

Annual Quality Report 2020 - 21



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”

Four key values underpin the work NIBTS does. These are as follows:

- Working together
- Compassion
- Excellence
- Openness and Honesty

These values are supported by five key themes:

The following statements set out the vision and strategic direction for NIBTS based on these five themes.

1. **Safety & Quality**
2. **Continuous Improvement**
3. **People/Culture**
4. **Partnership and Engagement**
5. **Resources**

The corporate goals, service improvement plans for individual departments and individual staff development reviews are linked to these themes reflected in the five key strategic objectives:

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
- 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
- Develop and implement updated digital infrastructure

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 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

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 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
- Continue to develop the skills set of all staff
- Ensure Board composition is appropriate and quorate
- Engage with staff on the development of the annual business plan

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
- 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
- Support the Harvey's Gang charity

Resources

- Continue to deliver services within budget, focussing 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

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



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 2020/21. A further review of quality objectives will be undertaken during 2021/22.

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 has provided the opportunity to focus on product improvement during 20/21. This involves an issue around improving the number of platelets within buffy coat derived pooled platelet product. NIBTS have identified several potential causal factors and working with the supplier of the processing equipment for this product have identified some programme changes which are providing good results within the qualification stages of this project.

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 2020/21 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. The identification of risks associated with change or delay in implementing changes remain area of focus for the organisation during 20/21 and we intend to develop this area within the 21/22 year specifically for those changes which do not meet their initial target date.

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 2020/21, we carried out user surveys for the patient testing and blood supply aspects of our organisation. Unfortunately, due to the restrictions imposed by the Covid 19 pandemic, we were unable to host follow up user meetings after the completion of analysis

of the surveys. 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. Due to on-going restrictions as a result of the Covid 19 pandemic, refurbishment work throughout the estate during 2020/21 was greatly reduced for most of the year. NIBTS, however, carried out significant work to ensure staff were kept as safe as possible whilst working on the premises, including the introduction 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. In line with all healthcare facilities, we increased our stock of PPE (masks, visors, gloves, aprons, sanitiser, etc.) and issued

this to all staff as appropriate for their working environments. Our Stores staff worked hard to ensure that space was made available in the warehouse for this significant amount of additional stock, so that all departments could continue with their work throughout the pandemic. Our other teams of support staff, domestics, facilities, receptionists, porter, etc. are also to be commended for the work they did, to help maintain the working environment for everyone throughout this pandemic. Support staff were continuously on site throughout the year, making sure areas were kept clean, staff facilities were kept supplied with tea/coffee and other food/snacks for their breaks, additional cleaning was done on touch points throughout the building, hand sanitisers were kept supplied, dealing with increased volume of calls on the switchboard etc.

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 2020/21, 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**

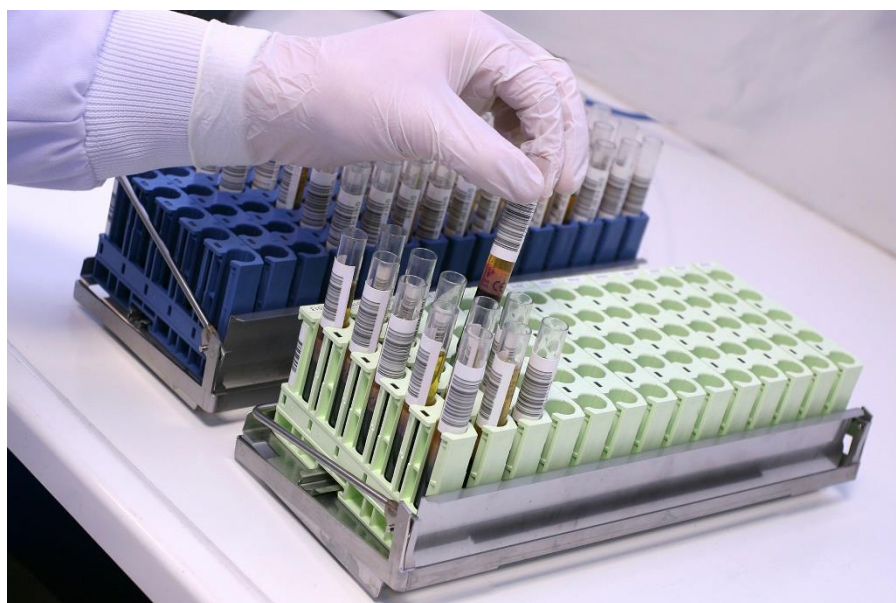
- 3. Good Manufacturing Practice**

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 2020/21 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 2020/21.



