



2021-22 Annual Quality Report

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 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 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.



The use of the trending mechanism had during the 20/21 had provided the opportunity to focus on product improvement involving an issue around improving the number of platelets within buffy coat derived pooled platelet product. NIBTS had identified several potential causal factors and working with the supplier of the processing equipment for this product, some programme changes

which provided encouraging results within the qualification stages of the project. During the 21/22 period the changes identified were made and embedded with significant improvements obtained with regard to product quality and consistency for buffy coat derived pooled platelet product.

Trending during 21/22 consolidated 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. Several actions have been identified and implemented and are currently being monitored to determine their effectiveness.

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 2021/22 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 2021/22 period we focused on the development and implementation of a risk assessment process for those changes which do not meet their initial target date. This was fully implemented in quarter 3 of the period allowing 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.

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 2021/22, we carried out user surveys for the patient testing and blood supply aspects of our organisation. Mindful of the restrictions imposed by the Covid 19 pandemic, we hosted the user meeting via Zoom which was well attended allowing valuable 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.

Additionally, a significant amount of work was carried out in improving the staff newsletter and encouraging input from staff members to promote ownership. This included the introduction of a competition for submission of the best spring, autumn, winter and summer photographs which has proven popular.

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.

Due to on-going restrictions as a result of the Covid 19 pandemic, refurbishment work throughout the estate during 2021/22 was greatly reduced for most of the year. NIBTS maintained measures put in place due to the Covid 19 pandemic to ensure staff were kept as safe as possible whilst working on the premises, including the use of protective screens, hand sanitising stations throughout each floor, re-designing office and other workspace to allow social distancing, and using previously designated meeting rooms, as staff break-out areas, to allow suitable socially distanced space for staff breaks.

Support staff continued making sure areas were kept clean with additional cleaning being done on touch points throughout the building and ensuring hand sanitisers were kept supplied.

Additionally, funding was secured to provide an outdoor seating area which staff can use during lunch and tea breaks. Work commenced on this project during the 21/22 financial year.

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 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 2021/22, 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 2021/22 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 2021/22.

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 2021/22 period 64% of staff were reviewed. This is an improvement in the percentage obtained during the previous year however 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 2022/23.

NIBTS aim to reduce staff absence rates both due to long term and short-term illness year on year. The absence rate target for 21/22 was to maintain or improve on >5.68%. The organisation absence rate at the end of 21/22 was 6.3% however 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 2021/22, NIBTS participated in or ran a number of programmes aimed at improving staff wellbeing each month including:

- Fresh Fruit January
- Knit and Natter knitting Class
- Love you Heart Week
- Employee Appreciation Day
- Start of Walking Group
- Nutrition and hydration week
- On your feet NIBTS
- Women's Health Week
- Mental Health Awareness Week
- National Work Life Week
- World Menopause Month throughout October
- Movember Men's Health Awareness Month
- Christmas Jumper Day
- Christmas – Decorate your door competition
- Flu and Covid vaccination programme.

In addition, the organisation has run several events to support charities including the World's Biggest Coffee Morning.

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 2021/22, the key aspects of NIBTS service objectives have been achieved. The service maintained an adequate panel of blood donors as well as collecting, testing, processing and issuing high quality blood components. In addition, the demand for blood components from hospitals was met, the various regulatory requirements delivered, relevant licences maintained and ISO 15189 accreditation maintained. The financial performance objective of breakeven was also achieved.

The ongoing Covid 19 pandemic continued to present some challenges in maintaining blood collections at an adequate level. NIBTS continued to avail of larger venue locations with the assistance of many community groups/leisure centres and schools throughout Northern Ireland to allow appropriate social distancing although after careful consideration a decision was taken to withdraw the triage system for donors prior to entering the donation venue.

Corporate Quality

During 2021/22 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.

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.

These changes were made with due consideration to any risk and progressed as appropriate through change management. The changes aimed to facilitate revised working patterns including working from home and to limit the need for direct staff contact and to a large extent have been maintained throughout the 21/22 period due to the ongoing restrictions.

Some of the above changes have proven effective in streamlining process and will be considered for permanent implementation during the 22/23 year.

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 KPI's for turnaround times throughout the year recording an improvement in the average number of days to produce a patient report but with a marginal decrease in average percentage turnaround for patient report issue when comparing the average yearly figure between 2020/21 and 2021/22 as follows:

Average number of days for report issue decreased from 1.72 days for 2020/21 to 1.71 days in 2021/22 a decrease in average reporting time of 0.1 days or 5.8 % improvement in time required to produce a report from the previous 2020/21-year period.

