Annual Quality Report 2024-25

Northern Ireland
Blood Transfusion Service

Introduction

The Northern Ireland Blood Transfusion Service (NIBTS) is the sole supplier of blood components and products to Health and Social Care (HSC) in Northern Ireland. All blood components prepared from donations are provided by our voluntary, non-remunerated donors. In addition to supplying blood components and products, NIBTS provides a Regional Antenatal Testing Service and Regional Reference Laboratory Service for Northern Ireland. NIBTS also supply Quality Management support and sample testing provision to the Musgrave Park Hospital Bone Bank.

NIBTS staff have a strong commitment to quality as demonstrated by our vision:

"Through our Donors and Staff, provide an outstanding blood service for the people of Northern Ireland"

NIBTS hold four key values

The 4 values stated below underpin the work NIBTS carries out.

Working together

Excellence

Compassion

Openness and Honesty

These values are reflected in five key strategic themes. These themes are used to determine the vision and strategic direction for NIBTS and inform the Corporate Plan which for the 2021 to 2025 period contains the following objectives:

Theme 1: Safety & Quality

- Reduce adverse events in donors
- Implement emerging blood safety recommendations
- Continue to ensure safe working environment for all staff
- Assess and implement where appropriate the lessons learned from the Infected Blood Inquiry
- Assess and implement where appropriate the lessons learned and best practices from the response to the COVID-19 pandemic
- Continue to improve the Donor and Patient experience
- Develop and implement updated digital infrastructure
- Promote excellent clinical practice in all aspects of transfusion practice
- Ensure all governance and risk management structures continue to comply with all relevant regulations and standards as well as other supporting guidance
- Continue to remain compliant with all quality and regulatory requirements
- Implement donor individualised risk assessment (FAIR)
- Develop plans for the upgrading of physical infrastructure

Theme 2: Continuous Improvement

- Ensure that blood components are only transfused according to best available evidence
- NIBTS continue to work with the Public Health Agency to progress the implementation of regional Foetal D screening.
- Continue to promote a culture of continuous quality improvement
- Test emergency planning protocols and business continuity plans in line with relevant DoHNI standards
- Complete the roll out of the Blood Production and Tracking (BPaT) IT solution
- Assess the physical infrastructure required to deliver a safe and sustainable collection strategy
- Continue to participate in benchmarking exercises with other UK Blood Transfusion Services and other Blood Services within the European Blood Alliance and use this information to drive service improvement
- Develop performance reporting arrangements across the organisation

Theme 3: People/Culture

- NIBTS continue to progress the development and implementation of a NIBTS HR Strategy
- Continue to ensure full implementation of effective individual staff development reviews and personal development plans linked to NIBTS corporate goals and objectives
- Ensure all relevant staff have up to date appraisal revalidation
- Ensure all relevant staff have a competency assessment including those with employment contracts elsewhere
- Continue to implement strategies to support the health and wellbeing of staff
- Continue to develop the skills set of all staff
- Continue to ensure effective learning and development for all staff through a range of methods including encouragement of continuing professional development, participation in the Post Entry Qualification scheme as well as bespoke management training interventions.
- Continue to develop the Board and Senior Management Team effectiveness including effective induction
- Ensure Board composition is appropriate and quorate
- Engage with staff on the development of the annual business plan

Theme 4: Partnership and Engagement

- Continue to further develop ways to engage and communicate with donors and other stakeholders
- Continue to support the genetic hemochromatosis (GH) programme
- Support the Harvey's Gang charity
- Continue to develop to work with the Pathology Network to transform pathology services including the development of the management structure blueprint
- Support the roll out of the regional NIPIMS programme
- Continue to collaborate and with UK Forum and EBA

Theme 5: Resources

- Continue to deliver services within budget, focusing on effective use of resources and efficiencies
- Continue to deliver a corporate business planning cycle which outlines the business planning process and the key business stages

A new corporate plan and strategic objectives for the next 4 year period is currently under development.

Maintaining a Blood Establishment Authorisation License

NIBTS is required to maintain a Blood Establishment Authorisation license in order to continue to supply blood and blood products. In order to retain this license, the organisation is required to maintain a Quality Management System to ensure the safety and quality of blood products in line with the Blood Safety and Quality Regulations 2005 (as amended) and to comply with the relevant EU legislation for Blood Establishments.

This system includes the following elements which contribute to quality improvement:

Furthermore, NIBTS has developed and maintains processes which ensure the effective management of:

- Internal Audit
- Audit and assessment by external bodies
- Processing of complaints
- Assessments of User satisfaction
- Participation in external quality assessment schemes
- Validation of equipment and processes

Quality 2020

In 2011, "Quality 2020: A 10-year Strategy to Protect and Improve Quality in Health and Social care in Northern Ireland" was launched by the Department of Health, Social Services and Public Safety.

