

DEVELOPING A CENTRE OF EXCELLENCE

A Model of Care for
Transfusion Medicine
and Associated Consultant
Resources in the Irish
Blood Transfusion Service
2023 to 2027



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Executive Summary

Traditionally, the requirements for a national blood transfusion service have been to deliver high quality blood components and high quality laboratory services and to secure a sufficient donor pool. Now, transfusion medicine is developing rapidly. Donor safety is a key driver of activity and all possible measures must be taken to ensure donor care. Advances in transfusion science have significantly increased laboratory requirements and services as personalised medicine and care have evolved. Testing is no longer only a matter of matching ABO and Rh blood groups - “personalised medicine” also involves extended antigen matching. The high level of international travel that is now possible and the increasingly complex social interactions imposes an on-going threat of transfusion transmitted infection, despite excellent screening programmes. Therefore, testing requirements and novel agents requiring additional screening must be constantly monitored and improved. The spectrum of blood components in use continues to increase, as whole blood and cold stored platelets are now widely used in the western world. The need for plasma to produce immunoglobulin's is also increasing every year.

Consequently, transfusion practice is constantly changing— patient blood management is a growing field that focuses on sustaining a safe blood supply and avoiding unnecessary transfusions. The increasing stem cell transplantation activities are requiring increasingly more donations from the Unrelated Bone Marrow Registries. Tissue banking and cellular therapies are expanding and modern blood services are now expected to deliver relevant supporting services. Activities within clinical research and education are also evolving and expanding, including international multicentre studies.

Context and Drivers for the Development of a Model of Care

For the first time in its existence the IBTS has developed a model of care for transfusion services. It has done so against the backdrop of an evolving transfusion landscape as described above, but also out of necessity. The IBTS is the only body with statutory responsibility for the provision of safe blood and blood and tissue products in the Republic of Ireland. As such, it is incumbent on the IBTS to be seen as a centre for excellence in the Irish health system. Developing a model of care and associated consultant resources will support the expansion of services, greater integration and collaboration with acute hospitals and third levels institutions and ultimately safeguard and future proof all aspects of the medical service from “vein to vein”.

Drivers for change are also evident in the population.

Irish demographic trends illustrate that the population is now over 5 million, which is the highest census figure on record since 1841 (CSO, 2022). Greater inward migration has increased population diversity and consequently, the transfusion needs of the population. Ireland also has an aging population with different transfusion requirements and increased demands for services. These demographic trends underpin the necessity for the IBTS to invest in and grow a diverse donor pool and develop services that can meet the changing needs of the population now and into the future.



The Model of Care (MOC) presented in this document has been designed to enable the expansion of current transfusion medicine services, donor care, patient services, screening and research development and facilitate the introduction of new services in component development and cellular therapies. To support the medical MOC and IBTS strategic ambitions, a modest increase in the current consultant workforce is necessary.

Appropriate consultant resourcing is fundamental in ensuring that robust clinical governance is in place, especially as services are expanding. It will also ensure that single points of dependency are eliminated as much as possible. Finally, the increased consultant resources will address longstanding deficits and allow for future planning including succession planning.

Over the next 5 years we are looking forward together to support better healthcare. Subsequent improvement plans will be undertaken that relate to current medical, scientific and nursing substructures. It is acknowledged that the medical MOC does not operate in isolation and can only be effective with the close collaborative working of the multidisciplinary team in the IBTS. The supporting medical, scientific and nursing workforce structures are not in scope in terms of this MOC document however, a review of the supporting structures will form part of a separate piece of work. Supporting scientific structures are also outside the scope of the report, as are the on call arrangements.

Fundamentally, this Medical MOC will ensure that the IBTS will be able to meet the needs of Irish patients now and into the future.

High Level Recommendations

The development of this MOC acknowledges the core principles of the IBTS, in working as “ONE IBTS”, in valuing the expertise of all IBTS centres, and the collaborative efforts of our people and all of our clinical disciplines working in the organisation.

The IBTS recognises the need to invest in the future of Transfusion Medicine and Transfusion Medicine Specialists. This is demonstrated by demographic trends, advancements and challenges in clinical service provision, succession planning and the need to create new consultant positions to meet current and future transfusion medicine needs across consultant clinical services and governance in the organisation’s centres. The future will be transformative in Transfusion, with the evolution in cellular therapies and blood transfusion. Thus, a diverse and sustainable medical team is essential to support forthcoming innovations and research in the IBTS and to provide clinical collaborations with hospital and industry partners.

Current States

The current IBTS medical MOC supports a variety of transfusion medicine services (Figure 1). There is a current medical consultant headcount of 7 people, with an established 5.3 Whole Time Equivalent (WTE) with a regional on call responsibility for patient care. Because of natural attrition and with on-going challenges attracting specialist medical staff there is a constant requirement for active workforce and succession planning.

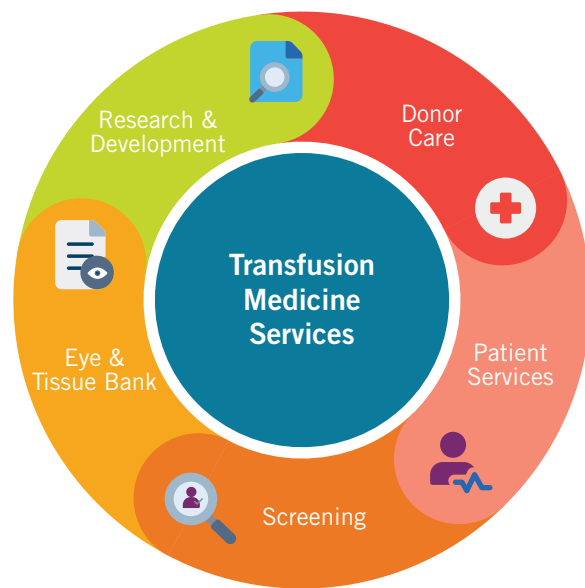


Figure 1. Current Medical Services

See Appendix A for further breakdown of current consultant workforce.

Future State

As a nation with a rapidly growing diverse population, there is a direct increase in the numbers of patients with high transfusion needs. The proposed medical MOC is necessary to support and sustain donor and patient healthcare now and into the future taking into consideration the demographic shift. It is also designed to future-proof the medical leadership and succession plan requirements for the organisation, in the context of evolving novel therapies requiring the support of Blood Establishments and Transfusion specialists.

It creates a robust clinical resource plan that addresses medical resource deficits, and reduces the risk of single points of dependency. Therefore, to support the emerging developments in Transfusion Medicine services in Ireland the proposed

MOC expands the remit of transfusion medicine services provided by the IBTS, promotes a partnership approach with our hospital partners and the HSE, advances a national on-call responsibility for patient care and modestly increases the consultant workforce (Figure 2).

This medical MOC proposes increasing the establishment from 5.3 WTE* to 8.4 WTE on a phased basis, with the consultant workforce headcount increasing from 7 to 12.