Our staff are required to participate in an annual staff development review process during which training needs are identified. During the 2020/21 period 58.4% of staff were reviewed. This is a significant reduction in the percentage obtained

during the previous years. The onset of the Covid 19 pandemic resulted in significant changes in working patterns including where possible staff working from home, split team working and some staff shielding all of which disrupted the ability to complete staff development reviews. Due to this change in work practice the organisation has made the decision to record SDR in a 12-month rolling cycle rather than April to March. The organisation will endeavour to improve their completion rates during 2021/22.

We strive to reduce staff absence rates both due to long term and short-term illness. The absence rate for 20/21 was > 6%. The organisation was able to meet this in 20/21 and strive to maintain or improve in subsequent years.

Allied to reducing staff absence is improving the health and wellbeing of our staff. During 2019/20, NIBTS participated in or ran a number of programmes aimed at improving staff wellbeing including:

- Stress Awareness Month
- Mental Health Awareness Week Biomedical Science day
- Fibromyalgia Awareness
- National Blood Cancer Awareness month
- National Cholesterol month
- World Menopause Day
- Movember Men's Health Awareness Month
- National work life week
- Breast Cancer Awareness month
- Cervical Cancer Prevention Week
- Time to Talk
- Flu Vaccination Programme
- Step up for 30 month
- Festival of Winter Walks

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 2020/21, 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 and implement a triage system for donors prior to entering the donation venue. Translink also provided assistance in supplying larger buses to safely transport staff to and from sessions.

Corporate Quality

During 2020/21 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.

The Covid 19 pandemic resulted in the need for some amendments to 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 have been maintained throughout the 20/21 period due to the ongoing restrictions. The changes included:

1. Amendment of the Document Control process to remove the need for wet signatures on new versions of hard copy documents such as policies and standard operating procedures. Staff were encouraged to reduce the number of hard copy documents issued where possible and the use of electronic documents encouraged.
2. The recall reconciliation process was amended to allow all paperwork to be scanned and e mail communications to be used as confirmation of completion of the process.
3. Internal audit schedule was reviewed and audits carried out remotely where possible or re-scheduled for a later date.
4. Amendments to the change management process to facilitate changes required due to Covid 19 which required rapid implementation
5. Minor amendments to the incident management process to allow acceptance of completed investigations submitted by e mail in place of hard copy documents.

Some of the above changes have proven effective in streamlining process and will be considered for permanent implementation post pandemic.

The incident management process was further developed during the period to provide greater capacity to monitor the progress of incident investigations and completion of identified corrective and/or preventative actions within the allocated target dates. This has facilitated the allocation of more appropriate time lines for completion of actions based on risk.

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 recording improvements in both metrics i.e. the average number of days to produce a patient report and average percentage turnaround for patient report issue when comparing the average yearly figure between 2019/20 and 2020/21 as follows:

Average number of days for report issue decreased from 1.85 days for 2019/20 to 1.72 days in 2020/21 a decrease in average reporting time of - 0.13 days or 7.03% improvement in time required to produce a report from the previous 2019/2020 year period.

Average percentage turnaround of reports issued within three days improved with a slight increase from 97.56% in 2019/20 to 97.96% for 2020/21 a 0.40% increase in the percentage of reports issued within three days from the previous 2019/2020 year period.

