

Annual Quality Report 2023-24



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 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"

Four key values

These underpin the work NIBTS does. These are as follows:



Working together



Excellence



Compassion



Openness and Honesty

The following statements set out the vision and strategic direction for NIBTS based on these five themes. These values are supported by five key themes:



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
- Support the region in implementing 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
- Roll out 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 driver service improvement
- Develop performance reporting arrangements across the organisation

Theme 3: People/Culture

- Develop and implement 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

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; by the identification of:

- Non-conformances
- Observations, suggestions etc. (opportunities for quality improvement)
- Risks

These in turn drive the process of Root Cause Analysis through to the implementation, monitoring and review of corrective and or preventative actions.

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

- Internal Audit – Assessment of user satisfaction
- Processing of complaints
- External quality assessment schemes
- Quality incidents
- Assessments by external bodies
- Change control
- Validation
- Risk management

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 2021/22. A further review of quality objectives will be undertaken during 2022/23.

Transforming the Culture

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.

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.



Several short term trends were identified and addressed before escalating any further. Additionally, two longer term trends were identified one of which continued from the previous year.

The trend noted during 22/23 relating to pH of apheresis platelet product at end of shelf life continued during 23/24 however at a reduced occurrence rate. pH is used as an indicator for product effectiveness and in a small number of apheresis platelets this has been shown to be lower than desirable. 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 during 23/24 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.

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.

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 desired benefits were delivered.

A Change Control Group representative of the organisation continued to meet on a weekly basis throughout 2023/24 to review new changes or revision of action plans for existing changes.

This supports dissemination of information regarding change throughout the organisation and encourages team working. We continue to review the process for managing change on an ongoing basis to identify improvements with a cohort of staff drawn from various sections of the organisation.

We 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 developed during 23/24. This framework aims to ensure adequate linkage is achieved between corporate objectives, departmental objectives and individual objectives set during the staff appraisals.

During September 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. 47% of NIBTS staff completed the survey. The outcomes of the survey were collated and shared with staff. The survey demonstrated both areas of strength and areas for improvements. NIBTS is currently working on an action plan to address those areas where improvements could be made.

We recognise that users of our service must also have the opportunity to voice any suggestion for improvements or concerns.

During 2023/24, we carried out user surveys for the patient testing and blood supply aspects of our organization and subsequently hosted user meetings to

present the findings of the survey and allow further interaction with our users.

The survey indicated high levels of satisfaction with the services provided and the suggestions made are being progressed where possible.

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 2023/24 which included:

- Significant resurfacing of the roads around the main HQ building and in the main staff car park
- Refurbishment works for the new Medical Directors Office and Medical Team offices
- Preparatory works for in the Old Checking Room for the introduction of 2 new Blast Freezers
- Significant re-design works to accommodate the locating of a new X-Ray machine to allow decommissioning of the current equipments used for irradiation of product in early 2025
- Following the electrical board survey in 2022/23, NIBTS have agreed a plan to upgrade the electrical boards. As new equipment is being introduced the relevant electrical boards will be upgraded as required. This approach has been taken rather than upgrading all boards as a single project which potentially

could cause significant disruption to service. During 2023/24 we replaced one board to accommodate the new X-Ray equipment and replacement of at least one other will take place during 2024/25 financial year.

- There are significant project plans in place to take forward in 2024/25 including major repairs to the roof

of the HQ building and the upgrade of the current lecture room facilities to include more advanced audio-visual technological equipment, to allow more efficient hosting and attending of meetings and events in the future.'

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 2022/23, we continued our commitment to support staff training by:

1) Delivery of mandatory training in:

- a) Fire Safety Awareness
- b) Health and Safety
- c) Equality and Disability Awareness
- d) Risk Management
- e) Manual Handling
- f) Recruitment and Selection Refresher Training
- g) Information Governance
- h) Fraud awareness
- i) Cyber Security awareness

2) Induction for new staff

3) Good Manufacturing Practice

A range of staff from various professional and non-professional backgrounds were supported in the completion of post entry qualifications. As with previous years all staff who applied for post entry study were granted assistance with costs and where applicable time for study and attendance at courses.



