care must be taken, however, to ensure continued support for the training of medical pathology staff, as routine sample dissection is a vital part of medical pathology training. To facilitate BMS involvement in dissection, these responsibilities should be recognised in BMS job plans with appropriate steps taken to back-fill their other duties.

It is important to ensure these processes are as efficient as possible, but also important to balance this against the need to ensure there can still be value in examining the macroscopic specimen. In certain specialities and for some specimens, the macroscopic appearance of a lesion could be influential in how it is analysed and interpreted.

RECOMMENDATION: Trusts and their pathology departments, supported through guidance from professional bodies and NHS England, should:

- a) Ensure BMS are being utilised to cut up specimens where possible, in accordance with 'Principles of Good Practice for Biomedical Scientists Involved in Histopathological Dissection'¹⁵.
- b) Explore the role of clinical scientists to support complex diagnostics and research. Clinical scientist input should be recognised in their job plans with backfill provided for existing duties.

REPORTING

Reporting in histopathology is still almost exclusively conducted by consultant pathologists. Consultant cellular pathologists are trained professionals who are expected to provide independent opinions on cellular specimens. In order to prepare for this level of responsibilities, cellular pathology trainees should report with increased independence as they progress through their training. This will also serve to increase reporting capacity. Trainee pathologists are usually closely supervised by consultants; in some training establishments little or nothing is reported without close checking of the trainee's work by a consultant.

There is scope for more senior trainees to do a greater proportion of work which is not directly supervised by a consultant, which could reduce the consultant workload. In more recent years there has been resistance to this, probably because of the potentially serious consequences of an error, although similar considerations do not seem to have inhibited unsupervised work in other medical specialties. There is also scope for more senior trainees to also attend and participate in MDTs.

The Royal College of Pathologists should also update their guidance document and increase its visibility.

RECOMMENDATION: Trusts and their pathology departments, supported through guidance from professional bodies and NHS England, should:

- c) Develop graduated increase in trainee responsibility and supervised reporting in accordance with the Royal College of Pathologists guidance on graded responsibility.¹⁶ The Royal College of Pathologists should update and promote their guidance document.

One potential additional solution would be to fill some of the shortfall in reporting capacity with non-medical staff. The Royal College of Pathologists and Institute of Biomedical Scientists have been working on a Biomedical Scientist Histopathology reporting programme. Candidates in this three-year programme are trained to report relatively simple gastrointestinal and gynaecological samples. Suspected malignancies can be referred to a pathologist, who has the required medical knowledge to provide a detailed report. This is not an entirely novel approach: an analogous practice is the reporting of cervical screening samples by advanced practitioner BMS rather than cytopathologists.

At the time of writing, the BMS reporting programme involves 38 staff, with the first cohort completing the programme in the summer of 2016. In order for this to impact the current shortfall in reporting capacity, this programme would need to be expanded to include a wider number of BMS staff, subject to there being a sufficient supply of willing and capable candidates. While it is unlikely that the number of reporting biomedical scientists will equal the number of histopathologists, they should form a significant minority of the reporting workforce, approximately 10%.

The Royal College of Pathologists and the Institute of Biomedical Scientists should expand this programme where possible, and gather data to monitor its success. In order to facilitate expansion, BMS job plans should include reporting, with appropriate steps taken to back-fill their other duties. It would also be helpful for the pay (AFC banding) for qualified BMS staff to reflect this additional skill, which is not always the case.

To enable this training programme to occur, we also need more investment in training so that pathologists can get involved in providing education and training.

It will be important to implement such a change with care, to avoid risks to patient safety. A clinical governance framework would be required, as in the cases of radiographer reporting and non-medical endoscopist activity. In these instances, suitably trained staff undertake the appropriate activity with medical oversight.

The areas which would lend themselves to BMS reporting have high levels of demand, a low number of potential diagnoses and a low proportion of specimens which are cancerous. The Royal College of Pathologists are looking at the expansion of this programme to include samples from skin biopsies, excluding melanomas.

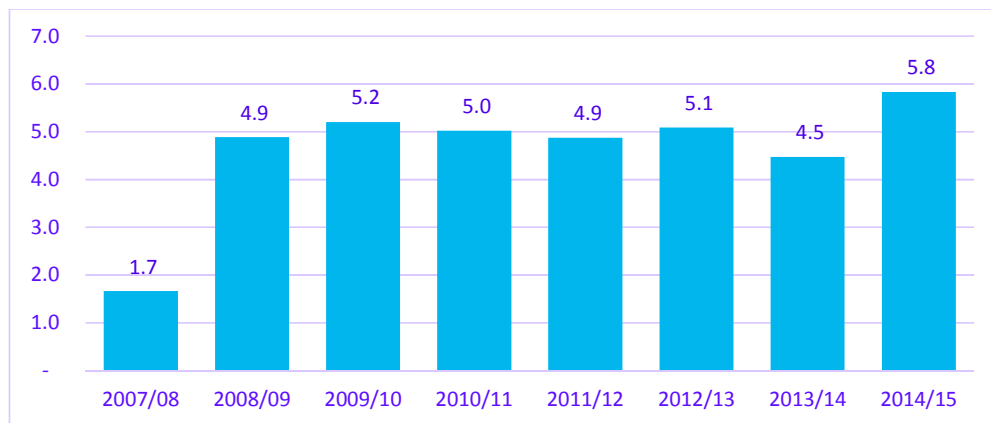
We would welcome continued work by the Royal College of Pathologists and Institute of Biomedical Scientists to audit the success of this programme.

Data from Keele Benchmarking Service shows that there has not been much of a change in the ratio of cellular pathology BMS to medical consultants over recent years, suggesting that changes to skill mix could be further explored.

RECOMMENDATION: Trusts and their pathology departments, supported through guidance from professional bodies and NHS England, should:

d) Ensure widespread use of biomedical scientist reporting following their completion of the Biomedical Scientist reporting programme.

FIGURE 15 RATIO OF BMS TO MEDICAL CONSULTANTS, MEAN PER LABORATORY FOR CELLULAR PATHOLOGY (UK)



Source: Data from Keele Benchmarking Service, issued May 2016

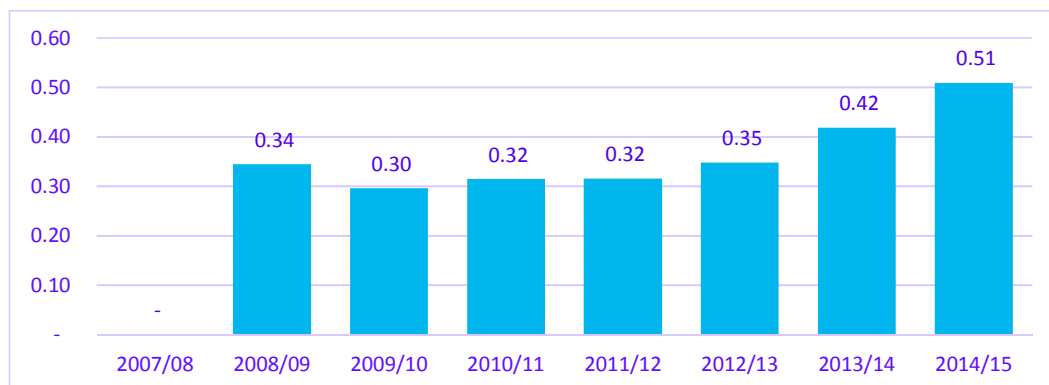
4.3.2 BLOOD SCIENCES

In blood sciences, large parts of the process are automated and do not require consultant input. For example, in diagnosis of blood cancers, the haematologist is only involved following the suspected detection of cancer in a blood sample. This means that a large amount of investigation can be completed by technical and BMS staff. In the Specialist Integrated Haematological Malignancy Diagnostic Service, there is a designated clinical lead who will oversee the diagnostic process and work completed by technical and scientific staff in each area, with an overall clinical director.

As a result of increased automation, skill mix is being explored further in haematology. The ratio of medical laboratory assistants to biomedical scientists has been increasing, as shown in .

Figure 16.