This Strategy has identified five strategic goals to be achieved by 2020 that will turn the vision of being "recognised internationally, but especially by the people of Northern Ireland, as a leader for excellence in health and social care" into a reality.

The five strategic goals are:

- Transforming the Culture
- Strengthening the Workforce
- Measuring the Improvement
- Raising the Standards
- Integrating the Care

The five strategic themes for NIBTS can be mapped to the strategic goals of Q2020 with some NIBTS themes encompassed by more than one of the Q2020 strategic goals:

Q2020 Goal	Corresponding NIBTS theme
1. Transforming the Culture	People & Culture
2. Strengthening the Workforce	People & Culture
3. Measuring the Improvement	Continuous Improvement/Resources
4. Raising the Standards	Continuous Improvement/Safety & Quality/Partnership & Engagement
5. Integrating the Care	Partnership & Engagement/ Resources/Safety & Quality

Many of the quality improvement initiatives undertaken by NIBTS are consistent with the strategic goals of Q2020. This report will demonstrate progress made under the five strategic headings during 2024/25. A further review of quality objectives will be undertaken during 2025/26.

Transforming the Culture

As in previous years the organisation used the mechanisms for trending root cause and fault categories previously developed to identify and investigate trends highlighted as a result of incident investigation and/or audit findings.

Short term trends are identified and addressed before escalating any further.

Longer term trends have been identified as continuing from previous periods.

Trending during 24/25 has identified a trend relating to pooled platelet product which is prepared from whole blood donations. This trend relates to the number of platelets in the pooled product, which for a percentage of the product prepared have been lower than the target value. The organisation has mitigations in place which have removed any risk to recipients from this trend and are currently working on a revised process for production of the product to improve platelet recovery in the final product.

Previous trend related to pH of apheresis platelet production at end of shelf life has periodically reoccurred across all UKBTS at a reduced occurrence rate. No single or definitive root cause for this issue has been identified and the process for managing this product issue is now well embedded with appropriate risk mitigation.

Trending data for NIBTS generated from the incident management system is collated and presented monthly to the Quality Improvement Review Group. Additionally, a further breakdown of trends to department level is carried out on a quarterly basis and the outcome shared with the relevant department.

We continue to strive to ensure a 'no blame' culture, with the incident management system used to address each incident in a fair and just manner.

To ensure learning across the organisation, incidents and their outcomes are reviewed on a monthly basis by the Incident Management Group with representatives from all areas of the organisation. Learning points identified and discussed at the group are then disseminated throughout the organisation via the group members.

One of the key elements to transforming the culture of an organisation is staff

involvement in changes and the recognition that these changes will improve the quality of products and services provided.

NIBTS recognises that change sometimes can be challenging for any organisation. NIBTS have a well embedded Change Management process to ensure risk and impact of change on staff, products or services is minimized. The Change Management Process aims to assess the impact of each change; put in place appropriate action plans to implement the change involving all stakeholders; monitor progress of the change and, after implementation, review the change to identify any learning points and determine if the expected benefits were delivered.

A Change Control Group representative of the organisation continued to meet on a weekly basis throughout 2024/25 to review and approve new changes or revision of action plans for existing changes.

The Change Control Group consists of a cohort of staff drawn from various sections of the organisation. The group supports dissemination of information regarding change throughout the organisation and encourages team working. This group continues to review the process for managing change on an ongoing basis to identify and implement improvements.

NIBTS continue to involve staff in the business planning process of the organisation with comments and suggestions invited from all members of staff.

To further encourage and engage all staff in achieving business objectives, a performance management framework has been implemented. This framework aims to ensure adequate linkage is achieved between corporate objectives, departmental objectives and individual objectives set during the staff appraisals.

During 2023 NIBTS undertook an in house survey which was anonymised to gain staff feedback, ideas and suggestions to help the organisation deliver the best possible services to our Donors and Clients with particular focus on staff engagement. NIBTS is currently working on an action plan to address those areas where improvements could be made, with a particular focus on the development of a staff reward and recognition policy.

NIBTS recognise that users of our service must also have the opportunity to voice any suggestions for improvement or concerns.

We recognise that communication is key to ensuring staff are informed of service developments.

The organisation continues to strive to improve communication with staff via a number of established channels such as:

- Posting news and documents on the staff intranet in a user-friendly format
- Use of screensavers, corporate email messages, noticeboards and team meetings to communicate information to staff
- Provision of data terminals in various locations for those staff who do not routinely interact with computers during their daily duties
- Staff briefings and daily staff huddles in certain operational departments.
- Events celebrating key achievements where staff are encouraged to present the role they played.
- Involvement of staff in drafting and agreeing the corporate objectives.

NIBTS recognises that the environment in which staff work is important in ensuring a culture which strives to produce the best possible service/product for our customers.