NIBTS continued to participate in GMC Revalidation procedures for all medical staff. The revalidation process for all Medical Staff during 2023/24 was

maintained. 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.

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 2023/24.

NIBTS Laboratories continue to participate in supporting Trainee Biomedical Scientist staff in the completion of the Institute of Biomedical Science (IBSMS) Registration portfolio to allow these staff members to achieve state registration and the IBMS Specialist Diploma to progress to Specialist Biomedical Scientist grade.

Our staff are required to participate in an annual staff appraisal review process

during which training needs are identified. The annual staff appraisal review target is 90%. During the 2023/24 period 92.2% of staff were reviewed. This percentage is now above target and shows a significant improvement from the previous year. The organisation will endeavor to continue to maintain and improve completion rates during 2024/25.

NIBTS aim to reduce staff absence rates both due to long term and short-term illness year on year. The absence rate target for 2023/24 was to maintain or improve on >6.08%. The organisation absence rate at the end of 2023/24 recorded a figure of 6.18%, 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.

Staff Health and Wellbeing

Allied to reducing staff absence is improving the health and wellbeing of our staff. During 2023/24, NIBTS participated in or ran a number of programmes aimed at improving staff wellbeing each month including:

- World Blood Donor Day
- Biomedical Scientist Day
- Schizophrenia Awareness Day
- Stroke awareness Day
- Christmas Tree Light turn on
- Christmas Jumper Day
- Flu and Covid vaccination programme.

Additionally as part of the Health and Wellbeing activities for staff NIBTS hosted a Christmas Breakfast. Some 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 Management and other staff.

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 2022/23, 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.



The implementation of an electronic booking system allowing donors to readily access appointment times for donation has greatly improved the efficiency of this aspect of the collection process.

Corporate Quality

During 2022/23 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.

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.

Conformance with the KPI target for document review has proven 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. A number of measures are being implemented to reverse these trends.

Automated Serology antenatal patient testing demonstrated marginal changes in values obtained for the target Key Performance Indicators throughout the year. An increase was recorded in the average number of days to issue a patient report and a slight decrease in average percentage turnaround within a three-day period when comparing the average yearly figure between 2022/23 and 2023/24 time periods which was as follows:

Average number of days for report issue increased slightly from 1.69 days for 2022/23 to 1.72 days in 2023/24 an increase in average reporting time of 0.03 days or 1.77 %.

Average percentage turnaround of reports issued within three days exhibited a slight decrease from 98.49% for 2022/23 to 98.22% for 2023/24.

Despite a small decrease in the percentage figure for turnaround times for Antenatal Virology report issue, this continues to meet the set targets. 97.16% reports were issued within three days with a mean day for report issue of 2.13 days.



The NIBTS Reference Laboratory provides a valuable service to hospital blood banks completing complex investigations in red cell serology, platelet immunology and molecular immunohematology as required. This area has seen a significant upturn in workload over recent years due to reliance on automation by hospital blood banks, a constantly changing population, changing treatment regimes at hospital level & development of new tests at NIBTS presenting significant challenges in maintaining report turnaround time. Average number of days for report issue increased from 1.1 days in 2022/2023 to 1.31 days in 2023/2024 an

increase in average reporting time of 0.2 days.

