

ANNUAL REPORT

2022



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Foreword

2022 was a challenging year for the IBTS but our staff rose above and beyond the challenge to ensure that we continued to provide a safe blood supply to the people of Ireland throughout the year. The demand for blood and tissue products was at its highest for a number of years as healthcare caught up after the pandemic. In order to ensure our healthcare partners could rely on continuity of supply we were very dependent on our pool of existing donors and we are extremely grateful to all of our donors for their continuing commitment and loyalty to the IBTS.

Happily, since pandemic restrictions were formally lifted during 2022 we have been able to bring new donors into our clinics and we are slowly, but surely, working to increase our numbers of new donors. The eligibility rules are under constant review so that we keep pace with the scientific evidence without compromising the safety of our products for recipients; for example, the prohibition on donors who had lived in the UK for a number of months was removed in recent years. We made very significant changes to our donor eligibility rules during 2022, so that all potential donors' eligibility is assessed on the basis of their individual circumstances and I encourage all potential donors to check their eligibility on <https://giveblood.ie/can-i-give-blood/>

At the IBTS we love our donors and several of our strategic projects in *'Connections that Count, Developing the IBTS 2021 to 2025'* are aimed at improving the customer experience for our donors. The introduction of individual donor risk assessment is the first and most important of these, introduced after extensive careful analysis led by our Medical & Scientific Director and the team of skilled haematologists and scientists in the IBTS. We look forward to continuing in 2023 to make the process of blood donation as efficient and safe as it can be for our donors.



Research and innovation have been growing exponentially in the IBTS since the publication of our first Research and Development Strategy in 2021, with very substantial and important research in relation to blood transfusion published. We were delighted with the success of BloodHIT in November 2022, a future-focused blood donation and haematology research symposium. (See section on Academic Activities, Research and Innovation for more information). Like other State companies, the IBTS is conscious of the contribution we must make towards achieving Net Zero by 2050. Acknowledging the scale of the challenge, we have increased our focus on sustainability and making meaningful reductions in our carbon footprint. I am very proud of the staff in our National Donor Screening laboratory (NDSL) which was the first Medical Science laboratory in Ireland to achieve the highest 'Green' status in the My Green Lab programme. Recognised by the United Nations Race to Zero campaign as a key measure of progress towards a zero-carbon future, My Green Lab Certification is considered the gold standard for laboratory sustainability best practice around the world.

The NDSL laboratory was assessed on its operations including energy and water use, waste management, sustainable purchasing and travel. The Green Lab Assessment Programme was developed by the non-profit organisation My Green Labs (MGL) and University of California representatives from Davis, Santa Barbara, San Francisco and Los Angeles to help reduce environmental impacts of laboratory

buildings. This successful pilot project in the NDSL will be rolled out to all IBTS laboratories both in the National Blood Centre, Dublin and the IBTS Centre in Cork.

We welcomed the decision of the Minister for Health to approve our vision for the Cork Centre at the end of 2022 and we are progressing the re-development of the Centre in Cork for the benefit of staff, donors and recipients in the Munster region.

In reviewing the year, I have to emphasise the immense gratitude we all owe to the staff of the IBTS who like many other frontline healthcare workers have literally kept the show on the road over the past three years. In donor clinics, testing laboratories, delivering blood products to where they are needed countrywide, ensuring the quality of products and systems and working in offices that were switched to their kitchen table overnight, and then back again, the staff of the IBTS have been stellar. The quality of our staff, led by the inimitable Orla O'Brien is second to none. When restrictions were lifted, the IBTS adapted quickly to the partial return to "normal" with enthusiasm. They have embraced the new challenges of working for a critical healthcare organisation which needs increasingly specialised blood products in larger quantities than ever before. On behalf of the Board, I thank each and every one of them.

Our donors are — literally — the life blood of the IBTS. On behalf of the Board, I extend my sincere thanks to each donor who has donated a life-saving unit of blood to the IBTS. An incredible number of donors have donated more than 50, or even 100 units of blood and I am very much looking forward to meeting you and thanking you in person at our Donor Awards Ceremonies during the year.

Deirdre-Ann Barr

Chairperson

Chairperson's Report

Report of the Chairperson of the Irish Blood Transfusion Service regarding the assessment of internal financial controls of a State body for the year ended 31st December 2022 in accordance with Appendix D of the Code of Practice for the Governance of State Bodies 2016, as amended.

1. I acknowledge that the Board is responsible for the Body's system of internal financial control.
2. The IBTS system of internal control can provide only reasonable and not absolute assurance against material error, misstatement or loss.
3. The Board confirms that there is an ongoing process for identifying, evaluating and managing significant risks faced by the IBTS. This process is regularly reviewed by the Board via reports from the Chief Executive and updates from the Audit Risk and Compliance Committee
 - i. Management are responsible for the identification and evaluation of significant risks applicable to their areas of business together with the design and operation of suitable controls. These risks are assessed on a continuing basis and may be associated with a variety of internal or external sources including control breakdowns, disruption in information systems, natural catastrophe and regulatory and compliance requirements.
 - ii. The Executive Management Team meets twice monthly on operational issues and risks and how they are managed. The Executive Management Team's role in this regard is to review on behalf of the Board the key risks inherent in the affairs of the IBTS with the Risk and Resilience Manager and the system of actions necessary to manage such risks and to present their findings on significant matters via the Chief Executive to the Board.
 - iii. The Chief Executive reports to the Board on behalf of executive management on significant changes in the work of the IBTS and on the external environment which affects significant risks. Where areas for improvement in the system are identified the Board considers the recommendations made by the Executive Management Team.
 - iv. The Director of Finance provides the Finance Committee with monthly financial information, which includes key performance indicators.
 - v. An appropriate control framework is in place with clearly defined matters which are reserved for Board approval only, or as delegated by the Board for appropriate Executive approval. The Board has delegated the day-to-day management of the IBTS and established appropriate limits for expenditure authorisation to the Executive. The Chief Executive is responsible for implementation of internal controls, including internal financial controls.
 - vi. The system of internal financial control is monitored in general by the processes outlined above. In addition, the Audit, Risk and Compliance Committee of the Board reviews specific areas of internal control as part of its terms of reference.

The Audit, Risk and Compliance Committee of the Board have satisfactorily reviewed the effectiveness of the system of internal control on behalf of the Board. The Audit, Risk and Compliance Committee carried out a formal review of these systems in respect of 2022 at its meeting on the 14th February 2023.

Additional Reporting Requirements

Compliance with the Code of Practice for the Governance of State Bodies

The Board is committed to complying with the relevant provisions of the Code of Practice for the Governance of State Bodies, published by the Department of Public Expenditure and Reform in August 2016 and amended in September 2020.

A code of business conduct for the Board and an employee code of conduct are in place. The Board has adopted a detailed Travel and Subsistence Policy which complies with all aspects of Government travel policy.

The IBTS Board reviewed reports on internal controls during the year along with regular reviews of the reports of the Health Products Regulatory Authority (HPRA) on operational and compliance controls and risk management. The Board will continue to review these reports and to work closely with the HPRA to ensure the highest international standards.

The IBTS has complied with disposal of assets procedures, as outlined in the 'Code of Practice for the Governance of State Bodies 2016' as amended. The IBTS complies with all relevant obligations as defined under Irish taxation law.

