

Annual Quality Report 2018 - 19

Northern Ireland
BLOOD TRANSFUSION SERVICE



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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 mission statement:

“To collect, process and deliver high quality blood and blood products and appropriate advice to the HSC in Northern Ireland to the standard required by the Regulators”.

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

- Respect the altruistic values of donors
- Treat donors as we would wish to be treated ourselves
- Listen to complaints and suggestions and respond positively to those
- Listen to our colleagues and value their contribution

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. Donor and Patient Safety**
- 2. Maintenance of Licences**
- 3. Maintenance of supply of blood and blood products to the HSC**
- 4. Prudent use of public funds**
- 5. Developing staff to improve the service**

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:

- **Donor/ Patient** – Improving the donor/patient experience
- **People** – Engage, empower and encourage learning and development
- **Improvement** – Embedding a Culture of continuous improvement.
- **Quality** – Ensuring governance and compliance
- **Resources** – Improving performance and achieving excellent results.

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).

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/Quality
2. Strengthening the Workforce	People
3. Measuring the Improvement	Quality/Improvement/Resources
4. Raising the Standards	Donor/Patient/Improvement/Quality
5. Integrating the Care	Donor/Patient/Resources

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 2018/19. A further review of quality objectives will be undertaken during 2019/20.

Transforming the Culture



We recognise that key 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.

During 2018/19 we 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 these mechanisms during 2018/19 has allowed further progress to be made on a trend first identified in the previous year involving the efficacy of the process for obtaining information regarding donor travel which may impact on product safety. Focus on this area has resulted in several improvements in the mechanisms for obtaining the information, the ability of staff to interpret the information and the records kept for decisions made. This has resulted in a decrease in this incident type.

Trending has also highlighted some issues around the storage of platelet product which potentially could impact on product efficacy at end of shelf life. Collaboration with our colleagues in other UK Transfusion Services has confirmed the existence of similar issues throughout the UK with regard to neonatal platelet product and has identified some differences in collection volumes which may contribute to the trend at NIBTS for adult product. This trend investigation has resulted in adjustments to the shelf life for neonatal product at NIBTS. NIBTS have instigated a process to examine the volume to platelet ratio in adult apheresis platelet product to obtain further improvements in maintaining platelet function during storage.

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 2018/19 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 2019/20 period NIBTS plans to strengthen the current process for identification of risks associated with each change to allow more robust and risk based action plans to be developed.

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 on a regular basis and had taken forward a range of objectives including events aimed at staff well being and improving cohesiveness.

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

During 2018/19, we carried out user surveys for the patient testing and blood supply aspects of our organisation. Follow up user meetings after the completion of analysis of the surveys allowed opportunity for further discussion of potential service developments. Both the survey and meeting indicated high levels of satisfaction with the services provided.

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.

NIBTS in recognition 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 continue to progress a programme of improvement to offices and communal areas within the building.

Strengthening the Workforce

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

During 2018/19, 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

- 2. Induction for new staff** – a new package for staff induction has been designed with its introduction during the 2019/20 period planned

- 3. Capability Management training**

- 4. Internal Audit Training**

- 5. 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 2018/19 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 2018/19.

Our staff are required to participate in an annual staff development review process during which training needs are identified. During the 2018/19 period 90 % of staff were reviewed.

We strive to reduce staff absence rates both due to long term and short term illness. The 2018/19 was < 6%. However this target was not met due in part to a significant number of serious long-term illnesses.

Allied to reducing staff absence is improving the health and wellbeing of our staff. During 2018/19, NIBTS ran a number of programmes aimed at improving staff wellbeing including:

- Men's Health Week where we had visits from the following organisations:
 - Action on hearing loss
 - Aware – (suicide awareness organisation)
 - Stroke NI – formerly Chest, Heart and Stroke NI
 - Slimming world
 - Men's shed
 - Inspire
- Yoga Classes
- Flu Vaccination Programme
- Flower Arranging Class

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 2018/19, 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.



Corporate Quality

During 2018/19 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.

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 meet the target KPI 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 2017/18 and 2018/19 as follows:

Average number of days for report issue decreased. from 2.23 days for 2017/18 to 2.02 days in 2018/19 a decrease in reporting time of - 0.21 days or 9.42% improvement in time required to produce a report from the previous year.

Average percentage turnaround of reports issued within three days improved with a slight increase from 93.31% in 2017/18 to 96.44% for 2018/19 a 3.35% increase in the percentage of reports issued within three days from the previous year.