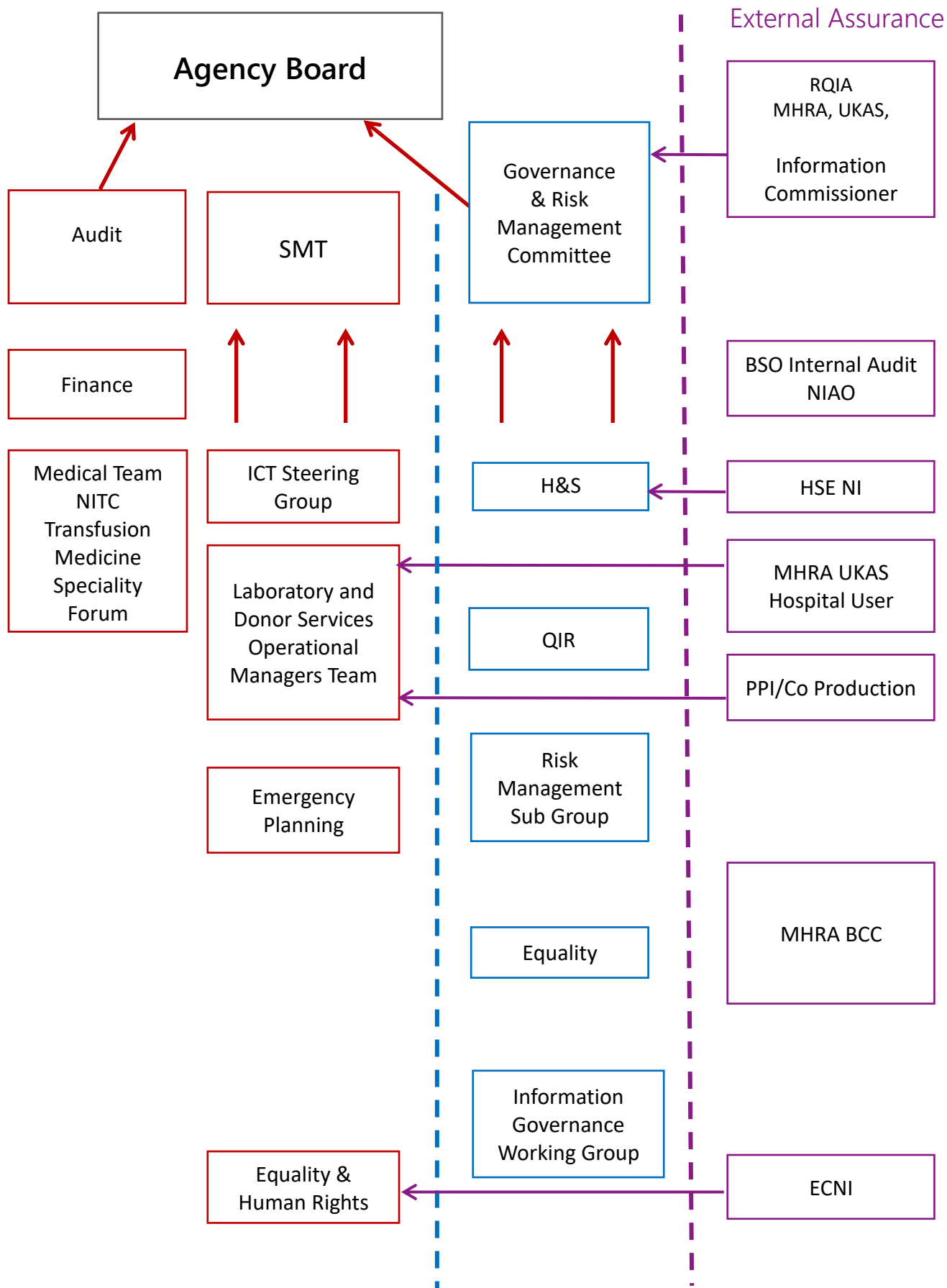
Average percentage turnaround of reports issued within three days decreased slightly from 99.08% for 2022/2023 to 98.11% for 2023/2024 reflecting a 0.97% decrease in the percentage of reports issued within three days from the previous year. Average percentage turnaround of reports issued within one day decreased from 73.57% for 2022 / 2023 to 69.07% for 2023/2024 reflecting a 4.5% decrease in the percentage of reports issued within one day from the previous year.