Average percentage turnaround of reports issued within three days exhibited a slight decrease from 97.96% for 2020/21 to 97.93 for 2021/22 a 0.03 % difference, resulting in a decrease in the percentage of reports issued within three days from the previous 2020/21-year period.

Turnaround times for Antenatal Virology report issue exceeded the set targets and improved on the previous year's figures. 98.23% reports were issued within three days with a mean day for report issue of 1.91 days.

The NIBTS Reference Laboratory provides a valuable service to hospital blood banks completing complex investigations as required. This area has seen a significant upturn in workload over recent years due to changing treatment regimes at hospital level presenting significant challenges in maintaining report turnaround time.

Average number of days for report issue increased from 0.60 days for 2020/2021 to 0.95 days in 2021/2022 an increase in average reporting time of 0.35 days.

Average percentage turnaround of reports issued within three days decreased slightly from 99.94% in 2020/2021 to 99.79% for 2021/2022 reflecting a 0.15% decrease in

the percentage of reports issued within three days from the previous year.

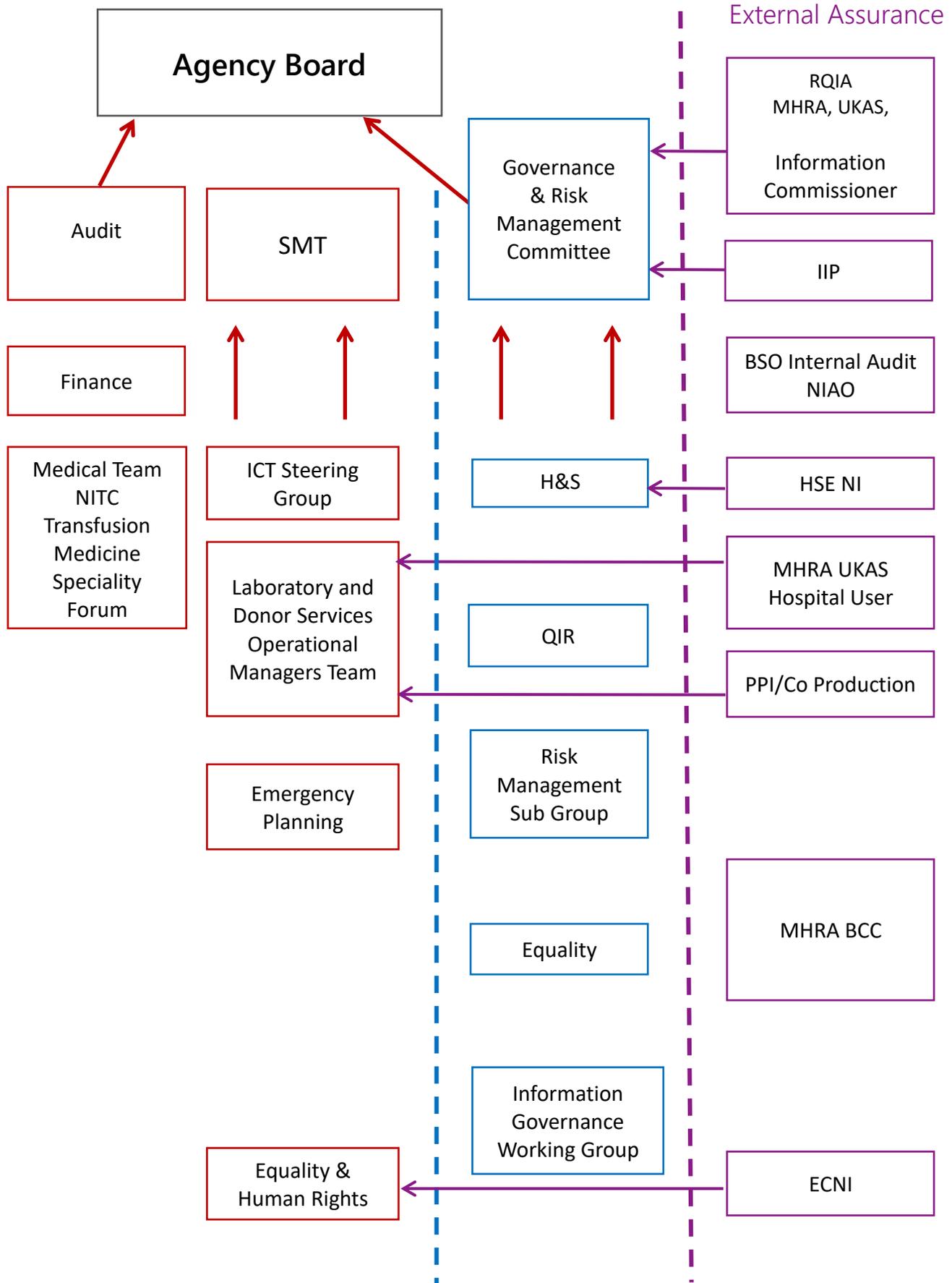
Average percentage turnaround of reports issued within one day decreased from 90.09% in 2020/2021 to 80.12% for 2021/2022 reflecting a 9.97% decrease in the percentage of reports issued within one day from the previous year.

