

Modernising HSC Pathology Services

Proposals for Change

28 November 2016

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Foreword

The last major review of Health and Social Care Pathology Services was carried out over 10 years ago. In the period since then we have seen significant innovation in the biomedical sciences which underpin pathology and improvement in the quality and responsiveness of the service provided to patients.

The time is therefore right to take the North's Pathology Service to the next level so that we have the capacity to address the challenges faced by the Service and fully embrace future development opportunities to support even better diagnostic outcomes for patients in the years ahead.

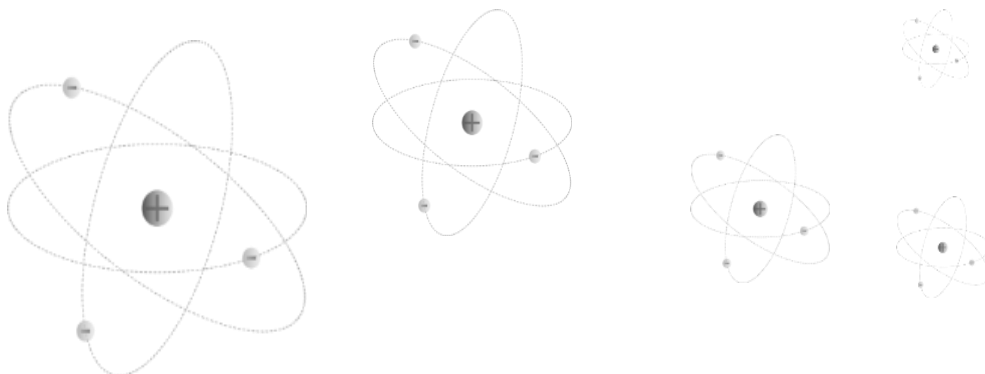
I am therefore pleased to launch this public consultation document which contains proposals to improve Pathology Services in the North. This project is a key part of my agenda to deliver the world class health and social care service which I aspire to in my Ministerial document, 'Health and Wellbeing 2026: Delivering Together'. However, before I reach a decision on the future shape of our Pathology Services I am asking everyone across the North, people who use the health service, their families, those who work in the health service and all stakeholders to take part in this public consultation on modernising Pathology Services.

Having your say in the future shape of the Service is vital because Pathology Services provide a very important but often unseen service for patients. It is estimated that between 70 to 80% of diagnoses depend on a pathology result right through from the GP surgery to the operating theatre. The service in the North costs around £100 million to deliver each year. It employs over 1,100 staff, and provides a service 24 hours

a day, seven days a week. We are therefore looking at both a significant level of investment and a service which is of central importance in meeting the needs of patients.

I would therefore ask you to please take time to read this document and complete the enclosed questionnaire. Your contributions are important and will be given full consideration in reaching my decision on the future Pathology Service.

Michelle O'Neill MLA
Minister of Health



Introduction and Summary

Document Purpose

This consultation document has been published to invite views from stakeholders on proposals to modernise Health and Social Care (HSC) Pathology services, including the Blood Transfusion Service (NIBTS).

Pathology Services

HSC Pathology services are responsible for a range of functions within the laboratory, and the provision of direct patient care. They manage the analysis of blood, tissue and other samples collected from patients to produce a report, alongside which they provide clinical advice to help make diagnoses. The service monitors how well treatment is working, and informs assessment of the likely future course of disease and the patient's prospects for recovery. The service provides testing for bacteria or viruses for direct patient care and public health purposes. NIBTS is responsible for the collection of blood that is voluntarily donated by the public, and its preparation and supply for use in hospitals. It also provides a range of specialist regional tests.

“Around 95% of clinical pathways rely on patients having access to efficient, timely and cost effective pathology services. Pathology touches all of our lives, from before we are born to, in many cases, after we die”

(National Pathology Programme: Digital First, p4)

Pathology services are currently provided by five HSC Trusts and NIBTS.

Background to the Proposals

HSC Pathology services face significant challenges requiring a regional strategic approach that will provide a more sustainable service for the future. To achieve this, investment is necessary. In a climate of financial constraint such investment can only be realised through a programme of regional Pathology service reform and modernisation. Our aim is to create a sustainable, world-class Pathology service that can:

- ✓ Meet current and future quality and regulatory requirements;
- ✓ Respond to changes in demand;
- ✓ Support new models of clinical care and new targeted treatments;
- ✓ Adopt new ways of working and innovative technologies;
- ✓ Provide a modern career structure for staff.

This document sets out proposals for modernising HSC Pathology services, including the Blood Transfusion Service, which have been developed by the Health and Social Care Board working in partnership with the Pathology Network. Pre-consultation on the proposals has been undertaken with a wide range of stakeholders including HSC Trusts, the Patient Client Council, Staff, Trade Unions, and Professional Bodies.

Patients, Blood Donors and Clinical Service users would not be directly impacted by these proposals, it is anticipated that the only change they would notice, if at all, would be an improvement in quality and safety.

Request for Responses

Responses to this consultation are welcome from all stakeholders.

Section 7 outlines how to respond, and the response form is included as Appendix 1.

Next steps

Information received during consultation will inform the development of a future service model that delivers a high quality, sustainable, cost-effective Pathology service for the local population. The future service model, as part of an evolving wider HSC infrastructure, will also take account of the outworkings of 'Health and Wellbeing 2026: Delivering Together' (DOH 2016).

Following completion of, and subject to the outcome of consultation, a business case and Equality Impact Assessment (EQIA) will be completed, and final proposals presented for consideration by the Department of Health and the Minister.

Document Structure

The structure of this document takes the reader through the strategic context (Section 1) and the current arrangements for the provision of HSC Pathology services (Section 2). The issues and opportunities facing Pathology services in the HSC are described in Section 3, and Section 4 outlines three proposals for modernising HSC Pathology services. Section 5 describes the equality considerations. Issues associated with implementation are included in Section 6. Section 7 provides information on how to respond to the consultation, and outlines the proposed next steps.

A form that can be used to respond to this consultation is included at Appendix 1. The document also contains a list of stakeholders that were engaged in pre-consultation (Appendix 2), a summary of the different Pathology Specialties (Appendix 3), and a list of the sources of information used to develop this document (Appendix 4).

1 Strategic Context

The purpose of this section of the consultation document is to describe the strategic context within which Pathology services are currently operating, and the policy and best practice guiding Pathology service delivery in the UK.

1.1. Policy and best practice in Pathology service delivery is documented in a number of regional and national publications which provide the basis for the proposals set out in this consultation. All publications and sources of information used to develop this document are listed in Appendix 4. Key policy documents are set out below:



**‘The Future of Pathology Services’ (DHSSPS 2006);
‘Recommendations on the Future of Pathology Services’
(DHSSPS 2007)**

The Department’s Recommendations on the Future of Pathology Services (2007) outline current HSC Pathology Policy and include:

- ✓ a Managed Clinical Network for Pathology;
- ✓ the consolidation of testing where results are not required rapidly for optimal patient management;
- ✓ reinvestment of resource released from consolidation in appropriate new service developments including modern information systems;
- ✓ closer collaboration with the Blood Transfusion Service and Universities;
- ✓ integration of the provision of pathology clinical advice within the acute hospital.



‘Review of NHS Pathology services in England’ (DH 2006);

‘Report of the second phase of the Review’ (DH 2008);

‘Review of Operational Productivity and Performance in English NHS Acute Hospitals: Unwarranted Variation’ (UK Govt. 2016)

All Chaired by Lord Carter of Coles on behalf of the Department of Health (DH) in England, or the United Kingdom Government (UK Govt.), these reports make recommendations for, and provide evidence of service consolidation and standardisation as an effective means of reducing unwarranted variation in practice, improving quality and safety, improving productivity and facilitating greater opportunities for workforce development. The 2016 report makes a specific recommendation that:

“...[NHS England acute hospital] Trusts should ensure their pathology and imaging departments achieve their benchmarks as agreed with NHS Improvement by April 2017, so that there is a consistent approach to the quality and cost of diagnostic services across the NHS. If benchmarks for pathology are unlikely to be achieved, Trusts should have agreed plans for consolidation with, or outsourcing to, other providers by January 2017”

(p40)



‘Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry’ (UK Govt 2013);

‘Pathology Quality Assurance Review’ (NHSE 2014).

The report of the UK Government (UK Govt.) commissioned independent public inquiry into events in Mid Staffordshire NHS Foundation Trust draws attention to the tragic consequences of not having a joined up system with clear governance and accountability to ensure the quality of service.

The NHS England (NHSE) Pathology Quality Assurance Review was commissioned following the Mid-Staffordshire Inquiry, to consider quality assurance in Pathology services in England. It makes a number of recommendations to improve the quality of Pathology services, including that quality and governance systems of pathology providers be integrated with Trust quality and governance structures.



‘Atlas of Variation in Diagnostic Services’ (PHE 2013);

‘Digital First: clinical transformation through pathology innovation’ (NHSE National Pathology Programme 2014)

These reports by Public Health England (PHE) and the NHS England (NHSE) National Pathology Programme highlight:

- ✓ Unwarranted variation in the quality of diagnostic services, which is associated with greater risk for patients and greater cost.
- ✓ The role of information systems in reducing unwarranted variation in practice and unnecessary patient testing.
- ✓ The rapid development in pathology technology that offers improved diagnostic opportunities for patients.



‘Transforming Your Care’ (DHSSPS 2011);
‘Aligning Diagnostics: Strategic guidance for Pathology Service reconfiguration’ (DH & PCC 2013);

These documents from the Department of Health, and the Department of Health (DH) in England and Primary Care Commissioning (PCC) note that modernisation of health service Pathology can support wider healthcare system transformation, including the delivery of new models of care closer to patients.



‘Accelerated Access Review - Interim Report’ (UK Govt 2015)
‘Research for Better Health and Social Care Strategy: 2016 to 2025’ (DOH 2016)

These UK Government (UK Govt.) and Department of Health documents note that research and development is essential for progress in Health and Social Care services, without it there would be no health screening programmes, diagnostic tests or treatments. In recognition of the speed of growth in technology and scientific discovery, the UK Government Accelerated Access Review is considering how to speed up access to innovative drugs, devices and diagnostics for people using NHS services, for example technologies that support the development of new models of care including near-patient testing, and targeted diagnostic tests and treatments. The reports identify that to achieve a faster system closer collaboration is needed between Pathology and other health services, academia and industry.



‘The Right Time, the Right Place’ (DHSSPS 2014)

Sir Liam Donaldson’s review published by the Department highlights concerns about the effectiveness of the current arrangements for the provision of Health and Social Care. The region currently has ten acute hospitals; each needs, and has, 24-7 laboratory testing facilities on site to support the provision of the clinical services it offers to patients.



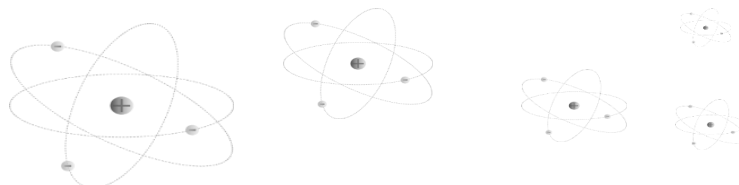
‘Systems not Structures: Changing Health and Social Care (Expert Panel Report 2016)

An Expert Panel Chaired by Professor Rafael Bengoa was convened in January 2016 by the Department of Health to facilitate debate on a sustainable way forward for the future provision of Health and Social Care. The report identified Pathology as one of the specialties in most need of reform. This report is very relevant for Pathology services, since any decision on acute hospital provision will impact the requirement for pathology services that support acute hospital clinical services.



‘Health and Wellbeing 2026: Delivering Together’ (Department of Health NI, 2016)

Within this document the Minister for Health included among her immediate priorities the launch of a public consultation on proposals to modernise and transform Pathology services, designed to improve service and workforce sustainability ensuring a high quality Pathology service for the future.