As a result of a review of the increasing workload within the Reference Laboratory provision of additional staff resource has been agreed to be implemented during the 2024/2025 period.

Quality of the products produced 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.

We, as part of our Quality Management System, have implemented a programme of internal audits. During 2022/23 a total of 41 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 2023/24 period with subsequent confirmation that accreditation to ISO 15189 had been maintained.

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 2023/24 period commenced a review on two areas of the quality management system with a view to identifying potential improvements these being in the areas of internal audit and supplier management.

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 2023/24 the plan included audits covering Finance, Risk Management, Management of Donor Services and Fleet Management. The audits undertaken and the level of assurance provided Internal audit were: Financial Review (Satisfactory), Risk Management (Satisfactory), Management of Donor Services (Satisfactory) and Fleet Management (Limited). NIBTS have agreed and are in

the process of implementing a remedial action plan to address those deficiencies noted within the Fleet Management audit.

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 2023/24, 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 2023/24, the UK Forum has focused on engagement with the Infected Blood Inquiry and recommendations from the Inquiry that were published in May 2024. NIBTS continues to engage with the UK Forum, Department of Health and other

agencies in order to address the recommendations relevant to the service.

The UK Blood Services Joint Professional Advisory Committee (JPAC) provides detailed service guidelines to blood establishments as well as providing advice to blood establishment medical directors and Departments of Health.

Both these committees have a number of sub-groups and advisory committees which focus on specialised areas of Blood Transfusion Practice including regulatory affairs, risk management, business continuity and emergency planning. In the last twelve months JPAC continued to focus on revising and updating donor eligibility rules, updating the Guidelines for the Blood Transfusion Services in the United Kingdom and completing risk assessments on blood donor screening for transfusion transmitted infections.

JPAC recommendations

NIBTS have implemented those JPAC recommendations related to donor selection criteria issued during 2023/2024.

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

Key Achievements

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

All laboratory departments are involved in regional changes to two major IT systems, Core LIMS which aims to introduce a common Laboratory Information Management System to all pathology laboratories in Northern Ireland and BPaT which aims to implement a single Blood

Production and Tracking System throughout the province. The Core LIMS system, Winpath Enterprise was validated for use within NIBTS throughout the 2023/2024 period with implantation achieved during June 2024.

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

Department: **Hospital Services**

Activities	Key Achievements
Preparation and manufacture of blood components	Ongoing equipment modernisation, including purchase and installation of new blast freezers.
Hospital issues department	<p>Qualification and introduction of new processes for frozen components improving manufacturing efficiency</p> <p>Participation in IBP1 blood pack tender and validation of new blood packs improving business contingency arrangements.</p> <p>Qualification of amended transport box system for transport of components and products to hospital blood banks and pharmacies.</p> <p>Ongoing participation in pathology LIMSmodernisation project, BPAT (Blood Production and Tracking).</p>

Department: Automated Serology

Activities

Blood grouping and antibody screening/identification of all blood donation samples

Blood grouping and antibody screening/identification of all Antenatal patient samples including medical reporting of at-risk pregnancy results

Key Achievements

- Validation commenced to allow the automation of high titre testing from blood serology analysers to NIBTS donor Laboratory Information Management System (LIMS) PULSE.
- On-going equipment modernisation with installation of antenatal sample reception refrigerator
- Ongoing participation in LIMS projects (Winpath Enterprise for patients and Blood production and tracking project (BPAT) for donors).
- Validation of ImmULINK interface to facilitate result data transfer to Winpath Enterprise

Department: Quality Control Laboratory

Activities

Quality monitoring of blood components

Bacteriological testing of platelet components

Environmental monitoring of component production areas

Key Achievements

- Participation in regional tenders for laboratory equipment, replacement of blood culture equipment, media and consumables
- Support and testing for validation projects in other laboratory departments notably blood packs purchased via the International Blood Pack tender
- Support and testing in the investigation of conformance for platelet count in buffy coat pooled platelets
- Participation in Blood production and tracking project (BPAT)

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.