FIGURE 16 RATIO OF MEDICAL LABORATORY ASSISTANTS TO BIOMEDICAL SCIENTISTS, MEAN PER LABORATORY (UK), HAEMATOLOGY

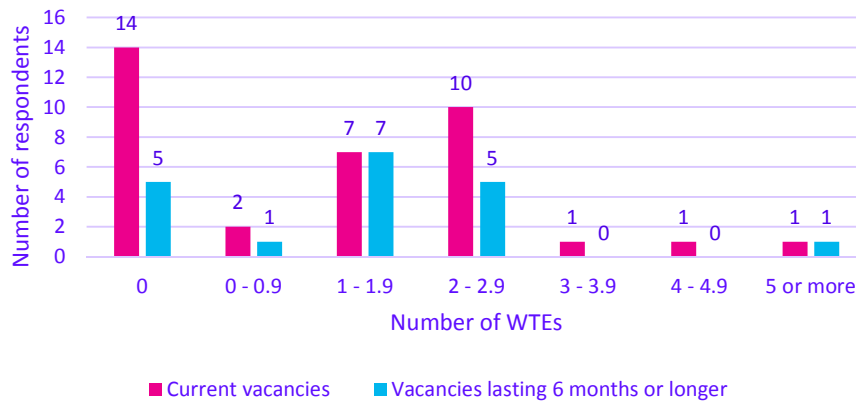


Source: Data from Keele Benchmarking Service, issued May 2016

4.4 RECRUITMENT OF STAFF

Recruitment of staff is becoming more difficult. Responses to a survey issued as part of this work show that of 36 laboratories responding to the question on vacancies among medical staff, 20 have at least one FTE vacancy among consultant staff, as shown in Figure 17. Of the 20 laboratories, 13 have had at least one FTE vacancy for 6 months or more.

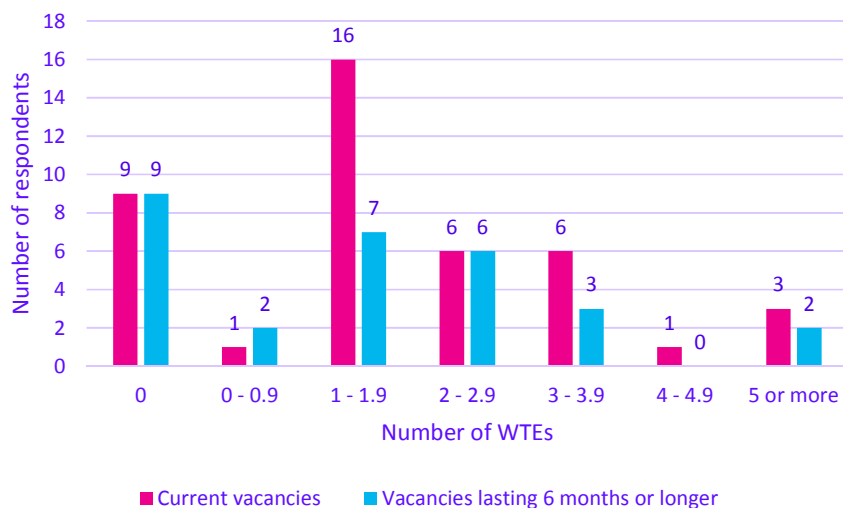
FIGURE 17 NUMBER OF FTE VACANCIES FOR MEDICAL STAFF



Source: Survey issued as part of this project. Responses to question: "How many vacant posts do you currently have where funding has been agreed, subject to identifying a suitable candidate (FTE)?" N = 54

As shown in Figure 18, of the 42 respondents who entered data for biomedical scientists, 32 had at least one vacancy for biomedical scientists, with 18 of these being in place for at least 6 months.

FIGURE 18 NUMBER OF FTE VACANCIES FOR BIOMEDICAL SCIENTISTS, ALL DISCIPLINES



Source: Survey issued as part of this project. Responses to question: "How many vacant posts do you currently have where funding has been agreed, subject to identifying a suitable candidate (FTE)?" N = 42

4.4.1 CELLULAR PATHOLOGY VACANCIES

The strongest theme emerging from our interviews is the difficulty of recruiting cellular pathology consultants. The exact number of vacancies is hard to specify as many departments have stopped advertising for long term vacant posts. In many hospitals, often rural district general hospitals, the work from a vacant post may be taken on by colleagues who share the salary from this post. Two thirds (66%) of the departments we spoke to had long term consultant vacancies and several had at least three vacant posts.³⁶

In England, the number of vacancy adverts for histopathology over 6 months increased from 444 in 2014 to 557 in 2015.⁶ The workforce is becoming pressured at both ends. As mentioned above, the number of training places has decreased for cellular pathology and haematology in England. In addition to this, there were not enough applicants of a sufficient standard to fill the training vacancies in histopathology – 20-30 training posts remain vacant.³⁷ This problem is more evident in rural centres, rather than large teaching centres.

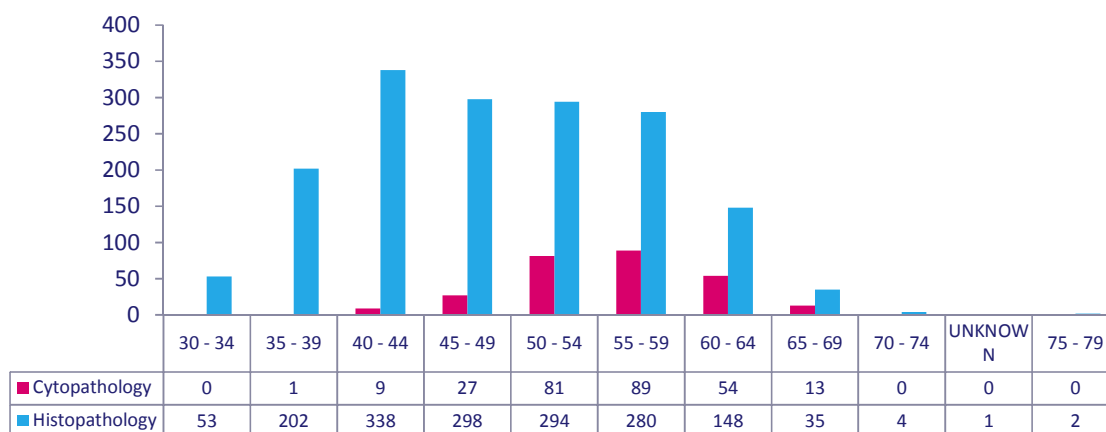
An interviewee for this study noted:

“The last seven or eight appointments we have made have had a single applicant. We have three unfilled consultant posts, but these have been empty for so long that it’s not actually clear how many consultants we need. I suspect our establishment figures are now too low.”

- Histopathology clinical lead

Data from the Royal College of Pathologists shows that 32% of cellular pathologists (around 615 people) are aged over 55, and most of these are expected to retire in the next five years (see Figure 19). From August 2015 – June 2016, 52 trainees in histopathology were recommended to the GMC for completion of training.³⁷ There is a clear mismatch in numbers becoming cellular pathology consultants and those leaving the profession.

FIGURE 19 AGE PROFILE OF CONSULTANT CELLULAR PATHOLOGISTS



Source: Workforce data from the Royal College of Pathologists

There have been a number of changes which have affected consultants’ retirement intentions, leading to an increased number of consultants opting to retire:

- Planned increased age of retirement for NHS pensions
- Increased requirements for revalidation
- Removal of Clinical Excellence merit awards, leading to less income for some consultants
- Change in pension scheme from a 'final salary' approach to valuation to a 'career average' approach
- Increased workload and demand on staff³⁷

"Of our 16 consultants, three have recently retired [...], two are due to retire imminently and five are retiring in the next three or so years."

