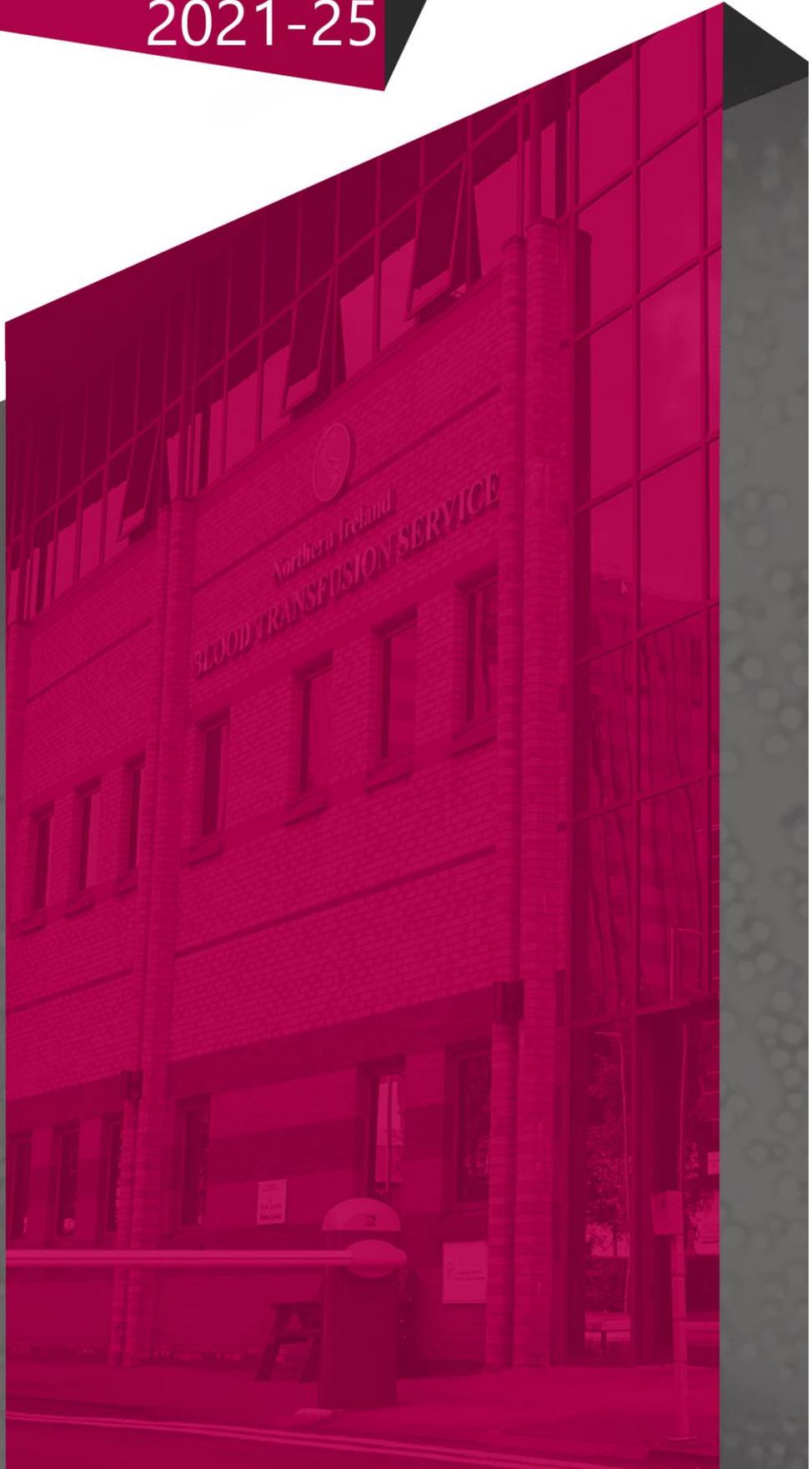


Corporate Plan

2021-25



Northern Ireland
Blood Transfusion Service



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1 INTRODUCTION

1.1 Background

The Northern Ireland Blood Transfusion Service (NIBTS) is the sole supplier of blood components and products to Health and Social Care bodies in Northern Ireland. All blood components prepared from donations are provided by voluntary, non-remunerated donors.

