

Annual Quality Report 2022-23



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.



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 Licence

NIBTS is required to maintain a Blood Establishment Authorisation licence in order to continue to supply blood and blood products. In order to retain this licence, 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 2022/23. A further review of quality objectives will be undertaken during 2023/24.

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.

The use of the trending mechanism had during the 22/23 highlighted an increasing rate of minor faults within some items of equipment used during blood collections.



This in turn precipitated a process to implement a schedule for replacement of the impacted equipment with the replacement process now well advanced

Trending during 22/23 continued to highlight a further trend related to platelet product this being pH at end of shelf life.

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. Although no definitive root cause for this issue has been identified, a process has been implemented to manage this issue with greater efficacy while ensuring product losses are minimised.

A trend identified within the testing laboratories involving current results showing discrepancies with historical data has demonstrated an improvement in sensitivity associated with upgraded technologies and reagents .

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.

We recognise that change sometimes can be challenging. To minimise the risk and impact of change to staff, products or services NIBTS have established a Change Management Process which 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 2022/23 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.

During the 2022/23 period we continued to embed the risk assessment process for

those changes which do not meet their initial target date, implemented late 2022. This aimed to achieve a more thorough assessment of the residual risk to the organisation due to delays in implementation of planned changes and therefore better ability to assign additional resource where required. Review of the change management metrics indicates this objective has been met.

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

The organisations Investors in People team, which consists of staff from across departments and disciplines continues to meet and take forward a range of objectives including events aimed at staff wellbeing and improving cohesiveness.

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

During 2022/23, 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 remained under restrictions for a significant part of 2022/23 due to the continued risks associated with Covid infection. However, as social distancing

requirements eased, works within the estate were able to be completed towards the end of the financial year.

- Replacement of the flooring in the main processing lab was completed in late March.
- The main phone system was upgraded to include new SIP lines to accommodate the changeover from analogue to digital telephony systems.
- A new electronic stock management system was introduced in early January which



has greatly improved the ability of stores staff to monitor stock levels and manage the FIFO (First in First Out) system of stock issue.

- Minor refurbishment was completed in small number of offices.
- Other estates related works included a survey of all electrical outlets and boards. This has identified that there will be some work required in the near future, to upgrade the existing electrical boards for the building, to allow

for any further expansion of energy requiring systems

- An outdoor seating area was completed within the 22/23 year

which has allowed staff to enjoy lunch and tea breaks outside during periods of good weather.

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 is with regard to clinical expertise, laboratory, processing, communication or management skills however the provision of training was more limited than in previous years due to the restrictions imposed as a result of the Covid 19 pandemic.

During 2022/23, however, 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 2022/23 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 2022/23.

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 development review process during which training needs are identified. During the 2022/23 period 56% of staff were reviewed. This percentage remains below target. The organisation has

introduced a 12-month rolling cycle for SDR completion rather than April to March. The organisation will endeavour to improve their completion rates during 2023/24.

NIBTS aim to reduce staff absence rates both due to long term and short-term illness year on year. The absence rate target for 22/23 was to maintain or improve on >6.3%. The organisation absence rate at the end of 22/23 met this target with a figure of 6.08% achieved, we will continue to strive to improve in subsequent years.

Staff Health and Wellbeing

Allied to reducing staff absence is improving the health and wellbeing of our staff. During 2022/23, NIBTS participated in or ran a number of programmes aimed at improving staff wellbeing each month including:

- On your feet NIBTS
- Women's Health Week
- Seasonal Photograph Competitions
- Mental Health Awareness Week
- World Blood Donor Day
- Biomedical Scientist Day
- World Lollipop Day
- National Work Life Week
- World Menopause Month
- Movember Men's Health Awareness Month
- Christmas Tree Light turn on
- Christmas Jumper Day
- Christmas – Decorate your door competition
- Flu and Covid vaccination programme.

In addition, the organisation launched a new outdoor seating area for staff to use during breaks, promoted events including lunchtime walks run by the Belfast Trust Health

Improvement Team, Webinars hosted by Chest Heart & Stroke, talks from subjects ranging from podiatry to managing chronic pain and participated in several charity fundraising events such as he World's Biggest Coffee Morning.