NIBTS undertook some significant estates works during 2024/25 which included:

- Major repair works on the roof of the main HQ building
- Refurbishment works and upgrade of audio-visual technology in the Lecture Room and Library
- Upgrade/Replacement of all Split Air-Conditioning units in the Hospital Services Lab areas – the Pooling Room, New Blast Freezer room and main Component Processing Lab area
- There are no major estate related project plans in place to take forward in 2025/26, however it is hoped that we will be able to introduce additional EV (Electric Vehicle) chargers in the main car park, and carry out several small renovation projects as part of our Estates Action Plan for 2025/26.
- These renovation projects are primarily to accommodate the introduction of new laboratory equipment throughout all laboratory departments. There will be some minor refurbishment works in some

offices, including the replacement of older fluorescent light fittings with newer and more energy efficient LED lights. We will also be looking to refresh publicly used areas, where appropriate, as part of the Action Plan for 2025/26.

- There will also be collaboration with the BHSCT estates Energy Management Team to develop an Environmental and Energy Management Strategy for NIBTS during 2025/26, with the objective of reducing the organisations' carbon footprint over the coming years. We will look at water and energy consumption, and waste generation and disposal, as part of the strategy and for ways to reduce our use of all of these in future years.

Strengthening the Workforce

Our staff are paramount to the delivery of quality products and service. We recognise the importance of staff being trained for the roles they fulfil whether this be with regard to clinical expertise, laboratory, processing, communication or management skills.

During 2024/25, we continued our commitment to support staff training by:

1) **Delivery of mandatory training in:**
   a) Fire Awareness
   b) Health and Safety
   c) Equality Good Relations and Human Rights
   d) Risk Management
   e) Manual Handling
   f) Recruitment and Selection
   g) Information Governance
   h) Fraud Awareness
   i) Cyber Security

2) **Induction for new staff**

Each new employee goes through a local induction. This allows the new employee to be introduced to their place of work and the team they will be working with as well as fill in any required paperwork.

NIBTS supports this induction with a Staff Induction Pack and checklist, giving new employees information on NIBTS's core vision and values, introducing them to each department and the Senior Leadership Team, as well as information on terms and conditions of service and training.

3) **Good Manufacturing Practice**

All new employees undergo Good Manufacturing Practice on commencement of employment.

During 2024/2025, NIBTS's Medical Department maintained full compliance with both the organisational appraisal requirements and GMC revalidation procedures. All Nursing Staff employed by NIBTS achieved NMC revalidation requirements by the required date.

NIBTS Biomedical Scientists are required to maintain registration with the Health and Care Professions Council (HCPC).

A condition of this registration is participation in continued professional development which is subject to audit. All Biomedical Scientists employed by NIBTS maintained their registration during 2024/25.

NIBTS Laboratories continue to participate in supporting Trainee Biomedical Scientist staff in the completion of the Institute of Biomedical Science (IBMS) Registration Portfolio to allow these staff members to achieve HCPC registration, and the IBMS Specialist Diploma or BBTS Specialist Certificate to progress to Specialist Biomedical Scientist grade.

Our staff are required to participate in an annual staff appraisal, during which employee and manager review and reflect on achievements and plan for the following year in line with the organisation's objectives. This also allows to identify any needed training and support the employ may require. The annual staff appraisal target is 85%. During the 2024/25 period 85.8% of staff had an appraisal, meeting our annual target. The organisation will endeavor to continue to maintain and improve completion rates during 2025/26.

NIBTS aim to reduce staff absence rates both due to long term and short-term illness year on year. The absence rate target for 2024/25 was to maintain or improve on the previous year of >6.18%. The organisation absence rate at the end of 2024/25 recorded a figure of 6.41%, slightly above the target value therefore the need to continue to strive for improvement in this area is recognized. To improve staff engagement in this area, all departments have agreed to add absence management to their departmental business objectives encouraging regular review at this level.

A range of staff from various professional and non-professional backgrounds were supported in the completion of post entry qualifications. This provides assistance with costs and where applicable time for study and attendance at courses.

Staff Health and Wellbeing

Allied to reducing staff absence is improving the health and wellbeing of our staff. During 2024/25, NIBTS participated in or ran a number of programmes aimed at improving staff wellbeing including:

- Cycle2Work
- World Blood Donor Day
- Arthritis Awareness Day
- Neurodiversity Awareness Day
- Alcohol Awareness Webinar
- Looking After your Mental Health Webinar
- Mindfulness Webinar
- Christmas Jumper Day & Breakfast
- Flu and Covid vaccination programme.

A number of other events were also held to raise funds for local charities including selling of Christmas Cards and other crafts and a number of raffles for hampers donated by Senior Leadership Team and other staff. Additionally, as part of the Health and Wellbeing activities for staff NIBTS regularly promote available resources and have a dedicated Health & Wellbeing page on the internal Intranet platform.

Measuring the Improvement

We recognise the importance of gathering data and statistics as a means of examining performance and identifying areas of strength and where improvements are required.