2 Current HSC Pathology Services

The purpose of this section of the consultation document is to describe the current arrangements for the delivery of HSC Pathology services.

2.1. HSC Pathology services underpin all HSC Clinical services, it is estimated that between 70 - 80% of diagnoses depend on a pathology result. The service in the North costs around £100 million to deliver each year. It employs over 1,100 staff, and provides a service 24 hours a day, seven days a week.

Pathology Service Users

2.2. The clinical service users of HSC Trust Pathology services are primarily the GPs in primary care and the doctors in hospitals that request laboratory tests. The service users of the Blood Transfusion Service are the HSC Hospital blood banks that use blood and blood components.

2.3. Clinical Service users, Patients or Blood Donors would not be directly impacted by these proposals; it is anticipated that the only change they would notice, if at all, would be an improvement in quality and safety.

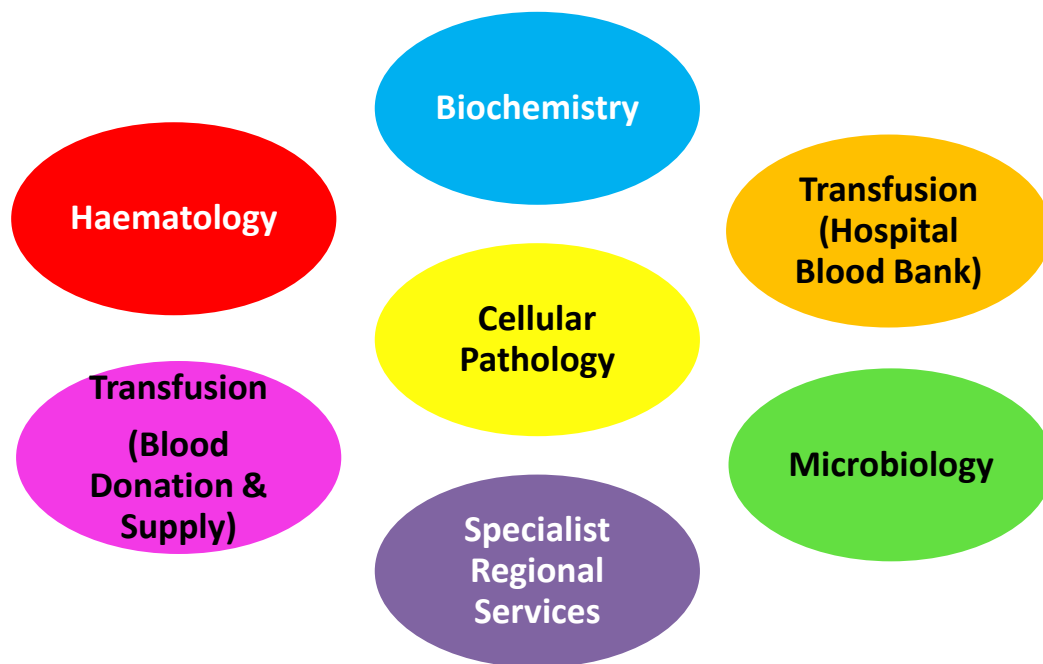
Pathology Functions and Specialties

2.4. Together, all Pathology services undertake six main functions:

- 1) the management of blood, tissue and other samples collected from patients;
- 2) the provision of clinical advice to help make diagnoses;
- 3) the provision of direct clinical care;
- 4) the management of blood donation and supply;

- 5) monitoring treatment efficacy and making prognosis; and
- 6) testing for bacteria or viruses for direct patient care and public health purposes.

2.5. In total there are 19 Pathology Specialties (defined in Appendix 3), and within these, many more sub-specialities, however all broadly fall into seven main 'disciplines':



Near Patient Testing & Precision Medicine

2.6. 'Near-Patient Testing' (outside of laboratories) and 'Precision Medicine' are particularly important areas of development in Pathology that have the potential to change the way health services are provided in future for the benefit of patients.

2.7. **Near-patient testing** (NPT) is testing performed for patients by healthcare professionals outside of the conventional laboratory, for example in operating theatres, hospital wards, or general practice (the use by patients of home-testing devices is not included in the term 'near patient testing').

2.8. **Precision medicine** is a new, rapidly evolving approach to improving the way diagnosis and treatment is provided. It helps increase our understanding about diseases and how they progress, which informs the development of evidence based diagnostic tests and targeted therapies that take into account the patient's biological characteristics, health status, medications they are already prescribed, and environmental and lifestyle factors. It results in better outcomes for patients and more cost effective services.

2.9. The Pathology aspects of precision medicine are closely integrated with specialist clinical services, particularly Cancer and Genetics, but increasingly also with other areas of clinical care. In the North there have been a number of significant developments that have strengthened the region's ability to deliver precision medicine for its population.

- ✓ Establishment of the Genomic Medicine Centre in the Belfast Trust, a regional partnership funded by the Medical Research Council and DOH (NI) through which the region will participate in the UK 100,000 Genomes initiative to support better diagnosis and treatments for patients with cancer and rare disease.
- ✓ Establishment of the Northern Ireland Molecular Pathology Laboratory in Belfast, its focus includes the growth of Precision Medicine for the benefit of patients and the Northern Ireland economy.
- ✓ Establishment of the Centre for Stratified Medicine in the Clinical Translational Research and Innovation Centre (C-TRIC) on the Altnagelvin Hospital site in Derry/Londonderry. A unique facility in the HSC pioneering medical research into chronic degenerative diseases.

The Pathology Network

2.10. The Pathology Network is a constituted, regional, HSC-led group which aims to provide direction and promote consistency in the delivery of HSC Pathology services. It provides advice to the Health and Social Care Board on the best way to commission pathology services. It is governed by a Network Board and delivers its objectives through strategic project groups and regional clinical 'Specialty Fora' representing all major Pathology disciplines, ICT and laboratory services general management.

2.11. The Network Board includes representation from:

- ✓ 5 HSC Trusts
- ✓ NIBTS
- ✓ The Health & Social Care Board (HSCB)
- ✓ The Public Health Agency (PHA)
- ✓ HSC Research & Development
- ✓ The Department of Health
- ✓ Queens University Belfast
- ✓ Ulster University
- ✓ The Patient Client Council
- ✓ The Royal College of Pathologists
- ✓ The HSC Business Services Organisation Procurement and Logistics Service
- ✓ Specialty Fora Chairs attend as required.



PATHNET NI

Pathology Network, Northern Ireland

Service Configuration & Management

2.12. The following diagram shows the current configuration of Pathology services in the HSC:

Belfast Trust			Northern Trust		South Eastern Trust	Southern Trust		Western Trust	
Royal Victoria Hospital	Belfast City Hospital	Mater Hospital	Antrim Area Hospital	Causway General Hospital	Ulster Hospital	Craigavon Area Hospital	Daisy Hill Hospital	Altnagelvin Area Hospital	South West Area Hospital
Biochemistry	Biochemistry	Biochemistry	Biochemistry	Biochemistry	Biochemistry	Biochemistry	Biochemistry	Biochemistry	Biochemistry
Haematology	Haematology	Haematology	Haematology	Haematology	Haematology	Haematology	Haematology	Haematology	Haematology
Transfusion	Transfusion	Transfusion	Transfusion	Transfusion	Transfusion	Transfusion	Transfusion	Transfusion	Transfusion
Microbiology	Public Health Microbiology (Regional service)		Microbiology	Regional Bowel Cancer Screening Lab (Biochemistry)	Microbiology	Microbiology		Microbiology	
Cellular Pathology	Cellular Pathology		Cellular Pathology			Cellular Pathology		Cellular Pathology	
Specialist Regional Services	Specialist Regional Services								
Northern Ireland Blood Transfusion Service									
Near Patient Testing in all Hospitals and some General Practices									

2.13. Routine non-specialist Pathology services are currently managed separately by the five HSC Trusts, and specialist regional Pathology services are managed by Belfast HSC Trust. The Blood Transfusion Service (NIBTS) is responsible for the management of blood donation and supply; it also delivers a number of specialist regional tests. Near-patient testing is provided in all hospitals and some general practices and pharmacies, supported by specialist advice from HSC Trust laboratory teams.

Estate

2.14. The buildings that house HSC Pathology services vary in quality and are not in all cases fit for purpose. The current laboratory estate is broadly as follows:



Belfast Trust

Laboratories in Belfast Trust are spread over multiple locations on three hospital sites (Royal Victoria, Belfast City and Mater Hospitals), and the fabric of the buildings ranges from poor to high quality. The Trust has advised the DOH of its desire to re-house all its Pathology services in one purpose built laboratory when funding is available (with the exception of essential diagnostic facilities to support specific clinical needs at other Belfast locations) in line with DHSSPS recommendations on the Future of Pathology Services (2007).



Northern Trust

There are two laboratories in Northern Trust, one in Causeway Hospital and one in Antrim hospital. The laboratories are in good condition; however the laboratory in Antrim is relatively small and not ideally sized for the current volume of activity.



South Eastern Trust

There is one laboratory in South Eastern Trust, it is a modern, state of the art building located on the Ulster Hospital site.



Southern Trust

Southern Trust has two laboratories, one located on the Craigavon Area Hospital site, the other in Daisy Hill Hospital. The fabric of the buildings ranges in quality from adequate to poor. The Trust has

included new laboratories in its proposal for the redevelopment of the Craigavon Hospital site



Western Trust

Two new state-of-the-art laboratories exist, one in Altnagelvin Area Hospital, and the other in South West Acute Hospital. Both are funded through Private Finance Initiatives (PFI).

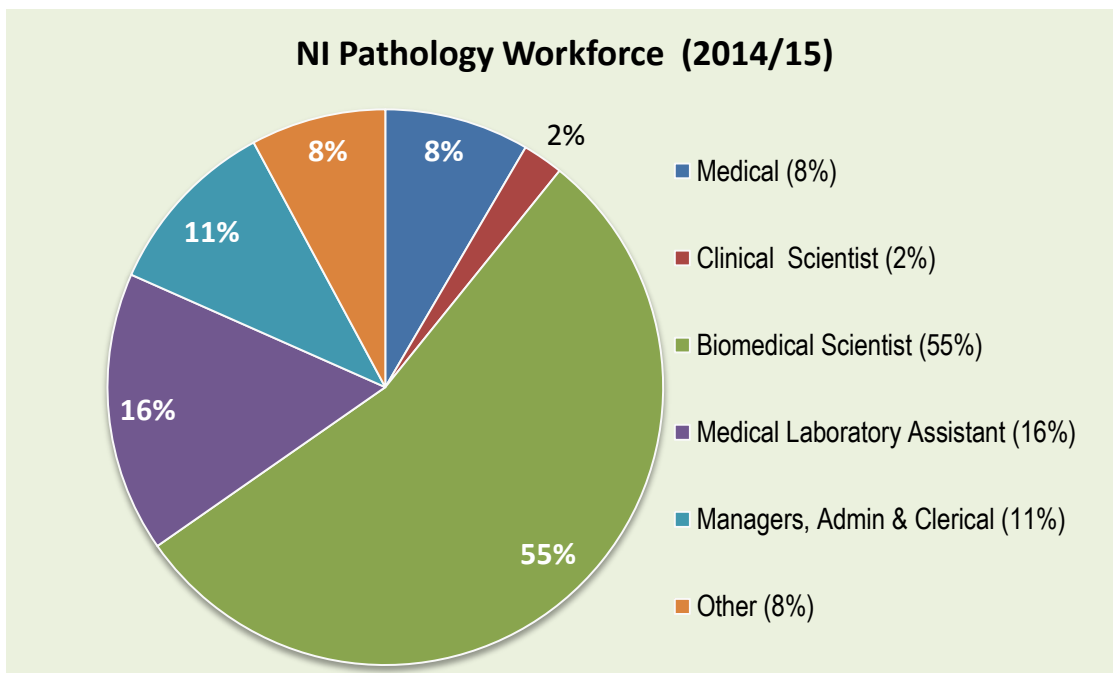


Blood Transfusion Service

NIBTS testing facilities comprise five separate laboratories, all located in its headquarters facility in the grounds of the Belfast City Hospital.