Christmas door competition



Seasonal Photograph competition

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 maintain maintenance of the relevant licences, ISO 15189 accreditation and the

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

financial performance objective of breakeven. The service however struggled to maintain an adequate panel of blood donors to allow adequate collection of blood to meet demand from hospitals. This resulted in the need to import 4% of red cell blood components used from other UK blood services.

Covid 19 restrictions played some part in the difficulties experienced in collecting adequate blood donations notably the social distancing requirements limiting the number of bleeding stations feasible at session venues. These restrictions have now been lifted allowing more efficient use of the bleeding area space on session. Challenges were also encountered with the appointment system introduced during the covid pandemic, with donors experiencing difficulties contacting NIBTS to make appointments. To address this NIBTS have improved connectivity via the upgrade of the phone system and the progression of the implementation of an electronic booking system which can be directly accessed by the donor.

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.

During the early stages of the Covid 19 pandemic a number of amendments were made to the operational/administrative aspects of the Quality Management System to facilitate the ongoing operation of the service while maintaining

appropriate levels of quality, safety and regulatory compliance.

Some of these changes have now been discontinued however where they prove effective in streamlining process have been adopted as routine practice. The Document Control process has perhaps benefited most from these changes with reductions in the time required to progress a revised document to an issued and effective state. The ability to complete a number of transactions within the quality management system via remote access has also been retained to facilitate working from home arrangements.

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 met the target Key Performance Indicators throughout the year recording an improvement in the average number of days to issue a patient report and a marginal improvement in average percentage turnaround within a three-day period for patient report issue when comparing the average yearly figure between 2021/22 and 2022/23 time periods as follows:

Average number of days for report issue decreased from 1.71 days for 2021/22 to 1.69 days in 2022/23 a decrease in average reporting time of 0.02 days or 1.17 % improvement in time required to produce a report from the previous 2021/22-year period.

Average percentage turnaround of reports issued within three days exhibited a slight increase from 97.93% for 2021/22 to 98.49% for 2022/23, a 0.56% improvement.

Turnaround times for Antenatal Virology report issue continue to meet the set targets. 98.02% reports were issued within three days with a mean day for report issue of 2.01 days.

The NIBTS Reference Laboratory provides a valuable service to hospital blood banks completing complex investigations in red cell serology, platelet immunology and molecular immunohaematology 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