Information is gathered throughout the organisation and presented at a number of fora to monitor performance. These include regular departmental and interdepartmental meetings and monthly meetings attended by the Senior Management Team. Reports are also provided for each Agency Board Meeting.

During 2024/25, NIBTS continued to meet those service objectives associated with maintenance of the relevant licenses, ISO 15189 accreditation and the financial performance objective of breakeven. The service also maintained an adequate panel of blood donors to allow adequate collection of blood to meet demand from hospitals.

Corporate Quality

During 2024/25 NIBTS have continued to provide an agreed governance report covering the key areas of the service on a quarterly basis at the Governance and Risk Management Meeting. Additionally, a corporate quality document with Key Performance Indicators and targets for collection figures, donor satisfaction and complaints, waiting times, financial targets, staff absence and Staff Development Review completion is presented at this forum.

Effectiveness of Quality Management System

A set of corporate quality metrics data for various elements of the Quality Management System - product quality, incidents (including trending data), documents, change management, audit, external assurance exercises and recall - is produced on a monthly basis and reviewed by the Senior Management Team. This data is shared at the Agency Board meeting.

These metrics have indicated some areas where further focus is required.

Conformance with the KPI target for document review has continued to prove problematic within a number of operational areas as has that for ensuring incident investigations and subsequent completion of corrective and preventative actions within the allocated target dates. Additionally, the completion of the self inspection schedule has been challenging with a significant degree of slippage experienced. These adverse trends have been widely discussed with staff and the Agency Board and a number of measures are being implemented to reverse these trends.

Quality of products and services

Progress on quality objectives and other quality indicators relevant to each department are reviewed during departmental and interdepartmental meetings with a standard quality metric template completed for each meeting.

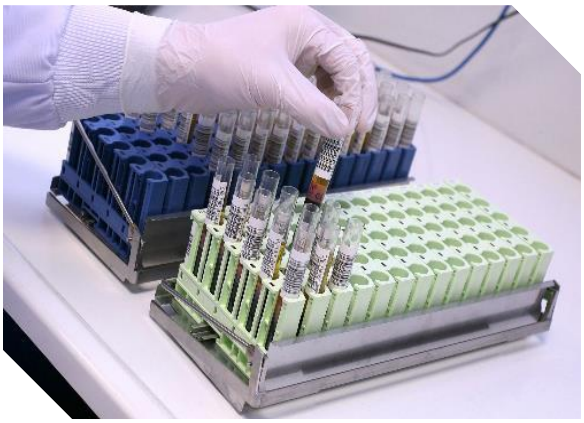
This template captures data such as progress on change controls, departmental incidents, equipment maintenance, audit progress, document review completion and turnaround times for reports. Targets are set for each of these areas and the captured data reviewed in line with these targets.

One of the more visible measures of the antenatal patient testing service to users is the turnaround time for samples to be tested and the report issued.

Automated Serology antenatal patient testing demonstrated an improvement in values obtained for the target Key Performance Indicators throughout the 2024/2025 year period.

A significant decrease was recorded in the average number of days to issue a patient report and a slight decrease in average percentage of reports issued within a three-day period when comparing the average yearly figure between 2023/24 and 2024/25 time periods as follows:

- Average number of days for turnaround of reports issued, decreased significantly from 1.72 days for 2023/24 to 1.33 days in 2024/25 a decrease in average reporting time of 0.39 days.
- Average percentage of reports issued within three days exhibited a slight decrease from 98.22% for 2023/24 to 96.83% for 2024/25.



Since the introduction of WinPath in conjunction with the increase in workload and the introduction of new complex tests, for example molecular genotyping and FMH quantitation by flow cytometry the Blood Group Reference Laboratory reviewed and revised their KPI targets to establish new turnaround times in keeping with other transfusion services.

The general approach for turnaround times from RCI labs are 95% of results reported within 5 working days whereas genotyping labs aim to have 85% of results reported within 10 working days and this approach has been adopted by the