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 2021/22 a total of 32 internal audits were performed with no critical or major findings identified.

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 June 2019 which confirmed NIBTS was operating to a satisfactory standard and confirmed maintenance of both the Blood Establishment Authorisation and Wholesale Distributors Licence.

A further audit was due in June 2021 however was postponed by MHRA due to Covid 19 pressures. NIBTS continue to maintain both licences. 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, a surveillance visit was due in January 2022 however was postponed by UKAS. Accreditation to ISO 15189 is however retained.

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 2021/22 period improved the process for change management by implementing a more effective system for risk assessing those changes which are not implemented within the original target dates set.

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 2021/22 this included Finance Audits, Corporate Risk Audits and Governance Audits. Audits in each of these areas received a satisfactory level of assurance based on the work undertaken by Internal 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.

In 2021/22, the usual DoH accountability review meetings (consisting of mid-year and year end accountability review meetings) were deferred due to Covid-19. These will resume in 2022/23 year.

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 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 2021/22, the UK Forum has continued to focus on maintaining services in the context of COVID as well as focusing 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 changes:

- 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).
- Following the FAIR (For the Assessment of Individualised Risk) steering group's recommendations and in line with the latest scientific evidence, blood donation has become more inclusive. More people could be eligible to donate blood based on their health, travel and sexual behaviour. The new guidance means donor eligibility is based solely on individual experiences, making the process fairer for everyone.
- Replacement of imported methylene blue treated frozen product for neonates with product produced from UK donors.

Key Achievements

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

All laboratory departments were involved in preparing for the changes in the EU Medical Device Regulations. This included both changes to some testing platforms and the sourcing and validation of CE marked reagents.

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">• Introduction of the Manufacture of neonatal FFP & Cryoprecipitate from NIBTS adult FFP to replace previously imported methylene blue treated product.• Validation and introduction of washed red cell product resuspended in Sag-M.• Validation and introduction of new platelet incubator/agitator.• Progression of changes to PULSE required to allow import of blood for the Irish Blood Transfusion Service.• Validation of new programme on G5 Compomat Equipment for production of Buffy Coat derived platelets in plasma.

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 and expand high titre testing from blood serology analysers to NIBTS donor Laboratory Information Management System (LIMS).• Evaluation of new donor High Titre assay ongoing• Optimised cut off values for donor genotype assays validated and installed in blood grouping instruments• Continued ongoing participation in pathology LIMS modernisation projects i.e. Core LIMS for patients and Blood production and tracking project (BPAT) for donors.• Two reagent refrigerators validated and installed.• New decontamination reagent and procedure validated and installed for decontamination of blood grouping instruments• Archiving to offsite company, donor and patient hardcopy documentation.

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.
- Successful validation & introduction of a second immunohaematology analyser to ensure timely processing of referred samples from hospital trusts.
- Continued automation of laboratory tests.
- Work initiated on numerous projects to ensure compliance with IVD regulations. New CE marked reagents and test platforms being introduced. A new CE marked molecular testing platform has been procured and successfully validated for Human Platelet Antigen typing & introduced to routine use.
- 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

- Installation of anti-HBc assay on the Architect instruments to test for the presence of Hepatitis B core antigen following a recommendation made by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) to test all donors at least once for the presence of Hepatitis B core antigen
- Completed an upgrade on the Cobas 6800 instrument which fixed some issues that had been encountered by users as well as making the instrument more user friendly

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 validation of Neonatal frozen product.
- Support and testing for validation projects in other laboratory departments
- Completion of tender process for coagulometer

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 2021/22. 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 22 complaints were received during 2021/22, decreasing by 14 when compared to the previous year. The high number of complaints in the previous year was attributed to complaints related to the pandemic.

We are a member of the Regional Forum for Personal and Public Involvement (PPI) which is central to the NIBTS programme of engagement with donors and service users. Unfortunately, no donor information events were held during 2021/22 due to restrictions related to the pandemic.

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 has been limited during 21/22. A new chair has recently been appointed and the NITC is due to resume on 21/10/22.