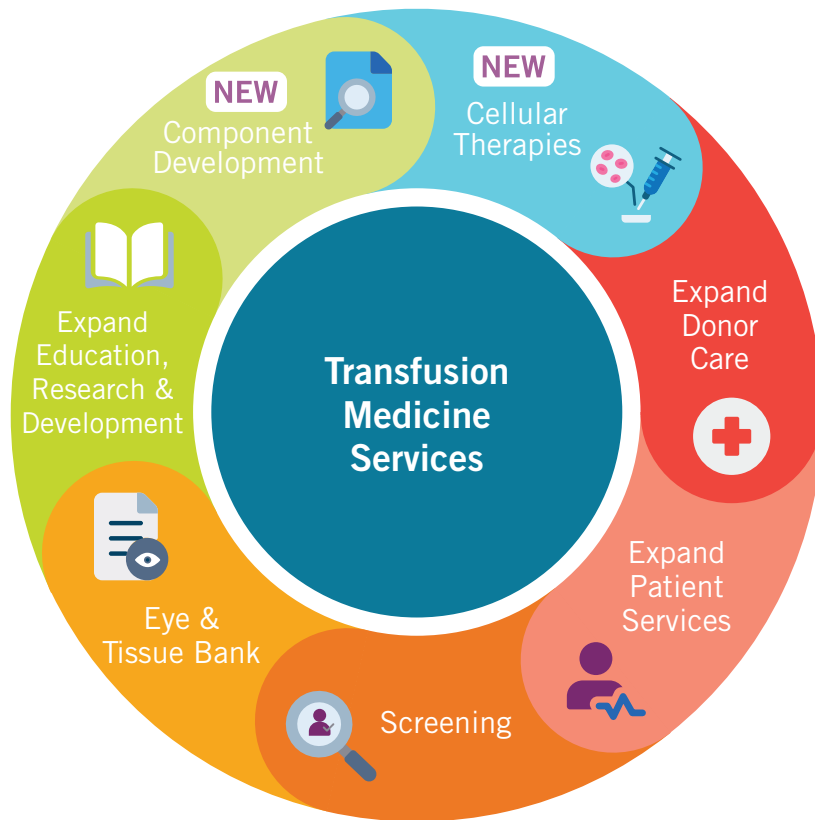


Figure 2. Future State Transfusion Services

*See Appendix A for note on HSE CLA component on one post and further breakdown of future consultant workforce

Importantly, the proposed WTE will include joint posts funded from hospital partners and the HSE.

Introduction

The Irish Blood Transfusion Service (IBTS) is a national organisation with statutory responsibility for collecting, processing, testing and distributing blood and blood products in Ireland. It relies completely on the generosity of voluntary non-remunerated donors to provide sufficient donations to ensure a consistent supply of blood and blood products to patients. It is a critical part of modern health care and provides blood, blood components and blood products for patients.

The functions of the IBTS are set out in Statutory Instrument No. 78 of 1965, Statutory Instrument No. 209 of 1988 and Statutory Instrument No. 22 of 2000 and are as follows:

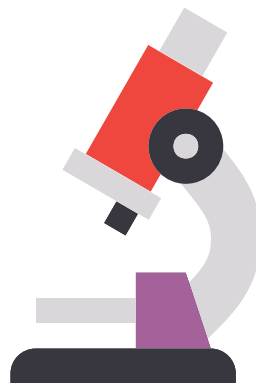
to organise and administer a blood transfusion service including the processing or supply of blood derivatives or other blood products, and also including blood group and other tests in relation to specimens of blood received by the Board;

- to make available blood and blood products;
- to make available equipment or reagents suitable for use in relation to the service;
- to make such charges (if any) as the Board thinks fit, for the services referred to above and, where the Minister gives any direction in relation to such charges, to comply with such direction;
- to furnish advice, information and assistance in relation to any aspect of the service to the Minister, any health authority or any hospital authority;
- to make any necessary provision for publicity in relation to the service;

- to organise, provide, assist or encourage research and the training and teaching of persons in matters relating to blood transfusion and preparation of blood products;
- to cooperate with other bodies with analogous scientific functions;
- to organise and administer a service for obtaining and assessing reports of unexpected or undesirable effects of transfusion of blood or blood components made available by the Board including the furnishing to the Health Products Regulatory Authority of reports of any unexpected or undesirable effects of transfusion of such blood or blood components;
- to organise and administer an eye banking service.

The IBTS has been assigned additional functions under EU Directives in the field of the quality and safety of blood and blood components including:

- to test, process, preserve, store and distribute human tissues and cells, as the Service thinks fit, subject to the provisions of the European Communities (Quality and Safety of Human Tissues and Cells) Regulations, 2006 (S.I. No. 158 of 2006) and EC (Quality and Safety of Human Blood and Blood Components) Regulations 2005 (SI 360 of 2005).



Background

In 2000, the responsible body for consultant appointments at the time, Comhairle na nOspidéal, reported a consultant establishment of 5 Haematologists in the IBTS and 17 Haematologists in clinical posts in Ireland. Since then, across Ireland there has been a steady increase in Consultant Haematologist posts in the HSE to support the development and specialisation in the field. (Comhairle na nOspidéal Consultant staffing, January 2000).

The IBTS is regulated as a Blood Establishment (BE) by the Health Products Regulatory Authority (HPRA) and hospital transfusion laboratories are mandated to be accredited to ISO 15189, as inspected by the Irish National Accreditation Board (INAB), a delegated function from the HPRA. All IBTS consultants have a requirement for BE expertise as a core competency as it applies to their area/s of specialty. This uniquely regulated healthcare service is delivered to patients and donors. A multidisciplinary team approach, crossing clinical specialties and healthcare professions, is required for the delivery of a safe and sustainable transfusion service from the IBTS.

Transfusion Expertise and Required Competencies

Transfusion medicine, a subspecialty of Clinical & Laboratory Haematology, within the Faculty of Pathology, is delivered to patients at a national, regional and hospital level. In addition, each blood and tissue establishment (B&TE) requires consultant expertise for optimum donor recruitment, selection and care, component/tissue preparation, with microbiologist expertise to inform and provide governance for best practice in transfusion associated microbiological risk minimization.