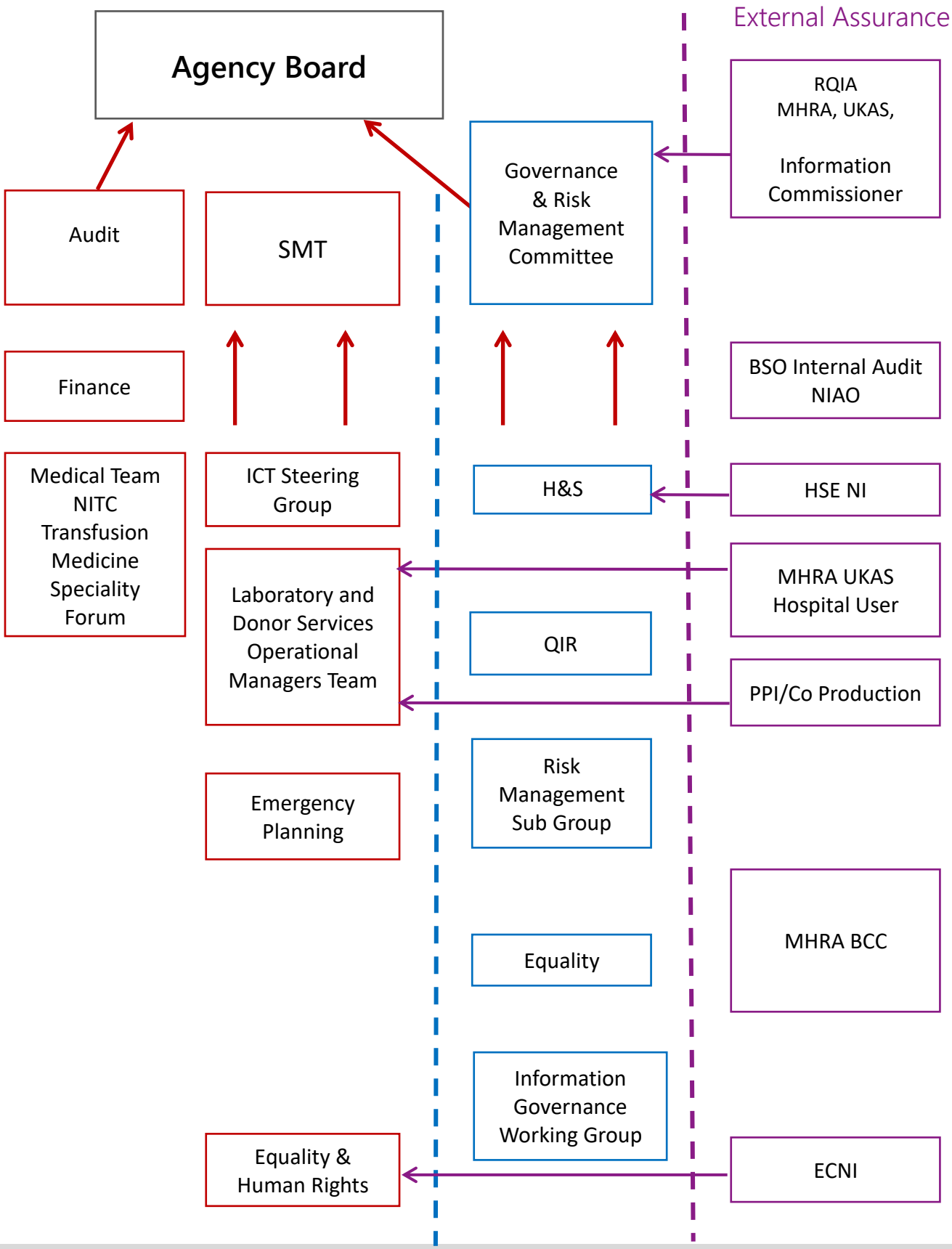
Reference Lab at NIBTS. During the 2024/2025 financial year 94.6.% of results were reported within the established turn around times.

Due to the increasing workload, the introduction of new LIMS and the referral of complex samples (e.g. samples from patients receiving monoclonal antibody therapies) the overall turn around times of reports has increased from previous years. Due to the increase activity in the area, a business case was completed and approved to augment the staffing quota within the Reference Laboratory. The majority of these posts have now been recruited with one additional post due recruitment shortly. It is anticipated this increased staff resource will allow the laboratory to manage the additional workload and assist the improvement of turn around times.

Quality of the blood components produced by NIBTS is monitored via a sampling programme on an ongoing basis with reports provided to the production department on a daily basis. A monthly report focusing on quality monitoring of the components produced is reviewed by senior staff from within collection, clinical, production and quality to ensure prompt address of any potential slippage in conformance and/or identify areas for improvement.

The following diagram diagrammatically shows how performance is monitored and managed throughout the organisation.

Performance Management



Through the Incident Management System, we have the opportunity to assess and improve working practices where appropriate. The organisation investigates all errors and incidents. The level of investigation required is determined by the risk level of the incident.

Incident investigations, actions taken as a result and any learning opportunities can be viewed by staff in electronic format and are discussed at various fora including the monthly incident management meeting attended by staff from throughout the organisation to promote sharing of any learning points.

The change management process allows full consideration of any changes to be made, what benefits are anticipated and the impact on all areas of the service and its users. Where appropriate, a review step is built into the process to allow an assessment of the completed change, any learning points and to determine if the benefits have been delivered.

NIBTS, as part of our Quality Management System, maintain a well established programme of internal audits. During 2024/25 a total of 35 internal audits were performed with no critical findings. Appropriate corrective and/or preventative actions were implemented.

External Regulation

NIBTS was subject to a re-inspection by UKAS during the 2024/25 period with subsequent confirmation that accreditation to ISO 15189 had been maintained, this inspection also applied the new ISO 15189:2022 Standard.