Corporate Governance

The Board's policy is to maintain the highest standards of corporate governance, in line with generally accepted policies and practices. The Board is accountable to the Minister for Health.

The Board has a manual for Board members. The Board reviewed and updated a number of governance documents at its meeting in September 2022 and agreed a 3 year time table for reviewing Terms of Reference for Board Sub-Committees. In line with the requirements of the Code of Practice for the Governance of State Bodies the Board completed an externally facilitated effectiveness review in the first half of 2022.

Workings of the Board

The Board is comprised of twelve members including a non-executive Chairperson appointed by the Minister for Health. There were eleven members of the Board in 2022.

The Board met on 6 occasions for ordinary meetings during the year. The Board also held a full day meeting to review progress on the Strategic Plan 'Connections that Count' and review the outputs of the Board's external effectiveness evaluation.

Attendance by Board members was as follows:

	February	April	June	September	November	December
Deirdre-Ann Barr	x	x	x	x	x	x
Brian O'Mahony	x	x	x			x
Kate Williams	x	x	x		x	
Dr Elizabeth Kenny	x	x		x	x	x
Dr Ronan Desmond		x			x	
Deirdre Cullivan	x	x	x	x	x	x
John Malone	x	x	x	x	x	x
Dr Satu Pastila	x	x	x	x	x	x
Dr Sarah Doyle			x	x		x
David Gray	x	x	x	x	x	x
Prof Sharon Sheehan*	x	x	x	x		

*Prof Sheehan on sick leave

All members receive appropriate and timely information to enable the Board to discharge its duties. The Board takes appropriate independent, professional advice as necessary. Guidelines for the payment of Board member fees and expenses are observed.

A schedule of attendance at the Board and sub committee meetings for 2022 is set out below including the fees received by each member:

	Board	Medical Advisory Committee	Audit, Risk & Compliance Committee	Finance Committee	Performance Development Committee	Research & Development Committee	Board Fees 2022 €
Number of Meetings	6	6	5	5	3	4	
Ms DA Barr* (Chairperson)	6	–	3	–	3	–	11,970
Mr B O'Mahony	4	–	–	–	–	4	–
Dr E Kenny	5	6	–	–	–	–	–
Ms K Williams	4	–	–	5	–	–	11,970
Dr R Desmond	2	3	–	–	–	–	–
Ms D Cullivan	6	–	–	5	3	–	11,970
Mr J Malone	6	–	–	5	–	3	11,970
Dr S Pastila	6	4	–	–	–	–	11,970
Dr S Doyle**	3	0	–	–	–	–	–
Mr DW Gray	6	–	5	–	–	–	11,970
Dr Sharon Sheehan	4	–	4	–	–	–	–
							71,820

* Ms DA Barr was appointed Chairperson on the 23rd June 2022 up to which point she was acting Chairperson.

From June onwards she no longer attended the Audit, Risk and Compliance Committee meetings.

** Dr Doyle's absence is due to her public health responsibilities for COVID 19

There were five Board members who did not receive a Board fee under the One Person One Salary (OPOS) principle.

Board members expenses in 2022 amounted to €3,326 broken down €1,059 mileage, €350 subsistence and €1,917 other travel related expenses and vouched food expenses.

The Public Spending Code

The Board is committed to complying with the provisions of the Public Spending Code and Circular 14/21 "Arrangements for Oversight of Digital and ICT related initiatives in the Civil and Public Service."

The IBTS has implemented a project management methodology, suitable for adaptation, depending on the size of the project in question.

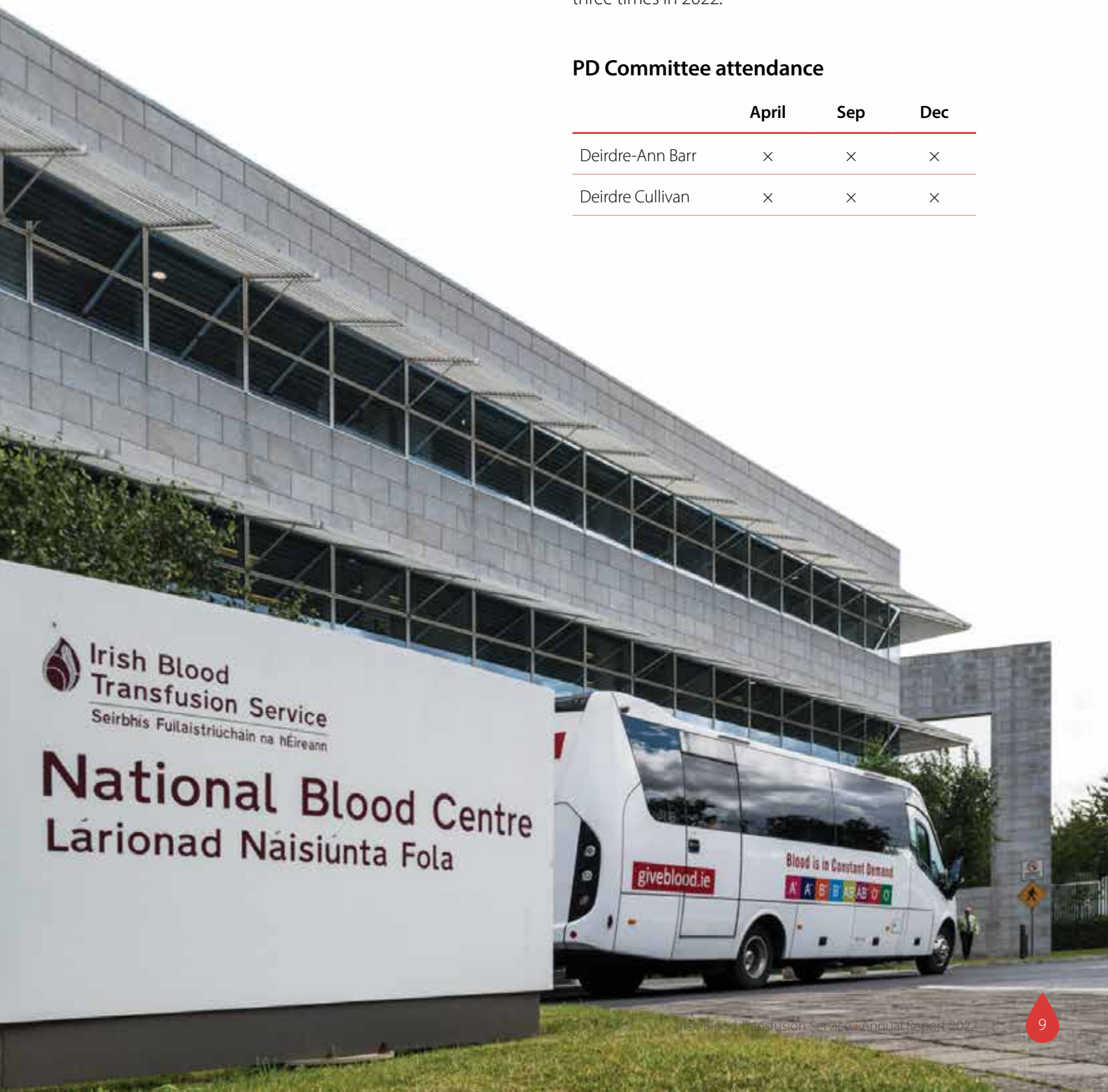
The Board has activated a committee structure to assist in the effective discharge of its responsibilities.