Validation 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.

Successful introduction of Fetal Maternal Haemorrhage (FMH) by Flow Cytometry. This test is offered as a regional service which has improved turnaround times and allowed referring hospitals to remain UKAS compliant with correct anti-D administration within 72 hours.

Participation in the National Genotyping Blood Group Programme for patients with haemoglobinopathy and rare inherited disease.

Validation of sickle cell screening assay (Sickledex)

Ongoing development of new laboratory tests and reagents to ensure compliance with in vitro Diagnostic Regulations (IVDR)

Ongoing participation in LIMS projects (Core LIMS for patients and Blood production and tracking project (BPAT) for donors).

Department: Transfusion Microbiology Laboratory

Activities

Testing of all donations for infectious diseases markers

Antenatal screening for infectious diseases in pregnancy

Key Achievements

- Upgrade of the AMS interface between the Abbott Architect testing platforms and the Laboratory Information Systems (DSS and PULSE) to version 3.2. This was required to facilitate the move from the current DSS LIMS system to Winpath Enterprise.
- Replacement programme for centrifuges continued with a further centrifuge replaced and qualified.
- Grifols Panther testing platform upgraded to version 7.2.
- Ongoing participation in IT projects (Core LIMS for patients and Blood production and tracking project (BPAT) for donors).

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 96.4% for 2023/24. 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 2.23 complaints per month.

Measures taken to improve donor satisfaction include the introduction of an on line booking system, introduction of heating/cooling equipment on sessions to better regulate temperature and customer service training for staff.

Integrating the Care

The NIBTS medical team work closely with the Northern Ireland Transfusion Committee (NITC) to ensure safe and effective use of blood in Northern Ireland. Members of the medical team attend the majority of Hospital Transfusion Committee (HTC) and NITC meetings and contribute to the agreed plans and initiatives to promote the highest quality transfusion standards in line with NICE guidelines, Better Blood Transfusion and PBM initiatives. The medical team ensures blood flow data is shared with all transfusion teams to support performance monitoring and the implementation of methods to reduce the need for allogeneic blood transfusion and the promotion of better transfusion practice in the region.

The NIBTS diagnostic screening laboratories have maintained accreditation from United Kingdom Accreditation Scheme for standard ISO 15189 and are in the process of transitioning to the new 2022 version of the standard.

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 2023/24 include:

- Continued comparison of key performance indicators
- Comparison/discussion of external audit reports to facilitate shared learning.
- Monitoring the workstreams of the subgroups.
- Comparison of recall times/mechanisms.
- Sharing of information for incident management processes
- Sharing knowledge and awareness of new and emerging changes in regulations and gap analysis of these.

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. IS15189:2022, Good Practice Guidelines, Guidelines for the Blood Transfusion Services in the UK (9th 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.
- 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 2023/24, NIBTS has continued to host the Pathology Blueprint Programme to identify options for the future management structure of pathology services – including NIBTS – for Northern Ireland. In the past year, following a thorough appraisal of all options, the

Blueprint Programme Board approved the preferred option of a single pathology agency. The Programme team has then guided stakeholders to develop the design of the management structure as well as the initial target operating model for this agency. The recommended option has

now formed the basis of a business case to support Phase 2: transformation to the new structure. This business case was approved by Programme Board in October 2024 and will now be considered by the Department of Health before submission to the Health Minister for approval. Subject to this approval, and funding availability, transition to the new management structure will commence during 2025/26.

NIBTS implemented the new core LIMS, CliniSys WinPath Enterprise, bringing the service in line with regional laboratories. The contract for the Blood Production and Tracking (BPAT) solution was awarded in early 2024. This aims to implement a single Blood Production and Tracking System throughout the region. Work is ongoing with the system supplier on detailed design and testing. The system is due to go live in early 2026.