The internal and external audits confirm that the Quality Management System (QMS) is operating at an effective level. However, we recognise that it is essential to both maintain and improve performance of the system and to this end continue to focus on implementing improvements to our systems. The organisation has within the 2024/25 period successfully implemented improvements to the internal audit and supplier management aspects of the quality management system, identified following a review of both these areas.

NIBTS is also subject to audit by the Business Services Organisation Internal Audit function which completes an annual plan of work which has been presented to and approved by NIBTS Audit Committee. During 2024/25 the plan included audits covering Finance, Cyber Security, Governance & Operation of Assurance Framework and Performance Management. The audits undertaken and the level of assurance provided by Internal audit were: Financial Review (Satisfactory),

IT Audit – Cyber Security (Satisfactory), Governance & Operation of Assurance Framework (Satisfactory) and Performance Management (Satisfactory).

Implementation of Internal Audit recommendations are the subject of detailed action plans and progress is assessed by the auditors at their mid-year and end of year reviews. The Chief Executive prepares a Governance Statement for the Annual Report which is supported by an Annual Report and opinion from the Head of Internal Audit. Overall, in their Annual Report, the Head of Internal Audit provided a satisfactory level of assurance on the adequacy and effectiveness of the organisation's framework of governance, risk management and control. In 2024/25, NIBTS continued to participate in DoH accountability review meetings.

Raising the Standards

NIBTS is one of four blood services in the United Kingdom. It also has links with other blood services within Europe through the European Blood Alliance (EBA).

Each year, NIBTS participates in the EBA Benchmarking Scorecard which compares data for key processes within blood services across Europe as well as influences policy on blood collection and sharing best practice and experience.

In addition, the UK Blood Services Forum collaborates in a number of areas including identifying best practice and shared learning.

The UK blood services have remained members of EBA post-Brexit. This is particularly relevant to NIBTS which remains subject EU Regulations and Directives for the supply of blood and blood components. The EU Regulations (SoHO : Substances of Human Origin) that govern the collection, processing and distribution of blood were ratified in June 2024 and due for implementation in 2027.

NIBTS is currently working with colleagues in the Department of Health, other UK blood services and government agencies to determine the adjustments required to the NIBTS quality system to meet the requirements of the regulations.

The UK Forum continues to identify and share best evidence-based practice and shares learning across the UK, Europe and worldwide. In addition, it agrees the strategic approach for challenges that affect the four UK blood services.

Examples include national procurement of essential consumables and equipment, support of the Joint Professional Advisory Committee (JPAC), representation to the advisory committee for Safety of Blood Tissues and Organs (SaBTO) on donor related issues and innovations in practice such as pathogen reduction and blood collection models as well as interaction with the Serious Hazards of Transfusion (SHOT) group.

In 2024/25, the UK Forum has continued to focus on addressing the recommendations from the Infected Blood Inquiry published in May 2024. NIBTS continues to engage with the UK Blood Services Forum, Department of Health and other key agencies in order to address the recommendations relevant to the service.

NIBTS has also contributed to the workstreams of both the UK Forum and JPAC through participation in specialised sub-groups and committees. These groups focus on regulatory compliance with MHRA and EU/UK standards, risk management, and business continuity and emergency planning. Through this involvement, NIBTS helped address emerging threats and safety concerns, while also preparing for potential service disruptions such as pandemics or supply chain challenges.

JPAC recommendations

NIBTS implemented all relevant technical and clinical updates issued by the Joint Professional Advisory Committee (JPAC) to all UK blood transfusion services. These updates included revisions to donor eligibility rules, enhancements of the Geographical Disease Risk Index (GDRI), protocols related to travel-associated outbreaks and other protocols to prevent transfusion-transmitted infections (TTIs).

During this period the Guidelines for the Blood Transfusion Services in the UK was revised. NIBTS have progressed several gap analysis projects to ensure the organisation continues to comply with this guidance.

During 2024/2025 the European Committee on Blood Transfusion issued the 21st and 22nd Editions of the Guide to the Preparation, Use and Quality Assurance of Blood Components. NIBTS have instigated a number of gap analyses to ensure compliance with this updated guidance

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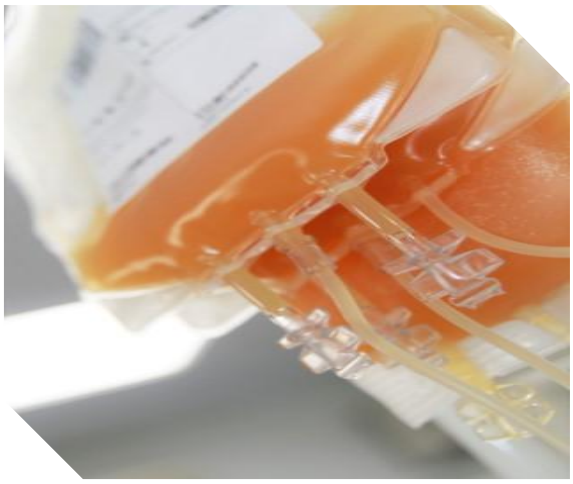
Donor Satisfaction

Donors give blood on a voluntary, non-remunerated basis and are critical to the success of our service. We monitor donor satisfaction levels and had a donor satisfaction level of 99.3% for 2024/25.