Performance and Development Committee

The Board has established a sub-committee to deal specifically with matters regarding the performance and development of the Chief Executive, and the Executive Management Team. The Board complies with Government policy on pay for the Chief Executive and employees. The Board also complies with guidelines on the payment of Director's fees. The Chief Executive's salary in 2022 was €159,531.38. The Performance and Development Committee met three times in 2022.

PD Committee attendance

	April	Sep	Dec
Deirdre-Ann Barr	x	x	x
Deirdre Cullivan	x	x	x



Medical & Scientific Advisory Committee

The Medical and Scientific Advisory Committee is comprised of some of the medically qualified members of the Board and the medical consultant staff of the IBTS as well as a number of external medical consultants and met 6 times in 2022. Its function is to monitor developments relevant to the field of transfusion medicine and related fields, to inform the Board of any such developments and to advise the Board on appropriate action.

M&SAC attendance 2022

	Jan	April	June	Aug	Oct	Nov
E Kenny	✓	✓	✓	✓	✓	✓
R Desmond	×	✓	×	×	✓	✓
S Pastila	✓	✓	✓	✓	×	×
S Doyle	×	×	×	×	×	×
B O'Mahony *	✓	×	×	✓	✓	✓
S Field **	✓	–	–	–	–	–
Tor Hervig ***	✓	✓	✓	✓	✓	✓
D Ó Donghaile	×	✓	×	✓	✓	✓
L Pomeroy ****	✓	✓	–	–	–	–
E McSweeney	✓	✓	✓	✓	✓	✓
J Power *****	×	✓	✓	✓	–	✓
N O Flaherty	✓	✓	✓	✓	×	×
N O'Connell	✓	✓	✓	×	✓	✓
C DeGascun	×	✓	✓	×	×	×
K Morris	✓	✓	✓	×	✓	✓
N Moore	✓	✓	✓	✓	✓	✓
R Hagan	✓	✓	×	✓	✓	✓
S Thomas	✓	×	✓	×	✓	✓
A Waters ****	–	✓	✓	✓	✓	✓
O O'Brien *****	–	–	–	✓	✓	✓

* Mr B O'Mahony is only in attendance at meetings not a full member of the M&SAC

** Prof S Field retired from IBTS on 13th March 2022

*** Prof T Hervig commenced in IBTS on 8th February 2022 (attended meeting in January as an observer)

**** Dr L Pomeroy retired on 11th July 2022

***** Dr J Power went on pre-retirement leave in September 2022

***** Dr A Waters became a member of the M&SAC in April 2022

***** Ms O O'Brien only in attendance at meetings not a full member of the M&SAC

Finance Committee

The Finance Committee met five times during the year and is comprised of three members of the Board. It is also attended by the Chief Executive, Director of Finance and Management Accountant. The Committee may review any matters relating to the financial affairs of the Board. It reviews the annual capital and operating budgets, statutory financial statements and monthly management accounts, financial KPIs, capital expenditure, working capital and cash flow. It also reviews business planning,

costing exercises, procurement, insurance arrangements, contracts, banking, financing arrangements and treasury policy. The Committee also reviews the funding and performance of the Board's pension fund. The Committee reports to the Board on management and financial reports and advises on relevant decision-making. The Finance Committee operates under formal terms of reference which are reviewed by the Board every three years.

Finance Committee attendance

	February	May	July	September	November
Ms K. Williams	×	×	×	×	×
Ms D. Cullivan	×	×	×	×	×
Mr J. Malone	×	×	×	×	×

Audit, Risk & Compliance Committee

The Audit, Risk and Compliance Committee met five times during the year and is comprised of three members of the Board and one independent external member. It is also attended by the Chief Executive, the Medical & Scientific Director, the Director of Finance, the Director of Production and Hospital Services, the Director of Donor Services and Logistics, the Chief Information Officer, the Director of Quality & Compliance, the Internal Auditor, Risk and the Resilience Manager and the Assistant Accountant acts as Secretary to the Committee. The Committee may review any matters relating to the financial, risk, regulatory or compliance affairs of the Board.

It reviews the annual statutory financial statements including the accounting policies and notes to the financial statements, compliance with accounting standards and the accounting implications of major transactions, reports of the Internal Auditor, quality reports both internal and from the HPRA, risk management including reviews of the corporate risk register. The external auditors meet the Committee to review the results of the annual audit of the Board's Statutory Financial Statements. The Audit, Risk & Compliance Committee operates under formal terms of reference, which are reviewed by the Board every three years.

Audit, Risk & Compliance Committee attendance

	February	April	June	September	December
Mr David Gray	×	×	×	×	×
Deirdre-Ann Barr*	×	×	×		
Prof. Sharon Sheehan**	×	×	×	×	

*Deirdre-Ann Barr ceased to be a member of the Audit, Risk and Compliance Committee on her appointment as Chairperson

**Professor Sheehan on sick leave

Research & Development Committee

The Research and Development Committee met four times during the year to oversee the implementation of the IBTS Research and Development Strategy. The Research and Development Committee is attended by the Chief Executive, the Medical & Scientific Director, the Finance Director and the Research and Development Lead Facilitator and a number of external members.

Research & Development Committee attendance

	February	May	August	November
Brian O'Mahony	x	x	x	x
John Malone	x	x		x

Risk Register

The risk register identifies various types of risks including strategic, reputational, clinical, IT, financial and operational risks to the organisation and the existing controls and further actions necessary to minimise the impact on the organisation, in the event of the risk occurring. A Risk and Resilience Manager has responsibility for overseeing the risk register and contingency arrangements. A set of inherent risks have been identified which are monitored by the Audit, Risk and Compliance Committee and the Board on a regular basis. At present the risk register is reviewed and updated by the Executive Management Team.

This monitoring ensures that the identified risks and controls are current and that new and emerging risks are identified and control measures put in place.

Going Concern

After making reasonable enquiries, the Board Members have a reasonable expectation that the IBTS has adequate resources to continue in operational existence for the immediate future. For this reason, they continue to adopt the going concern basis in preparing financial statements. In light of the pension deficit and the potential for further post reporting date changes in the value of the pension scheme's assets and liabilities, the Board in evaluating the appropriateness of the going concern concept to the current set of Financial Statements considered all of the pension fund valuations and cash flow for the twelve months from the date of approval of the financial statements and is of the opinion that the Board can meet all its liabilities including funding of the IBTS pension scheme as they fall due. In these circumstances the Board considers the going concern concept appropriate to the preparation of these set of Financial Statements.

Internal Control

The Board is responsible for internal controls in the IBTS and for reviewing their effectiveness. The Board's system of internal financial control comprises those controls established in order to provide reasonable assurance of:

- The safeguarding of assets against unauthorised use or disposition; and
- The maintenance of proper accounting records and reliable financial information used within the organisation.