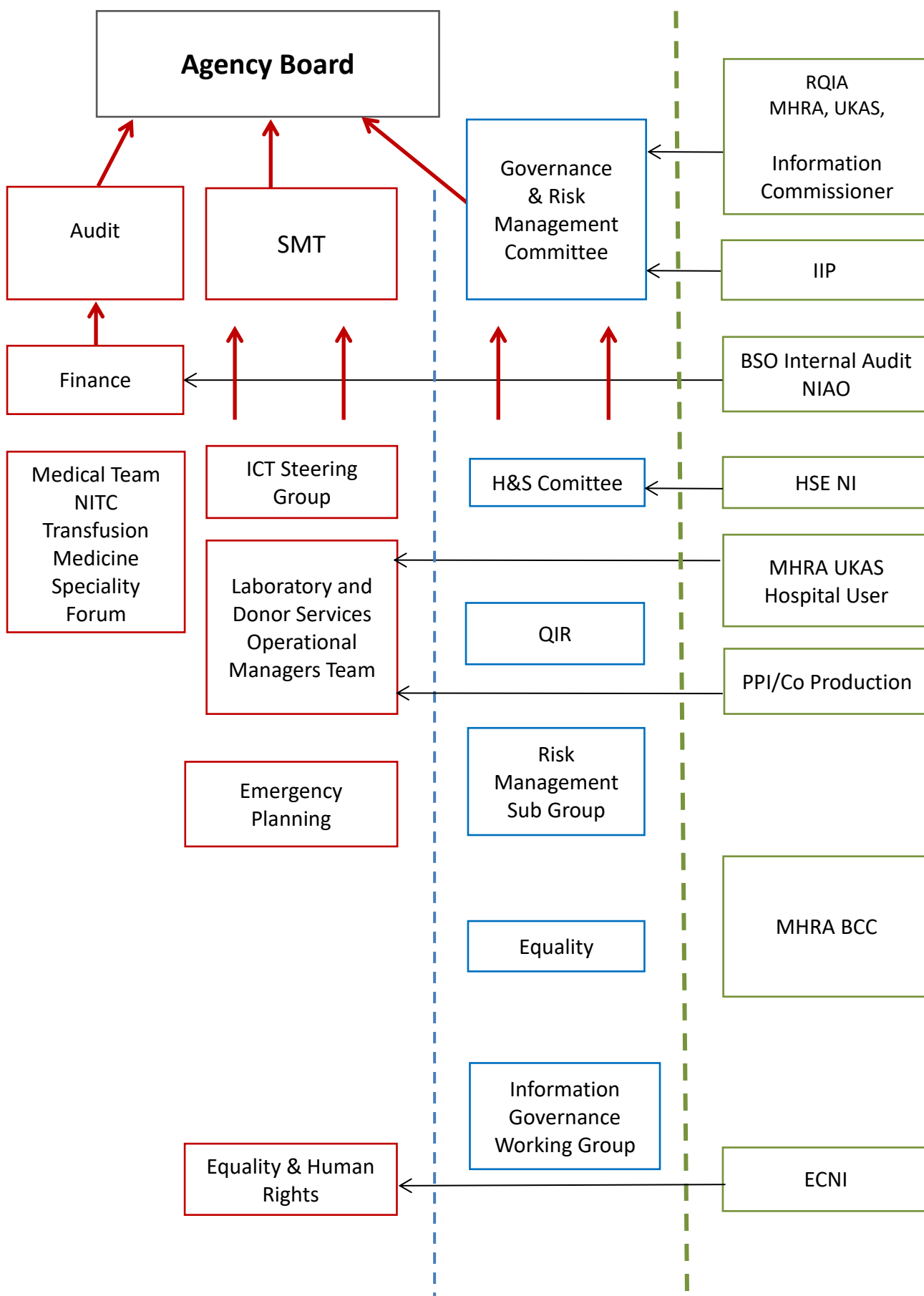
Turnaround times for Antenatal Virology report issue also exceeded the set targets and improved on the previous year's figures. 96.72% reports were issued within three days with a mean day for report issue of 2.20 days.

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 2018/19 a total of 78 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 surveillance visit by UKAS during the 2018/19 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 2018/19 period

strengthened process around equipment via the introduction of an annual equipment requalification process and continue to develop the change management process in line with the recommendations of the task and finish group formed to review this aspect of the QMS.

NIBTS is also subject to audit by the Business Services Organisation Internal Audit function which completes an annual plan of work. During 2018/19 this included Finance Audits, Corporate Risk Audits and Governance Audits. For all audits in each of these areas satisfactory assurance was reported. 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 2018/19, a Mid-Year Assurance Statement was completed for Department of Health (DoH). There were mid-year and end of year accountability review meetings with Department of Health, both of which had satisfactory outcomes.

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.