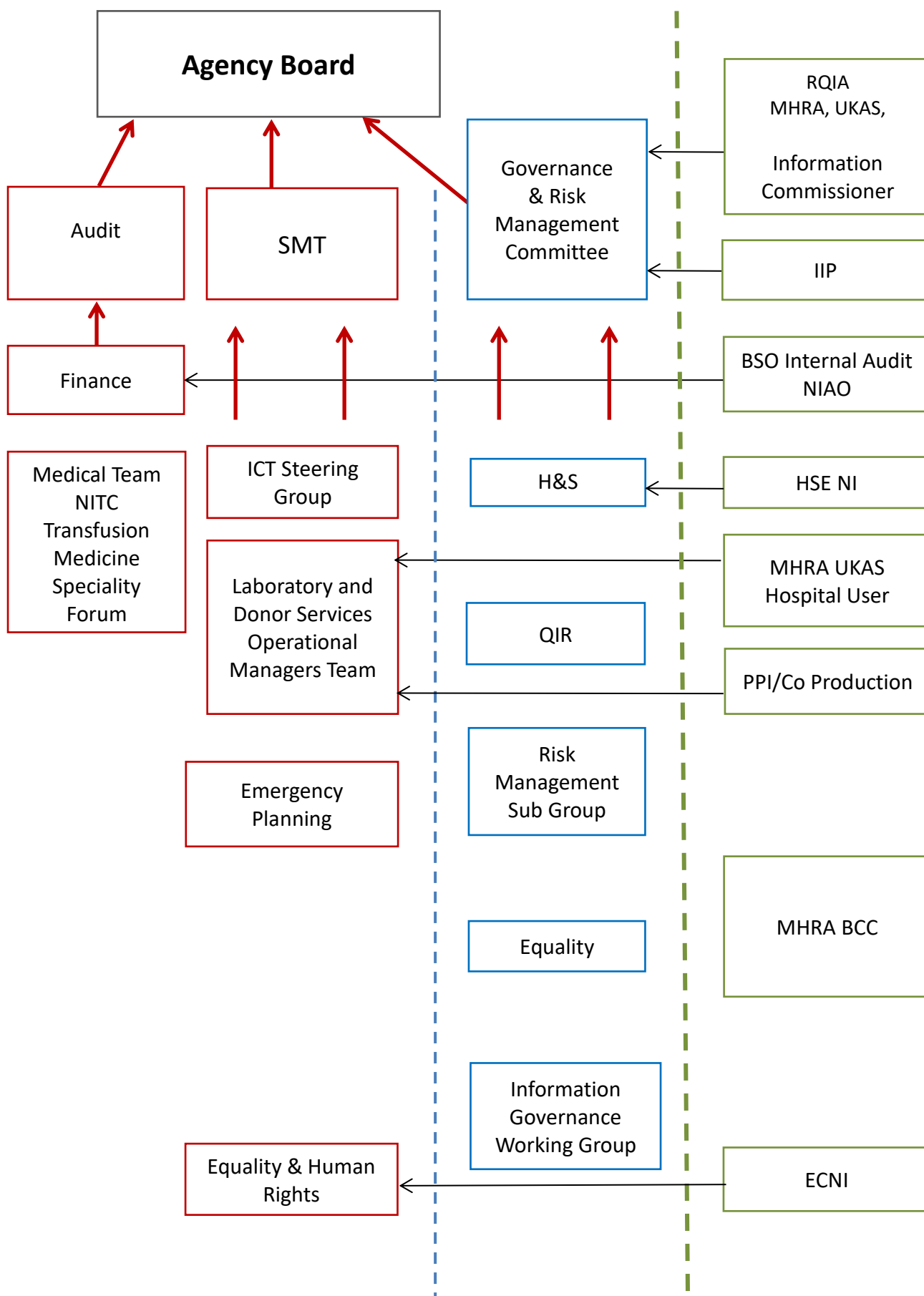
Turnaround times for Antenatal Virology report issue also exceeded the set targets and improved on the previous year's figures. 97.58% reports were issued within three days with a mean day for report issue of 2.10 days.

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 focussing 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

External Assurance



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 2020/21 a total of 30 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. 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.

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 2020/21 period improved the process for

incident management by implementing a more effective system for monitoring completion of investigation and corrective/preventative actions within the assigned timeframes.

NIBTS is also subject to audit by the Business Services Organisation Internal Audit function which completes an annual plan of work. During 2020/21 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 2020/21, the usual DoH accountability review meetings (consisting of mid-year and year end accountability review meetings) were deferred 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 will remain members of EBA post-Brexit.



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, the UK Forum has continued to focus on the impact of Brexit on blood components supply – particularly in relation to ongoing compliance with EU regulations in Northern Ireland. In addition, the Forum has collaborated closely to ensure business continuity in light of pressures linked to both the pandemic and EU Exit.