- Histopathology clinical lead

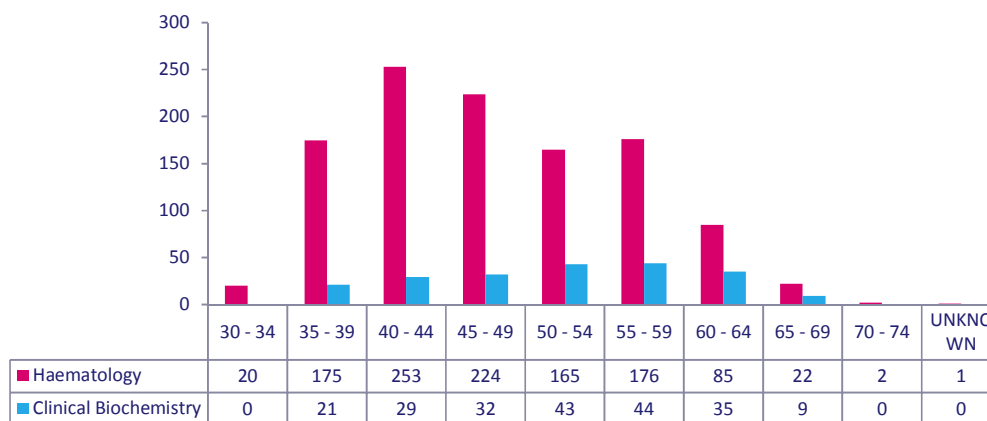
4.4.2 BLOOD SCIENCES VACANCIES

Respondents in haematology and clinical biochemistry reported difficulties in attracting and retaining consultant level staff, although to a lesser extent than in cellular pathology.

In England the number of vacancy adverts for chemical pathology and haematology over 6 months increased from 138 and 935 in 2014 to 195 and 1,216 in 2015.⁶

According to Royal College of Pathologists workforce survey data, 25% of haematologists and 41% of clinical biochemists are aged over 55 (see Figure 20).

FIGURE 20 AGE PROFILE OF CONSULTANT HAEMATOLOGISTS AND CLINICAL BIOCHEMISTS



Source: Workforce data from the Royal College of Pathologists

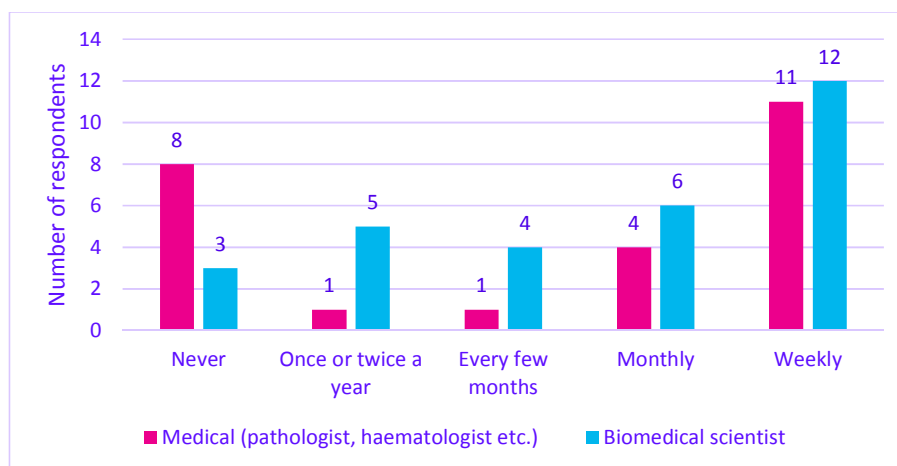
It has not been as difficult to recruit biomedical scientists and technical staff, but there are some areas that are under greater pressure – for example, bioinformaticians in the field of molecular diagnostics.

4.5 PATHOLOGY SERVICES ARE BECOMING MORE EXPENSIVE TO PROVIDE

In order to keep up with reporting demand, many departments are utilising overtime and some are outsourcing reporting services. Figure 21 shows the frequency with which certain

staff members conduct overtime, based on responses to a survey issued as part of this work.

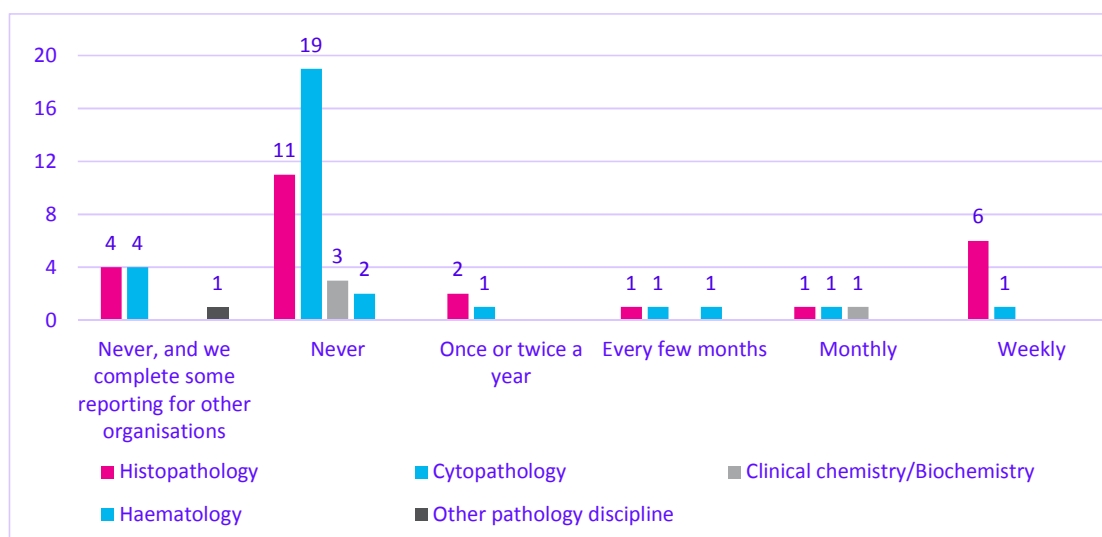
FIGURE 21 RESPONSES TO SURVEY QUESTION REGARDING OVERTIME



Source: Survey issued as part of project, June 2016. Responses to question: "For the role selected in Question 2, how often is overtime completed by members of this group?" N = 55

In addition to overtime payments made, some departments also send out work to be reported by other organisations. In radiology there are a large number of companies providing outsourced reporting services, whereas this is not yet as common in pathology. This outsourced reporting will be conducted at a premium cost, leading to further financial pressure. Figure 22 shows the responses to a survey question about outsourced reporting across different disciplines. Not all trusts are experiencing a situation where demand is outstripping capacity, with some NHS departments providing outsourced reporting services for other trusts.

FIGURE 22 RESPONSES TO SURVEY QUESTION REGARDING OUTSOURCED REPORTING FREQUENCY



Source: Survey issued as part of project, June 2016. Responses to question: "Do you send samples relating to an actual or potential diagnosis of neoplasia to be reported elsewhere? (Reporting related to primary diagnosis only, rather than supplementary tests)" N = 60

Outsourced samples are sent to a number of different organisations, as shown in Table 6.

TABLE 6 RESPONSES TO SURVEY QUESTION REGARDING OUTSOURCED REPORTING ORGANISATIONS

Organisation Type	Proportion of respondents outsourcing reporting to this type of organisation
NHS laboratory in own network	10%
Other NHS laboratory	40%
Joint venture	10%
Private company	50%

Source: Survey issued as part of project, June 2016. Responses to question: "If you do send samples out to be reported, what type of organisation completes this work? (Please select all that apply)"

4.6. BOOSTING WORKFORCE SUPPLY

4.6.1 ATTRACTING TRAINEES

There has been a shortfall in the number of people successfully applying for specialty training in cellular pathology. More work is required to make pathology an attractive choice for medical trainees.

The Royal College of Pathologists offers a summer school programme to give medical students an insight into the field of medical pathology. We would recommend that it conduct some follow-up research with students who have taken part in this programme to measure how many have chosen pathology as a specialty or continue to have an interest in the field.

Rotations in pathology laboratories should be made available to junior doctors, in order to give them more exposure to this specialty. Some specialties, such as dermatology, may be endorsed to report on a limited range of biopsies, and expansion of this process may allow a greater profile of cellular pathology.

Given the many other specialties to be included in the medical undergraduate curriculum – as well as pathology's unique similarity to a scientific, rather than clinical, career – it may be more productive to encourage scientific undergraduates to study post-graduate medicine, with the aim of becoming a pathologist. While it would be difficult to achieve, an ideal pathway would reduce the amount of required clinical experience in order to ensure a more rapid introduction to the pathology workforce

RECOMMENDATION: Health Education England should include cellular and molecular pathology within their review of the cancer and related workforce, to enable longer-term workforce planning. Health Education England may need to explore increasing the provision of training places for pathology. Pathology may need to be included on the curricula in medical schools where it is not currently offered. The Royal College of Pathologists should continue to run programmes aiming to attract more staff to cellular pathology.