Workforce

2.15. The HSC Pathology workforce consists of over 1,160 whole time equivalent staff with associated pay costs of approximately £56 million. The service is made up of five main professional groups who work in a coordinated way to deliver Pathology services, shown in the following chart:



2.16. The roles of the different staff groups are described here:



Biomedical scientists (BMS)

Biomedical Scientists make up more than half of the HSC Pathology workforce. BMS working in the HSC are registered with the Health & Care Professions Council (HCPC). They work in partnership with doctors, nurses and other healthcare professionals to perform many different roles in NHS / HSC laboratories. BMS staff range in grade from Agenda for Change Band (AfC) 5 through to Consultant BMS (AfC 8d).



Medical Laboratory Assistants (MLA)

Medical Laboratory Assistants represent the second largest group of staff employed in HSC Pathology services. MLAs assist Biomedical Scientists with their laboratory work, including input of patient identification information into Laboratory Information Management Systems, labelling, sorting and storage of samples, checking equipment and stock, and general clerical duties. MLA staff in the HSC range in grade from AfC 2 to 4.



Clinical Scientists

The Clinical Scientist workforce in Pathology is small but important. Clinical Scientists are trained to a high level and are qualified as Fellows of the Royal College of Pathologists in the same way as Medical Pathologists; they typically oversee specialist tests for diagnosing and managing disease. They advise doctors on testing strategies and interpreting data, and carry out research to understand diseases. Clinical Scientists range in grade from Trainee AfC 6 to Consultant (AfC 8d in the HSC, AfC 9 elsewhere in the NHS).



Medical Staff

Doctors in Pathology make up less than 10% of the HSC Pathology workforce. They are responsible for diagnosing disease, providing direct patient care, and providing clinical advice to other specialties, including on the management of infection control and public health incidents. Some medical staff also hold management responsibilities. Medical staff working in Pathology range in grade from Doctors in Training to Consultant. There are also a small number of academic pathologists, who are senior lecturers or Professors and often hold joint-appointments between health organisations and a University.



Managers, Administration & Clerical Staff

Together these two groups of staff make up around 8% of the Pathology workforce.

Managers of Pathology services perform a range of administrative, strategic and operational oversight functions including workforce planning, procurement, recruitment, and reporting. Managers range in grade from AfC 6 to Assistant-Director.

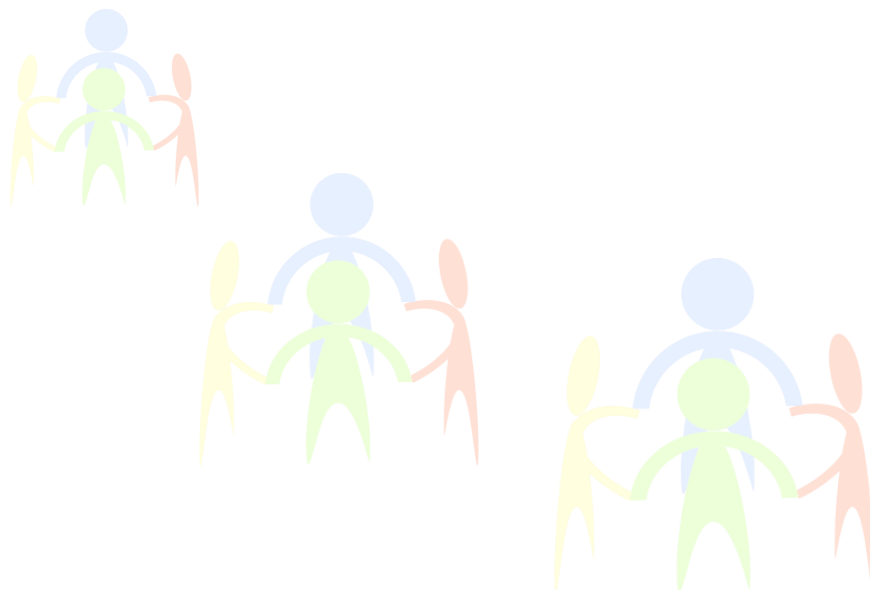
Administrative and Clerical (A&C) staff play an important role in keeping a laboratory running, their roles include input of patient demographic details into the LIMS, the provision of secretarial support to Consultants and other general clerical duties. A&C staff are employed at various grades depending on their role, ranging from AfC 2 to 6.



Other Staff

The other staff employed in HSC Pathology services include:

- ✓ Advanced Practitioners, highly trained staff who were qualified Biomedical Scientists and whose role has evolved to undertake specialist scientific work, for example dissecting tissue samples from patients so that they can be analysed.
- ✓ The non-laboratory staff of the NIBTS, including Nurses, Blood Donor Session Assistants, and staff involved in Blood Donor recruitment and management.
- ✓ Associate Practitioners carry out many functions similar to BMS, but are not Health & Care Professions Council (HCPC) registered and therefore do not authorise results.
- ✓ Haemovigilance Staff who normally either have a Nursing or Biomedical Science background, and who work to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient.
- ✓ Specialist nurses including Infection Control nurses, and Familial Hypercholesterolaemia Screening Nurses.



Activity Levels

2.17. Each year, millions of pathology tests are undertaken in the HSC.

Demand for pathology testing is growing; for example increasing cancer incidence, an ageing population and efforts to improve outcomes means that the demand for cancer diagnostics, including pathology, has never been higher. Details of total tests performed by the four largest Pathology disciplines in one year (including specialist and non-specialist tests), and how these numbers have changed in the past three complete years are shown below¹:

Pathology Discipline	Number of Tests 2014/15 ('000)	Total % change 2012/13 to 2013/14	Total % change 2013/14 to 2014/15	Total % change NI 2012/13 to 2014/15
Biochemistry	36,000	+4.10%	+1.93%	+6.10%
Haematology	4,600	+2.29%	+2.51%	+4.85%
Microbiology	1,600	-1.91%	+0.13%	-1.78%
Cellular Pathology	283	+5.45%	+0.11%	+5.56%

2.18. Activity in NIBTS during the past year included the collection of around 55,000 whole blood donations and 5,000 platelet component donations, as well as delivery of just under 100,000 tests. Demand for red cells in hospitals has reduced by 10%, which is expected to continue at a similar level until 2018/19. The demand for platelets has increased by around 15% since 2011, and is expected to continue to increase until 2020/21.

2.19. In specialist regional services demand is also increasing significantly in response to the growth in precision medicine, an

¹ Keele University National Benchmarking Scheme for UK Laboratories (KUBS)

increase in demand for allergy testing, and the growth in kidney transplants.

Quality and Accreditation

2.20. All HSC Laboratories are quality accredited. This means that the quality of the work the laboratory performs is quality assured by an independent assessor as meeting all the required standards.

2.21. Pathology Laboratories in the HSC are accredited by the United Kingdom Accreditation Service (UKAS). The main over-arching standards are:

- ✓ ISO standard 15189:2012 quality management and competence of medical laboratories;
- ✓ ISO standard 22870:2006 Point-of-care testing (near-patient testing)

2.22. The Medicines and Healthcare products Regulatory Agency (MHRA) also has an essential role in assuring the quality of laboratories. All hospital blood banks must comply with MHRA Blood Safety and Quality Regulations (BSQR) requirements. The Blood Transfusion Service holds a Blood Establishment Authorisation license and a Wholesale Dealers licence awarded by the MHRA and is also inspected for compliance with BSQR, which have legal effect.

Laboratory Information Management Systems (LIMS)

2.23. Laboratory Information Management Systems (LIMS) are needed to enable HSC Pathology services to produce a timely, accurate report for service users. In addition, LIMS have an important role in reducing unwarranted variation in practice and unnecessary patient testing, and providing information that can help benchmark performance and plan future service requirements.

2.24. The following main LIMS are in place within HSC Pathology services (not an exclusive list):

System	Description	Status
BSO LIMS	An in-house system using modern technology developed and hosted by the HSC Business Services Organisation including haematology, blood bank, biochemistry, and microbiology for Northern, South Eastern, Southern and Western Trusts.	Around 25 years old, the system has evolved to keep pace with changing quality requirements, so only staff with specific experience of the system have the knowledge to manage it. If experienced staff were to leave the service suddenly they could not be easily replaced.
LabCentre	Belfast Trust holds the contract for this commercial system for the region; it includes haematology, blood bank, chemistry, and microbiology for Belfast Trust, and cellular pathology for Belfast, Northern, Southern and Western Trusts .(Belfast Trust provides the service for the South Eastern Trust)	Around 17 years old, there are a number of significant problems with the system that indicate it may not continue to meet the needs of the service for more than a few years.
Pulse	The main information management system for the blood donation / testing aspect of NIBTS, bespoke for transfusion services.	Pulse will require replacement within the next few years.
Diagnostic Services	LIMS for the management of information for NIBTS specialist testing services.	Requires replacement within the next few years. This system aligns with HSC systems.
STAR LIMS	Belfast Trust holds the contract for this commercial system which is for the regional Genetics service.	STAR LIMS requires upgrade.
Manzen	Belfast Trust holds the contract for this commercial system which is for the regional Histocompatibility and Immunogenetics (H&I) service.	Manzen is currently fit for purpose however at some future point there will be a need to replace the system.

2.25. LIMS are critically linked with the technology used in HSC Pathology services. A project has commenced to explore the potential replacement of existing HSC Pathology Information Systems.

Technology

2.26. Pathology services rely on many different types of technology to analyse millions of samples every year, it is fundamental to their effective operation. Technology accounts for a significant proportion of HSC Pathology expenditure. The following paragraphs summarise the technology that exists in HSC Pathology services:

- ✓ All HSC Pathology services across 10 acute hospital sites are equipped with the large automated blood analysers needed to process thousands of blood samples every day required by doctors on each acute hospital site, and GPs in primary care;.
- ✓ The region's five cellular pathology laboratories are equipped with specialised instruments used to prepare tissue samples for examination by Pathologists;
- ✓ The region's five microbiology laboratories are equipped with specialised incubators or other analytical technologies are used to identify disease-causing bacteria or viruses and determine their sensitivity to antibiotics,
- ✓ Near-patient testing (NPT) technologies offer on-the-spot testing for patients, for example blood glucose testing. They are currently used in all hospitals and in a range of primary care settings including some pharmacies and general practices; in accordance with quality standards, support for the safe effective

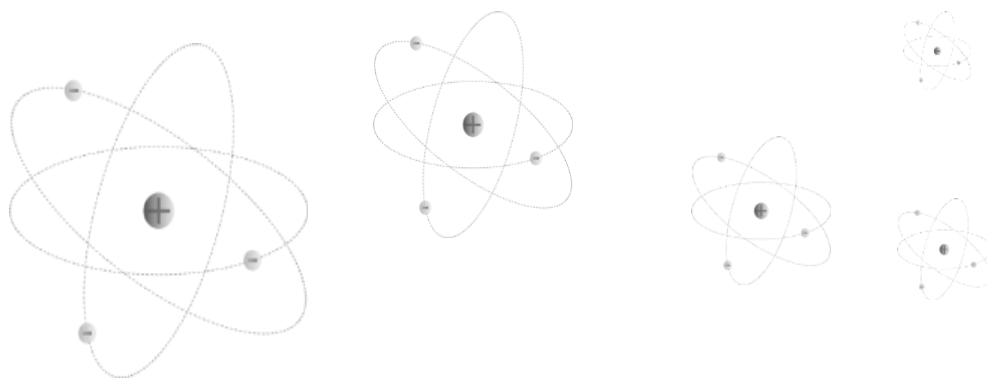
use of these technologies is available from hospital laboratory teams.