The key elements of the Board's system of internal financial control are as follows:

- A comprehensive system of financial reporting
- Annual Budget prepared and presented to both the Finance Committee and the Board
- Monthly monitoring of performance against budgets by Finance Committee and Board
- Sign off by budget holders on individual budgets
- Budget reviews with budget holders
- Clearly defined finance structure
- Appropriate segregation of duties
- Clear authorisation limits for capital and recurring expenditure approved by the Finance Committee
- Key financial processes are fully documented in written procedures

- Regular stock takes and reconciliations carried out by staff independent of stores staff
- Financial system possesses verification checks and password controls
- Issues of products are reconciled to ensure all of the Board's activities are fully billed
- Regular monitoring of credit control function
- Purchase orders signed by Purchasing Officer or authorised substitute
- Stock items are requisitioned by means of automatic ordering
- All non stock invoices signed and coded by budget managers or their authorised signatories
- All stock invoices are independently matched with stores Goods Received Notes (GRN) and purchase orders
- Payment verification checks of supplier invoices by staff independent of accounts payable staff

The Board is aware that the system of internal control is designed to manage rather than eliminate the risk of failure to achieve business objectives. Internal control can only provide reasonable and not absolute assurance against material mis-statement or loss.

The Financial Statements for the year ended 31st December 2022 have been prepared under FRS102.



Statement of Board Members' Responsibilities

The Board is required by the Blood Transfusion Service Board (Establishment) Order 1965, to prepare financial statements for each financial year which, in accordance with applicable Irish law and accounting standards, give a true and fair view of the state of affairs of the Irish Blood Transfusion Service and of its income and expenditure for that year. In preparing those financial statements, the Board is required to:

- Select suitable accounting policies and then apply them consistently;
- Make judgements and estimates that are reasonable and prudent;
- Disclose and explain any material departure from applicable accounting standards;
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Irish Blood Transfusion Service will continue in business.

The Board is responsible for keeping proper books of account, which disclose with reasonable accuracy at any time, the financial position of the Irish Blood Transfusion Service and to enable it to ensure that the financial statements comply with the Order. It is also responsible for safeguarding the assets of the Irish Blood Transfusion Service and hence taking reasonable steps for the prevention and the detection of fraud and other irregularities.

Procurement

The IBTS is in compliance with current procurement rules and guidelines as set out by the Office of Government Procurement.

Asset Disposal

There were no assets disposed of in 2022 in line with reporting requirements of the Code of Practice.

Protected Disclosures

The IBTS complies with the requirements under the Protected Disclosures Act 2014 and confirms that procedures are in place for the making of protected disclosures in accordance with section 21(1) of the Protected Disclosures Act 2014 as amended in 2022. There were no protected disclosures in 2022.

Commercially significant developments

The IBTS arranged two shipments of blood bags and reagents to the Ukrainian Red Cross to the value of €60,000.

Deirdre-Ann Barr

Chairperson



Chief Executive's Report

It is with great pleasure that I present the 2022 annual report for the Irish Blood Transfusion Service. As the COVID-19 pandemic entered a third year, its impact lessened as we finally emerged from the public health restrictions that had dominated the previous two years. Nonetheless, COVID-19 had not gone away and particularly towards the end of the year the level of viruses circulating in the community did impact on donor and staff availability and made it challenging to maintain the blood supply at the level needed. This led to us importing a small number of whole blood units from our contingency partner twice during the year. We also ran two separate national appeals which resulted in a magnificent response from our donors and the public. We are hugely grateful for their on-going and loyal support.

In addition to our day-to-day activities, we delivered important initiatives aligned to our strategic plan, *Connections that Count: Developing the IBTS 2021–2025*. Many of our projects are multi-year in nature and many staff were involved in progressing them throughout the year. We held a Board Strategy Away Day in May to review our progress and discuss some of our bigger projects. One of the more significant achievements was the introduction of the Individual Donor Risk Assessment (IDRA) in November, a change that brings more inclusive blood donation policies for our donors. Other achievements included the introduction of new phone systems, new PK analysers in our Donor grouping Laboratory and new haemoglobin testing equipment in our donation clinics. We began production of allogeneic serum eye drops in August and have already seen steady demand for the new product. Our Research and Development team hosted our inaugural BloodHit conference in



November and our Red Cell Immunohaematology laboratory successfully achieved ISO15189 accreditation in December. Our project to reintroduce the use of Irish donor sourced plasma also continued this year, a project that will take a number of years to complete. Further achievements from our Corporate Strategy, People and Culture Strategy, Research and Development Strategy and IT Strategy are reported on throughout this annual report.

We have a lot of ground to make up in terms of getting numbers of new donors back up to pre COVID-19 levels and this will be a focus for our donor services team in 2023. To make it easier for donors to access us, work on a bespoke Donor Appointments System continued in 2022 and will launch in 2023. This will be a significant enhancement for our donor's engagement with the IBTS and make it easier for them to make and manage their own donation appointments.

Sustainability came into sharp focus in 2022, against the backdrop of rising energy costs, the publication of the Government's climate action plan and the "reduce your use" campaign. While some of our strategic initiatives relate specifically to the sustainability agenda, further projects and actions will emerge in 2023 to support us meeting the 2030 energy efficiency saving target. A sustainability working group has been established and will work with our Energy Performance Officer to develop a sustainability strategy in 2023 and continuously implement actions from our climate action plan.

We began the process of examining our organisation structure in 2021 and the Board approved four recommended enhancements in April 2022. Implementation of the enhanced structures commenced immediately and included the redesign of the operations directorate to create two directorships, Director of Donor Services and Logistics and Director of Production and Hospital Services, and the establishment of four sub-structure governance groups to enhance mid level leadership engagement and pro-active participation.

In February, we said farewell to our outgoing Medical and Scientific Director, Prof Stephen Field, on his retirement and welcomed Prof Tor Hervig on his appointment. We extend a huge thanks to Stephen for his leadership on many significant medical policy decisions in the IBTS, including his work on the reversal of vCJD deferrals in 2019 and IDRA implementation in 2022. Dr Hervig continued the work on the first ever Model of Care for transfusion medicine in the IBTS, work which will be completed in early 2023. We also said farewell to two of our consultants, Dr Louise Pomeroy and Dr Joan Power, on their retirements after many years of dedicated service to the work of the IBTS. We thank them both for their enormous contributions and wish them a long, happy and healthy retirement. As part of the IT strategy, we welcomed our Chief Information Officer in March 2022 to drive the ambitious programme of IT transformation, modernisation and reform.

In December, the Department of Health announced the IBTS plan for the redevelopment of the Munster Regional Transfusion Centre on the grounds of St Finbarr's Hospital in Cork we look forward to progressing this project with the Department and our stakeholders over the coming years.

Unfortunately, we were not in a position to return to our much celebrated Donor awards ceremonies in 2022 for both our whole blood and platelet donors. We did however continue to recognise their significant donation milestones both on clinic for donors reaching their 10th and 20th donations, and donor award packs for those who achieved their 50th and 100 plus donations. We also donated to Children's Health Ireland to mark their achievements. Despite all the challenges, our donors have been incredible in their support and have continued to show up and

donate in 2022, with just under 150,000 attending our clinics. We are truly grateful for that. We are returning to in-person award ceremonies in June 2023 after a three-year absence and are very much looking forward to paying tribute to our donors in person.