4.6.2 RETIRING STAFF

It will be important to avoid losing the skills of the substantial number of pathologists approaching retirement from the workforce. These pathologists have a wealth of knowledge and expertise that could be used to grow and strengthen education and training provision.

Organisations will need to be proactive in retaining these staff, allowing flexible working arrangements and supporting individual requirements. Digital pathology may facilitate this, for example by enabling home working. This would make continued working a more positive option for pathologists. For any pathologists undertaking a much smaller volume of work than previously, in relative isolation from colleagues, a quality assurance system should be put in place to ensure that their reporting remains of a high standard.

Given the high throughput of an experienced consultant pathologist, retention of this staff member in some capacity beyond the expected duration will have a significant impact on a department's throughput.

We suggest that the Royal College of Pathologists should investigate affiliation with, or creation of, an outsourced reporting organisation. This would allow the college to direct laboratories to a trusted outsourced reporting provider, and allow retiring consultants to become part of an organisation that they can trust.

RECOMMENDATION: Trusts should engage with near-retirement consultants in order to encourage them to remain at the organisation, for example by implementing flexible working and home reporting. NHS decision makers should give individual organisations flexibility to decide the terms that they arrange with individuals. In England, when considering the new consultant contract, the Department of Health and NHS Employers should consider the impact on near-retirement consultants.

4.6.3 SPECIALIST SCIENTIFIC TRAINING

There is also a chronic shortage in staff with scientific specialties, particularly those related to molecular pathology and genetic sequencing. This problem is not limited to the United Kingdom. Given the improvements in sequencing technology, it is important to make sure that the workforce is equipped to deal with future demand. Bioinformatics will be an important field in the future of pathology, but there is currently a shortage of staff qualified in this discipline in the UK workforce.

The higher specialist scientist training scheme has had some success in boosting the numbers of people qualified in these fields. It would therefore be useful to increase the posts available for those who have undertaken higher specialist scientist training. The scheme organisers – Health Education England – should encourage more people to take up places on courses. The number of places could also be increased by training providers. Employers will need to concomitantly increase the posts available for those who have undertaken higher specialist scientist training.

5. FUTURE-PROOFING PATHOLOGY

5.1 DIGITISATION

The NHS is facing an increasing need to digitise, as can be seen in the commitment in the Five Year Forward View for the NHS in England to go fully paperless by 2020. While some elements of pathology have become automated and adapted to digital technology, for example with the use of autoanalysers in blood science or barcodes in cellular pathology, large parts of the cellular pathology process have so far not pursued digitisation. Discussion of digitisation within pathology can refer either to capture, storage and transfer of digital images, or to support reporting with image analysis software.

5.1.1 DIGITAL IMAGE STORAGE AND SCREEN REPORTING

The approach to reporting in cellular pathology still involves looking at a slide through a microscope, a process which has not changed significantly in decades. While almost all radiological images are stored and transferred digitally, sharing images in cellular pathology still often requires the physical transport of microscope slides.

It is possible to capture microscope slides digitally, but there are a number of challenges to overcome:

- Equipment – slides would have to be loaded into a specific machine, which captures an image of the slide. This would require manual intervention and an additional process step.
- Storage space – a high quality digital copy of a single microscope slide takes up several gigabytes of storage. Given the fact that there could be dozens more slides relating to an individual patient, storing the images for a single patient might require hundreds of gigabytes of memory (this is much more than the equivalent for a radiological image).
- Processing power – in addition to requiring a large amount of digital storage space, digital images also require computer processing power to be viewed. A manual microscope can move the field of view very quickly, boasting an ‘image refresh rate’ that is faster than many computers. This may change with new technology.
- Working styles – changing cellular pathology reporting from slides viewed on a microscope to slides viewed on a computer would require staff to possess a different set of skills. Pathology training would need take this into account.

Although parallels with radiology can be made, it should be recognised that unlike radiology where an image captured digitally is replacing the production of an analogue image; this is an additional step in the usual cellular pathology process – as slides still have to be prepared, and a digital image then created.

There are currently experiments in digitisation within cellular pathology in England, notably work being completed at University Hospitals of Coventry and Warwickshire to utilise a fully digital slide storage and viewing system.³⁸ This may have benefits in implementing pathology networks and telepathology, which will reduce the impact of workforce shortages, as well as smoothing the process for providing and reporting images for a multidisciplinary team meeting. While digital image capture is not commonly used in the UK, other nations have a more developed approach to it. For example, it is used in Canada and Sweden to allow for rapid, remote diagnosis.^{39,40}

Pathology reporting can occur remotely through telepathology without necessarily storing images digitally, but through remote control and visualisation of a microscope. This can allow specialist and secondary reporting and can support laboratories which may lack expertise for certain rare samples.⁴¹ Facilitating timely discussion of cases with colleagues can increase quality of care and shorten the diagnostic interval for patients. It can also be used to mark salient features in the slide, facilitating MDT review of the case. By saving slides as digital images, preparation for MDTs can be more efficient, and the images can be used again for research, teaching or reviewing the case.

5.1.2 DIGITAL IMAGE INTERPRETATION

Technology is changing, presenting new opportunities to improve pathology. Some companies are currently exploring the viability of digital image recognition and reporting. The full realisation of digital image recognition could remove the need for a doctor to be involved in the interpretation of images – radiological or microscopic. This would have a profound impact on the demand for pathologists to report. It is possible to see how cellular pathology would develop along the lines of blood sciences, where samples are investigated automatically by digitised equipment. One example would be its use to quantify the cells expressing an immuno-histochemical marker. More generally, any anomalies or samples above a set positive predictive value threshold are presented to a consultant. Developments in this area would greatly reduce the reporting demand for cellular pathologists.

However, digital pathology image analysis (to the level of actually making a diagnosis) is still in its infancy, so it is likely to take several years, or even decades, to develop the infrastructure and volume of digital images to support the introduction of digital image recognition. In addition, its implementation could face challenges of a technological, quality, medico-legal and cultural nature. Without having computers fully interpret pathological images, software could still be used to enhance reporting by highlighting suspected anomalies and providing additional value to the reporting process.

Computer software can currently add value to reporting by allowing faster and more accurate quantification and annotation of images. Quantification of results is becoming increasingly important in modern pathology, and digital pathology and digital image analysis allows cellular pathology to be quantified.

It is likely that digital pathology will have an impact on future demand for the pathology workforce. Given the potential market for this technology, many businesses will refine an approach to whole slide imaging and digital reporting. Developments pioneered by international organisations, some of which are currently developing technology for digital reporting in medical contexts, will benefit the UK. Trusts should continue to invest in the infrastructure to obtain and store images digitally in order to support networked working and remote reporting.

RECOMMENDATION: Departments and trusts should invest in infrastructure to support digital pathology and businesses/researchers should look at how to make this worthwhile. Sharing results and on-screen examination of histological slides should both be utilised in the short term to enable more efficient, networked services. Electronic requests should also be used.

5.2 RESEARCH

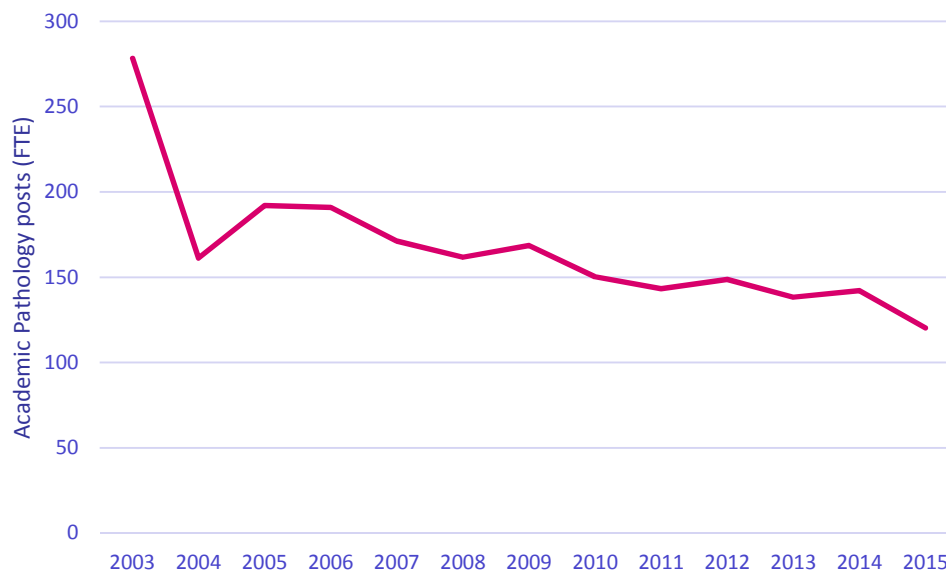
As increases in the pathology workforce have not kept pace with growing activity, cellular pathologists have had to change their working style in order to cope with the increase in demand. This means spending less time on non-reporting or supporting professional activities, such as teaching, taking on leadership roles and research. Interviewees mentioned that the amount of research completed had greatly decreased, and very few departments contained staff members who were conducting their own research.