Transfusion medicine is a broad discipline that includes areas of expertise that vary from the acute hospital sector to the IBTS. Areas of consultant medical expertise required for transfusion health care delivery includes:

- Blood Establishment (BE)
- Tissue Establishment (Eye Bank and Tissue Bank)
- Blood Supply and distribution management
- Bone marrow registry (IUBMR)
- Component processing and development
- Donation procurement
- Donation/donor/component testing, release and associated consultations and referral
- Microbiology risk and Emerging Infectious Disease surveillance
- Donor selection, welfare and vigilance
- Environmental monitoring
- Histocompatibility and immunogenetics
- Immunohaematology
- Optimum clinical application of blood components
- Therapeutic apheresis
- Transfusion associated adverse reactions and events - haemovigilance (and biovigilance)
- Transfusion associated pathogen risk management (lookback and traceback)
- Consultative Transfusion Medicine service for Irish Hospitals
- Teaching and Mentorship of Non-Consultant Doctors in training
- IBTS legacy special projects
- Clinical Transfusion Practice
- Patient blood management
- National and International Representation for Ireland at Transfusion regulatory directorates



Consultants BE competencies include:

- Regulatory activities for substances of human origin (SoHO) - accreditation (including role of deputy responsible person)
- Inspection
- Donor/tissue selection and testing for release for human use
- Investigation of transfusion adverse events implicating components/tissue issued
- Managing within a quality management framework including risk assessment, validation, incident reports, investigation and management, controlled change, Corrective and Preventative Actions (CAPA), participation in external quality assessment schemes etc.

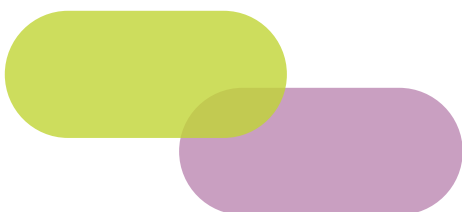


Guiding Principles

The IBTS consultant group are aligned with the principles and vision set out in the IBTS Strategic plan and developed a series of core principles to inform the development of this MOC.

‘Connections that Count - providing excellent blood and tissue services that improve patients’ lives through the generosity of our donors, the expertise of our people and in collaboration with the healthcare community’.

- Alignment to the statutory functions of the IBTS - including associated ‘bodies’ (e.g., National Haemovigilance Office (NHO)) and transfusion policy service developments within a regulated quality framework of ‘One IBTS’. Key focus on sustainability of safe supply while ensuring optimum quality service to donors, patients and specialist healthcare colleagues with minimum risk. Addressing a reduction in donation and transfusion associated morbidity. Recognising a sustainable and patient matched donor base requires a focus on diversity and inclusion.
- Alignment with IBTS strategic plan ‘Connections that Count’ - building relationships with HSE model 4 and specialist hospitals and bodies of analogous function (e.g., National IVirus Reference Lab (NVRL)) through shared posts and active engagement with overarching transfusion committees (OTCs), among others. To be recognised as a centre of excellence and a resource of national expertise in transfusion medicine.
- Alignment to national principles of medical service delivery in Ireland e.g. consultant delivered service supported by non-consultant medical staff, scientists and specialist nursing staff in partnership with patients (and donors for IBTS).
- Active engagement in education, research and development, with a clinical audit programme (in addition to GMP audit). Alignment with the National Doctors Training and Planning (NDTP), professional bodies and societies to attract future consultant talent. Grow collaborations with academic institutions.
- Alignment with principles of sustainability - Consultant resourcing to match service needs and demands with the elimination of single points of dependency. Supporting flexible working practices and promoting engagement with a national on-call service. Shared posts to be at a minimum 50% IBTS based with consultant haematologists contributing to IBTS on-call.
- Alignment with current and future healthcare service developments – Adapting and evolving as advancements occur while promoting the IBTS as a centre of Transfusion Excellence.
- Alignment with Medical and Scientific Director (MSD)/consultant special interests and international developments in transfusion medicine, organisations and societies, notwithstanding the indicative roles and responsibilities set out in the proposed model.



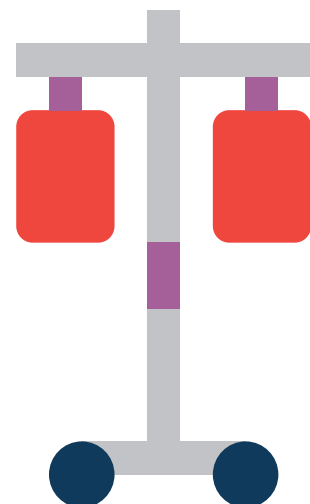
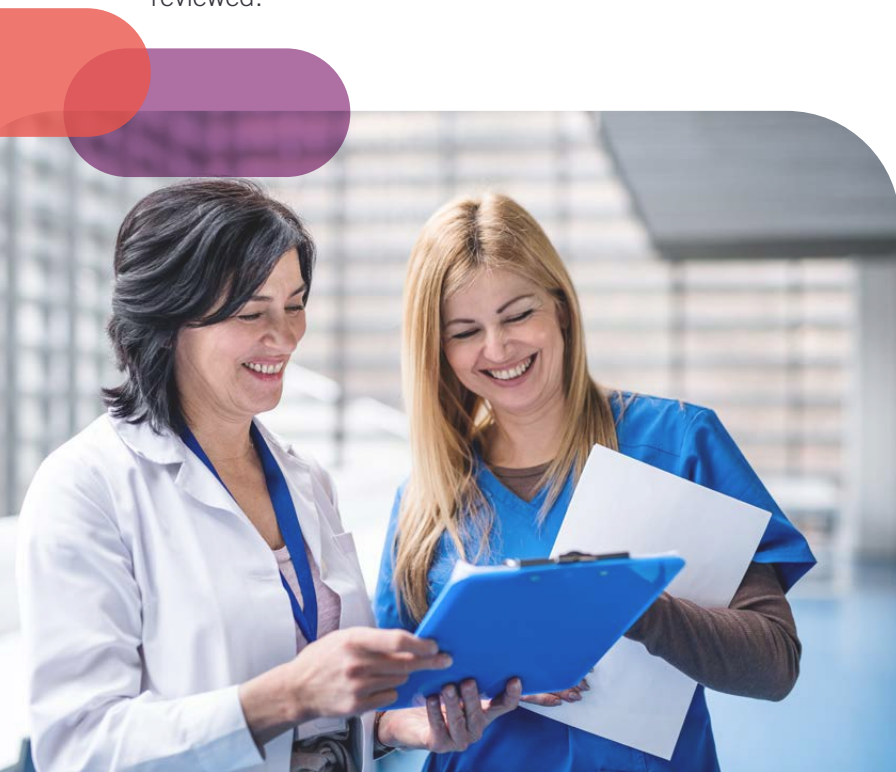
Approach and Methodology

Known as experts in the field of transfusion medicine the IBTS medical consultants have undertaken to design and develop their first MOC for the IBTS to meet future demands. The primary purpose of the development phase was to gather evidence, assess the current Consultant workforce, identify gaps and identify future service needs. The culmination of this analysis informed the recommendations that are presented within for an appropriate and future focused consultant workforce addressing current challenges and plans for future service demands.

The methodology employed in the development of this MOC is adapted from the HSE “Model of Care Development Guidance Framework” guidelines (National Clinical Strategy and Programmes, under the office of the Chief Clinical Officer (CCO), HSE), Other published Model of care documents, including ‘A National Model of Care for Paediatric Healthcare Services’ and a surgical specialty model were also reviewed.