We continued to collaborate and develop relationships with our key stakeholders. We worked extensively with our European counterparts and made significant contributions to the European Blood Alliance. We also maintained our close working relationships with our nearest blood establishments and visited our Northern Irish colleagues in June. We continued to work with the Health Products Regulatory Agency (HPRA) on regulatory matters but also on specific work to strengthen governance arrangements between the IBTS, National Haemovigilance Office and the HPRA. This work will continue in 2023.

Following the Russian invasion of Ukraine in February, the IBTS, liaising with the Department of Health and the European Commission, made two humanitarian donations consisting of blood bags and reagents to the Ukrainian Red Cross. We hope it helped, even if only in a small way.

I want to express my sincere appreciation to staff who have given loyal and dedicated service to the organisation who retired or moved on during the year. I would also like to congratulate the Chairperson Deirdre Ann Barr on her appointment in June 2022 and for her continued guidance and support. I am indebted to the Board, Executive Management Team and staff for their extraordinary efforts and support throughout the year as we continued to provide our services to patients and donors in a challenging environment.

As we settle into our new normal, we will continue to bring new and innovative ideas to our work in the interests of our people and the patients and donors we have the privilege of serving. Our purpose is clear and we remain committed to 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.

Orla O'Brien
Chief Executive

Medical & Scientific Director's report

I am thankful for the kind reception I got when I took over Prof. Stephen Field's position when he retired in early 2022. He is congratulated for his great work. The IBTS is an organisation with many excellent people and it is a common aim for all of us to further expand and improve our services to Irish patients.

Social Behaviours Advisory Group — Individual Donor Risk assessment (IDRA)

The Advisory Committee for the Social Behaviours Review was established in June 2020. Chaired by Professor Mary Horgan, the group reported their recommendations on how donor criteria should be based on individual risk assessment in August 2021. The recommendations were implemented in March 2022; with the exception that oral sex was still regarded as an exclusion criterion. However, the main intention of the recommendations, to reduce the deferral period for men that have sex with men (MSM) from 12 months to 4 months was achieved.

Further changes in the donation criteria were linked to introduction of an electronic questionnaire. However, as this implementation was unavoidably delayed, work continued to develop a document that contained the information necessary for the full implementation of the individual risk assessment. The final donor questions were phrased after feedback obtained from focus groups that included members from the gbMSM and LGBTQ+ communities. The implementation of IDRA on 28th November was successful and the effects of the new donor selection criteria will be closely monitored.



The SARS CoV 2 (COVID19) Pandemic and the blood supply

The pandemic continued in 2022, causing huge challenges for donation clinics. The requirements related to social distancing, illness among donors and staff members and the practical problems of recruiting new donors caused serious challenges for the blood supply. Twice during the year, it was necessary to import blood components from the UK. We are very grateful for this assistance. Similar situations occurred in many countries and it is crucial to highlight that the shortage occurred despite magnificent responses from the donors, great efforts from our staff members and close collaboration with and support from our hospital partners. Further details on the blood stock situation are provided in other parts of the report.

The IBTS contributed significantly to the serosurveillance of the COVID-19 situation in Ireland and there is a related research project.

Plasma

Work to reintroduce Irish plasma for transfusion continued during 2022. In agreement with the plasma users, it has been decided to produce plasma from Irish donors and that the surplus of Irish plasma will be made available for fractionation. The time frame will be dependent on agreements with plasma fractionation companies.

Pathogen Reduction

The validation of a method for pathogen reduction of platelet concentrates is on-going. The final decision concerning implementation will be based on the final results of the validation and stakeholder engagement.

Research & Development

The first international conference arranged by the IBTS — BloodHIT — was a huge success. Also, the research activities within the IBTS are expanding. A full account of Research and Development activity appears elsewhere in this annual report.

Tissue activities

The work to re-establish the Irish Eye Bank also continued in 2022. This will need a specific IT system. The allogeneic serum eye drops were successfully introduced. The demand is currently exceeding the supply and measures are being taken to maximise production.

Laboratories

A major achievement was that the (RCI) Red Cell Immunohaematology Laboratory was awarded ISO 15189 accreditation on December 15th after assessment in May. This will facilitate similar processes in other IBTS laboratories. However, the accreditation is a “living award” and lots of effort is required to maintain the status. In the (ADG) Automated Donor Grouping Laboratory, the Beckman Coulter PK 7400 was introduced as the primary instrument after impressive validation work. The Virology Laboratory is contributing significantly to the National Serosurveillance Programme. The importance of this programme has been demonstrated during the pandemic. The (NHIRL) National Histocompatibility and Immunogenetics Reference Laboratory is continuing to provide a comprehensive range of

advanced analysis and new methods are under investigation. There is also work on-going to join an international Blood Group Genetics Consortium.

The Bone Marrow Registry

The activities of the Bone Marrow Registry increased significantly after a successful campaign to recruit young donors. Details are provided elsewhere in the annual report.

National Transfusion Advisory Group (NTAG)

NTAG is essential for the collaboration between the IBTS and the hospitals. The collaboration has been instrumental for the safety of the blood supply. When the stocks have been low, joint measures have ensured that all patients had access to the necessary blood components at all times.

The pandemic and the Clinical Lead Advisor retirement in 2022 impacted meeting frequency. However, there have been many meetings with collaborators. The Life Threatening Haemorrhage national frameworks are under development and some guidelines have been issued. The HSE and the IBTS agreed to continue the role of Clinical Lead Advisor and the joint position will be filled in 2023.

Dr Tor Hervig

Medical & Scientific Director



Donor Services & Collections

Key Achievements

- Maintaining the National blood supply throughout another extremely challenging year.
- Donor Services saw a slight increase of 0.6% in donor attendances at clinics in 2022. Including an increase in the number of first time donors (in excess of 25%) attending clinics. This was as a result of beginning the process of reversing some of the public health measures (social distancing etc.) introduced to comply during the COVID-19 pandemic.
- Donor Services staff handled approximately 270k inbound (mostly clinic appointments and medical queries) and outbound tele-recruitment telephone calls (specific blood type requirements). This was an increase of over 14.4% calls on the previous year.
- Introduction of Individual Donor Risk Assessment (IDRA).
- Greater inclusivity for transgender and non-binary donors with non gender based assessment of high risk activity.
- A structural change in the IBTS splitting the operations function into two, Donor services and collections and Manufacturing and Issue.
- The introduction of a new telephone system across the Donor Services department which significantly improved both the capacity and the management of donor calls and queries.
- The introduction of new Hemocue 301 medical devices which significantly reduced the time of the haemoglobin testing process on clinic.
- Maintaining the availability of a suitable number of clinic venues in a year of continued pressure on supply.

- On-going marketing and recruitment support for local clinics and national messaging.

Maintaining the National blood supply

2022 continued to be a challenging year with a steady stream of external events putting additional pressures on services already stretched with increased demand for blood components as the health service continues to recover from the effects of COVID-19.

A 'twindemic' of both COVID-19 and flu.

This caused significant illness levels amongst staff and donors significantly impacting in reduced clinic capacity and cancelled and no show appointments.