Medical Schools' Council annual survey data shows the decrease in number of academic pathological staff (see **Error! Reference source not found.** While this decrease is not uncommon across medical specialties, pathology suffered a significant decrease (37%) in academic pathology posts from 2005-2010, during a time when overall, academic posts were increasing by 5%.⁴²

The National Cancer Research Institute report, 'Fostering the Role of Pathology in Research'⁴³, published in 2009 identified the difficulties in gaining pathology input into research. The report made four recommendations for increasing research in NHS pathology, but it is unclear how much this has advanced in the intervening years. Ten NCRI partners committed to fund a new initiative, the Cellular Molecular Pathology initiative (CM-Path) which launched in early 2016. CM-Path aims to achieve the change needed to support academic cellular molecular pathology in the UK and make the resulting benefits available to the wider research community.

A survey conducted by pathologists working with the Experimental Cancer Medicine Centres network during the development of the CM-Path found that 71% of the cellular pathologists surveyed (n= 213) stated a desire to undertake research. Key enabling factors identified were protected time, research funds, technical support staff and collaboration with established academic groups. Currently, absence or limitation of these factors poses major barriers to cellular pathologists' undertaking research.⁴⁴

FIGURE 23 FTE ACADEMIC PATHOLOGY POSTS IN THE UK



Source: A Survey of Staffing Levels of Medical Clinical Academics in UK Medical Schools as at 31 July 2015: A Report by the Medical Schools

RECOMMENDATION: There should be continued support from the NHS, researchers, funders and professional bodies for the CM-Path initiative (which aims to achieve the change needed to support academic cellular molecular pathology in the UK) and delivery of the four workstreams within its strategy. Workforce initiatives should allow pathologists to spend time on research. The recommendations from 'Every Patient a Research Patient'¹⁷ should also be implemented to encourage a more positive research environment in the NHS, including investment in academic pathology training posts and chairs.

The recent reduction in pathology research completed and number of academic pathologists is troubling, and continued lack of investment in these areas will have a profound impact on the future of cancer research and on diagnostics more broadly.

The investment of £635,000 by the National Cancer Research Institute in the Cellular Molecular Pathology (CM-Path) programme represents a vital step towards increasing the amount of research completed in this area.

5.3 MOLECULAR PATHOLOGY SERVICES

The field of molecular pathology has grown greatly in recent years. Between 2011 and 2014, molecular diagnostic testing activity for lung cancer, colorectal cancer and melanoma increased by 51% per year in England.⁹ In Wales over the same time period, testing activity for lung cancer, colorectal cancer and melanoma increased by 13% per year.⁴⁵ However, there are issues with the commissioning of these tests.

According to Cancer Research UK's reports on Molecular Diagnostic Provision, in 2014 there were shortfalls in testing for molecular diagnostics in three cancer types: melanoma, lung cancer and colorectal cancer.⁹ In England this was a 41% shortfall: based on cancer incidence rates and testing protocols, 59,294 tests should have been requested, but only 34,765 were provided.⁹ The picture is similar in Wales, with a 52% gap: 3,092 should have been requested but only 1,582 were conducted.⁴⁵ In Northern Ireland in 2014 estimates suggest around 570 molecular diagnostic tests were not undertaken, based on potential demand.⁴⁶ While work has not been completed in Scotland specifically in this area, it is possible that the same situation is occurring.

'Molecular Diagnostic Provision in England' states that at least £13.32m would be required annually to fund molecular diagnostics for England in the three cancer types listed above.⁹ Using the same method to estimate, investment is also required in Scotland (£1.3m), Northern Ireland (£0.44m⁴⁶) and Wales (£0.72m⁴⁵).

However, it is likely that the actual figure for this would be higher – the current figure is based on the cost of providing the test only and does not reflect the required level of staffing or training. As molecular diagnostics becomes more commonplace, the number of tests requested is likely to increase. As more tests are approved, the amount of money required is likely to increase, however this increase is unlikely to be linear – the cost of testing decreases greatly with scale as larger laboratories can provide tests for a very efficient cost profile.

5.3.2 INTEGRATED REPORTING

As molecular pathology takes on a large role within cancer diagnostics, closer collaboration

and integrated reporting will be essential in all types of cancer.

In blood cancers, there is a large amount of integration between molecular pathology, blood sciences and histopathology. This approach allows a more coherent approach towards treatment planning and targeted therapy. We would welcome further work by the Royal College of Pathologists on how molecular pathology could be more closely integrated with cellular pathology and blood sciences in solid tumours. This could take the form of integrated reporting, overseen and compiled by a single member of the team.

RECOMMENDATION: Molecular pathology should be more involved with the whole diagnostic process for solid tumours (including how molecular pathology results are reported), in a similar way to blood cancer. This should be facilitated through better IT connectivity and closer working between relevant staff groups.

5.3.3 COMMISSIONING

In England, the services providing molecular diagnostics will be subject to review. We know that steps have been taken in England to ensure that funding is unlocked for treatments which are prescribed as a result of this testing. A commitment was made in NHS England's cancer strategy delivery plan that any new test linked to use of a new cancer drug will be mandated for use across the system when the drug is recommended by NICE. This should provide clear guidance for commissioners to ensure funding is available for both the test and the treatment for specific targeted therapies.

In England, the level of provision of molecular diagnostic tests has recently been audited by NHS England to understand if there are areas where patients are not receiving the level of testing that would be expected. This should continue.

Standardisation of testing could be achieved through the National Laboratory Medicines Catalogue, which is intended to act as the professional reference for all pathology tests approved for use in the UK.

6. IMPROVE UNDERSTANDING OF PATHOLOGY PROVISION

6.1 PATHOLOGY DATA COLLECTION

There is a lack of data collected about pathology provision in the UK. There must be reliable data to enable effective planning and commissioning of services. Without sufficient data, it is difficult to quantify how demand has grown or changed over time, and difficult to look at whether there are systematic problems with turnaround times or vacancies. This is not new. In 2006, the report by Lord Carter said, “we were struck by how little the available information – financial, operational, workforce or performance – currently tells us about pathology [...] This appears to hold true at national, regional and local levels”.¹⁰

The Royal College of Pathologists currently collects workforce information by recommending that individual pathologists respond to the college workforce survey. We recommend that the college proactively collects information required for informing decisions relating to cancer services in pathology through a department-level survey. This should collect:

- Workforce information
 - Current establishment figures for pathologists and BMS
 - Vacancies
 - Levels of overtime and spend on locum staff
 - Consideration of workload complexity
- Turnaround time
 - Current figures
 - Backlog snapshots
- Management costs
 - Level of outsourcing: Volume and cost

While there would be initial difficulties in implementing the pro-active approach, it would allow for wider coverage and more in-depth information. It could then be adjusted for local population characteristics to highlight unwarranted variation.

Using a similar approach to the Royal College of Radiologists, these data should be published in an annual workforce summary, focusing on the key challenges in order to indicate where action is required.⁴⁷ This would also allow organisations such as Cancer Research UK to access this information and use it to inform policy development.

The figures for workforce should be compared with those held by other bodies, such as commissioners or NHS Digital (formerly HSCIC) in England, to ensure consistency in the picture for workforce.

In England, there are several national initiatives looking at collecting information on pathology, including the National Laboratory Medicines Catalogue (NLMC) and the Pathology Quality Assurance Dashboard. It is not clear that these programmes will provide the required information as they are currently progressing.