Additionally, we record complaints from donors or members of the public to allow analysis, investigation and improvement to the service.

The number of complaints per month were above our target of <4 per 10,000 for some months during the period however when averaged across the 12 month period exceeded this target with a figure of 3.08 complaints per month.



Key Achievements

NIBTS Laboratory Departments identify a series of quality objectives each year to improve service delivery/quality.

During 2024/2025 The Core LIMS System, Winpath Enterprise (a common Laboratory Information Management System for all pathology laboratories in Northern Ireland) was successfully implemented in NIBTS.

All NIBTS laboratory departments are involved in the regional BPaT IT project, which aims to implement a single Blood Production and Tracking System throughout the province, with validation of this system ongoing throughout 2024/2025.

The key Laboratory objectives/achievements are included in the following tables:

Department: Transfusion Microbiology Laboratory

Activities	Key Achievements
Testing of all donations for infectious diseases markers Antenatal screening for infectious diseases in pregnancy	• Tender for the NAT instruments completed and the contract awarded. • Replacement programme for centrifuges completed with the third centrifuge replaced and qualified. • Roche 6800 platform upgraded to 1.4.9. • Ongoing participation in IT projects (Core LIMS for patients and Blood production and tracking project (BPaT) for donors). • External controls for Statistical Process Monitoring replaced by a CE marked alternative

Department: Hospital Services

Activities	Key Achievements
Preparation and manufacture of blood components Hospital issues department	• Validation of new blast freezers, optimising frozen manufacturing. • Replacement of critical GMP equipment with new technology, improving business continuity. • Completion of IBP1 blood pack validations and commenced participation in IBP2 procurement exercise. • Successful requalification of transport boxes, including introduction of new systems for transport of components and products to hospital blood banks and pharmacies. • Validation work completed to improve pooled platelet conformance. • New component assessment processes introduced, to improve quality. • Ongoing participation in pathology LIMS modernisation project, BPAT (Blood Production and Tracking).

Department: Quality Control Laboratory

Activities	Key Achievements
Quality monitoring of blood components Bacteriological testing of platelet components Environmental monitoring of component production areas	• Participation in regional tender for replacement of blood culture equipment • Support and testing for validation projects in other laboratory departments such as blood packs purchased via the International Blood Pack tender and the introduction of new blast freezers • Support and testing in the investigation of conformance for platelet count in buffy coat pooled platelets • Participation in Blood production and tracking project (BPaT) • Participation in Plasma for Medicines project • Introduction of media containing neutralizing agents for environmental monitoring of blood processing areas

Department: Automated Serology

Activities	Key Achievements
Blood Grouping, antibody screening / identification of all blood donation samples Blood grouping, antibody screening / identification of all antenatal patient samplers including medical reporting of at-risk pregnancy results	• Successful validation and embedding of new patient LIM: WinPath • On-going participation in configuration and validation of blood donor LIM: eProgesa • Validation and installation of patient interface ImmuLINK v2.2 to WinPath • On-going upgrading of ImmuLINK interface to v3.2 • Procurement and validation of four new front line blood group, antibody screening and phenotyping analysers for antenatal patient and blood donor testing • Achieved compliance to updated UKAS ISO 15189:2022 standards

Department: # Blood Group Reference Laboratory

Activities

Specialist referral service for hospital blood banks for complex red cell investigations and cross matching red cell units for difficult clinical cases: Includes on call service.

Automated extended phenotyping of red cell donations with download of test results to Pulse.

Provision of platelet antibody testing.

Provision of molecular immunohematology service.

Provides support to the regional kidney transplant programme (titres to facilitate transplant of ABO incompatible kidneys).

Key Achievements

- Continued training of staff for participation in the on-call rota and training of hospital lab staff and medical staff. Training of Scientific Training Programme (STP) students in blood group serology.
- Further validation & successful introduction of a number of Red Cell Genotyping tests which complement the serological tests resulting in less sample referral to NHSBT labs.
- Extended red cell phenotyping / genotyping is being performed for patients receiving monoclonal antibody therapies, sickle cell patients, etc. with the aim to provide matched blood to prevent alloimmunisation and reduce morbidity. Genotyping Working groups set up across the transfusion services in the UK and ROI has increased the level of knowledge for interpreting and reporting genotyping results.
- Participation in the National Genotyping Blood Group Programme for patients with haemoglobinopathy and rare inherited disease.
- Successful introduction of the sickle cell screening assay (Sickledex) to provide HbS negative blood for Sickle Cell patients and neonates to ensure compliance with guidelines.
- Ongoing development of new laboratory tests and reagents to ensure compliance with in vitro Diagnostic Regulations (IVDR)
- Introduction of Core LIMS (WinPath) for patient testing. Ongoing development of Blood production and tracking project (BPaT) for donors).