The UK Forum has continued to support and monitor the impact of the ongoing Infected Blood Inquiry as well as the Council of Europe European Directorate for the Quality of Medicines and Healthcare (EDQM) consultation on the revision of EU Directive 2002/98/EC which was translated in to the Blood Safety and Quality Regulations (BSQR) in the UK.

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.

The Northern Ireland Blood Transfusion Service medical team collaborates closely with the Northern Ireland Transfusion Committee and haemovigilance network however due to Covid 19 pressures the output of this group has been limited over the last year

Key Achievements

NIBTS undertook the replacement of the telephone system with one that will be ready to support the VOIP (Voice over Internet Protocol) system, once the major changes in analogue systems support come into effect, currently scheduled to end around 2025.

Significant work was completed in the Reference Laboratory to combine it with the Teaching laboratory to facilitate the introduction of new testing equipment and improve the facilities for carrying out reference testing to support local hospital blood banks.

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:

Department	Activities	Key Achievements
Hospital Services	<p>Preparation and manufacture of blood components</p> <p>Hospital issues department</p>	<p>Introduction of the manufacture of convalescent plasma from whole blood donations and Plasmapheresis collections for the treatment of Covid 19.</p> <p>Introduction of e-mail ordering for hospital blood banks placing blood component requests</p> <p>3-year expiry applied to all frozen products manufactured</p> <p>De commissioning of 8 x G4 Compomats</p> <p>Review of Pulse specs relating to hospital services procedures in preparation for Pulse upgrade v 23.4</p> <p>On-going participation with LIMS project development for Blood Production and Tracking BPaT.</p> <p>Validation of 3 x Panasonic cooled incubators and 3 x Terumo TSCDII Sterile connecting units for routine use.</p>

<p>Automated Serology</p>	<p>Blood grouping of all donations</p> <p>Blood grouping and antibody screening of all donations including medical reporting of at-risk pregnancy results</p>	<p>Project on-going to automate and expand high titre testing from blood serology analysers to NIBTS donor LIM.</p> <p>Continued ongoing participation in Pathology LIM modernisation projects i.e. Core LIMS for patients and Blood production and tracking project (BPAT) for donors.</p> <p>Two Gram reagent refrigerators installed, validated and operational and further two replacement Panasonic refrigerators at installation and operational qualification stage.</p> <p>Three Grant water baths installed, validated and operational.</p> <p>Electronic system of notification of rejected samples operational.</p> <p>External remote access to blood serology analysers via BSO software validated and operational.</p> <p>Participated in regional Coronavirus seroprevalence study and participation in an assessment of a next generation blood serology analyser.</p> <p>Maintained operational effectiveness during Coronavirus pandemic</p>
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Department	Activities	Key Achievements
<p>Blood Group Reference Laboratory</p>	<p>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. Provision of platelet antibody testing.</p>	<p>Continued training of staff for participation in the on-call rota and training of hospital lab staff and medical staff.</p> <p>Procurement of a second immunohaematology analyser to ensure timely processing of referred samples from hospital trusts.</p> <p>Continued automation of laboratory tests.</p> <p>Successful validation of Foetal Maternal Haemorrhage (FMH) estimation by flow cytometry with planned implementation during 2021.</p> <p>Ongoing participation in LIMS projects (Core LIMS for patients and Blood production and tracking project (BPAT) for donors).</p>

Department	Activities	Key Achievements
<p>Transfusion Microbiology Laboratory</p>	<p>Testing of all donations for infectious diseases markers</p> <p>Antenatal screening for infectious diseases in pregnancy</p>	<p>Successfully installed PCR test for Covid 19 on Roche Cobas 6800 instrument. Assisted Belfast Trust staff in the performance of testing of samples for Covid 19 and remain the contingency for this testing.</p> <p>Installation of SARS Cov-2 antibody test on Abbott Architect Analyser to evaluate its suitability for assessing plasma to be used as Convalescent plasma.</p> <p>Evaluated the Procleix SARS-CoV-2 Assay on the Grifols Panther instrument.</p> <p>Installed new HCV assay on Architect instruments to improve quality of testing.</p>
<p>Quality Control Laboratory</p>	<p>Quality monitoring of blood components</p> <p>Bacteriological testing of platelet components</p> <p>Environmental monitoring of component production areas</p>	<p>Completion of implementation of replacement haematology analyser.</p> <p>Completion of implementation of microbiological safety cabinet.</p> <p>Replacement of laboratory fridges.</p>

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 98% for 2020/21. 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 36 complaints were received which is an increase of 10 from the previous year. This increase 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 2020/21 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 20/21.