RECOMMENDATION: There should be investment in technology so departments can comply with requirements to supply pathology data to the Cancer Outcomes and Services Dataset (COSD). The Royal College of Pathologists should pro-actively collect comprehensive workforce information from departments across the UK.

6.2 PATHOLOGY INVOLVEMENT IN DECISION MAKING AND VISIBILITY

Pathology is a key diagnostic specialty, but often funding and strategy documents reference radiology and endoscopy without making reference to pathology. This can lead to difficulty in achieving key turnaround targets and a greater cost implication of providing pathology services.

The pathology demand and capacity data analysed in this report should be used to understand the current situation in pathology, bringing to light the financial implications of delivering pathology at a premium rate through outsourced and overtime reporting. Working groups and decision-making bodies in diagnostics should have pathology representation. For example, in England there should be liaison regarding pathology between the National Clinical Director for Diagnostics and the Deputy Chief Science Officer as many issues are linked.

This should also be viewed at individual trust level. We recommend that all trust decisions regarding demand and volume address the implications on pathology and other diagnostic areas.

In England, NHS planning documents have asked for sustainability and transformation plans to “Agree trajectory for increases in diagnostic capacity required to 2020 and achieve it for year one.”⁴⁸ Pathology input is essential for this. Pathology should also be considered as part of diagnostic pathway redesign and changes, including the introduction of the new 28 day ‘Faster Diagnosis Standard’.

RECOMMENDATION: Any changes to diagnostic pathways or processes should factor in the impact on pathology. Health service workforce and resourcing plans must ensure pathologists and clinical scientists are involved in the dialogue.

7 CONCLUSION

Pathology plays a crucial role in cancer diagnosis. Gradually increasing demand has put pressure on this part of the diagnostic process. The demand for cancer diagnostic services is likely to continue to increase with rising incidence and prevalence in the UK. However, it is possible that the role of the cellular pathologist in cancer diagnosis will change in the future as well.

In some places, new tests have replaced cellular pathology investigations. For example, HPV as the primary test in cervical screening will reduce demand for cytological investigation of cervical samples. As technology develops, it is also possible that certain types of investigation will reduce the need for cellular pathology activity by allowing more focused use of cellular pathology investigations. For example, a current trial into the use of multiparametric-MRI in suspected prostate cancer cases is expected to greatly reduce the volume of prostate biopsies required, focusing on patients who are more likely to have a positive result and reducing the number of negative results.⁴⁹

The full realisation of digital image recognition could greatly reduce the demand for cellular pathologists. While there are many barriers to full implementation of this process, there are some developments which may increase pathologist reporting capacity. Current technology can supplement the capacity of the pathologist to report on a digital image by highlighting and annotating it, for example by identifying tumour markers.

Any discussion of the future of pathology should highlight the fact that different areas of pathology are becoming more integrated. In haematopathology, reports are produced which integrate the findings of cellular pathology, blood sciences and molecular pathology. As more molecular tests are developed for each cancer type, further integration of the different aspects of pathology will be required.

In current cancer diagnostic investigations, pathology plays a key gatekeeping role. While there is potential for technological and other innovations to change the pathologist's role over the long term, this role is unlikely to change in the next 10 years, so for the foreseeable future the demand for cellular pathologists is likely to remain high.

IN THE SHORT TERM (1-3 YEARS), PATHOLOGY IS LIKELY TO BECOME MORE EXPENSIVE FOR PROVIDERS AND COMMISSIONERS, AND WAITING TIMES WILL CONTINUE TO INCREASE

Barring unforeseen major changes, demand and activity in cellular pathology will continue to outpace reporting capacity, which in turn is likely to impose pressure on diagnostic pathways.

Histopathologists have increased their reporting workload at the expense of other aspects of their role, including training and research, leaving reporting more like a 'production line'. This adjustment to working style can only be made once – the workforce cannot adapt to further demand. Due to the large amount of automation within blood sciences and molecular pathology, these disciplines should be able to absorb the increased demand within the existing capacity of the service.

Consultants' willingness to work long days on an ad hoc basis to deal with backlogs, as they currently do, will have a limit. It is likely, therefore, that cellular pathology will see an increase in 'in-sourcing', where consultants receive payments for work they complete for the trust over and above their expected workload. This practice is currently common in radiology.

In addition to 'in-sourcing', there is likely to be an increase in the number of third-party

companies offering a reporting service to cellular pathology departments. Again, this can be seen in radiology: the Royal College of Radiologists estimate that £58 million was spent on outsourced radiology in 2013-14.⁵⁰ Given the accreditation requirements, there is a barrier to entry to new, small organisations, meaning that there are likely to be a few large private organisations, or perhaps other NHS trusts, which will provide outsourced reporting capacity.

As seen through waiting times, the number of patients waiting more than six weeks for a pathology investigation has been increasing year-on-year. This relates to all pathology diagnostics, not just cancer-related work, and, as providers prioritise cancer activity, it is likely that many patients waiting more than six weeks may not have been referred with suspected cancer. Moreover, given the penalties to organisations for failing to provide timely cancer diagnostics, it is likely that providers will aim to minimise any impacts on cancer waiting times. Still, waiting times for pathology as part of an investigation of suspected cancer are likely to increase to some extent along with increasing demand.

There are plans in England to introduce a 28-day target for informing a patient of a cancer diagnosis (the 'Faster Diagnosis Standard') – pathology will have a crucial role in the diagnostic pathway and processes which allow this aim to be achieved.

IN THE MEDIUM TERM (5-10 YEARS), PATHOLOGY IS LIKELY TO EXPERIENCE STAFFING DIFFICULTIES WHICH WILL HAVE AN IMPACT ON ROUTINE WORK

Based on the number of pathologists currently in training and the age profile of the current workforce, there is likely to be a severe crisis in pathology capacity within the next 5-10 years. The shortfall will be most severe in cellular pathology, where consultant pathologist input is required in the vast majority of reporting. A major change to training may be required to avert this outcome.

As mentioned above, productivity increases may help, but are unlikely to enable departments to keep up with demand. Technology, such as development of Whole Slide Imaging, capturing a digital image of the microscope slide, with electronic storage and transfer, may alleviate some of the impact in the most severely affected areas.

RECOMMENDATIONS

Without action taken now to address workforce issues and improve efficiency, waiting times are likely to increase as it will take longer to process and report all requests. This means more people will be left in limbo when they require tests, and it may delay patients' diagnosis and treatment.

Turnaround times will increase to unacceptable levels which could compromise efforts to diagnose cancer earlier. Immediate action is needed to avert a crisis in pathology capacity and ensure we have a service that is fit for the future.

RECOMMENDATION 1^g: NHS England and NHS Improvement should continue to support Sustainability and Transformation Plan footprint areas (STPs) and Trusts to consolidate pathology services, in order to facilitate testing taking place at the appropriate level.

RECOMMENDATION 2: Trusts and their pathology departments, supported through guidance from professional bodies and NHS England, should:

^g This recommendation only applies in England

7. Ensure BMS are being utilised to cut up specimens where possible, in accordance with 'Principles of Good Practice for Biomedical Scientists Involved in Histopathological Dissection'¹⁵.
8. Explore the role of clinical scientists to support complex diagnostics and research. Clinical scientist input should be recognised in their job plans with backfill provided for existing duties.
9. Develop graduated increase in trainee responsibility and supervised reporting in accordance with the Royal College of Pathologists guidance on graded responsibility.¹⁶ The Royal College of Pathologists should update and promote their guidance document.
10. Ensure widespread use of biomedical scientist reporting following their completion of the Biomedical Scientist reporting programme.

RECOMMENDATION 3: Those in charge of medical education and training must include pathology within their strategic workforce planning. In England, Health Education England should include cellular and molecular pathology within their review of the cancer and related workforce, to enable longer-term workforce planning. The Royal College of Pathologists should continue to run programmes aiming to attract more staff to cellular pathology.

RECOMMENDATION 4: In considering the new consultant contract, the Department of Health and NHS Employers should consider the impact on near-retirement consultants.

RECOMMENDATION 5: There should be continued support from the NHS, researchers, funders and professional bodies for the CM-Path initiative and delivery of the four work streams within its strategy. Workforce initiatives should allow pathologists to spend time on research. The recommendations from 'Every Patient a Research Patient'¹⁷ should also be implemented to encourage a more positive research environment in the NHS, including investment in academic pathology training posts and chairs.