The statutory duties of NIBTS are set out in The Northern Ireland Blood Transfusion Service (Special Agency) (Establishment and Constitution) Order (Northern Ireland) 1994 and the subsequent Northern Ireland Blood Transfusion Service (Special Agency) Accounts and Financial Provision Direction (NI) 1995.

We hold a blood establishment authorisation licence from the MHRA which licences the collection, processing, storage, testing and distribution of blood components.

We also retain a wholesale distributor's licence for plasma products.

The Blood Safety and Quality Regulations (BSQR) 2005 (as amended) require adherence to good practice principles which are supported by a quality management system. We are committed to retaining these licences and maintaining a state of readiness for licensing inspection visits.

We also provide the regional antenatal testing programme and specialist immunohaematology support to hospital blood banks which are UKAS accredited to ISO 15189 standards.

In order to protect against the possible risk from variant Creutzfeldt-Jakob Disease (vCJD) in the UK population, since June 1998, UK Transfusion Services have been required to use imported plasma for the manufacture of plasma products. However, in late 2020, this guidance changed following a review of available evidence by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). Effective from December 2020, it is now possible to collect and use UK human plasma for the manufacture of medicinal products for UK patients.

We are currently working with the Department of Health in Northern Ireland and other UK blood services to explore how this change in guidance, might affect the collection strategy for Northern Ireland.

We will also consider the lessons learned from the COVID-19 pandemic as well as recommendations from the ongoing Infected Blood Inquiry in future business planning assumptions.

We have established Service Level Agreements (SLAs) with Northern Ireland hospital Trusts for the supply of whole blood and blood components.

In addition, we supply products used in the management of haemophilia patients that are funded by the HSC Board. There is also an SLA between NIBTS and the HSC Board for the provision of patient testing services including antenatal testing.

As with all organisations operating in Northern Ireland, we will continue to abide by all of its statutory responsibilities in relation to Equality and Human Rights as contained within Section 75 of the Northern Ireland Act (1998). We have developed an Equality Scheme which describes how we fulfil our duties required by Section 75.

1.2 Facilities and Services

We operate from our headquarters on the Belfast City Hospital site which incorporates:

- whole blood and plateletpheresis collection unit
- processing and testing laboratories
- donor administration
- medical team
- nursing team (which provides staff for headquarters and mobile donation units that collect blood around the eastern area of Northern Ireland)
- quality and regulatory compliance department incorporating the quality control laboratories and
- corporate functions including Finance and HR

Additionally, we have a satellite blood collection team based in Omagh. There is a donation facility in College Street, Belfast and a purpose-built BloodMobile Unit that supports the collection of blood across Northern Ireland.

During the COVID-19 pandemic, we have developed the capability to collect convalescent plasma by plasmapheresis for use in clinical trials. This knowledge could

be used in future for the collection of human plasma for the manufacture of medicinal products.

1.3 Our Purpose

Saving and improving lives by providing blood and testing services

1.4 Our Vision

Through our donors and staff, provide an outstanding blood service for the people of Northern Ireland

1.5 Our Values

These reflect the four values defined for all HSC organisations:

- Working Together
- Compassion
- Excellence
- Openness and Honesty

These values are reflected in the five key strategic themes detailed in the Board Assurance Framework:

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

2 STRATEGIC CONTEXT

2.1 Regional



At a strategic level, our objectives stem from the Northern Ireland Executive's Programme for Government (PfG). PfG for 2021/22 is yet to be finalised. However, we will be cognisant of the strategic outcomes contained within PfG and, where relevant, develop its strategic vision accordingly.

Additionally, the recommendations and actions flowing from Health and Wellbeing 2026: Delivering Together, as well as the Bengoa Report: Systems Not Structures – Changing Health and Social Care, of October 2016 will influence our strategic goals and ambition. In particular, proposals for modernising HSC Pathology Services highlight our pivotal role

and our unique regulatory environment within the HSC. A range of proposals for reform of pathology services are currently under consideration, pending consultation with stakeholders.