Integrating the Care

The NIBTS Medical Department plays a pivotal role in ensuring the safe, effective, and sustainable use of blood across Northern Ireland. The team works in close collaboration with the Northern Ireland Transfusion Committee (NITC), actively participating in the majority of Hospital Transfusion Committee (HTC) and NITC meetings.

Through this engagement, the medical team contributes to the implementation of regional transfusion practices aligned with NICE guidelines, Better Blood Transfusion principles, and Patient Blood Management (PBM) initiatives.

In 2024/25, the medical team provided clinical leadership to support the coordination of the regional transfusion practice, the implementation of the Infected Blood Inquiry (IBI) recommendations, and to strengthen consistency and safety of transfusion practices across hospital sites.

The department continues to monitor and share blood flow data with transfusion teams across the region, enabling performance benchmarking and supporting efforts to ensure resilience and promoting self-sufficiency in blood supply.

In addition, the medical team remains focused on ensuring donor and patient safety through clinical oversight, and the development of evidence-based policies to ensure that Northern Ireland maintains high standards in transfusion medicine.

The NIBTS diagnostic and screening laboratories have achieved accreditation from United Kingdom Accreditation Scheme for standard ISO 15189:2022

We continue to work closely with colleagues in the three other UK Blood Services with representation in the UK Quality Managers group and linked subgroups which concentrate on Quality Monitoring, Supplier Audit, Regulatory Changes, Validation and Data Integrity.

This allows sharing of expertise, information and learning throughout the four services and assists benchmarking similar process such as recall rates and categories, SABRE reportable incident occurrence and bacterial positivity rates in platelet components. Regulatory audit outcomes for all services are shared as are any actions taken to address non-conformances.

Each group aims to meet up to four times per year with meetings either face to face or via teleconferencing. Participation in these groups ensures each service is aware of changes and developments in service provision and maintains consistency of service across the UK.

Notable workstreams for the UK Quality Managers Group during 2024/25 include:

- Continued comparison of key performance indicators
- Comparison/discussion of external audit reports to facilitate shared learning.
- Monitoring the workstreams of the subgroups.
- Sharing of information for incident management processes
- Sharing knowledge and awareness of new and emerging changes in regulations and gap analysis of these.
- Collaboration in sharing information on and actions being taken regarding issues with consumables
- Sharing of actions required to progress plasma for medicines programme and current status of each service

The workstreams of the Quality Monitoring, Supplier Audit, Regulatory Radar, Data Integrity, and Validation subgroups include:

- Discussion and sharing of gap analyses for new and updated regulations e.g.

  ISO 15189:2022, Good Practice Guidelines, Guidelines for the Blood Transfusion Services in the UK (online edition)
- Collaboration between all UK Blood Services with regard to SoHO regulations
- Sharing progress pertaining to compliance with Medical Device Directives.
- Collaboration and identification of best practice in area of validation, ensuring regulatory compliance
- Participation in workshops between the UK and Ireland Blood Services, showcasing approaches to processes, new technologies, audit/project experiences and sharing lessons learnt
- Topical discussions on new or emerging trends within the area of Validation such as: impact of Cloud 'SaaS' solutions and maintenance of validated state.
- Commonality in approaches to ensure data integrity.
- Collation and discussion of Quality Monitoring statistics from all the UK Blood Services. Knowledge sharing between blood services, to ensure best practice.

- Collation of testing information to include equipment used, QC and NEQAS details for all UK Blood Services
- Review of effectiveness of pH as a marker of platelet quality and potential replacements.
- Sharing supplier audits to reduce duplication of effort between services and collaboration in completion of audits.
- Continued maintenance of and sharing approved supplier lists to demonstrate where services have common suppliers.
- Sharing information regarding supplier approval processes to identify best practice.

Northern Ireland Pathology Transformation

Throughout 2024/25, NIBTS has continued to host the Pathology Blueprint Programme. The Programme Team is currently working with stakeholders to update the business case in response to advice from Department of Health (DoH) Economists and a Gateway Review. The scope and mandate of the Programme has been extended by DoH to enable the Programme Team to consider the broader management arrangements to deliver a regional pathology agency for Northern Ireland.

The new core LIMS, CliniSys WinPath Enterprise solution has now been introduced in al HSC Trusts and NIBTS placing all regional laboratories and NIBTS on a single digital system hosted by BSO. Preparation for the implementation of the Blood Production and Tracking (BPaT) solution is ongoing with a planned implementation date scheduled for mid-2026. This aims to implement a single Blood Production and Tracking System throughout the region.