RECOMMENDATION 6: Departments and trusts should invest in infrastructure to support digital pathology and businesses/researchers should look at how to make this worthwhile. Sharing results and on-screen examination of histological slides should both be utilised in the short term to enable more efficient, networked services. Electronic requests should also be used.

RECOMMENDATION 7: Molecular pathology should be more involved with the whole diagnostic process for solid tumours (including how molecular pathology results are reported), in a similar way to blood cancer. This should be facilitated through better IT connectivity and closer working between relevant staff groups.

RECOMMENDATION 8: NHS Trusts should invest in technology so departments can comply with requirements to supply pathology data to the Cancer Outcomes and Services Dataset (COSD). The Royal College of Pathologists should pro-actively collect comprehensive workforce information from departments across the UK.

RECOMMENDATION 9: Health service decision-makers should ensure all work on diagnostic pathways factors in the impact on pathology. NHS workforce and resourcing plans must ensure pathologists and clinical scientists are involved in the dialogue.

APPENDIX A: CONTEXT AND METHODOLOGY

This report has been prepared on behalf of Cancer Research UK to evaluate the ability of pathology services to meet the needs of cancer patients and people with suspected cancer across the UK, both now and in the future. The aims of the project were to understand the current state of pathology relating to cancer; to identify any barriers that may exist to delivering high quality cancer diagnostics and research; and to identify potential solutions and make recommendations to ensure that pathology services are equipped to deal with the demand which will be placed on them in the future.

Due to the specific focus on cancer, the project focuses on a subset of pathology services – mostly cellular pathology, but also blood sciences and molecular pathology.

This report is based on a combination of interviews, data analysis and desk research. Interviews took place from January to April 2016 and were conducted with:

- Staff in cellular pathology, haematology and biochemistry within the NHS/health services
- Independent sector staff
- Key stakeholders in each nation.

A list of the local organisations interviewed is given in Appendix B.

Data used for the report came from nationally available datasets and individual laboratories. In total, 11 laboratories returned data that had been requested. As discussed in Section 3, the data available for pathology is limited and can be difficult to access.

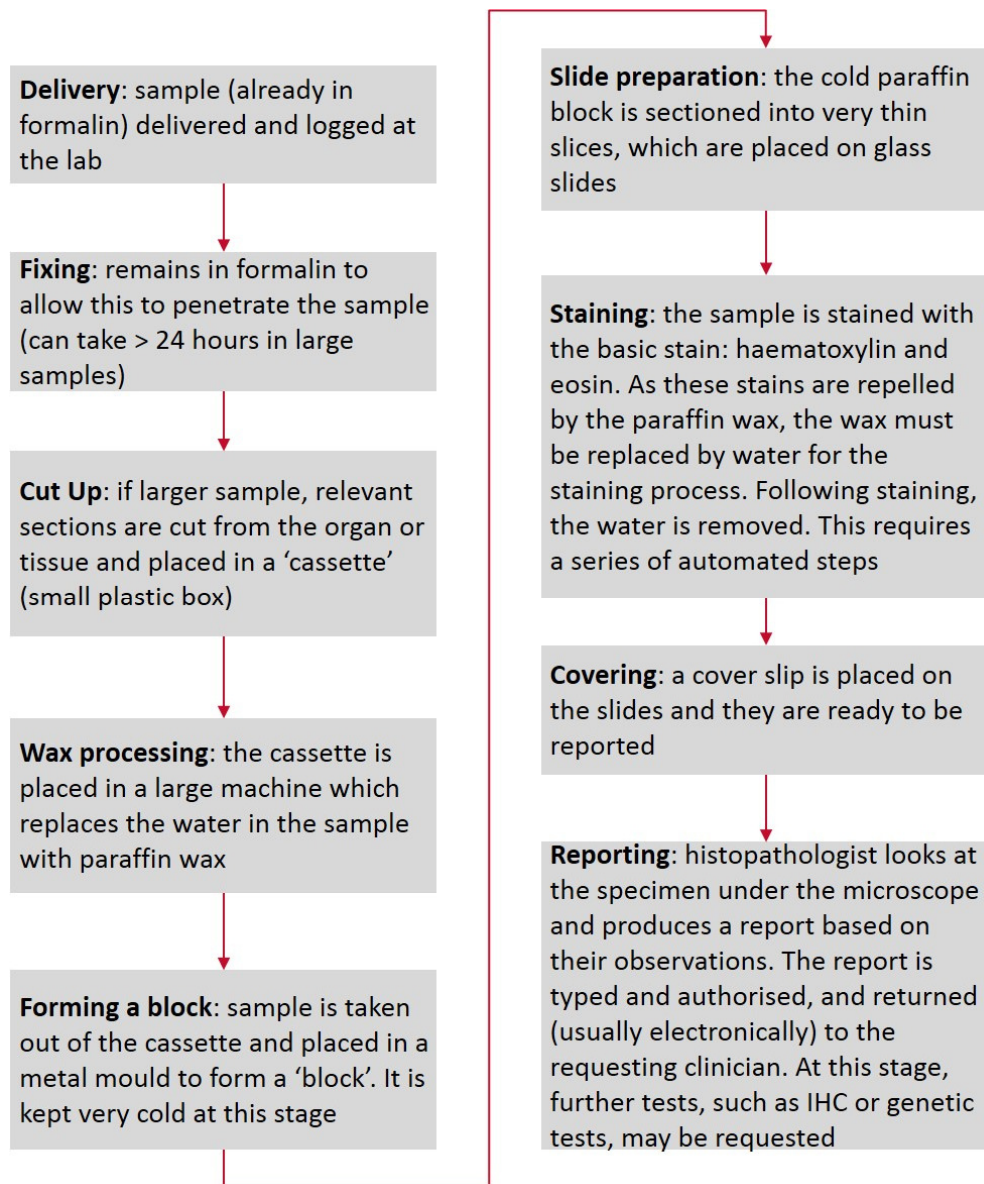
Keele Benchmarking Service also provided some headline data to show year-on-year growth. Approximately 55 cellular pathology laboratories from across the UK submitted data to the Keele Benchmarking Service over this time.

APPENDIX B: LIST OF ORGANISATIONS INTERVIEWED

Over the course of this project, we spoke to individuals from the below laboratories or providers. We are very grateful for their input and time.

NHS Greater Glasgow and Clyde	Scotland
NHS Highland	Scotland
NHS Tayside	Scotland
Cardiff and Vale Health Board	Wales
Hywel Dda Health Board	Wales
Northern Ireland Pathology Network	Northern Ireland
Belfast Health and Social Care Trust	Northern Ireland
Northern Health and Social Care Trust	Northern Ireland
Southern Health and Social Care Trust	Northern Ireland
Western Health and Social Care Trust	Northern Ireland
Barts Health NHS Trust	England
Blackpool Teaching Hospitals NHS Foundation Trust	England
Cambridge University Hospitals NHS Foundation Trust	England
County Durham and Darlington NHS Foundation Trust	England
George Eliot Hospital NHS Trust	England
Leeds Teaching Hospitals NHS Trust	England
Liverpool Clinical Laboratory	England
London Northwest Healthcare NHS Trust	England
Maidstone and Tunbridge Wells NHS Trust	England
North Middlesex University Hospital NHS Trust	England
Plymouth Hospitals NHS Trust	England
Salford Royal NHS Foundation Trust	England
Sherwood Forest Hospitals NHS Trust	England
The Doctor's Laboratory	England
The Royal Wolverhampton NHS Trust	England
United Lincolnshire Hospitals NHS Trust	England
Viapath	England