The Ukraine war created a situation of fuel crisis in terms of both supply and cost and the continued shortage of availability of some venues previously used by the IBTS for clinics. A tight labour market particularly in specialist healthcare areas such as nursing caused some challenges in staffing our collection teams. We continue to proactively address this in what is a very competitive labour market nationally and internationally.

A very hot summer caused significant temperature challenges with blood components both on clinic and transportation logistics.

Blood component supply

The IBTS strives to have a constant supply of blood components available for the Irish healthcare system. We target 7 days' supply across all whole blood groups and three days for platelets. This has been an International challenge with numerous European and World blood services facing the same issues. Many countries had to declare blood component

shortages which have had severe impacts on their own national health services.

Whole blood red cells

Total red cell issues was 124,501 an increase of 2.1% when compared to 2021.

The IBTS called two national appeals during the year. National appeals are called to try and avoid calling Amber alerts (a warning system agreed with the IBTS and the National Transfusion Advisory Group, NTAG). Amber alerts involve working with all the hospitals nationally to take steps to conserve blood, to avoid blood component shortages which could affect day to day hospital activity and patient care. In addition to the national appeals the IBTS imported blood from our main contingency partner on two occasions, 350 units were imported in March and 390 units in November. As a result of all of these actions the IBTS did not activate any amber alerts during the year.

The IBTS policy of focusing on the regular donor base continued in 2022. We did not run any national marketing programmes. National marketing campaigns will recommence in 2023 to encourage first time donors.

A new donor web portal is due in 2023 which will allow donors to make their own appointments on-line. This will ensure donors have a smoother online experience with the IBTS.

Platelets

Platelet demand from hospitals has continued to run in excess of 0.7% against last year.

The current 'live' apheresis donor panel is made up of just over 2,000 donors. Recruitment work to grow the platelet panel further will continue with a number of initiatives planned to increase the size of the platelet panel.

During 2023 we will upgrade and replace our apheresis machines (both hardware and software) to the latest versions. It is expected this will increase the platelet yield.

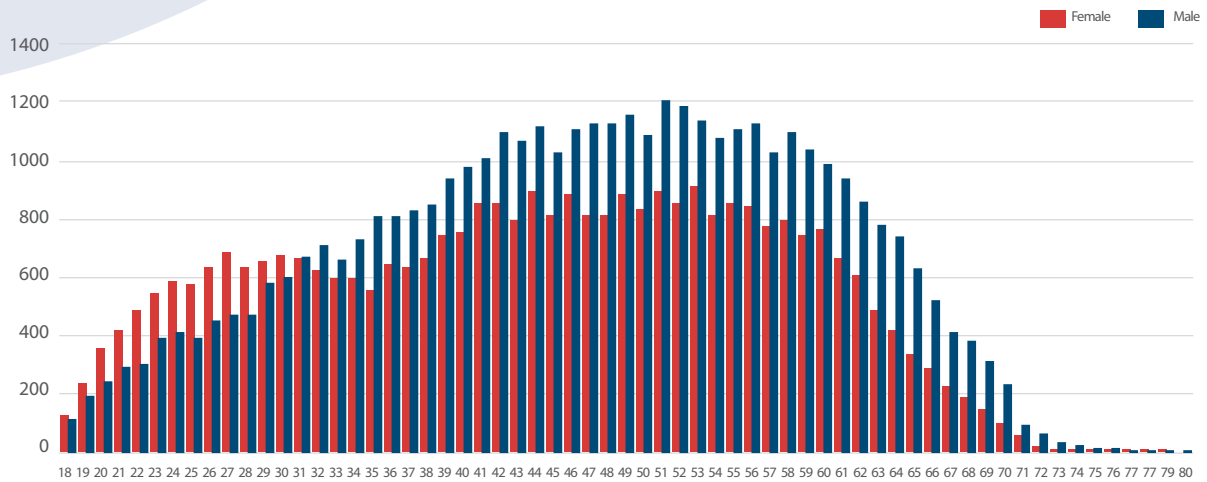
Individual Donor Risk Assessment (IDRA)

In November the IBTS introduced a significant policy change by introducing Individual Donor Risk Assessment (IDRA) for all donors. IDRA has enabled the IBTS to ask the same health and lifestyle criteria questions to all existing and potential new donors rather than ask different questions to different sections of donors. This means that any deferrals are applied based on the donor's individual specific risk profile. This was the culmination of several years' work to move away from group based assessments for high risk groups. This has been very well received by all donors. We will be introducing an electronic version of the paper based Health and Lifestyle Questionnaire during 2023 as part of the drive to improve donors experience with the IBTS.

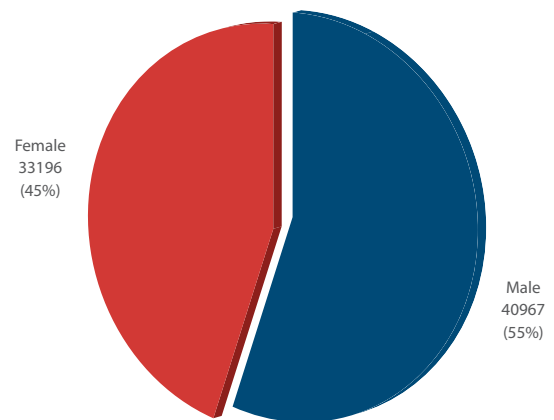
Donor Services went live with a new cloud PC-based telephone system in early September, which has significantly improved call management and waiting times for donors calling to make appointments to donate or with queries.

The quality of haemoglobin measurements for all donors was improved with the introduction of new Hemocue 301 equipment across all clinics. This equipment is a part of the overall process which helps protect donors at high risk of iron deficiency when their levels are below the set tolerances. This new equipment also reduced the amount of time a donor spends in the clinic during donation as it measured the haemoglobin significantly faster than the old measuring devices.