A benchmarking survey tool was also developed and distributed by the IBTS consultants through the European Blood Alliance (EBA). International benchmarking was challenged by the difference in Blood Service and Hospital Transfusion Team (HTT) professional structures.

External facilitation was procured and IBTS consultants and stakeholders held a number of interactive workshops to assess the current state, identify gaps, identify future service needs and design the optimum future state. The approval process will follow the established IBTS governance pathway that includes the Executive Management Team (EMT), Medical and Scientific Advisory Committee (MSAC, a sub-committee of the IBTS Board), Board and Department of Health. The support of key stakeholders is fundamental to timely and successful implementation.



Benchmarking

The consultants' group noted the output from a review of several European and North American transfusion services by Dr Ó Donghaile in 2016 that there was marked variability in comparison with Ireland's health care demand, Blood Transfusion Service configuration, medical/consultant and other professional roles. Further inquiry in 2021/2022 to Nordic Blood Services and Sanquin in the Netherlands showed similar results. It is evident from the benchmarking exercises that there is no 'international best practice' standard or 'one size fits all' solution and clinical governance is handled differently across Blood Establishments (NHS National Services Scotland, Welsh Blood Service, Belgian Red Cross and the Finnish Red Cross).

In the UK, there are several bone marrow registries. These include blood service based but also organisations whose sole purpose is to work in the area of blood stem cells, as does the Anthony Nolan Trust.

The most relevant comparator is the Scottish National Blood Transfusion Service (SNBTS). SNBTS is a strategic business unit of NHS National Services Scotland. The SNBTS clinical services include blood banking - routine and reference, histocompatibility and immunogenetics, stem cells, therapeutic apheresis and other specialist services. SNBTS is the preferred provider of tissues for Scotland including bone, tendons, heart valves and skin and stem cell services.

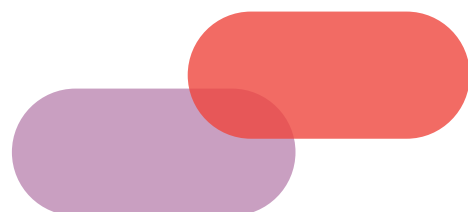
SNBTS shares important similarities to the IBTS as follows:

- Similarity in population served
- Components issued (2021)
- Consultants in pathology disciplines in Scotland and Ireland share training pathways and exit training examinations recognised by the Irish Medical Council for specialty registration

- Quality framework within the SNBTS is comparable at this point to the IBTS as it is currently derived from the same EU Directives, with the Medicines and Healthcare products Regulatory Agency (MHRA) as the regulatory oversight body
- Clinical services are delivered through a multi-centre model

While many service demands and developments are comparable, unlike the Irish environment there is significant additional supporting medical resource external to SNBTS. This includes:

- The UK Forum, the Forum's Joint Professional Advisory Committee (JPAC), which publishes the 'Red Book' of transfusion guidelines and operates the UK wide change notice system.
- The Advisory Committee on the Safety of Blood Tissue and Organs (SaBTO) standing advisory committees, including SACTTI, SAC-parasite, SAC-BACTeriology, and SAC-TISSUE, which inform Scottish microbiological blood and tissue safety.
- UK Health Security Agency (replacing Public Health Scotland) government agency responsible for public health protection and infectious disease capability. NHSBT collaborates with the HSA Epidemiology Unit in relation to transfusion related microbiology/epidemiology.
- SHOT the UK wide Serious Hazards of Transfusion, is a significant external resource managing the haemovigilance system.



Current State

Patients' healthcare in acute hospitals across Ireland is heavily dependent on sufficiency of safe transfusion supply. Where supply is restricted, as recently experienced during the SARS-Co-V2 pandemic, hospital activity may be limited in a pre-planned way to prioritise patient transfusion on a 'criticality of need' basis. This ensures equity of access to transfusion for patients across the country. The Irish Healthcare system is also dependent on therapeutic patient testing and services delivered by the IBTS.

External Context

Drivers of change include the following:

- **Sustainability of the blood supply** - This has the dual requirement of reducing demand by more appropriate clinical application (Patient Blood Management (PBM) and significantly widening the donor base to meet the increasing diverse supply requirements.
- **Sustainability of consultant posts** - Recognising the importance for the IBTS to be attractive for new consultants including having a clinical dimension, and access to research.
- **Threat of emerging infectious diseases (EID)**, changes to transfusion-associated risk for known infectious diseases (IDs) and rationalisation of testing strategies.
- Increasing international focus on **donor welfare and reducing donor harm incidents**.
- **Learning from haemovigilance** by capturing relevant incidents, expert data analysis and development of quality improvement programs in partnership with the HSE/private hospitals.
- Requirement to **further develop expertise** in clinical areas of specialty - neonatology, obstetrics, intensive care, pre-hospital care etc.
- **Demographics** – upward trends in the age profile of the Irish population, the ethnicity of the population and the overall population are driving expansion of the donor pool to meet patient needs. Shortages in universal donor group O RhD negative blood in recent years has resulted due to population needs changing.
- **Developments in transfusion medicine and technology** – e.g. pathogen reduction technologies (PRT); procurement of Irish donor plasma for plasma derived and recombinant human plasma proteins; component developments, developments in bone marrow registries and cellular therapies; advances in molecular testing (possible now for most blood cell antigens), next generation sequencing (NGS) approaches targeting HLA, HNA, HPA and RBC genes.
- **Requirement for (big) data procurement and analysis** e.g., screen/portal to HIPE (hospital in-patient enquiry), to inform practice trends and cycle of national and local audits of transfusion practice – proposal to NOCA from Clinical Lead Advisor (CLA) in line with UK 'National Comparative Audit' program.
- **Health Service Reform/Service Reconfiguration/Government Policy** - development of national guidelines and standards via the National Transfusion Advisory Group (NTAG) to ensure equity of access for patients across the country, partnering quality improvement plans to reduce inappropriate transfusion, patient harm incidents as reported to the NHO, additional engagement in research and closer engagement with hospital services.
- **Regulation and Accreditation** – requirement to extend ISO accreditation across patient testing services. In addition, we anticipate regulation and inspection of clinical transfusion activity (current legislation laboratory focused) and evolution of European Directives.

There have been numerous recent developments in the field of transfusion medicine with many Health Services identifying a need to tackle the challenges faced by blood establishments, such as those outlined above. The UK transfusion service National Health Service Blood and Tissue (NHSBT) and the National Blood Transfusion Committee (NBTC) developed a 5-year plan for clinical and laboratory transfusion in England “Transfusion 2024”, from a multi-professional symposium in March 2019 supported by NHS England and Improvement (Allard S, 2021).