- ✓ Specialist technologies to support precision medicine, such as equipment to analyse DNA or other genetic material, are currently available in more than one Trust.
- ✓ Video and tele-conferencing are used by all Pathology services to facilitate regional meetings and clinical Multi-Disciplinary Team Meetings to decide on patient management.

Sample Transport Arrangements

2.27. Every day thousands of samples are transported across the North between GP surgeries and laboratories, hospital wards and theatres and laboratories, and between laboratories. A range of different approaches exist to the management of laboratory sample transport in HSC Trusts including:

- ✓ Wider Trust transport services manage transport of samples alongside other items for transport in the same van;
- ✓ Wider Trust transport services manage dedicated sample transport on behalf of the laboratory;
- ✓ Direct laboratory management of sample transport.

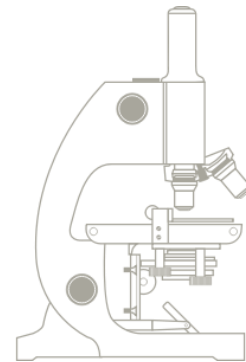


3 Issues and Opportunities

In delivering a pathology service of the range and scale of that in the HSC, a number of issues and opportunities exist which have implications for how the service might be managed and delivered in the future; this section of the consultation document explores these.

- 3.1. The Health and Social Care system in the North faces a range of challenges outlined in Transforming Your Care (DHSSPS 2011). Pathology services have an important role in helping the wider HSC meet these challenges through the provision of clinically appropriate services that will support new models of care. However to do so they must be capable of delivering sustainable, safe, high quality, accurate, and timely pathology services in a way that ensures continuous quality improvement and delivers value for money.
- 3.2. HSC Pathology costs around £100 million per year to deliver, of which the single largest element is the workforce (£56 m). UK evidence demonstrates that it is possible to improve pathology service quality, reduce risk and cost, and improve career structures and training for staff through:
 - ✓ Consolidation of non-time-critical non-specialist pathology testing into fewer locations, and
 - ✓ Integration of management structures.
- 3.3. This type of improvement can be implemented without impact on Patients, Blood Donors and Clinical Service users, who continue to access the services in exactly the same way they have always done.

- 3.4. At present in the North, non-time-critical, non-specialist pathology testing is provided in 10 laboratories located on acute hospital sites. There are significant opportunities to be gained in the North by delivering this work on fewer sites, releasing resource for reinvestment in ongoing Pathology modernisation and reform.
- 3.5. Furthermore, all of the region's Pathology laboratories are awarded accreditation by the United Kingdom Accreditation Service (UKAS), and all hospital blood banks are deemed compliant by the Medicines and Healthcare products Regulatory Agency (MHRA) Blood Safety and Quality Regulations (BSQR) requirements. UKAS and MHRA compliance activity is replicated by five Trusts and the NIBTS. Having a single integrated management structure would reduce the current compliance and management overhead.



Growing Demand

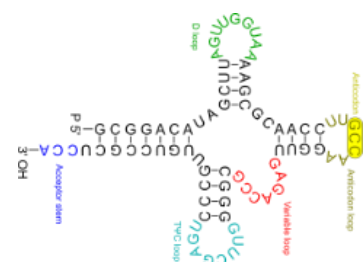
- 3.6. As described in Section 2, demand for HSC Pathology services is growing. Future service demand will be influenced by many factors, including rapid expansion in precision medicine and how demand is managed. There are some examples of excellent practice in demand management in both primary and secondary care that have been implemented by individual HSC Trusts, however the North does not currently have arrangements in place to monitor and manage demand effectively at a regional level. To do this effectively, high quality region wide data on test requesting patterns in primary and secondary care would be required, which in turn requires standard coding of test requests.

3.7. Standard information technology systems for test ordering, a regionally consistent approach to coding, and a single regional management structure would create the governance and operational arrangements necessary to manage demand effectively on a regional scale, leading to the creation of safer services for patients and more efficient use of HSC resource .

Quality & Safety

3.8. In Pathology services, standardised practice should take place in all laboratories to make sure clinical users and patients receive a regionally equitable high quality service. Sometimes variation from the standard approach occurs; if there is no valid clinical reason for it, this is referred to as ‘unwarranted variation’ and it is associated with increased risk to patients and cost to the service.

3.9. The Review into Operational Productivity & Performance in English NHS Acute Hospitals (UK Govt 2016) states that tackling unwarranted variation improves quality and safety, and could also save up to £200m in pathology and imaging services in NHS England acute hospitals. It goes on to say that unwarranted variation is most effectively addressed by service integration, standardisation and consolidation and recommends that NHS England acute hospital trusts introduce the Pathology Quality Assurance Dashboard to provide assurance that quality and safety levels are maintained and improved upon, and that they standardise how pathology tests are counted.



3.10. As in England, unwarranted variation in practice exists in HSC Pathology services, for example:



Coding: Lack of standard test naming and coding can mean a Clinician may miss important diagnostic information in a report, potentially leading to misdiagnosis.



Consistency: Northern Ireland hospitals do not have standard 'profiles' for all commonly requested groups of tests (profiles are groups of tests that together help a make a diagnosis). Profiles that include more than the clinically appropriate tests are more costly, may require more blood, and may not change the diagnosis.



Standardisation: Waste and duplication in the blood supply chain exists due to a lack of standardisation. An integrated blood supply chain supported by robust ICT and technology can reduce duplication and waste and support compliance with regulatory requirements and professional standards.

Productivity

3.11. The Review of Operational Productivity in NHS Acute Hospitals (UK Govt 2016) noted that a productive Pathology department should cost around 1.6% of the operating expenditure of an NHS acute hospital. The most efficient Pathology services in the cohort of 32 hospitals examined in the review saved up to 15% through consolidation of services and workforce transformation.

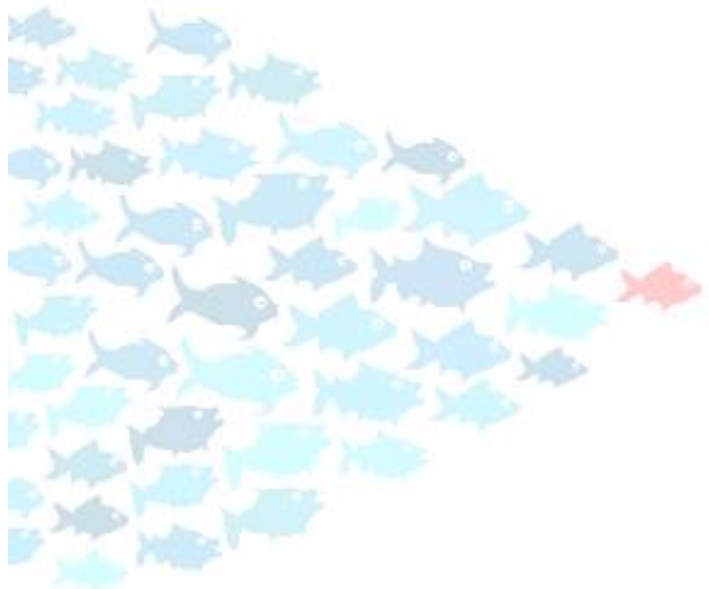
3.12. Tools exist to help understand productivity in the main four HSC Pathology services, all of which participate in Keele University Benchmarking Service (KUBS) and therefore have access to national data to see how their laboratories and others in the North compare to others in the UK. KUBS includes measures of productivity; these along with other benchmarking data indicate that

there is a significant opportunity to improve the productivity of HSC Pathology services.

- 3.13. In the development of these proposals, visits were undertaken to Pathology services elsewhere in the UK including Path Links in Lincolnshire, and NHS Greater Glasgow & Clyde. These services demonstrate approaches to improving quality and productivity through service consolidation, including integration of management arrangements. The North's HSC Pathology services can learn from effective practice elsewhere to inform how it moves forward.

Regional Management, Governance and Accountability

- 3.14. Regional decisions are required to enable HSC pathology services to reduce unwarranted variation and improve quality; at present these decisions rely on reaching consensus among six separate management organisations. This has impeded progress to date on a number of regional issues. A single integrated management, governance and accountability structure for HSC Pathology services could respond more quickly and decisively to changing quality requirements, and mandate appropriate, evidence based regional standardisation on all laboratory sites under an accredited, regulated regional quality system.



Laboratory Information Management Systems (LIMS)

- 3.15. As noted in Section 2, there are currently no fewer than six LIMS for HSC Pathology services. The review of Pathology services in 2007 recommended a single regional laboratory information management system, and while this recommendation has not been implemented, a project has begun to explore replacing existing LIMS. There is broad regional acceptance that the two main LIMS, LabCentre and BSO LIMS, need to be replaced to help Pathology services meet quality future requirements. This requires investment.
- 3.16. LIMS are critically linked with Pathology diagnostic technologies and receive test results from them to be compiled into a report for clinical service users. Modern quality standards dictate a requirement for an integrated report which combines a range of test results, often from different pathology disciplines, into a single report. In the HSC the ability to produce an integrated electronic report is limited by multiple LIMS with varying functionality. In many cases the production of an integrated report relies on manual activity. Unintended human error is inherent in manual processes, for example missing out an important result would create a potential risk to patient care. A region-wide pathology information system would significantly reduce this risk.



Technology

- 3.17. Appropriate technology is fundamental to the effective operation of high quality pathology services. Increasing automation of pathology techniques is freeing-up doctors and scientists to ensure a more appropriate use of their time. Furthermore, the same test type can be processed using the same type of equipment by scientific staff with similar levels of training in a wide range of pathology disciplines. This commonality of process presents an opportunity for staff to work in more than just one pathology discipline in the future.
- 3.18. Advances in technology have expanded the range of equipment available that can better reflect disparities in test volume, repertoire, and throughput between different laboratory sites. Matching equipment to service requirements on each site is necessary to optimise efficiency in the future. Consolidation provides an opportunity for the HSC Pathology service to streamline its equipment profile and reduce cost.
- 3.19. The growth in technologies and diagnostic tests associated with precision medicine is both rapid and significant, and presents a challenge for all UK pathology services. Investment is required to support the introduction of clinically appropriate new precision medicine related testing as part of agreed clinical pathways in the North.
- 3.20. New technology exists for the use of digital imaging in Pathology that has been successfully piloted elsewhere in the UK. It offers the potential to revolutionise the way Cellular Pathology services are delivered in the future, from providing the ability to seek international second opinion in real time, to enabling clinicians to work in the heart of clinical



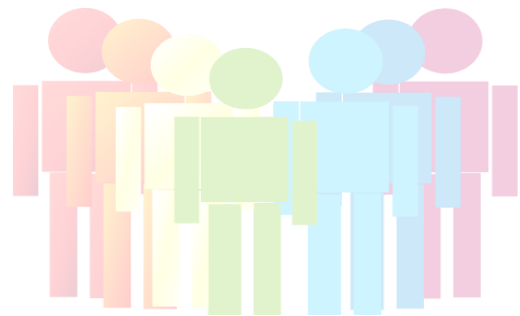
services and still have access to images remotely in any location.

There is an opportunity to make the North's HSC Cellular Pathology services world class by investing in this technology.

- 3.21. Appropriate near-patient testing (NPT) technologies can support the provision of new models of care closer to patients. NPT services supporting acute care should be regionally managed, accredited, aligned to clinical pathways, and results integrated within the patient record. There is potential for the development of NPT Services in GP and other Primary Care settings, the quality assurance aspects of which will need to be considered. Further development in NPT, in whichever setting will require investment.