A patient information leaflet on consent for transfusion has however been completed with input from this committee and is available to the hospital Trusts on request,

The NIBTS diagnostic screening laboratories have maintained accreditation from United Kingdom Accreditation Scheme for standard ISO 15189 post completion of a re-inspection visit by this body.

During the early stages of the Covid 19 pandemic NIBTS worked closely with the Belfast Trust to install an PCR test for Covid 19 on Roche Cobas 6800 instrument to allow rapid expansion of the testing facilities. NIBTS assisted Belfast Trust staff in the performance of testing of samples for Covid 19 and remain the contingency for this testing.

The organisation also participated in a UK wide trial to establish if plasma collected from donors who had recovered from Covid 19 infection (convalescent plasma) could be successfully used in the treatment of this disease. NIBTS successfully established a programme for collection of this product both from whole blood and apheresis donors. Unfortunately, the trial did not demonstrate that the product provided significant benefit in the treatment of patients however further work is planned within the UK to look at the potential to use this product in the treatment of immunocompromised patients with the disease.

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 2020/21 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 Falsified Medicines Directive
- Preparation for the implementation of the Medical Device Directives
- Sharing of information for incident management and change management processes

The Quality Monitoring, Supplier Audit, Data Integrity and Validation subgroup's workstreams 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 specification limits for new edition of Guidelines for the Blood Transfusion Services in the UK and agreement of concessionary release limits compliance.
- Review of effectiveness of pH as a marker of platelet quality.
- Sharing supplier audits to reduce duplication of effort between services and collaboration in completion of audits.
- Shared training for lead auditors.

Covid 19 Arrangements and Lessons Learnt

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.

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.

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

A triage process was introduced for all visitors to the building including contractors and for donors attending donation sessions. This involved ascertaining the individual's temperature, ensuring they had not had/did have any symptoms associated with Covid 19 or had been in contact with others who had tested positive and ensuring they had sanitised their hands.

During the initial lockdown phase, staff in departments were split into teams to reduce the number of staff on site at any one time and to provide contingency should one team be impacted by the virus.

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.

The use of fluid resistant masks was introduced in all shared areas of the building or where social distancing could not be continually maintained.

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 is used to facilitate meetings and provide a means for managers to keep in touch with staff working off site. Daily meetings were held to update senior staff on any issues related to Covid initially with the frequency of these meetings reduced to twice weekly once the risks were established and appropriately mitigated.

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 be provided for booster vaccinations.

Lessons Learnt

The Covid 19 pandemic remains an ongoing concern and the organisation continues to adapt based on lessons learnt over the course of the pandemic to date. A full review of lessons learnt will be undertaken once the pandemic is no longer considered a significant threat. A number of 'lessons learnt' have been identified and are noted below.

Communication is vital to ensure effective implementation of agreed actions. While decisions regarding actions to take were generally made quickly, on occasion, the delivery of these actions was sometimes not as effective as it could have been due to staff being at home or off site at donation sessions.

Homeworking presented many challenges to the way we operate some of our processes and solutions to these were required quickly whilst ensuring these did not impact on product quality and safety. Such changes were delivered while meeting these criteria. A cohort of staff continue to work from home or via a blend of home and on site working with several benefits identified from this arrangement. NIBTS intend to consider maintaining a blend of home working and on-site working post pandemic.

Challenge can be a positive driver - the pandemic has shown that some pre-conceptions the organisation has held regarding the acceptability of changes to the way donation sessions are managed to both staff and donors were incorrect and the changes introduced have been well received and popular with both.

Change can also be a source of anxiety. Due to the changes required for Covid 19, many of our staff were required to make significant changes to working practices and patterns. This required high levels of co-operation from all staff and allowed the organisation to maintain full service. Some staff members however found and continue to find the increased anxiety around Covid 19 infection and the changes required challenging. This highlighted 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.