The Royal College of Pathologists have noted a vacancy rate of >9% for haematology positions currently, and a 6% retirement in the coming 5 years in the UK. These positions support some 200 hospital transfusion laboratories. This trend is mirrored in Ireland and action is being taken by a number of Healthcare institutions to tackle this challenge.

In Ireland, the Faculty of Pathology, as the responsible training body, is collaborating with HSE National Doctors Training and Planning (NDTP) and clinical programme for Pathology, to develop a medical workforce plan for all the specialties of pathology. This project is looking at the supply and demand of consultant pathologists out to 2035, to inform intake of trainees to Higher Specialist Training (HST). The number of Pathology trainees had only grown from 108 to 113 between 2015 and 2020 (HSE). The IBTS haematology and microbiology specialties are included in this project.

Similarly, a pathology staffing project is being undertaken by the National Health and Social Care Professions Office as a national strategy to inform laboratory medicine. This was established by the CCO and has an independent chair. The focus is on acute hospital laboratories. There are representatives from all the stakeholder groups including the NCP Pathology and Faculty. The IBTS consultants are engaging in the Faculty/NDTP process. This process will align IBTS applications to CAAC with the national process in relation to consultant staffing.

Internal Context

Current Delivery Model

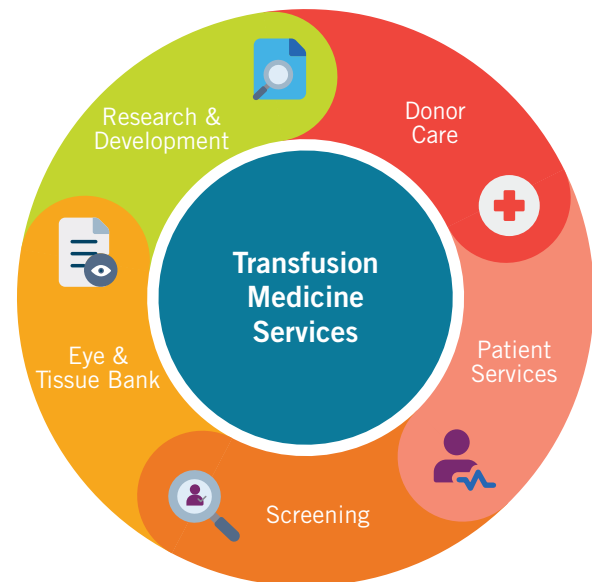


Figure 3. Current State Transfusion Services

The IBTS adopts a two-center model for donor and patient services from Dublin (National Blood Centre - NBC) and from Cork (Munster Regional Transfusion Centre - MRTC). The majority of Consultant posts are joint posts with hospital attachments or attachments to external bodies or the HSE. Some of these joint posts are also jointly funded.

Current Structure and Organisation of Services

The Medical & Scientific Director (MSD) is central to the effective delivery of a safe and sustainable blood supply. The MSD leads the medical and scientific staff and has responsibility for all medical consultant staff.

The MSD is accountable to the Chief Executive and provides advice in all aspects of medical research, technical policy and practice at the IBTS. The MSD shares responsibility for the quality of service provided by the IBTS and for its strategic direction. The MSD has responsibility for a headcount of 108 staff, nine senior direct reports and holds executive responsibilities as a member of the IBTS leadership team.

Two Consultants are based in the Munster Regional Transfusion Centre (MRTC) in Cork. They are responsible, under the supervision of the MSD, for medical support for patients, donors, transfusions and assisting hospitals regarding transfusions and patient services.

Five other medical consultants are based in the National Blood Centre in Dublin. These consultants are responsible for Donor Medical Services, The Red Cell Immunohaematology (RCI) Laboratory, Automated Donor Grouping (ADG), Blood Group Genetics Laboratory (MBG & HLA), the Irish Unrelated Bone Marrow Registry (IUBMR) and virology laboratories.

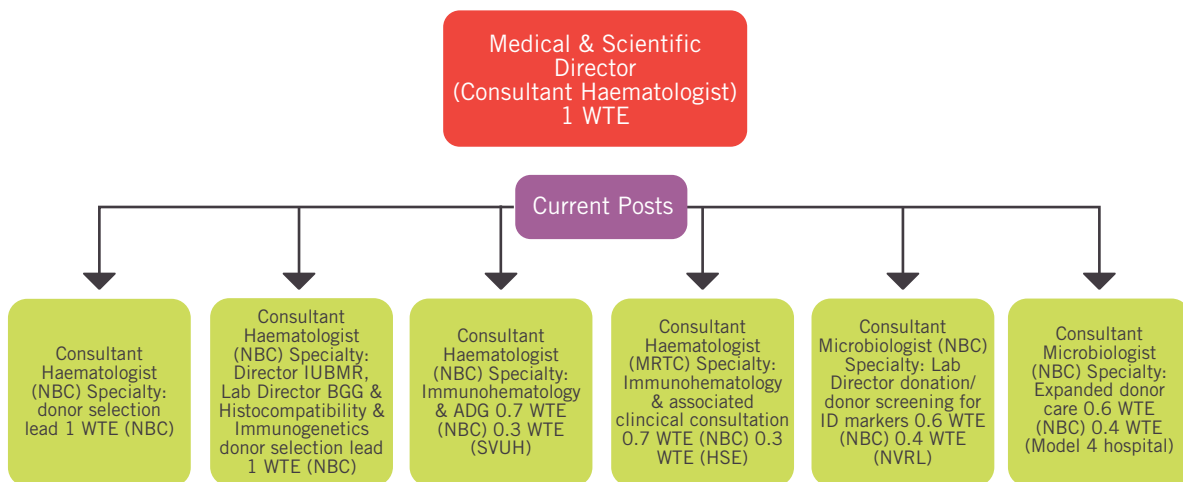
The Head of Testing has three direct reports and oversees the Nucleic Acid Testing (NAT) laboratory, laboratory services and laboratory training activities. The Chief Medical Scientist reporting to the MSD oversees the Tissue and Limbal Stem Cell laboratory.

The MSD acts as the Deputy Responsible Person with the Director of Quality and Compliance, who acts as the Responsible Person (RP) under SI 360/2005 and SI 15/2006. The MSD attends the Board, Medical & Scientific Advisory Committee, the Research and Development Committee and attends Governance meetings with the Department of Health.

In terms of medical consultant staff, there are 7 consultants equating to 5.3 WTE broken down as follows.

- 1 x MSD
- 4 x Consultant Haematologist, of which
 - 1 x donor role
 - 3 x patient facing/clinical roles covering Sustainability of the blood supply, Patient laboratory services - Immunohaematology, Histocompatibility and Immunogenetics, Blood group genetics; therapeutic apheresis (from MRTC), Bone marrow registry
- 1 x Consultant Microbiologist
- 1 x Infectious Disease Specialist

On-call services are managed locally. This has created some challenges with service delivery at a national level. Therapeutic Apheresis services are only provided by the medical team in the Cork Centre. Ten specialist medical officers (SPMO) (5 x Dublin, WTE 5.0; 5 x Cork, WTE 3.1) support the IBTS consultant team with associated administrative and nursing support.