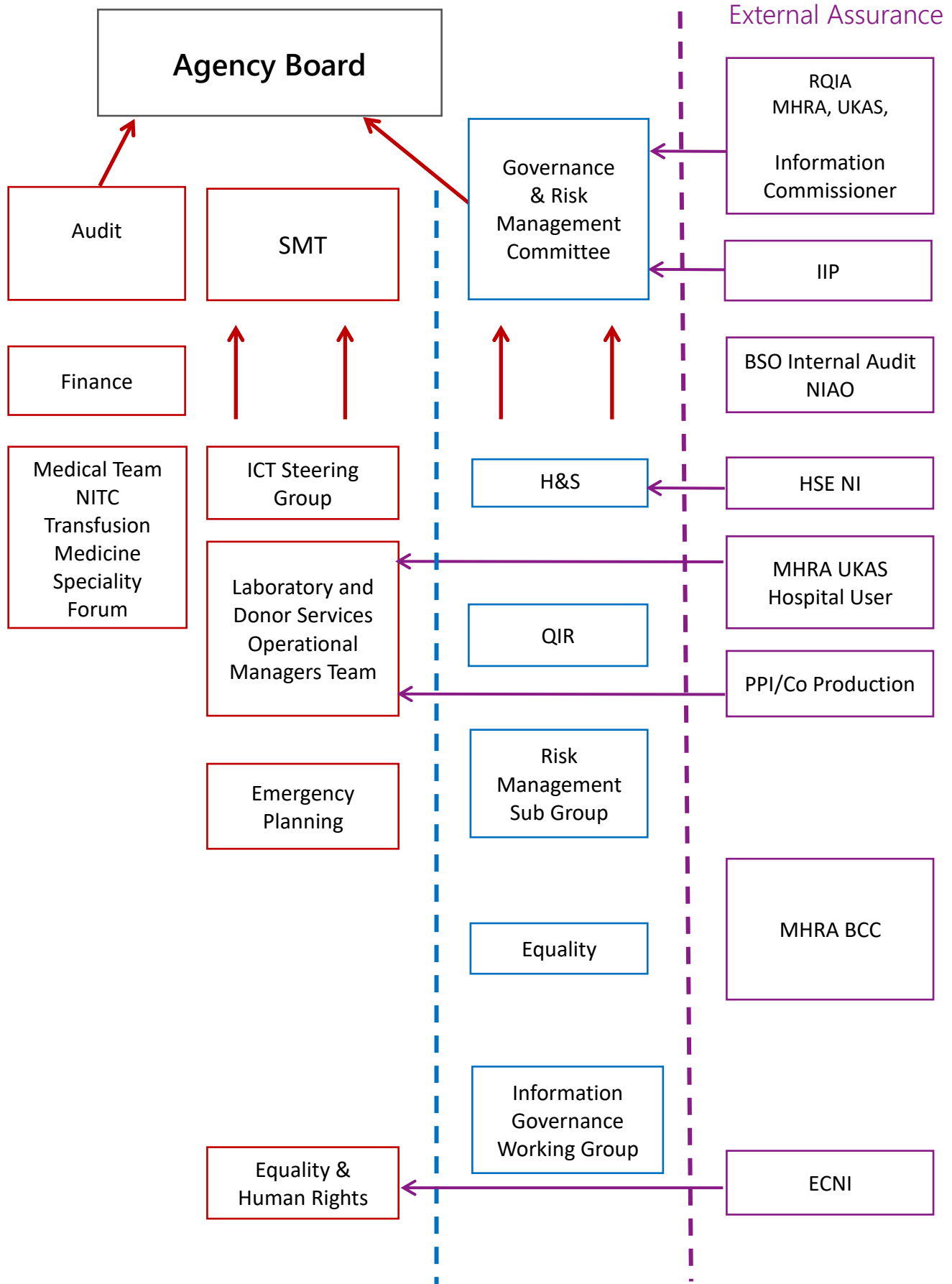
for report issue increased from 0.95 days for 2021/2022 to 1.11 days in 2022/2023 an increase in average reporting time of 0.16 days.

Average percentage turnaround of reports issued within three days decreased slightly from 99.79% for 2021/2022 to 99.08% for 2022/2023 reflecting a 0.71% 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 80.12% for 2021/2022 to 73.57% for 2022 / 2023 reflecting a 6.55% decrease in the percentage of reports issued within one day from the previous year.

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 35 internal audits were performed with no critical findings, one finding was classified as 'major', this initiated an investigation via a quality incident which determined the non-conformance had no adverse impact on patient/donor safety or product quality. Appropriate corrective/preventative actions were implemented.

External Regulation

NIBTS is subject to inspection by the Medicines and Healthcare Products Regulatory Agency (MHRA) and UKAS. An inspection by MHRA was carried out during August 2022 which confirmed NIBTS was operating to a satisfactory standard and confirmed maintenance of both the Blood Establishment Authorisation and Wholesale Distributors Licence.

NIBTS was subject to a re-inspection by UKAS during the 2020/21 period with subsequent confirmation that accreditation to ISO 15189 had been maintained, surveillance visits were due in January 2022 and January 2023 however were postponed by UKAS. Accreditation to ISO 15189 is however retained with a combined 22/23 surveillance visit scheduled for the latter half of 2023.

The 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 2022/23 period focused on embedding the risk assessment process for those changes which are not implemented within the original target dates set.

ISO 9001 Internal Auditor Training was delivered to a further 7 members of staff to allow expansion of the number of available auditors and allow maintenance of the internal audit schedule.

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 2022/23 the plan included audits covering Finance, Corporate Risk and Governance. The audits undertaken and the level of assurance provided Internal audit were: Financial Review (Satisfactory), Information Governance (Satisfactory), Management of

Medical Devices (Satisfactory) and Performance Management (Limited).