Workforce and Training

- 3.22. The HSC has a highly skilled, expert Pathology workforce which is of great value to the wider HSC and could enable the region to have a world class Pathology



service. However, there are areas where regional approach to planning and delivery would allow the HSC to maximise that resource.

- 3.23. HSC Pathology services are struggling to staff those services which are required on a 24 hour basis during the out of hours period and addressing this within the current structures has resulted in greater cost, a regionally inequitable position on staff contracts and an increase in the movement of staff between Trusts. Analysis of the current workforce structure compared with other Pathology services in the UK (Keele University National

Laboratory Benchmarking Scheme 2014/15) indicates that HSC Pathology services as a whole have a proportionally higher skill mix profile, compared with all UK Pathology services as a whole. Currently Trusts are addressing these issues internally, with the support of the Pathology Network and HSCB. However, consolidation of services and integration of management arrangements would create the opportunity to develop a regional workforce plan that enables the service to restructure over a defined timeline, and align the workforce with an agreed staffing benchmark without loss of valued staff expertise.

3.24. The HSC Pathology service needs to offer an attractive career proposition to retain its experienced workforce. Staff training, development and retention are essential elements of any modern pathology service, however at present there is no regional training strategy for HSC Pathology staff, and the HSC is the only part of the NHS with no Scientific Training Programme for Clinical Scientists. To support clinical transformation in the wider health service, investment is required in a regional approach to ensuring that the HSC Pathology workforce is appropriately skilled for the future, and does not lose talented staff.

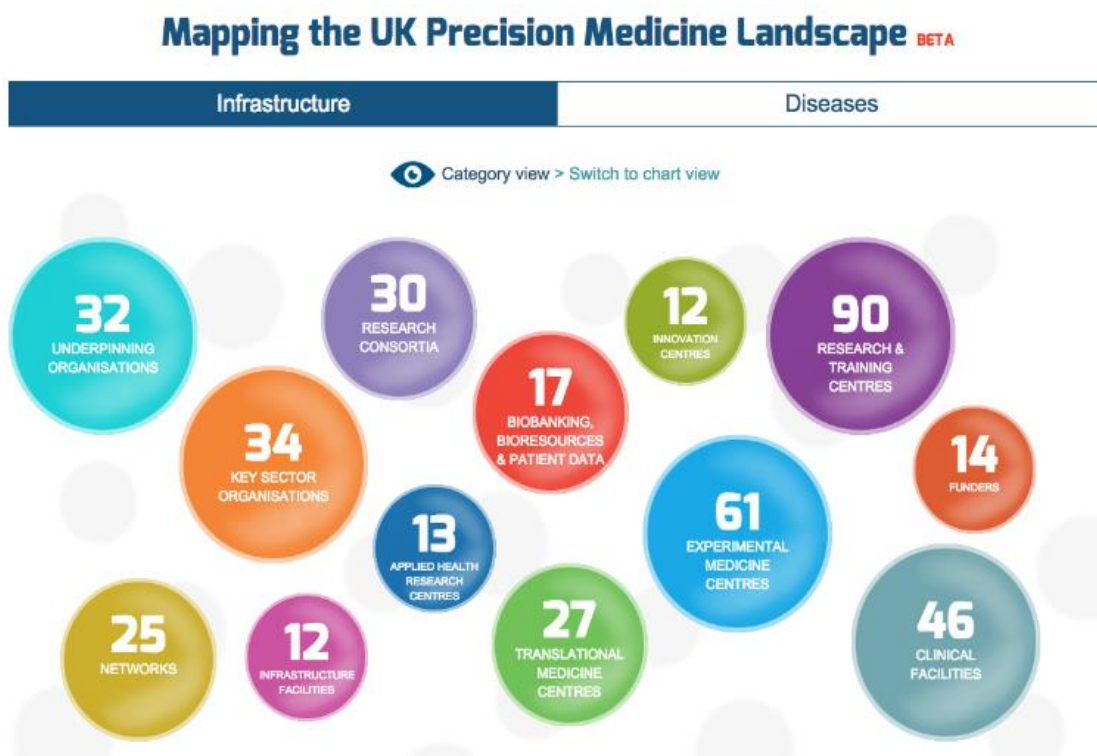
Transport

3.25. Current HSC sample transport arrangements are not optimal; the Pathology Network has noted delays in sample transport between laboratories impacting on the service's ability to produce results in a timely manner. The Medicines and Healthcare products Regulatory Agency (MHRA) requires staff involved in the transport of blood to be appropriately trained, and competent.

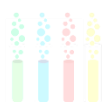
3.26. Best practice indicates that direct laboratory input into how sample transport is planned and managed can improve quality and safety. It can also smooth out the peaks and troughs in activity in a laboratory by staggering the deliveries of tests throughout the working day. Smoother flow of work into the laboratory would mean the service would not require the current profile of equipment, and could manage its equipment resource more efficiently.

Research, Innovation and Precision Medicine

3.27. Precision medicine results in better outcomes for patients. Doctors using the tools of precision medicine can make faster more accurate diagnoses and provide patients with treatments that are most likely to work for them. It is the fastest growing area of modern medical practice; the diagram below illustrates the size and scale of the current UK infrastructure (Innovate UK 2016):



- 3.28. Precision medicine relies on the development of accurate diagnostic tests and the availability of high quality information across all pathology disciplines; therefore HSC Pathology services have a key role in driving its development and enabling the region to deliver world class precision medicine for the North's patients.
- 3.29. Pathology services are just one part of the precision medicine landscape, which is much wider. Greater collaboration and new ways of working across Health, Academia and Industry are needed to accelerate the process of bringing the benefits of precision medicine to patients. At present the region is at the forefront of progress, as demonstrated by recent developments including the new regional Genomic Medicine Centre in Belfast. However, regional decisions will be required of HSC Pathology services to ensure that they play their part in ensuring this region does not lose this momentum and lag behind other parts of the UK. Current HSC pathology governance structures are not optimal to support effective regional decision making and there is a risk that this could limit the North's ability to make further progress in precision medicine. A single integrated management structure would facilitate timely strategic decision making.
- 3.30. The region has recently launched the 'Research for Better Health and Social Care Strategy (2016-25)'. All HSC Pathology services have an important role in realising the objectives of this strategy, and the regional specialist clinical and Pathology services have an absolutely critical role in bringing the benefits of precision medicine to patients in the North.



4 Proposals for Change

The purpose of this section of the consultation document is to put forward three broad proposals to address the issues and take advantage of the opportunities described in the previous chapter, in a manner consistent with policy and best practice.

4.1. There are three broad proposals for change which are closely interlinked; as a group they represent a cohesive, evidence-based strategic direction for HSC Pathology services into the future. They can be summarised as:

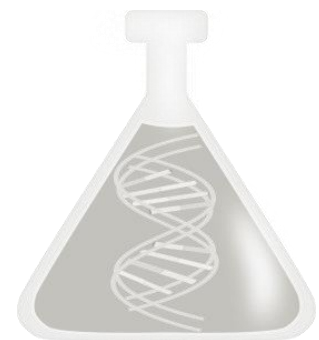
1. Consolidation of 'Cold' Activity
2. Infrastructure Development
3. Managerial Reform

4.2. The proposed changes would not directly impact Patients, Blood Donors and Clinical Service users, who would continue to access the services in exactly the same way they have always done. It is anticipated that the only change they would notice, if at all, would be an improvement in quality and safety. Details of each proposal are provided in the paragraphs below.

Proposal 1: Consolidation of Cold Activity

To separate the delivery of 'hot' and 'cold' pathology testing, with cold testing being delivered on an appropriate number of cold hubs for the region and 'hot spokes' linked with a defined cold hub existing at any acute site that currently has a laboratory.

- 4.3. As described in Section 2, millions of Pathology tests are undertaken in the North every year. These fall into two broad categories: those that need to be processed within a few hours to support optimal patient care ('hot' or time-critical tests); and those that do not need to be processed as quickly for optimal patient care ('cold' or non-time-critical tests). The vast majority of tests requested by GPs and many of the tests requested by hospital clinicians are cold, non-time-critical. At present each of the HSC's 10 acute hospital sites delivers both hot and cold testing services.
- 4.4. Best practice indicates that by consolidating the high volumes of cold tests onto a smaller number of sites, there is potential to achieve significant economies of scale with improved quality and reduced cost.
- 4.5. It is therefore proposed that non-specialist cold HSC Pathology services (initially the tests requested by GPs) be consolidated onto fewer large laboratory sites or 'hubs'. All acute hospitals would continue to have on-site hot testing facilities ('spokes'), with close connections to a cold hub.
- 4.6. There would be very close governance and operational links between cold hub/s and hot spokes to reduce unwarranted variation in practice and ensure robust arrangements for out



of hours cover. The creation of larger teams would mean more opportunities for staff training and development. Both hot and cold testing services would continue to be quality accredited, with the addition of new regionally accredited near-patient testing services. All HSC Pathology services would be subject to a detailed regional service specification including turnaround times and other associated performance indicators to reflect user requirements.

4.7. Patients, Blood Donors and Clinical Service users of HSC

Pathology services would not be directly impacted by the proposal. It is anticipated that the only change they would notice, if at all, would be an improvement in quality and safety.

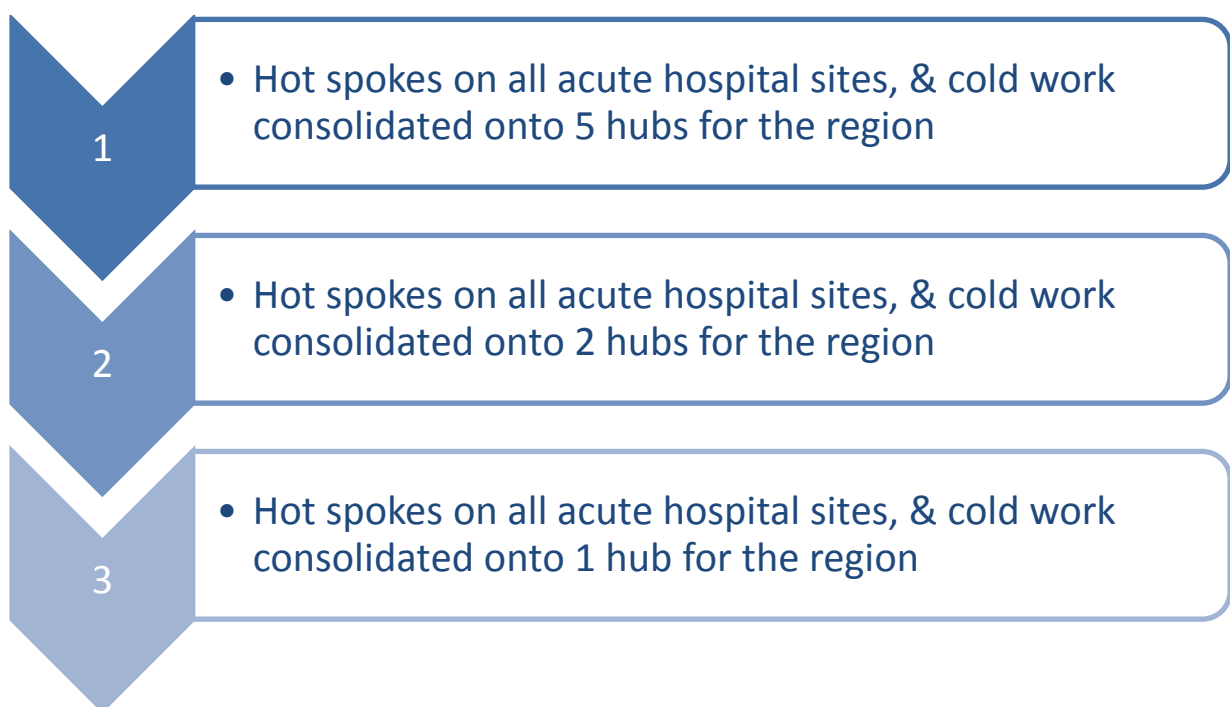
4.8. Key benefits for the consolidation of cold testing services (hubs) with linkages to hot services on acute sites (spokes) include:

- ✓ A reduction in unwarranted variation in practice, resulting in improved quality and reduced risks to patient care;
- ✓ Improved cost effectiveness, freeing up scarce resources to modernise services and associated infrastructure, to invest in staff training and development, and to introduce clinically appropriate new tests, for example to support precision medicine;
- ✓ A more flexible and responsive service with greater opportunities for staff to broaden their skills and experience through appropriate rotation between hot and cold services.