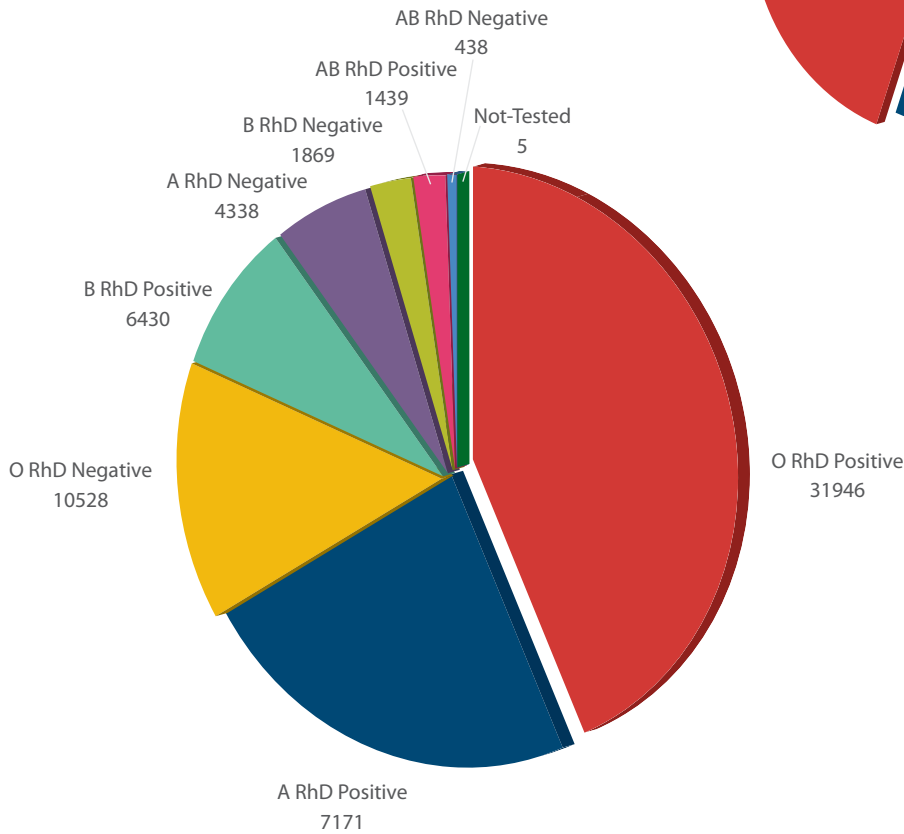
Whole Blood Donors by Age and Gender



Whole Blood Donors by Gender



Whole Blood Donors by Bloodgroup





Partnerships

Celebrating World Blood Donor Day with Vodafone Foundation

The IBTS and Vodafone have a long standing partnership for many years. Vodafone sponsor all of the text messages that the IBTS send to donors encouraging them to make an appointment. Approximately 6 million texts are sent to donors annually informing them about upcoming clinics. Donors are also texted to let them know where and when their blood donation has been issued.

As part of our celebrations of World Blood Donor Day 2022, a video of the IBTS Chief Executive, Orla O'Brien and Vodafone Chief Executive, Ann O'Leary was launched. This video explained how this special partnership works. As part of this launch we shared stories involving Vodafone employees, who are also blood donors, across our social media platforms and national media. These stories highlighted the amazing gift from these donors, their motivation to keep giving blood and how this wonderful altruistic act has made an impact on patients receiving these donations in hospitals nationally.



Seán Gilligan, Vodafone Ireland employee and blood donor.

"When COVID began, I made a resolution to myself to donate as much as possible. I've been donating in the Stillorgan clinic ever since. I go every 90 days which is the minimum amount of days you can wait between donations. Last year my father-in-law was diagnosed with stage 4 cancer. He's undergone a lot of severe surgeries and battled through countless infections, and other complications with chemo. He has certainly had his fair share of scares but has been a grateful recipient of many blood transfusions in recent times. I'm happy to say, as of last month, he has completed his last session of chemotherapy and is recovering in leaps and bounds!"



Kildare GAA partnership

In November, the IBTS ran a blood donation clinic with Kildare GAA with senior players from the male and female inter county teams, giving blood during their off season from GAA inter county competitions. Over 80 players and staff attended from over 20 clubs in Kildare. The players are supporting us by continuing to promote blood donation to their individual clubs throughout the season as the IBTS hold clinics in their local areas.

The IBTS was delighted to be able to renew its partnership with the Defence Forces Benevolent Fund with a concert in October at the National Concert Hall. The Defence Forces are a vital support for our clinics particularly during challenging weather, but also as a regular source of platelets and blood donors including hosting clinics at various army camps across the country.



IBTS second blood bag donation in support of Ukraine Red Cross

In May the IBTS arranged a second shipment of blood bags to the Ukrainian Red Cross. Four thousand blood bags were shipped directly from the manufacturing plant in Poland to the nominated border crossing on the Poland/Ukraine border to get them to the Ukrainian Red Cross as soon as possible.



Blood donation awareness

Social Media

The social media platforms used by the IBTS continue to support communication and engagement with donors. During the year audiences increased across the four main social media platforms used by the IBTS; Facebook, Instagram, LinkedIn and Twitter. Instagram and LinkedIn are the fastest growing platforms for the IBTS.

Local Clinic supports and the return of lost friends

Venue availability continued to be a challenge but we were able to return to some smaller more local venues (our lost friends). It will take some time to build up these donor panels again but the process has started with the return of a number of one day clinic venues. A number of on site college clinics such as UCD and UCC also recommenced. The IBTS aims to increase the donor base by 15,000 in 2023.



O Negative campaign (the universal blood group)

In the build up to Christmas, a short campaign to increase the number of O negative donors at clinics was launched. The communication focused on the need for O negative blood donors as this blood type is always in demand. Donors with this blood type were encouraged to make an appointment at their local clinic. O Negative donor recruitment and advertising will continue to be a major focus as demand for this blood type is always high. Over 14% of all blood issued to hospitals annually is O Negative, but just 8% of the population who have O negative blood donate.

A promotional poster for a blood donation event. At the top, a red banner contains the text 'giveblood.ie'. Below this is a large red blood drop graphic containing the text 'Give blood, save lives. #WeCountOnYou'. To the right of the drop is a circular logo with a vampire face and the text 'DONATE BLOOD ORBSE'. Below the drop, the event details are listed: 'University College Dublin Astra Hall, Student Centre', 'Mon 10th October - Thurs 13th October 2022', and '11:00am - 02:30pm'. At the bottom, there is a red banner with the text 'Call 1800 731 137 or giveblood.ie To check your eligibility' and social media icons for Facebook, Instagram, Twitter, and LinkedIn. At the very bottom, a row of colored boxes represents blood types: A+, A-, B+, B-, AB+, AB-, O-, O+.

www.giveblood.ie

The giveblood.ie website is our information source for current and potential donors. Over 363,000 people visited our website during the year. 'Clinic Finder' and 'Eligibility Quiz' sections were among the top most visited pages. giveblood.ie was also enhanced with a specific clinical and research section for health professionals.



Donor Awards Presentation pack

891 donors received their 50 times donation award and pack, and 157 donors received their award and pack for contributing 100 lifesaving donations. In person donor awards ceremonies will recommence in 2023.



Production, Hospital Services, Supply Chain & Logistics, Scientific Support and Component Development

Key achievements

- Options analysis process completed to inform the future use of Irish plasma.
- Maintained blood stocks across the supply chain, ensuring blood and blood product availability to meet patient's needs.
- Maintained frontline functions through-out COVID-19 pandemic. A high level of commitment, adaptability and compliance was upheld by all teams.
- Worked with internal and external healthcare partners to maximise and optimise the use of blood components for all patient groups.
- Continued replacement of critical blood processing equipment to maintain state of the art processing capability and operational best practice including the replacement of high throughput rapid plasma freezers.
- Validation of technology for the pathogen reduction of platelets was commenced.
- Replacement of temperature controlled fleet has commenced in the NBC and Cork Centre which includes the introduction of two crew cabs for transport of staff on clinic.

The Components Production function is responsible for processing, labelling and banking of all whole blood donations, platelet pools and platelet apheresis donations nationally.

The Hospital Services function is responsible for inventory management, receipt and issuing of blood and blood product orders from hospitals.

The Supply Chain, Transport & Logistics functions are responsible for supporting internal and external business needs.

The Scientific Support and Component Development team are responsible for the management of all platelet products, non-routine whole blood and red cell products issued from the NBC. This team also provides day to day scientific support for numerous departments and encompasses the product development function.