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.

In 2022/23, NIBTS participated in DoH accountability review meetings which were re established following an absence due to Covid-19.

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 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 to EU Regulations and Directives for the supply of blood and blood components.

The UK Forum identifies and shares 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 2022/23, the UK Forum has focussed on rebuilding services following the COVID pandemic and continuing to focus on engagement with the Infected Blood Inquiry.

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.

JPACs recommendations

As per JPACs recommendations, NIBTS have implemented the following significant change:

- To further reduce the risk of Hepatitis B entering the blood supply, all donors must now be screened for anti-Hepatitis B core antibody to identify Occult Hepatitis B (OBI). Testing was introduced on 30th May 2022. To date, no OBI donors have been identified in NI. NIBTS continue to progress the additional aspects of this project regarding identification of previous donations from donors who test positive for this test so as to co-ordinate a lookback exercise to identify any at risk recipients. The patient pathway for the lookback exercise is being addressed via a regional group chaired by NIBTS.

Key Achievements

NIBTS Laboratory Departments identify a series of quality objectives each year to improve service delivery/quality. The key Laboratory objectives/achievements for 22/23 are included in the following table:

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.

Department: Hospital Services

Activities	Key Achievements
<p>Preparation and manufacture of blood components</p> <p>Hospital issues department</p>	<ul style="list-style-type: none"> • Validation of the use of plasma filters on BAT packs (T4049) to maximise production of plasma products from red cell donations. • Replacment of flooring in the component preparation area. • Participation in irradiator audits (DAERA, CTSA and HSENI) with no non-compliances identified. • Decommissioning of a range of outdated equipment.

Department: Automated Serology

Activities	Key Achievements
<p>Blood grouping and antibody screening/identification of all blood donation samples</p> <p>Blood grouping and antibody screening/identification of all Antenatal patient samples including medical reporting of at-risk pregnancy results</p>	<ul style="list-style-type: none"> • Project on-going to automate high titre testing from blood serology analysers to NIBTS donor Laboratory Information Management System (LIMS) PULSE. • On-going equipment modernisation with installation of three validated cell washers and one validated double door refrigerator • Continued ongoing participation in pathology LIMS modernization projects i.e. Core LIMS WinPath for antenatal patients including ImmuLINK analysers interface and Blood production and tracking project (BPaT) for donors. • Participation in BMS specialist portfolio training

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 immunohaematology 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 compliment 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.
- Introduction of a new Luminex test platform in conjunction with a CE marked platelet antibody identification test has proved invaluable in identifying antibodies in thrombocytopenic patients.
- Participation in blood group reagent tenders is complete ensuring reagents are available at a competitive price.
- 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

- Mandatory upgrade to the Architect testing instruments to version 9.4.5 installed.
- Replacement programme for centrifuges used to process donor and patient samples commenced with one centrifuge replaced and validated.
- Qualification was completed on new tips on the Grifols Panther and Xpress Systems allowing continuity of NAT testing for HEV.
- Ongoing participation in IT projects (Core LIMS for patients and Blood production and tracking project (BPAT) for donors).

Department: Quality Control Laboratory

Activities

Quality monitoring of blood
components

Bacteriological testing of
platelet components

Environmental monitoring of
component production areas

Key Achievements

- Testing and support for qualification of production of Fresh Frozen Plasma product for BAT pack type.
- Support and testing for validation projects in other laboratory departments
- Installation and initiation of validation process for coagulometer
- Participation in Blood production and tracking project (BPAT)