Education, Research and Development

IBTS consultants are actively engaged in education contributing to the training of current and future General, Haematology and Transfusion healthcare professionals.

Tissue Banking and Cellular Therapy

The IBTS requires Blood (and tissue) Establishment medical consultant governance for tissue banking and for development of cellular therapies. The IBTS is re-establishing an eye bank and will be engaged in cell therapy. Demand for stem cell facilities has already outstretched supporting infrastructure and the IBTS is in a key position and opportunity exists to provide the GMP facilities for cryobiology laboratory in the second centre and co-join this development with the therapeutic apheresis service. Clinical oversight for the Eye Bank is provided by an Ophthalmic Director with an IBTS WTE of 0.08 (3 hours per week). It is expected that the Director will work collaboratively with the future IBTS consultant haematologist who will have IBTS oversight of the eye bank and tissue bank.

Bone Marrow Registry

IBTS hosts the Irish Unrelated Bone Marrow Registry (IUBMR) like the arrangement in several European countries (e.g., Swiss and Finnish Red Cross among others). The registry has 26,000 potential donors, is licenced by the HPRA under the EU Tissue Directive 2004/23/EC. This is an international co-operative registry that provides blood stem cell donors for Irish and international patients supporting allogeneic hematopoietic cell transplantation (HCT). Bone marrow and blood stem cell donor registries have the ability to participate in cellular therapy provision.

Haemovigilance and the NHO

Haemovigilance is internationally recognised as essential to the development of safe clinical transfusion practice. It collects and assesses information on unexpected or undesirable effects resulting from blood transfusion, and develops strategies and systems to prevent their occurrence or recurrence. Haemovigilance

in Ireland is co-ordinated by the National Haemovigilance Office (NHO), based at the IBTS. Since the programme commenced in 1999 over 8,000 serious adverse transfusion reactions and events have been reported.

The NHO liaises with and supports hospital based Haemovigilance Officers (HVOs) throughout Ireland and also Medical Consultants with Haemovigilance responsibilities. In addition, the NHO maintains links with colleagues internationally through the International Haemovigilance Network (IHN) and the UK Transfusion Network (SHOT).

Mandatory serious adverse events (SAEs) relating to the quality and safety of blood under EU Blood Directive 2002/98/EC and non-mandatory SAEs relating to the clinical aspects of blood transfusion are reviewed by the NHO. These reports come from blood establishments, hospital blood banks and facilities.

In compliance with Commission Directive 2005/61/ EC Annex II D and III C, all hospitals transfusing blood together with all blood establishments must complete and return an Annual Notification of Serious Adverse Reactions and Events (ANSARE) form to the NHO. The Competent Authority for implementation of all aspects of the EU Blood Directive is the Health Products Regulatory Authority (HPRA) and regular case review meetings are held with the NHO to discuss reported incidents.

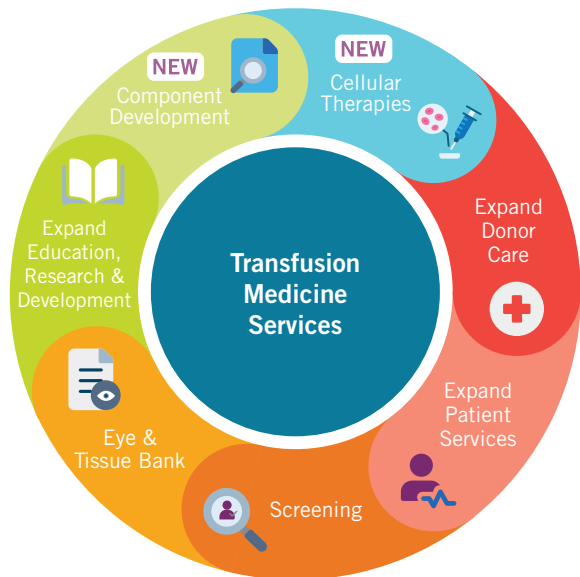
Workforce and Succession Planning

Over 70% of the current IBTS consultant workforce are expected to retire by 2027. This represents a significant loss of expertise that the IBTS is using as an opportunity to transform transfusion and build talent pools for the future. Consideration has been given to the elements which will attract and retain future transfusion medicine specialists, including but not limited to; National Medical and Scientific Directors, Consultant Haematologists, Microbiologists and Specialist Medical Officers.

Future State

Future Transfusion Medicine Services

To address the challenges presented and support the growth of the IBTS as a centre of excellence the following integrated medical MOC is proposed:

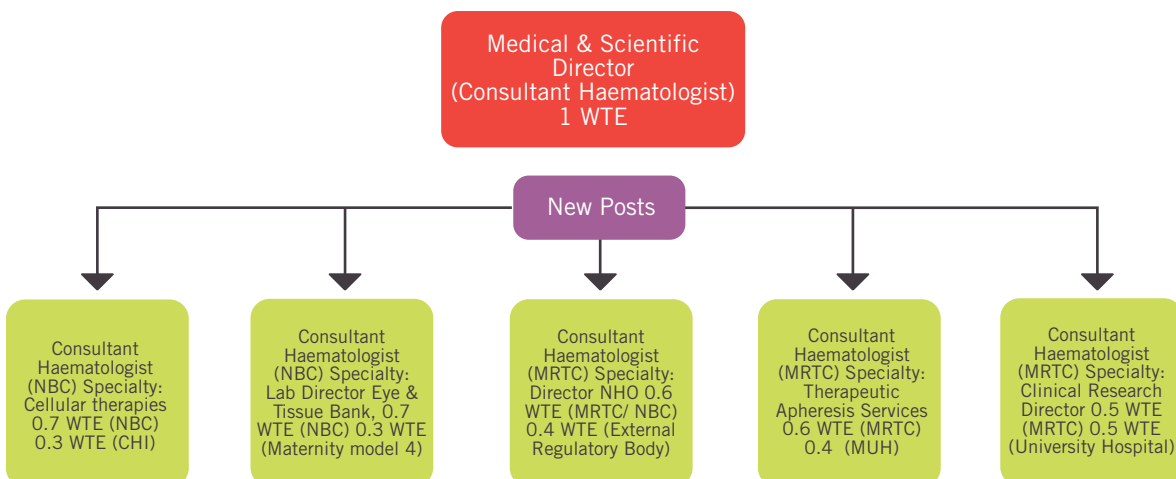


Future Structure and Organisation of Services

The IBTS MOC and complimentary consultant workforce plan addresses the current and future clinical governance needs, consultant workforce and succession plans and aims to overcome the challenges faced in transfusion medicine. It sets out an ambitious plan for the future. The consultant group are mindful of the core principles of alignment with special interests and international developments.