Mindful of the strategic changes outlined above and the potential outcomes for NIBTS, this Corporate Plan has been developed to ensure our aims and objectives for the next four years continue to support resilience and readiness for strategic change. This will ensure we continue to provide a safe, high quality service to patients – underpinned by regulators – and to further enhance our excellent reputation within the HSC and with the Northern Ireland public.

Financial challenges

Whilst the extent of funding available during this period is unclear, we are required to deliver services efficiently, ensuring value for money with maximum productivity. As a consequence, we will develop a number of work streams to support these objectives which will be agreed with the HSCB and DoH.

2.2 Blood Transfusion Environment

We must maintain two licences and one accreditation:

- The Medicines and Healthcare products Regulatory Agency
 - Blood Establishment Authorisation
 - Wholesale Dealers Licence
- UK Accreditation to ISO 15189 standards for NIBTS diagnostic screening laboratories.

We are also subject to inspection by the Regulation and Quality Improvement Authority (RQIA) which also assesses compliance with IRMR regulations.

In addition, we are required to ensure we retain Investors in People accreditation.

We are a member of the UK Forum of blood establishments with the blood establishments of England, Scotland of Wales. We also maintain post Brexit membership of the European Blood Alliance which includes the blood establishments of EU member states as well as Iceland, Norway and Switzerland. These alliances provide opportunities to share best practice, innovations and benchmarking information to ensure that NIBTS continues to provide the best possible products and services to the population of Northern Ireland.

2.3 Blood Stocks and Supply to Hospital Blood Banks

Demand for red cell components has reduced in the past three years but is expected to plateau in the coming years due increased elective surgery capacity to support the post-COVID recovery as well an increasingly complex demographic.



The main reason for recent reductions in demand is the changes to clinical practice following NICE guideline NG24 which is recommending minimal transfusion at higher transfusion thresholds. There are a number of target patient groups such as haemato oncology and patients with acute

upper gastrointestinal haemorrhage where further reductions in red cell transfusions might be possible.

Ongoing liaison with Trust transfusion committees and the Northern Ireland Transfusion Committee will focus on the appropriate use of O negative red cells and reduction of wastage across the supply chain. Both of these will be supported by the implementation of a new Blood Production and Tracking digital system which will enable visibility of blood donations from donor vein to patient vein. All of which will further support the self-sufficiency of the Northern Ireland supply chain reducing reliance on other UK and Irish blood services for top up of supply.

The wider transformation of pathology services will enable improved logistics which, in turn, will enable the introduction of scheduled deliveries.

2.3.1 Projected Demand

| Financial Year | Red Cell Components Issued |
|----------------|----------------------------|
| 2021/22 | 41,000 |
| 2022/23 | 41,000 |
| 2023/24 | 41,000 |
| 2024/25 | 41,000 |

The situation for platelet components is more fluid and expected increases in the last three years have not materialised. It is therefore anticipated that demand will increase by around 2.5% year on year over the next four years

Clinical practice guidelines and audit activity with action plans for continued improvement have optimised appropriate use. For example, historically, multiple unit platelet transfusions accounted for 30% of transfusion episodes but this has reduced to 10%.

The patient demographic, the increasing incidence, earlier diagnosis and more intense treatment protocols for cancer illnesses will still impact demand. The effect of delayed diagnosis and treatment due to the pandemic is difficult to predict at present. Indications are that there will be an increase in demand and this will be closely monitored to ensure the collection strategy reflects this. With these caveats in mind, projections for the medium term are given in the table below.

| Financial Year | Platelet Components Issued |
|----------------|----------------------------|
| 2021/22 | 8,250 |
| 2022/23 | 8,456 |
| 2023/24 | 8,668 |
| 2024/25 | 8,884 |

Estimates for frozen components issued are given in the table below.

| Financial Year | Fresh Frozen Plasma Components Issued |
|----------------|---------------------------------------|
| 2021/22 | 3,675 |
| 2022/23 | 3,675 |
| 2023/24 | 3,675 |
| 2024/25 | 3,675 |

| Financial Year | Pooled Cryoprecipitate Components Issued |
|----------------|--|
| 2021/22 | 900 |
| 2022/23 | 900 |
| 2023/24 | 900 |
| 2024/25 | 900 |

2.4 New Developments

2.4.1 Plasma for Fractionation (PFF)

As detailed previously, the change in guidelines for the collection of UK plasma are being assessed in collaboration with DoHNI to establish whether the collection of PFF in Northern Ireland is feasible.