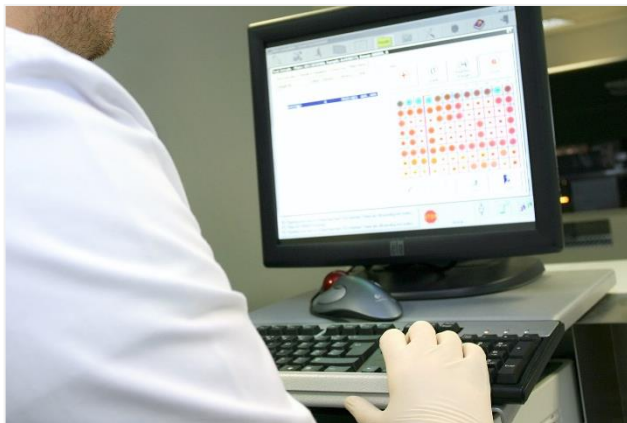
Donor Satisfaction

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% for 2022/23. We also record complaints from donors or members of the public to allow analysis,

investigation and improvement to the service. Donor complaints for this period were above our target of <4 per 10,000 donor attendances. A total of 27 complaints were received during 2022/23, NIBTS will strive to address this adverse trend within the 23/24 year.

Integrating the Care

The NIBTS medical team actively collaborate with the Northern Ireland Transfusion Committee (NITC) on an agreed programme of work. The work programme is derived from the clinical practice guideline issued by NICE referred to as NG 24.



Unfortunately, due to the Covid 19 pandemic and the retirement of the chair (July 2020) progression of projects initiated via this committee was limited during 21/22. A new chair (Dr David Millar) was however appointed last year and the NITC meetings have resumed. Full implementation of NG 24 in NI has now been agreed by the committee and this is currently being rolled out across the trusts.

NITC also conducted a regional audit on O RhD negative red blood cell use in November 2022 and have recently published the report with recommendations.

The NIBTS diagnostic screening laboratories have maintained accreditation from United Kingdom Accreditation Scheme for standard ISO 15189.

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, 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 currently being

held 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 2022/23 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 and work on standardizing categorization.
- Review/revision of quality management sections of Guidelines for Blood Transfusion Services within the UK in preparation for issue of new document.
- 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, Data Integrity and Validation subgroups include:

- Commonality in approaches to ensure data integrity.
- Collaboration and identification of best practice in area of validation.
- Collation and discussion of Quality Monitoring statistics from all the 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.
- Collation of and sharing approved supplier lists to demonstrate where services have common suppliers.
- Exploring the possibility of standardisation of the supplier questionnaire.

Northern Ireland Pathology Transformation

Throughout 2022/23, 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. This Programme has enabled pathology stakeholders to guide the

design of the management Blueprint and explore the different options for creating this structure. The recommended option was shared with the Department of Health in the summer of 2023. Subject to this recommendation receiving Ministerial approval, and funding availability, transition to the new management structure will commence during 2024/25.

NIBTS continue to participate 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.

Covid 19 Arrangements

NIBTS maintained 'business as usual' throughout the Covid 19 pandemic. This was been possible thanks to the co-operation and help from our donors and our staff. Department of Health and Public Health guidance was been noted and reviewed constantly throughout the pandemic with appropriate measures put in place to ensure compliance.

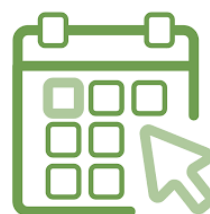
Several amendments to processes were made during the pandemic which have now either been discontinued or where these have proven beneficial integrated permanently into the organizational process with appropriate consideration of risk and control.

Lessons Learnt

The organisation has adapted and continues to adapt based on lessons learnt over the course of the pandemic.

Hybrid working arrangements for staff have continued where feasible and shown to be meeting the needs of the organization.

The appointment system for donors introduced to manage donor attendance times and facilitate social distancing has proven popular with donors and has been retained. Improvements to the



mechanisms for making appointments are underway with the implementation of an online booking system.

NIBTS continues to facilitate a number of meetings via Microsoft Teams to maximise the ability of staff to attend and promote communication.

As outlined previously some changes made within the Quality Management System during the pandemic have now

been adapted permanently notably the streamlining of the issue process for documents with electronic approval on Q Pulse now substituting the previous requirement for a wet signature on revised/new documents such as Standard Operating Procedures and Policies.

The pandemic also brought focus on the need to ensure that the organisation had in place robust business contingency arrangements and appropriate risk assessments. The need to challenge the arrangements in place to ensure robustness is an area of focus for 23/24.