Indicative new and re-imagined positions are summarised in Appendix A. Laboratory directors will have an on-site presence specific to their laboratory location. Therapeutic apheresis service (TAS) director/ consultants will have an on-site presence specific to Cork city hospitals. Other positions are flexible for location.

Figure 4. Future State Transfusion Services



Consultant haematologists will contribute to on-call rotas, some local on-call rostering is required for TAS in Cork. All IBTS consultants will engage in development, research, publication, teaching, support links with academic institutions and participate with national and international colleagues / groups on behalf of the IBTS.

This MOC has identified the need for a headcount of 12 consultant posts, specifically 10 Consultant Haematologists (CH) and 2 Consultant Microbiologists (CM), or other suitably qualified specialists.

This results in an increase in the establishment from 5.3 WTE to 8.4 WTE.

The ambition is to develop collaborations for joint posts that align with the future direction of transfusion medicine and this MOC.

The enhanced MOC proposes to re-imagine a current post to support the enhanced MOC, and an IBTS consultant haematologists with 5 years' experience in transfusion medicine will be invited to express interest in the position of Deputy Medical & Scientific Director.

Blood demand and Patient Blood Management (PBM)

It is imperative that a national agreed programme of blood management (PBM) is developed and implemented to support appropriate use and sustainability of blood supply (Muller, 2019, Power, 2021). Such systems require resourcing for the education, data capture and audit components as a minimum. Such data is required for PBM to 'turn data into intelligence'. Well defined, consistent data collection & recording (numerator, denominator, inclusions and exclusions) of high quality to give a full picture across the systems, allow benchmark against relevant comparisons (clinical activity, distance to supply etc.), allow actionable insights that facilitate safe, effective and appropriate transfusion.

The IBTS will play a significant role in continuing to strengthen the National Transfusion Advisory Group (NTAG) through the development of national policies, guidelines and documents to support blood demand and on-going practice enhancement.

Expanding the donor base will require additional resources in the form of infectious disease investigation and onward referral of donors with previously undiagnosed infections. New donors, including sample only new donors (born outside Ireland or the UK), and those from previously deferred categories and from high Malaria, HIV, HBV, HCV endemic countries will require additional resources to be afforded a duty of care.

Component Development

The IBTS requires BE medical consultant governance with pro-active stakeholder engagement for use of component development. This will include extended use of whole blood with trials of platelet efficacy and shelf life, cold stored platelets, plasma components and component processing including pathogen reduction technologies (PRT). The sentinel questions to be addressed in the latter include the effect on platelet components, efficacy, quality, demand, impact on immunogenicity, infectivity reduction capacity and how to achieve impact for non-enveloped viruses and bacterial spores. In addition, safety for red cells as the technology develops. IBTS is working to select the most appropriate plasma component/ derivative recovered from donors to the IBTS.

Expand Education, Research and Development

The small pool of transfusion medicine and microbiology expertise in the IBTS must have dedicated time for research and teaching to ensure sustainability and support the IBTS towards enhanced and developing services and building its reputation as a centre of excellence in Transfusion Medicine.

IBTS consultants will require dedicated time to contribute to the IBTS Research and Development strategy, engaging research bodies, continued engagement with genomic consortium, the Research Roadmap of the European Haematology Association (EHA), and the Biomedical excellence for safer transfusion collaborative (BEST) group.



Cellular Therapies

The emergence of CART- cell therapies is anticipated to grow with further developments in this field. The IBTS is in a unique position to optimise the opportunities presented by supporting our healthcare partners. Risk evaluation and mitigation strategies (REMS) will be required and active Biovigilance for the known serious risks (severe cytokine release syndrome, CNS toxicity, infection, cytopaenias etc.) together with long term safety profile including oncogenesis and unknown risks. NHO expertise should be developed to assist the necessary associated clinical learning.

The IBTS is also in a position to review the opportunities for establishing additional stem cell facilities and potentially link this with the therapeutic apheresis service in Cork.

International Bone Marrow Registry

The IUMBR has successfully changed its method of recruitment. Through the blood donor clinics, younger donors are prioritised, being the best donors for patients with haematological malignancies, undergoing unrelated blood stem cell transplantation. The demand for Irish donors will increase with time as advances in medicine are enabling more patients become eligible for transplant.

Furthermore, such registry donors can become a source of blood and other stem cells in the future. In the UK and the US, international registries have begun collecting stem cells for clinical research and biotherapies for patients. These include the Anthony Nolan Trust and in the USA, Be The Match Biotherapies.

Haemovigilance and the NHO

Discussions are currently in progress between IBTS and the HPRA to strengthen structures and governance in relation to reporting and oversight. Consequently the post identified in this MOC (medical consultant with transfusion expertise as director of NHO) will ultimately be determined by that process. Nevertheless, this MOC identifies this role as critical to the success of the NHO in fulfilling its objectives as set out in the EU blood directive.

Workforce and Succession Planning

The proposed Medical MOC should help to attract and retain the consultant expertise and allow for more stable succession planning into the future. The IBTS consultant group acknowledges the significant level of investment required by the IBTS to support the delivery of this MOC. All necessary governance procedures will be adhered to and proactive consultation and agreement for funding with external partners is identified as a critical success factor.

Pathway to Success

This document sets out the proposed consultant resourcing considering the gaps, service

challenges and developments for the national blood transfusion service.

The proposal is an increase in the IBTS establishment from 7 to 12 posts and 5.3 WTE to 8.4 WTE.

	Proposed Consultant Headcount	Proposed IBTS Consultant WTE	Proposed External component
Dublin	8	6.0	2.0
Cork (inc post No. 12 Dub/Cork)	4	2.4	1.6
Total	12	8.4	3.6

Figure 5. Proposed IBTS consultant posts and split

Considering the anticipated recruitment challenges, as noted earlier, the consequences of not implementing this MOC are severe and would have serious implications for the ability of the organisation to meet its statutory obligations with resultant consequences for patients.

The support of the MSAC, Board and the DOH for this level of resourcing is critical and will allow the IBTS to progress engagement with external bodies to secure joint positions that are mutually beneficial. We acknowledge potential relationships with hospitals which have to date expressed interest and indicative relationships that present opportunities for further exploration. Our ambition is to develop agreements with our stakeholders for joint positions that include funding arrangements. In our view, this will be of enormous assistance in attracting and retaining new consultants to the IBTS.

Funding the Proposed MOC

Two consultant posts are included in the 2023 budget that will allow prioritised posts to progress. This work is underway as part of the immediate requirements and form part of the phased implementation plan.

Further posts will form part of subsequent annual budgets once posts, agreements with level 4 hospitals, approvals and funding have been agreed.

As the intention will be to minimise the cost implications, only posts where joint funding and other cost saving measures have been agreed will be progressed in the annual IBTS budgetary process. This will also require business cases to be developed for the proposed increase in WTE in line with usual governance procedures.