Question 1:

Do you think the proposal to separate and consolidate cold activity on fewer sites is appropriate?

- 4.9. Achieving the maximum benefit possible from consolidation depends on the approach taken to deliver the proposal. A number of options exist that would provide varying degrees of consolidation of cold testing, ranging from five cold hubs to just one.
- 4.10. The following table sets out a **range of options for consolidating cold non-specialist testing in fewer locations**:



Question 2a:

Which option for consolidating cold work do you think is most appropriate?

Question 2b:

Would you suggest any alternative options?

4.11. In deciding the most appropriate **number and location** of cold hubs it is proposed that the following criteria would be considered:

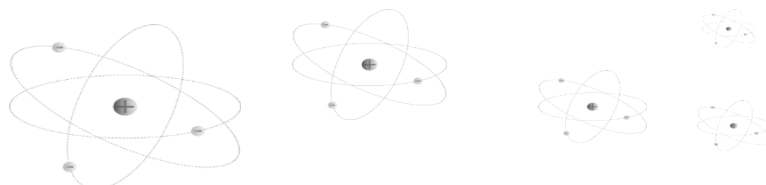
- 1) **Quality** – the extent to which each option would reduce variation in practice and improve quality and safety.
- 2) **Resilience and sustainability** – the extent to which each option would create a resilient, sustainable service that would attract and retain high quality staff.
- 3) **Flexibility and responsiveness** – the extent to which each option would create a flexible, responsive service that can respond to new models of care and other opportunities for modernisation.
- 4) **Cost** – the capital and revenue costs associated with the delivery of each option, including transportation costs.
- 5) **Collaboration** – the extent to which each option would be deliverable, securing the support of key stakeholder groups.

Question 3a:

Do you think the proposed criteria to decide on the right number and location of cold hubs are appropriate?

Question 3b:

Are there any other criteria that should be considered?



Proposal 2: Infrastructure Development

To modernise the enabling infrastructure for HSC pathology service delivery, to include:

- The development of a region-wide pathology information system;
- Maximising the use of pathology technology to facilitate cross-region working and enable wider HSC clinical transformation;
- A review of current sample collection and transport arrangements to ensure the safest, most cost effective option for the region.

4.12. As described in Section 3, there are a range of infrastructural issues facing HSC Pathology services including outdated information systems, difficulties with responding to new opportunities presented by technology, and the need for more effective arrangements to transport samples.

4.13. These issues are closely interlinked, and limit the services' ability to respond effectively to evolving quality standards and changing demand, in turn limiting the region's ability to bring about wider HSC clinical transformation.

Information Systems

4.14. At present there are no fewer than six different information systems in use by laboratories and NIBTS in the North, presenting significant challenges in terms of the sharing of information across systems, production of an integrated report, ease of use by clinical staff, and the extent to which they facilitate the effective management, quality assurance and oversight of services locally and regionally. A new,

a region-wide pathology information system would address these issues.

Technology

4.15. At present there is no regional strategy in place to ensure the procurement of, or optimisation of, standard technology for HSC Pathology services, including digital imaging for pathology, near patient testing and precision medicine, which have the potential to enable wider clinical transformation. The region currently has greater equipment capacity than it requires, and could benefit from new equipment bespoke to the volume of activity. Modernisation of technology in Pathology services needs to be accompanied by new ways of working, and staff will require training to fully realise the opportunities afforded by new technologies. A new regional training strategy complementary to a regional procurement strategy would help address this.

Transport

4.16. At present a range of different approaches exist to the management of sample transport in HSC Trusts. A detailed review of Transport would help to determine the safest, most cost effective option for a regional approach to sample transport that supports the production of timely and accurate results for clinical service users.

4.17. Patients, Blood Donors and Clinical Service users of HSC Pathology services would not be directly impacted by this proposal, it is anticipated that the only change they would notice, if at all, would be an improvement in quality and safety.

4.18. Benefits associated with modernising the enabling infrastructure for HSC pathology service delivery include a reduction in unwarranted variation resulting in improved quality and safety, an enhanced

ability to support wider HSC clinical services in the provision of new models of care and safe, timely and cost effective sample transport for HSC Pathology services.

Question 4:

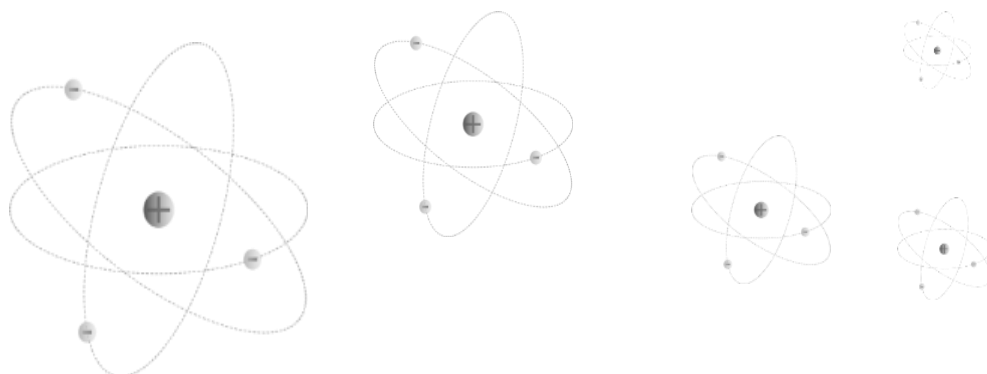
Do you think the proposal for the development of a region-wide pathology information system is appropriate?

Question 5:

Do you think the proposal to maximise the use of technology to facilitate cross region working and enable wider clinical transformation is appropriate?

Question 6:

Do you think that a review of current sample collection and transport arrangements to ensure the safest, most cost effective option for the region is appropriate?



Proposal 3: Integrated Management Structure

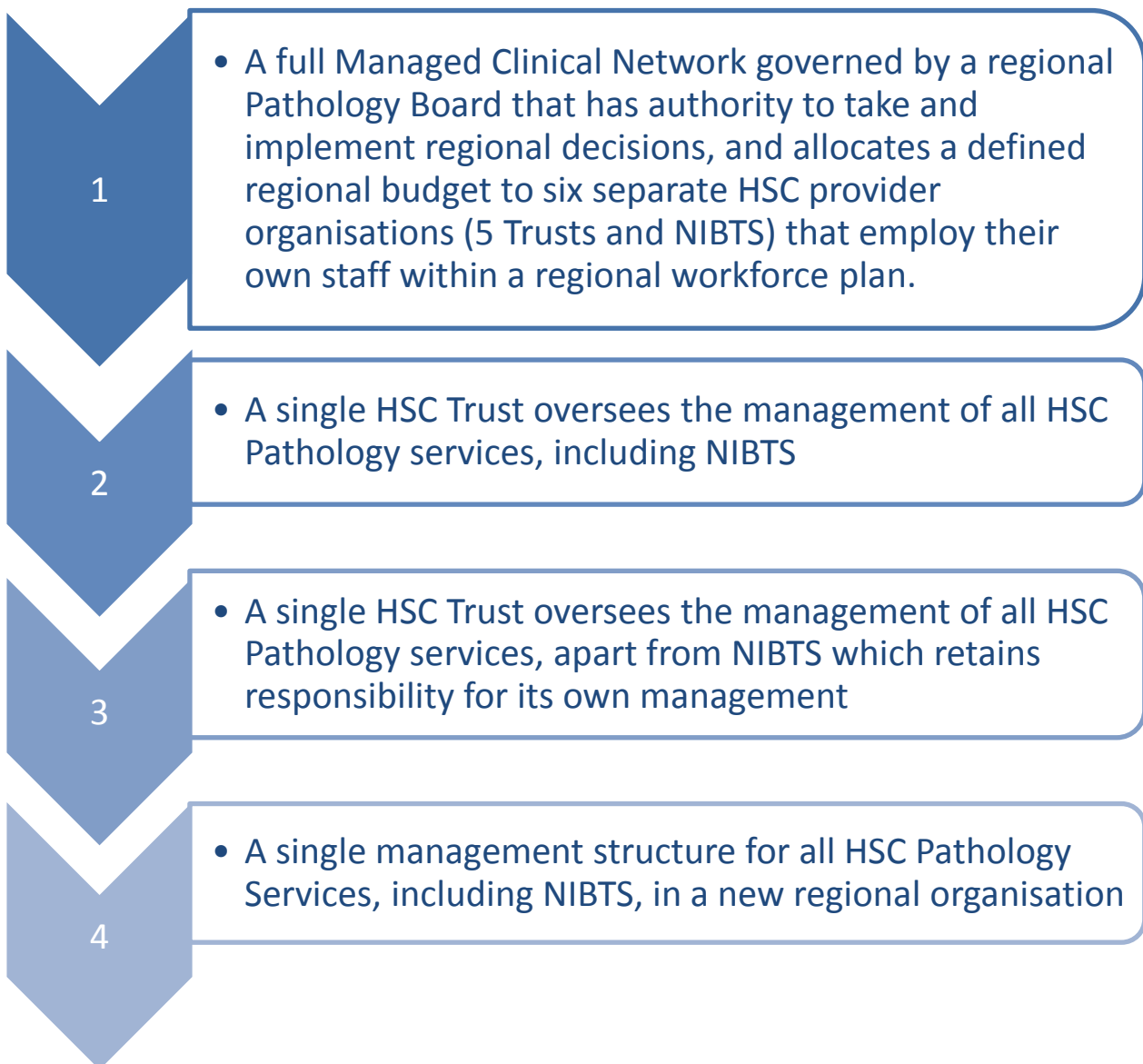
To bring all HSC Pathology services including NIBTS into a single regional integrated management structure which will provide a guaranteed level of service to its users, defined in Service Level Agreement/s that meet recognised quality standards and demonstrate quality and performance using agreed metrics.

- 4.19. Non-specialist pathology services are currently managed separately by five HSC Trusts, with specialist regional services being managed by Belfast HSC Trust. The Blood Transfusion Service (NIBTS) is a stand-alone agency responsible for the management of blood donation and supply. It also delivers a number of regional tests.
- 4.20. Wider HSC transformation and, subject to the outcome of consultation, Pathology modernisation will require timely strategic decisions for HSC Pathology services. Notwithstanding the recent establishment of a regional network for pathology services, the current management arrangements are fragmented and do not facilitate effective regional decision making due to reliance on consensus. This has impeded progress required to improve the quality of HSC Pathology Services.
- 4.21. It is therefore proposed to change the current arrangements, with the management of all HSC Pathology services being integrated into a single management structure. As part of this integration, particular consideration to linkages with specialist regional services will be required.
- 4.22. Patients, Blood Donors and Clinical Service users of HSC Pathology services would not be directly impacted by this proposal.

It is anticipated that the only change they would notice, if at all, would be an improvement in quality and safety.

4.23. The benefits associated with the proposed change include the ability to ensure more effective regional strategic decision making, planning and resource allocation, more sustainable and equitable services, and a service better able to modernise and evolve in response to changing clinical and quality requirements.