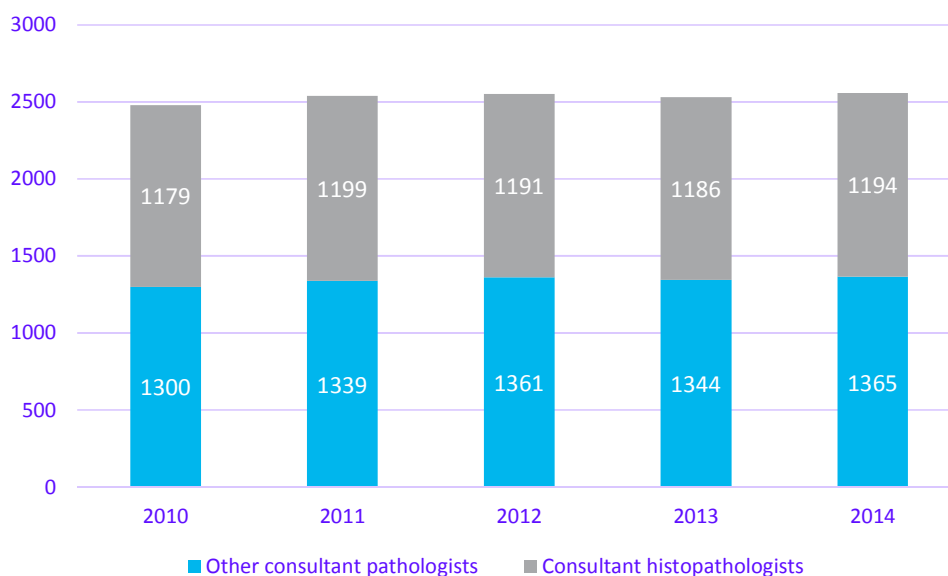
APPENDIX C: STEPS INVOLVED IN PROCESSING A HISTOPATHOLOGY SAMPLE



APPENDIX D: ENGLAND WORKFORCE DATA FROM NHS IVIEW

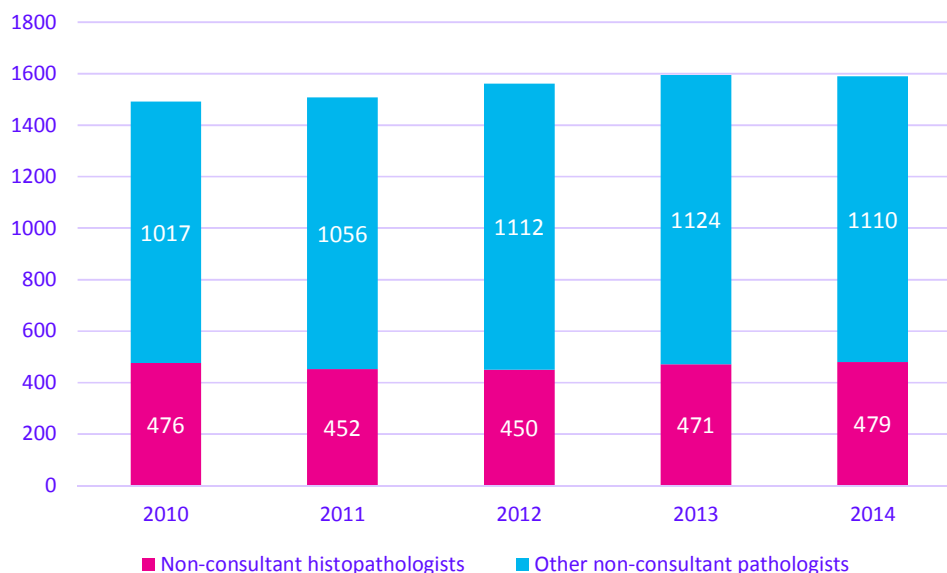
Data from NHS iView shows an increase in consultant histopathologists in England of approximately 1.2% per year, which is higher than the overall rate of growth of consultant pathologists at 0.8%.⁶

FIGURE 24 FTE CONSULTANT PATHOLOGISTS IN ENGLAND



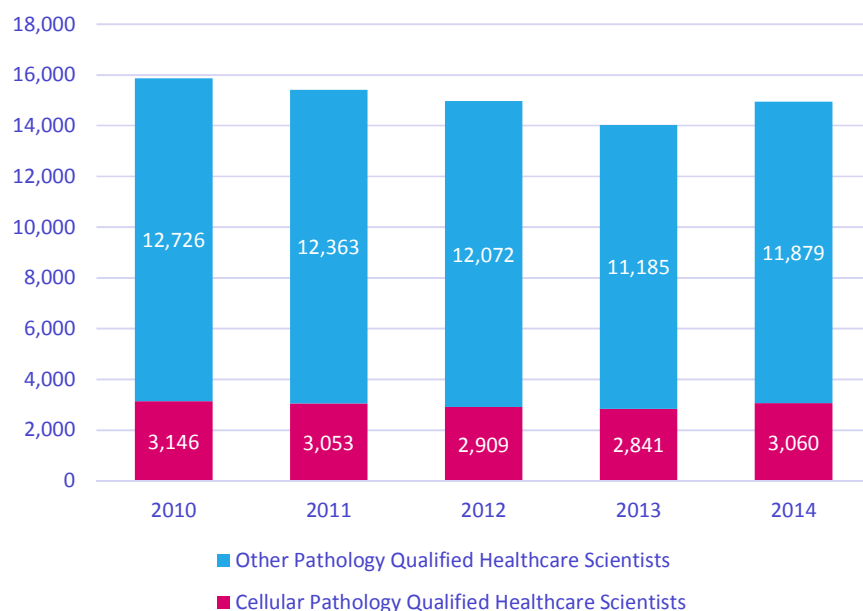
The number of FTE non-consultant histopathologists grew at 0.2% per year in England from 2010 to 2014. The equivalent figure for non-consultants in all disciplines in pathology is 2.2%.⁶

FIGURE 25 FTE NON-CONSULTANT PATHOLOGISTS FOR ENGLAND



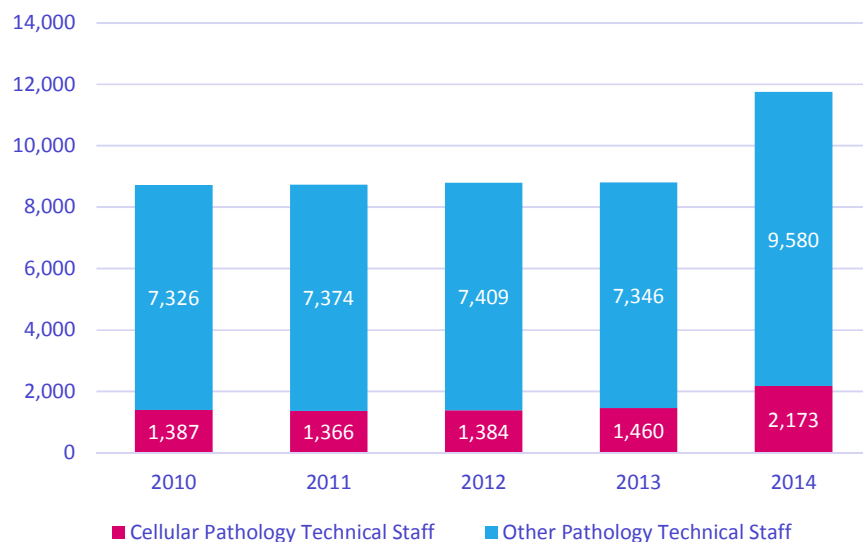
According to iView figures, between 2010 and 2013 there was a decrease in the number of non-medical science staff. There was a change between 2013 and 2014 in how these data were coded, so it is hard to ascertain the level of decline. From 2010 to 2013, there was a drop of 4% per year in the number of FTE biomedical scientists. The number recorded in 2014 is higher than previous years, but it is not clear if that reflects a real trend or just the coding change.⁶

FIGURE 26 FTE PROFESSIONALLY QUALIFIED CLINICAL STAFF IN PATHOLOGY (NON-MEDICAL) FOR ENGLAND



For technical staff, as with biomedical scientists, a change in coding makes it difficult to compare data from 2014 onwards with earlier figures. From 2010 to 2013, the number of FTE technical staff appeared to remain roughly constant. The number appears to be considerably higher in 2014 but, again, it is difficult to know how to interpret this change.⁶

FIGURE 27 FTE SUPPORT TO CLINICAL STAFF IN PATHOLOGY FOR ENGLAND



While we have been writing this report, the Health and Social Care Information Centre (now NHS Digital) has revealed that headcount figures for the NHS in England in December 2015 were overestimated. It is unclear what impact this will have had on FTE figures for staff in pathology services, but a systemic miscount would be unlikely to have affected year-on-year trends.

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