2.4.2 Collection Strategy

COVID 19 presented significant challenges for the collection of blood and platelets. These led to the introduction of a new appointments system, triage and increased distancing between donation couches requiring larger venues for sessions. The legacy

of these changes needs to be assessed and will affect the future NIBTS collection strategy.

2.4.3 Clinical Transfusion Practice and Haemovigilance

Our medical team continues to work collaboratively with the Northern Ireland Transfusion Committee and other key stakeholders in haemovigilance, hospital blood banks and medical specialties.

We are part of the Northern Ireland Transfusion Committee (NITC) which has developed a work stream to implement NICE guideline NG24.

These recommendations have the potential to assist in the appropriate management of red cell and platelet component demand.

The next four years will see a number of new developments in transfusion practice including the introduction of individualised donor risk assessments, plans for an updated digital blood production and tracking system that will enable donor vein to patient vein tracking of donations through a single system as well as the potential to implement foetal RHD screening to support maternity services across Northern Ireland.

We will continue to support hospital colleagues with transfusion advice and intend developing this support as additional medical staff are recruited.

We will also continue to work with Medical colleagues across the UK through the UK Forum of blood establishments as well as active participation in the Joint Professional Advisory Committee (JPAC).

2.4.4 Infrastructure

In order to continue to deliver a transfusion service that meets the regulatory compliance requirements of BSQR (2005), it is essential that the physical infrastructure for NIBTS meets the requisite standards. The existing NIBTS headquarters building was commissioned in 1995 and is now the oldest blood centre in the UK and Ireland. As the building and infrastructure ages, it is becoming increasingly difficult to meet compliance standards. As a result, we will evaluate options for upgrading and providing laboratory and collection facilities for Northern Ireland.

2.4.5 Laboratories

The technology supporting safe transfusions continues to evolve. We will continue to evaluate emerging technologies – including molecular - that support automated serology, reference, microbiology and quality laboratories to ensure that the platforms we use meet the required standards.

Together with colleagues in hospitals, we will develop a training programme for staff in hospital blood banks that will reduce reliance on the regional reference laboratory.

We will also continue to support the Harvey's Gang charity providing opportunities for young people and their families to see behind the scenes what happens in our laboratories and testing facilities.

3 STRATEGIC OBJECTIVES

This section sets out the key developments and improvements expected by us over the next four years against each of the five strategic themes. The financial context for the next four years is also referenced.

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

Partnership & 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

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

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



4 Glossary

Buffy coat platelets: The buffy coat is the fraction of anticoagulated blood that contains most of the white blood cells and platelets following density gradient centrifugation of the blood. The buffy coat of four whole blood donors can be combined to produce a buffy coat platelet component for patient use.

Foetal genotyping: Blood test to predict the blood group status of foetuses at risk from haemolytic disease of the foetus and newborn (HDFN).

Haemochromatosis: An inherited condition in which iron levels in the body slowly build up over many years.

Hepatitis E Virus (HEV): Hepatitis E is a viral hepatitis caused by infection with a virus called hepatitis E virus. It is one of five known human hepatitis viruses: A, B, C, D, and E. HEV is a single-stranded non-enveloped RNA virus. Principally it has a faecal-oral transmission route, but can be transmitted via blood transfusion and organ transplantation.

NICE guideline NG24: National Institute for Health and Care Excellence is an executive non-departmental public body of the Department of Health in the United Kingdom. This guideline (NG 24) covers the assessment for and management of blood transfusions in adults, young people and children over 1 year old.

Platelets: Also called thrombocytes, are a component of blood whose function is to stop bleeding by clumping and clotting blood vessel injuries.

Variant Creutzfeldt-Jakob Disease (vCJD): Rare and fatal human neurodegenerative condition which is classified as a Transmissible Spongiform Encephalopathy (TSE) because of its ability to be transmitted and the characteristic spongy degeneration of the brain that it causes.