4.24. The following table sets out a **range of options for managerial reform**:



Question 7:

Do you think the proposal to integrate existing management structures, including NIBTS, is appropriate?

Question 8a:

Which option for managerial reform do you think is most appropriate?

Question 8b:

Would you suggest any alternative options?

4.25. In deciding the most appropriate **management structure** it is proposed that the following criteria would be considered:

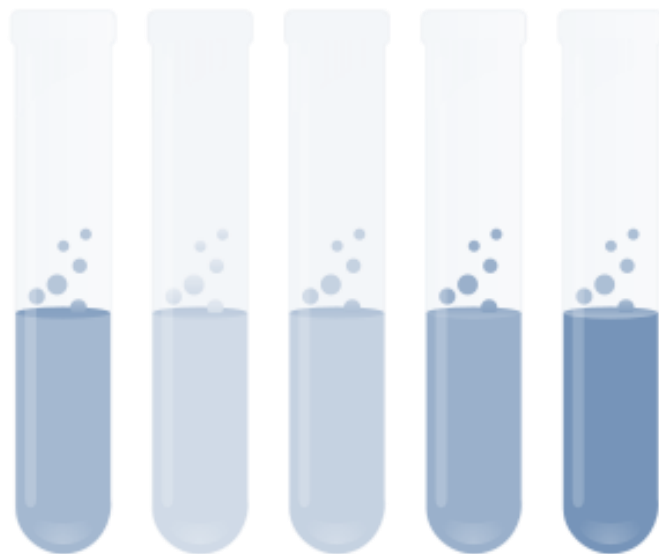
- 1) **Modernisation** - the extent to which each option would facilitate the delivery of a modern, cost-effective, resilient, sustainable and flexible service.
- 2) **Cost** – the revenue costs associated with each the delivery of each option.
- 3) **Governance** – the extent to which each option ensures effective governance and accountability, including capacity to meet all regulatory and quality accreditation requirements.
- 4) **Public Confidence** – the extent to which option ensures no detrimental impact to the quality or availability of HSC Pathology services, including blood products.
- 5) **Synergies** – the extent to which each option supports research, service development and the growth of effective synergies with academia and industry to support the development of precision medicine and new models of care.
- 6) **Collaboration** – the extent to which each option would be deliverable, securing the support of key stakeholder groups.

Question 9a:

Do you think the proposed criteria to decide on the best option for managerial reform are appropriate?

Question 9b:

Are there any other criteria that should be considered?



5 Equality, Good Relations and Human Rights

The purpose of this section of the consultation document is to describe the consideration given to the potential equality, good relations and human rights impact of these proposals.

5.1. The Health and Social Care Board is required to consider the likely impact on equality of opportunity, good relations and human rights for those affected by any proposed policy or policy change, in particular the potential impact for each of groups identified under Section 75 of the NI Act 1998.



- 5.2. Patients, Blood Donors and Clinical Service users of HSC Pathology services would not be directly impacted by these proposals. It is anticipated that the only change they would notice, if at all, would be an improvement in quality and safety.
- 5.3. Staff working in HSC Pathology services, and staff engaged in transporting pathology samples from General Practice to HSC laboratories would be impacted by the proposals. As part of an extensive pre-consultation exercise, information was produced for staff which included questions to encourage thought about the potential impact of the proposals, and to ask them to provide feedback about this during pre-consultation. These questions have also been included in the response form for this consultation.

- 5.4. A screening exercise considering the potential equality, good relations and human rights impact of these proposals has been undertaken and is published alongside this consultation document.
- 5.5. Screening indicates that the anticipated equality, good relations and human rights impact on staff is not likely to be major, because the proposals could be implemented in a phased manner which would provide scope to take advantage of natural workforce movement to minimise any potential negative impact. In addition, the HSC has developed defined principles and protocols to manage structural and transformational change, for example the Regional Human Resources Framework that was subject to consultation with Trade Unions during the Review of Public Administration and local change management arrangements including agreed protection arrangements for staff. Furthermore, the Transfer of Undertakings and Service Provision Change (Protection of Employment) (Amendment) Regulations (NI) 2011 may also be applicable. It is anticipated that such principles would be used in the management of any change as a result of the proposals.
- 5.6. The proposals for HSC Pathology modernisation set out a strategic direction and include a range of options. Screening highlighted the need to assess the potential impact of the proposals again when more is known about how the different options might work in practice. For this reason, a full Equality Impact Assessment would be prepared taking into account the report of the consultation and the business case.

Question 10a:

Based on belonging to any of the Section 75 groups, do you have any particular requirements with regard to the proposals?

Question 10b:

Generally, do you think there are any particular requirements for any of the Section 75 groups? If so, what would you consider as a potential solution?



6 Implementation

The purpose of this section of the consultation document is to consider factors relevant to the implementation of the proposals.

- 6.1. So far this consultation document has described HSC Pathology services, the issues and opportunities that exist for them, and three proposals for change.
- 6.2. Responses to the consultation will be considered by the Health and Social Care Board, including any relevant legislative, equality, good relations and human rights issues. As appropriate, a business case and Equality Impact Assessment (EQIA) including assessment of the impact on Human Rights will be completed by the Health and Social Care Board, and final proposals along with any other necessary information will be presented to the Department of Health, and the Minister for consideration.
- 6.3. Implementing any changes to HSC Pathology services would follow standard Health and Social Care Project Management practice, including:
 - ✓ A governance structure including appropriate stakeholders with specific arrangements service user input;
 - ✓ External quality assurance;
 - ✓ An appropriately resourced project team;
 - ✓ A defined project plan and timeline;
 - ✓ A Human Resources framework;
 - ✓ A change management strategy;
 - ✓ A risk register.

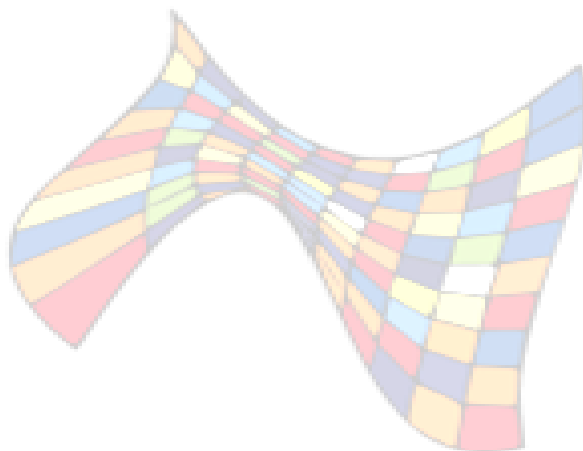
- 6.4. If appropriate, a phased approach to implementation could be adopted. Flexibility to accommodate any changes to wider HSC structures would also be required.

Question 11a:

Do you think that the proposed approach to implementation is appropriate?

Question 11b:

Are there any other factors that should be considered?



7 How to respond

The purpose of this section of the consultation document is to let you know how you can respond to this consultation.

7.1. This document constitutes a formal public consultation on three proposals for HSC Pathology modernisation. The consultation period will run for a period of 13 weeks, **from Monday 28 November 2016 until Friday 24 February 2017.**

7.2. Responses are welcome from all stakeholders to the consultation questions including:

- Clinical users of HSC Pathology services;
- Staff working in HSC Pathology services and their representatives;
- Staff involved in the collection and transport of samples from General Practice to HSC laboratories;
- Patient groups and their representatives;
- Blood donors and the NIBTS blood transfusion communities partnership groups;
- Pathology accreditation and regulatory bodies;
- Universities;
- Any person/s or group, who is likely to be affected by or who has opinions about these proposals.

7.3. The consultation questionnaire is included as Appendix 1 of this document. You can respond to the consultation online, by e-mail or in writing as follows:

- 1) The electronic web-response form is available on the HSC Board website: <https://hscforms.hscni.net/modernisingpathology>
- 2) The email address for typed response forms is: PathologyModernisation@hscni.net
- 3) The postal address for handwritten response forms is:
Modernising HSC Pathology Services Consultation
3rd Floor, Commissioning Directorate
HSC Board Headquarters
12-22 Linenhall Street
Belfast
BT2 8BS

7.4. The Health and Social Care Board is committed to making information as accessible as possible, and to promoting meaningful engagement. The consultation document can be made available on request and where reasonably practicable in an alternative format e.g. braille, audio formats, large print or minority languages to meet the needs of those for who English is not their first language.

7.5. **Responses must be received no later than 5pm on Friday 24 February 2017.** Before you submit your response, please read Annex A in Appendix 1 of this document regarding the confidentiality of responses to public consultation exercises in the context of the Freedom of Information Act 2000.

Appendix 1: Response Form

You can respond to the consultation online, by e-mail or in writing as follows:

- 1) The electronic web-form is available on the HSC Board website:
<https://hscforms.hscni.net/modernisingpathology>
- 2) The email address for typed response forms is:
PathologyModernisation@hscni.net
- 3) The postal address for handwritten response forms is:

Modernising HSC Pathology Services Consultation,
3rd Floor, Commissioning Directorate,
HSC Board Headquarters
12-22 Linenhall Street
Belfast
BT2 8BS

Responses must be received no later than 5pm on Friday 24 February 2017.

Before you submit your response, please read Annex-A in Appendix 1 of this document regarding the confidentiality of responses to public consultation exercises in the context of the Freedom of Information Act 2000.

Modernising HSC Pathology Services – Proposals for Change
28 November 2016

Consultation Response Form

Do you wish your response to remain anonymous? (Please tick)

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

I am responding	As an individual:	<input type="checkbox"/>
	On behalf of a Group, Professional Body or other Body:	<input type="checkbox"/>
Your Name	<input type="text"/>	
Name of Group, Professional Body or other Body	<input type="text"/>	
Job Title	<input type="text"/>	
Address	<input type="text"/>	
Email	<input type="text"/>	

Please tick:

		Yes	No
I am a Clinical service user of HSC Pathology services			
I am a Patient / a Patient Advocate / a Blood Donor			
I am currently employed in HSC Pathology Services			
I am currently employed in the Private Sector diagnostics industry			
I am currently employed in a University			
Other (please state)			

Question 1:

Do you think the proposal to separate and consolidate cold activity on fewer sites is appropriate?

Yes	
No	
Don't Know	
No Opinion	

Comments:

Question 2a:

Which option for consolidating cold work do you think is most appropriate? (Please tick)

Option 1	
Option 2	
Option 3	
I don't believe any are appropriate	
Other (Please comment)	

Comments:

Question 2b:

Would you suggest any alternative options?

Yes	
No	

If yes, please state alternative options:

Question 3a:

Do you think the proposed criteria to decide on the right number and location of cold hubs are appropriate?

Yes	
No	
Don't Know	
No Opinion	

Comments:

Question 3b:

Are there any other criteria that should be considered?

Yes	
No	

If yes, please state:

Question 4:

Do you think the proposal for the development of a region-wide pathology information system is appropriate?

Yes	
No	
Don't know	
No Opinion	

Comments:

Question 5:

Do you think the proposal to maximise the use of technology to facilitate cross region working and enable wider clinical transformation is appropriate?

Yes	
No	
Don't know	
No Opinion	

Comments:

Question 6:

Do you think that a review of current sample collection and transport arrangements to ensure the safest, most cost effective option for the region is appropriate?

Yes	
No	
Don't know	
No Opinion	

Comments:

Question 7:

Do you think the proposal to integrate existing management structures, including NIBTS, is appropriate?

Yes	
No	
Don't Know	
No Opinion	

Comments:

Question 8a:

Which option for managerial reform do you think is most appropriate?

Option 1	
Option 2	
Option 3	
Option 4	
I don't believe any are appropriate	
Other (Please comment)	

Comments:

Question 8b:

Would you suggest any alternative options?

Yes	
No	

If yes, please state alternative options:

Question 9a:

Do you think the proposed criteria to decide on the best option for managerial reform are appropriate?