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 2021/22 include:

- Continued comparison of key performance indicators
- Comparison/discussion of external audit reports to facilitate shared learning.
- Monitoring the workstreams of the subgroups.
- Preparation for the implementation of the Medical Device Directives
- 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 and change management processes

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.
- Input to paper on Leucodepletion Specification Justification
- Review of SPC Tools for Quality Monitoring Data Analysis
- 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.

Covid 19 Arrangements

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

Several amendments to processes have been required due to the pandemic and are noted throughout the report. However, a summary of the actions taken during the pandemic to ensure continued service delivery at an appropriate level of quality and safety whilst safeguarding donors and patients is detailed below.

A series of risk assessments were completed to establish and mitigate risks to staff, donors and essential contractors as well as the operation of NIBTS during the pandemic. These risk assessments continue to be reviewed periodically in light of new information and guidance. Some measures put in place initially e.g. triage of donors and visitors to the building, removal of information leaflets from session have been withdrawn as a result of ongoing review of the risks and current guidance.

Home working arrangements were put in place for those members of staff who could complete their duties off site. This

included the provision of IT equipment and the amendment of some process to allow the submission of electronic documents and approvals rather than hard copies. Over time and in line with guidance issued by the Department of Health the percentage of staff working on site has increased with many staff now working a large percentage of their working hours on site and the remainder working remotely.

Hand hygiene arrangements were enhanced throughout the building with sanitiser made available at regular intervals and at entry/exit points.

Office spaces and other areas were assessed to determine the maximum number of individuals who could share the area while maintaining social distancing and this number indicated on the door to the area. NIBTS continue to apply where possible the two-meter rule for staff and the use of screens between working areas.

The use of fluid resistant masks was introduced in all shared areas of the building or where social distancing could not be continually maintained. This arrangement has been maintained throughout the 21/22 period.

Social distancing arrangements for donors and session staff were enhanced by:

- Introduction of donor appointments to better control the flow of donors
- Larger venues were sourced for donation sessions
- Larger vehicles were sourced to transport staff to the session venues

To ensure staff were able to keep in touch, Zoom continues to be used to facilitate meetings and provide a means for managers to keep in touch with staff working off site.

Lessons Learnt

The Covid 19 pandemic continued over the 21/22 period albeit with more knowledge becoming available with regard to the most likely routes for transmission and thus better ability to determine the risks associated with various activities combined with a high uptake of vaccines giving both staff and donors enhanced protection. The organisation continues to adapt based on lessons learnt over the course of the pandemic to date. The following details a number of 'lessons learnt' during the entire period of the pan.

Communication is vital to ensure effective implementation of agreed actions. This was one of the earliest lessons learnt. Traditional methods of delivering information were not fully effective especially in the early stages of the pandemic where change was occurring rapidly and frequently. This combined with changes in working patterns and the

A Covid 19 section was added to the NIBTS Intranet Site to provide a central point of information for staff.

Staff were offered the opportunity to be vaccinated against Covid 19 as part of the roll out of the vaccination programme for health care workers and it is anticipated that a similar arrangement will continue be provided for booster vaccinations.

lack of ability to communicate face to face with large numbers of staff at one time enforced the need to ensure the methods of communication being used were suitable for the type of communication and reached the appropriate staff.

NIBTS were able to adapt to a significant percentage of staff working remotely within a short time period of the pandemic beginning, although this did necessitate some changes to a number of processes, this was delivered in a controlled manner ensuring the continued safety and quality of product and services. A cohort of staff continue to work from home or via a blend of home and on site working during the 21/22 period. It is the intention of the organisation to revert to the majority of staff working on site during 22/23 although blended working arrangements will be considered for those staff who wish

to continue to avail of the opportunity to work remotely.

The pandemic necessitated change and for many of those changes to be within relatively short time periods. The need for the change to happen quickly encouraged co-operation between departments to assist with the various required actions and helped increased understanding of the roles each department plays in service delivery. Conversely the rate of change did raise levels of anxiety for some staff members again emphasising the need to ensure all staff were kept fully aware of all changes, the measures being taken to minimise risk to both staff and donors and the need to maintain contact with those

staff members primarily working from home

As more information became available regarding the transmission routes of the virus and the risk decreased due to better treatment options and the availability of vaccines the need to continually review working practices and processes has become more apparent to ensure continued delivery of an efficient service. The organisation has to this end continued to review the risks associated with Covid 19 and where appropriate amend or remove the measures put in place initially to mitigate the risks from Covid while still maintaining those considered necessary to protect staff, donors and visitors.