Expressions of interest will commence for the role of Deputy Medical and Scientific Director and be open to current IBTS Consultants. In parallel discussions with current unfunded joint consultant posts will also commence to review and agree a future focussed and sustainable funding agreement.

A detailed 5 year implementation plan will be developed and progress against this plan will be reviewed six monthly by the IBTS consultant group and key stakeholders. Once the MOC is implemented, it will provide diverse expertise to serve the IBTS and to contribute in partnership with our nursing and scientific colleagues to achieve our organisational goals now and into the future.

Appendix A

	Post	Location	Specialty	WTE IBTS	WTE External	Role
Current Consultant Haematologists	1	Dublin	Consultant Haematologist	1	0	Medical and Scientific Director
	2	Dublin	Consultant Haematologist	1	0	Lead Donor selection (whole blood and apheresis)
	3	Dublin	Consultant Haematologist	0.7	0.3 SJH funded	Director International Unrelated Bone Marrow Registry Laboratory Director , Blood Group genetics & Histocompatibility and immunogenetics, and associated clinical consultation
	4	Dublin	Consultant Haematologist	0.7	0.3 SVUH	Laboratory Director immunohaematology & automated donor grouping; Clinical liaison routine hospital transfusion laboratory service, reference laboratory and associated consultation
	5	Cork	Consultant Haematologist	0.7*	0.3* HSE funded	Lead BE and laboratory patient services. Laboratory Director immunohaematology and associated clinical consultation; CLA NTAG, Maternity OTC IBTS representative.
Current Consultant Haematologist Sub TOTAL WTE				4.1	0.9	
Current Consultant Microbiologist & ID Specialist	6	Dublin	Consultant Microbiologist	0.6	0.4 NVRL	Laboratory Director donation/donor screening for ID markers. Testing/ID surveillance, TTI investigation, link national sero-epidemiology unit
	7	Dublin Repurposed role	Consultant Microbiologist	0.6	0.4 Model 4 hospital	Expanded Donor care/screening/Eye & Tissue bank Contribution to donor eligibility/selection, Look-back, trace back, TTI investigation, Component bacterial testing/processing Environmental microbiological monitoring (EM); infection prevention and control (IPC)
TOTAL Current WTE				5.3	1.7	

New Posts						
Future Consultant Haematologists	8	Dublin	Consultant Haematologist	0.7	0.3 Children's Health Ireland (CHI)7	Cellular Therapies /component development Component Processing and development, Tissue and cell banking, Link to stem cell facility NTAG; Paediatric OTC IBTS rep
	9	Dublin	Consultant Haematologist	0.7	0.3 Maternity model 4 hospital	Expanded Donor care/Patient Services & Eye and Tissue Bank Laboratory Director Eye & Tissue Bank Donor vigilance and audit programme Donor/donation; Communication with personal injuries assessment board (PIAB), associated clinical referrals and legal issues; HH donor programme; Consultative transfusion medicine services for Irish hospitals & associated BE activity
	10	Cork	Consultant Haematologist	0.6	0.4 MUH	Expanded patient services/cellular therapies & donor care Director Therapeutic Apheresis Service, BE activity donor and patient and associated clinical consultation, MUH haemoglobinopathy
	11	Cork	Consultant Haematologist	0.5	0.5 University Hospital	Expand Education, Research and Development/Cellular Therapies/Donor Care Clinical Research Director (Professor)
	12	Cork/ Dublin	Consultant Haematologist	0.6	0.4 HPRA	Director of NHO; WTE 0.4 will have associated haemovigilance responsibilities per competent authority. WTE 0.6 will be spent on haemovigilance activities that are unrelated to the reporting responsibilities of the HPRA as competent authority, as well as non-haemovigilance blood establishment activities, including patient blood management and education, donor recruitment and college lectureship.
Future New Consultant Haematologist Sub TOTAL WTE				3.1	1.9	
GRAND TOTAL WTE				8.4	3.6	IBTS WTE increase = 3.1

Notes:

*This post was historically a 1 WTE IBTS post. Funding by the HSE for 0.3 was agreed in 2022 and the split outlined above reflects the new funding arrangement. The HSE funding is for a period of 2 years only after which the post and CLA requirement will be reviewed.

**The table above shows the posts splits rather than financial split. Some current joint posts are joint funded while others are not.

References

Allard S et al. Transfusion 2024 Transfusion 2024: A 5-year plan for clinical and laboratory transfusion in England. *Transfusion Medicine*. 2021; 31; 395-399

Anthony Nolan Trust. <https://www.anthonynolan.org/BeTheMatch> Biotherapies. <https://bethematchbiotherapies.com/Comhairle na nOspidéal>. Consultant staffing. 1st January 2000. Corrigan House, Fenian Street, Dublin 2. Table 1G-Consultant pathologist posts by sub-specialty as at 1st January 2000, page 6.

Grant Thornton - Options Appraisal and Analysis of the IBTS site on St. Finbarr's Hospital campus in Cork City. Irish Blood Transfusion Service. November 2021.

Farmer LS, Towler S., Leahy MF, Hofmann A, Drivers for change: Western Australia Patient Blood Management Program (WA PBMP), World Health Assembly (WHA) and Advisory Committee on Blood Safety and Availability (ACBSA). *Best Pract Res Clin Anaesthesiol* 2013; 27(1):43-58. doi: 10.1016/j.bpa.2012.12.007.

HSE Medical Workforce Report 2020-21 NDTP. <https://www.hse.ie/eng/staff/leadership-education-development/met/ed/rep/medical-workforce-report-2020-21.pdf>

IBTS Connections that Count: Developing the IBTS 2021 – 2025. IBTS Transforming Together: People: Culture: Connections, 2021 to 2025 <https://www.giveblood.ie/about-us/>

Muller MM et al., Patient Blood Management: Recommendations from the 2018 Frankfurt Consensus Conference. *JAMA*. 2019. 12; 321(10):983-997. doi: 10.1001/jama.2019.0554.

National model of care for paediatric healthcare services in Ireland <https://www.hse.ie/eng/about/who/cspd/ncps/paediatrics-neonatology/moc/chapters/>

NHSBT NBTC UK – Transfusion 2024- <https://www.transfusionguidelines.org/uk-transfusion-committees/national-blood-transfusion-committee/transfusion-2024>

SHOT Annual report 2021 <https://www.shotuk.org/shot-reports/>

Sláintecare <https://www.gov.ie/en/publication/6996b-slaintecare-implementation-strategy-and-action-plan-2021-2023/>

WHO – A decade of patient safety 2021 – 2030 <https://www.who.int/news-room/articles-detail/the-third-public-consultation-for-review-of-draft-global-patient-safety-action-plan-2021-2030>

Wood EM, Ang AL, Bisht A, et al. International haemovigilance: what have we learned and what do we need to do next? *Transfusion Medicine*, 2019, 29, 221–230. doi: 10.1111/tme.12582



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