Yes	
No	
Don't Know	
No Opinion	

Comments:

Question 9b:

Are there any other criteria that should be considered?

Yes	
No	

If yes, please state:

Equality of Opportunity Questions

The Health and Social Care Board aims to advance equality of opportunity for a range of groups during the development of its proposals for the Modernisation of Pathology Services.

Under Section 75 of the NI Act 1998; nine groups of people are identified and consideration of their different needs is important. These groups are:

1. Age (older and younger people);
2. Gender (including transgender and men and women generally);
3. Marital Status (including Civil Partnership);
4. Religion;
5. Ethnicity;
6. Political Opinion;
7. Dependant Status;
8. Disability; and
9. Sexual Orientation.

The HSCB would value feedback on how the proposals may impact equality of opportunity and the following two questions have been included for this purpose. Responses to these questions will be anonymised in the report of the consultation.

Question 10a:

Based on belonging to any of the Section 75 groups, do you have any particular requirements with regard to the proposals?

Comments:

Question 10b:

Generally, do you think there are any particular requirements for any of the Section 75 groups? If so, what would you consider as a potential solution?

Comments:

Question 11a:

Do you think that the proposed approach to implementation is appropriate?

Yes	
No	
Don't Know	
No Opinion	

Comments:

Question 11b:

Are there any other factors that should be considered?

Comments:

Thank you.

Annex A to Consultation Response Form

Freedom of Information Act (2000) – Confidentiality of consultations

The Health and Social Care Board will publish a summary of responses following completion of the consultation process. Your response, and all other responses to the consultation, may be disclosed on request. The Health and Social Care Board can only refuse to disclose information in exceptional circumstances. Before you submit your response, please read the paragraphs below on the confidentiality of consultations and they will give you guidance on the legal position about any information given by you in response to this consultation.

The Freedom of Information Act gives the public a right of access to certain types of information held by a public authority, in this case the Health and Social Care Board.

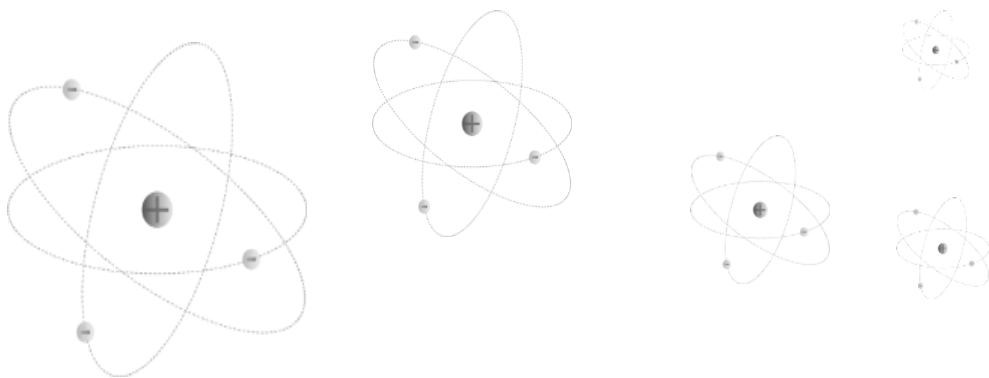
This right of access to information includes information provided in response to a consultation. The Health and Social Care Board cannot automatically consider as confidential information supplied to it in response to a consultation; however, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity should be made public or be treated as confidential.

This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances. The Lord Chancellor's Code of Practice on the Freedom of Information Act provides that:

- the Health and Social Care Board should only accept information from third parties in confidence if it is necessary to obtain that information in connection with the exercise of any of the Health and Social Care Board's functions and it would not otherwise be provided;
- the Health and Social Care Board should not agree to hold information received from third parties "in confidence" which is not confidential in nature;
- acceptance by the Health and Social Care Board of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner.

For further information about confidentiality of responses please contact the Information Commissioner's Office (or see web site at:

<http://www.informationcommissioner.gov.uk/>).



Appendix 2: Pre Consultation Record

1. Association for Clinical Biochemistry and Laboratory Medicine & the Federation of Clinical Scientists.
2. Belfast Health & Social Care Trust Laboratories Senior Team & Clinical Service Users
3. Biochemistry & Point of Care Testing Specialty Fora, NI Pathology Network
4. British Medical Association
5. Business Services Organisation Equality Team
6. Business Services Organisation Department of Legal Services
7. Trust nominated Cellular Pathology Representatives
8. Chief Executives (Trusts)
9. Chief Executives (HSCB, PHA and Trusts)
10. Department of Health (Northern Ireland)
11. Haematology and Transfusion Specialty Fora, NI Pathology Network
12. Trust Human Resources Directors
13. Health and Social Care Board Electronic Health Directorate
14. Health and Social Care Board Senior Management Team
15. Institute of Biomedical Science
16. Local Health and Social Care Group Chairs
17. Microbiology and Virology Specialty Fora, NI Pathology Network
18. Northern Health and Social Care Trust Senior Team - Laboratories
19. Northern Ireland Blood Transfusion Service
20. Northern Ireland General Practitioner Committee
21. Northern Ireland Pathology Network Board
22. Patient Client Council
23. Public Health Agency
24. Queens' University Belfast

25. Royal College of Pathologists
26. South Eastern Health and Social Care Trust Senior Team - Laboratories
27. Southern Health and Social Care Trust Senior Team - Laboratories
28. Staff working in HSC Laboratories across Northern Ireland
29. Trade Unions
30. Transport Manager Belfast Health and Social Care Trust
31. Transport Manager Northern Health and Social Care Trust
32. Transport Manager South Eastern Health and Social Care Trust
33. Transport Manager Southern Health and Social Care Trust
34. Transport Manager Western Health and Social Care Trust
35. Transforming Your Care Office, Health & Social Care Board
36. Ulster University
37. Western Health and Social Care Trust Senior Team - Laboratories



Appendix 3: Pathology Specialties

1. **Clinical biochemistry:** Also called biochemistry, the pathology specialty that is concerned with the analysis of body fluids such as blood and urine. Clinical Biochemists can diagnose, treat and monitor diseases by interpreting the level of different chemicals in samples.
2. **Clinical cytogenetics:** The pathology specialty that involves the microscopic analysis of chromosomal (DNA) abnormalities that may result in disease.
3. **Clinical embryology:** The specialty that involves the handling of gametes (sperm and eggs) and embryos to treat male and female infertility.
4. **Cytopathology:** Cytopathology is the study of abnormal cells in body fluids, smears and tissue samples, for example, cervical smears for the detection of changes in the cervix that could lead to cancer.
5. **Dermatopathology:** The branch of pathology that studies disease of the skin. For example, rashes, lumps and skin cancer.
6. **Forensic pathology:** This is the branch of pathology in which doctors examine people who have died, usually when there is concern that the cause of death was unnatural (for example, not due to an illness). Forensic pathologists often give evidence in court, for example in murder trials. Although this is a branch of pathology that many people have heard of, it is one of the smallest specialties.
7. **Haematology:** The pathology discipline involved in the care and treatment of patients with blood disorders such as anaemia or leukaemia.
8. **Histocompatibility and immunogenetics:** The study of organ transplantation and tissue matching. These pathologists make sure

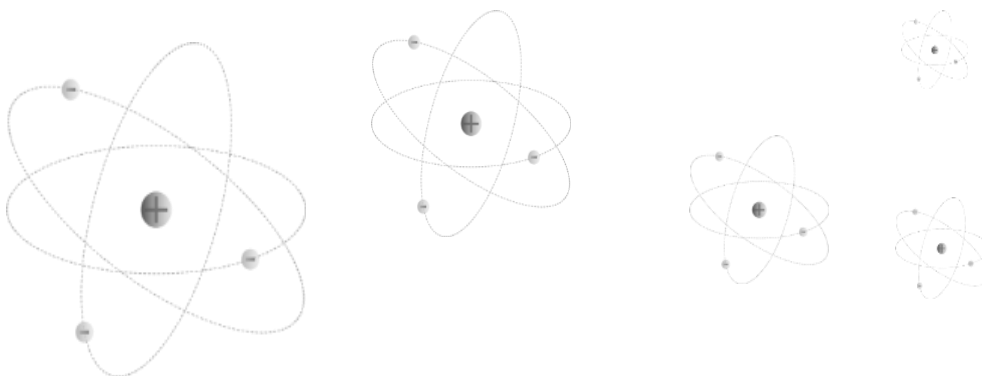
that transplanted organs are suitable for the recipient to try and avoid the organ being rejected.

9. **Histopathology:** The branch of pathology that involves looking at tissue under the microscope to diagnose disease. If you have a mole or a breast lump removed, the histopathologist will examine it to work out what it is.
10. **Immunology:** The science of disorder of the immune system. Doctors who specialise in the diagnosis and treatment of disorders of the immune system are called Clinical Immunologists. They often also run the specialist laboratories that provide testing for immunological disorders as well as looking after people with autoimmunity, immune deficiency and allergies.
11. **Medical microbiology:** The branch of pathology which deals with the investigation, treatment and monitoring of infections in humans.
12. **Metabolic medicine:** A group of overlapping areas of clinical practice with a common dependence on the detailed understanding of basic biochemistry and medicine. These areas fall within the territory of both physicians and chemical pathologists. They include clinical nutrition, lipid abnormalities, diabetes, metabolic bone disease, porphyria and adult inherited metabolic disorders.
13. **Molecular genetics:** The study of heredity and variation. Genetics also includes the study of the changes underlying genetic diseases, for example, cystic fibrosis.
14. **Near Patient Testing:** (see 'Point of Care Testing').
15. **Neuropathology:** The branch of cellular pathology that is concerned with the diagnosis of diseases of the brain, spinal cord, skeletal muscle and nerves by the examination of biopsy specimens and through post mortem examinations. Neuropathologists diagnose conditions such as brain tumours, muscular dystrophy and dementia.

16. **Paediatric and perinatal pathology:** The branch of pathology concerned with diseases and disorders of babies and children, including foetuses. Paediatric pathologists look at samples under the microscope and also perform post mortem examinations following the death of a foetus or child.
17. **Point of Care Testing:** defined by the Institute of Biomedical Science: Near-patient testing and Point-of care testing are used synonymously to describe analytical procedures performed for patients by healthcare professionals outside of the conventional laboratory (the use by patients of home-testing devices is not included.) Advances in technology have led to the development of instruments and kits designed for use in this role and which are able to provide an increasing repertoire of tests. Analytical tests are now available for use in operating theatres, hospital wards, or outpatient departments in the acute sector, in general practice surgeries and in the homes of patients in primary care.
18. **Precision Medicine:** defined by the UK's Programme Coordination Group in precision medicine: precision medicine refines our understanding of disease prediction and risk, onset and progression in patients, informing better selection and development of evidence based targeted therapies and associated diagnostics. Disease treatment and other interventions are better targeted to take into account the patient's genomic and other biological characteristics, as well as health status, medications patients are already prescribed and environmental and lifestyle factors.
19. **Toxicology:** The branch of pathology concerned with the study of drugs and poisons and their effects on the body.

20. **Transfusion medicine:** As defined by NIBTS: The branch of medicine concerned with collection, processing and testing of donor blood and the clinical application of blood component therapy.

21. **Virology:** The term applied to the study of viruses and the diseases caused by them. The term 'Medical Virology' is applied to human diseases caused by viruses. Specialists in medical virology help in the investigation and treatment of patients suspected of having a viral infection.



Appendix 4: Source Documents

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5. Department of Health (England) 2006, *Report of the Review of NHS Pathology Services in England*.
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36. Mid Staffordshire NHS Foundation Trust 2013, *Public Inquiry*.
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40. NHS Wales 2008, *The Future Delivery of Pathology Services in Wales*.
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