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

NIBTS is one of the four UK blood services that is part of the UK Forum of Blood

Establishments. The NIBTS Chief Executive chairs the UK Forum and holds the voting rights for the UK in the European Blood Alliance (EBA). EBA collects data from its alliance of blood establishments to populate a benchmarking scorecard which compares data for key processes within blood services as well as influences policy on blood collection and sharing best practice and experience.

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.

In 2019, the UK Forum has continued to focus on the impact of Brexit on blood components supply as well as the implications for the ongoing relationship with the EBA. In addition, NIBTS has collaborated closely with NHSBT to ensure continuation of supply should a mass casualty event occur.

The UK Forum has also supported and monitored 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 is 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 has focussed 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. Achievements in the last twelve months include further reductions in issues of blood components, standardisation of blood transfusion related documentation, and progress towards finalising a user specification for the proposed new regional laboratory information management system.

Key Achievements

NIBTS Laboratory Departments identify a series of quality objectives each year to improve service delivery/quality. The key Laboratory objectives/achievements for 2017/18 are included in the following table:

Department	Activities	Key Achievements
<p>Hospital Services</p>	<p>Preparation and manufacture of blood components</p> <p>Hospital issues department</p>	<p>Completion of EPG2 Phase 2 validation for new blood collection and storage packs.</p> <p>Movement of Intravenous and subcutaneous Immunoglobulins to Trust Pharmacies.</p> <p>Validation and introduction to routine use of new Irradiation indicator label.</p> <p>Continued training of staff for participation in on-call rota and expansion of competency assessments for Biomedical scientist and Medical Laboratory assistant staff.</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>Continuing modernisation of the Automated serology department facilitating reliability improvements and efficiency gains of reduced repair.</p> <p>Equipment replaced: refrigerators X2, waterbaths X3, and updating of a more efficient testing assay.</p> <p>Participation in Pathology LIM modernisation projects i.e. Core LIMS for patients and Blood production and tracking project (BPAT) for donors.</p>

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 on-call rota and training of hospital lab staff and medical staff.</p> <p>UKAS accreditation obtained for platelet antigen typing (HPA-1 & -5).</p> <p>In collaboration with Public Health Authority exploring potential to implement foetal Rh(D) typing by analysis of maternal cell-free foetal DNA routinely for Ante-natal patients.</p> <p>Ongoing verification of manual examination procedures to maintain UKAS compliance.</p> <p>Initiation of validation and implementation of new automated immunohaematology analyser. (BioRad IH-500)</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>Validation and implementation of Grifols platform for HEV screening for donors.</p> <p>Validation and implementation of Syphilis Assay.</p> <p>Software upgrade to Procleix Panther System. Participation and implementation in regional tender for sample tubes.</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>Validation and implementation of 2 x Flow Cytometers.</p> <p>Commencement of tender process for replacement of current haematology analyser.</p> <p>Exploration of solutions for retrieval of archived flow cytometry results.</p> <p>Software upgrade to Bacteriology Testing Systems.</p>

Donor Satisfaction

Donors give blood on a voluntary, non-remunerated basis and are critical to the success of our service. We have a system to record complaints from donors or members of the public to allow analysis, investigation and improvement to the service. We also record and monitor donor satisfaction levels with a 96% satisfaction level recorded for 2018/19 Donor complaints for this period were well below the target of <4 per 10,000 donor attendances (a total of 7 complaints were received).

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.



During 2018/19 we held two Donor Information evenings where donors were invited to attend. These evenings included presentations by the Chief Executive, senior staff and the launch of a new video showing the journey of blood from collection to issue.

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.

Key achievements in 2018/19 are detailed in the table below.

Project	Status
Current	
Single unit red cell transfusion	A regional survey of all red cell components transfused in the two week period beginning 27/02/17 confirmed 47% of transfusion episodes were administered as a single unit. Clinicians have been advised to transfuse one red cell unit in stable patients before reassessing the need for further units.
Transfusion trigger threshold for red cell transfusion	NITC invited clinical staff in early 2019 to participate in a consultation on the regional guidelines for the use of red cells, and in particular NG 24 recommendation for a transfusion trigger of 70g/L in stable patients. NITC are currently drafting updated regional guidelines for red cell transfusion on responses received.

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

We 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 either face to face or by 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 2018/19 include:

- Continued comparison of key performance indicators
- Comparison/discussion of external audit reports to facilitate shared learning.
- Monitoring the workstreams of the subgroups.
- Brexit Preparations

The Quality Monitoring, Supplier Audit, Data Integrity and Validation subgroup's workstreams include:

- Commonality in approaches to ensure data integrity.
- Collation and discussion of Quality Monitoring statistics from all the UK Blood Services.
- Review of specification limits/concessionary release
- Technologies in use for Quality Monitoring
- Agreement to share completed supplier audits and collaboration in completion of audits.
- Potential to standardise supplier approval processes