Blood Component Activity

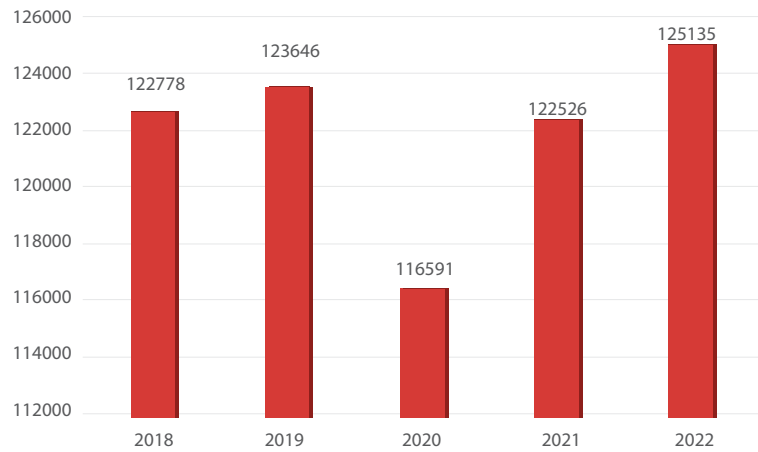
There was an increase in red cells (+2.1%) and platelets (+0.7%) issued to hospitals in 2022, compared to 2021. Demand varied throughout the year, however, over the course of the year demand increased for both red cells and platelets compared to 2021.

Red cell units were imported from the NHS Blood and Transplant to supplement blood stocks on two occasions in March and November, to ensure blood support for patient care a total of 740 units were imported.

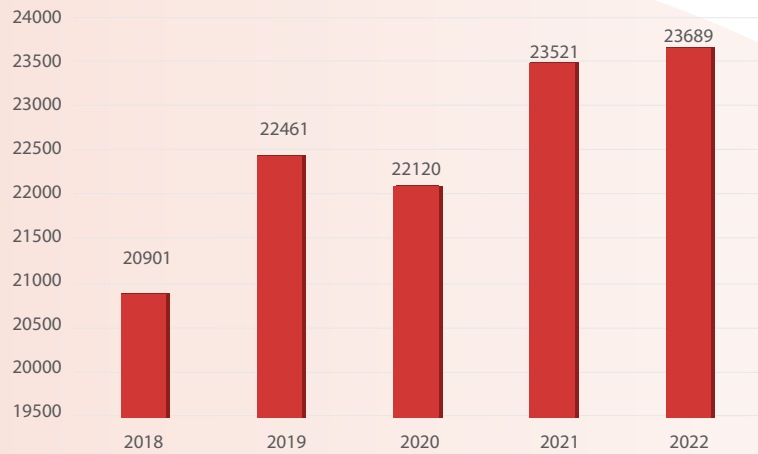
Medicinal Product Activity

There was an increase in medicinal products issued in 2022, compared to 2021. There was an 8.2% increase in LG-Octaplas issued and 6.8% increase in Riastap (Fibrinogen) issued.

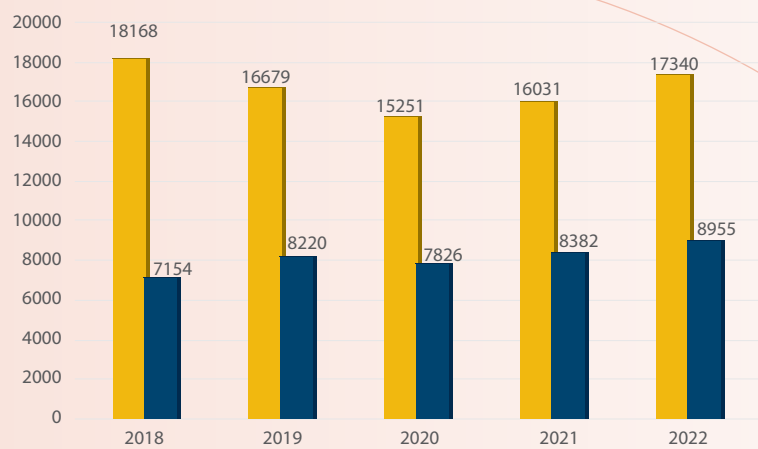
Red Cell Issues 2018 to 2022



Platelet Issues 2018 to 2022



LG-Octaplas and Riastap Issues 2018 to 2022



● LG-Octaplas ● Riastap

Testing



The National Donor Screening Laboratory (NDSL)

The NDSL encompasses the three donor testing laboratories: Automated Donor Grouping (ADG), Virology, and Nucleic Acid Testing (NAT). This extensive collaboration between the three donor testing laboratories allows for optimum workflow analysis, strategic utilisation of key scientific personnel, up skilling of scientific personnel in multiple scientific disciplines, increased research and development in all areas and the increase of testing services available to the IBTS.

Key achievements of the NDSL included:

- The ADG laboratory successfully completed a very significant project in 2022 with the validation and introduction of the PK7400 primary blood group analysers in ADG in November 2022. ADG tested over 18,000 samples in the course of this large validation exercise, and provided valuable new information to the supplier which has led to updates to the instrument instructions for use.
 - The advancement of the cross-training programme with support from the Training and Education Officer provided cross functional support between staff in the three departments which has contributed to developing a cohesive and collaborative team in the NDSL.
 - The NDSL received the PWC Business Post Inaugural Sustainable Business team of the year award in recognition of its achievement of the highest green certification with My Green Lab, a non-profit organisation that is leading the way in improving global laboratory sustainability. The maintenance and improvement of the My Green Lab NDSL certification was a key part of the NDSL's sustainability strategy in 2022. The Virology laboratory validated two Malaria screening assays, one of which will be used for the malaria testing of blood donors which will be introduced in 2023.
- Participation by the Virology team in a study to investigate the haemoglobin and ferritin iron levels in Irish blood donors.
 - Supervising a number of third level research projects in Virology. These included:
 - i. Validation of the Architect Chagas antibody screening assay and assessing the viability of qualifying Brazilian nationalities for donation in Ireland.
 - ii. Estimating the seroprevalence of quantitative antibodies to SARS-CoV-2 in adult blood donors (as part of the on-going in COVID 19 National Serosurveillance Programme in collaboration with the Seroepidemiology Unit (SEU) in the Health Protection Surveillance Centre (HPSC)).
 - Training and participation in an internal audit team based on ISO (International Organisation for Standardisation) requirements.
 - NDSL staff completed a lean pilot programme which consisted of Lean Six Sigma training and coaching and the achievement of yellow belt certification. As part of this programme a review of 7 Biosafety cabinets in use has led to 99% reduction in power consumption (66,231 kWh to 548 kWh) and CO₂ emissions (24,039kg of CO₂ to 192 Kg CO₂), as well as 71% reduction in annual operating costs from €21,252 to €5,076.

NDSL Laboratory Activity

In 2022 the NDSL tested 138,651 donations, with 131,894 coming from repeat donors (95%) and 6,757 (5%) of these donations coming from first time donors. In addition, 926 sample only new donors were also tested.

All donations were tested for:

- ADG: ABO/Rh, extended Rh phenotype (CcEe), donor antibody screen and high titre A/B

Selected donations were tested for ADG extended antigen types.

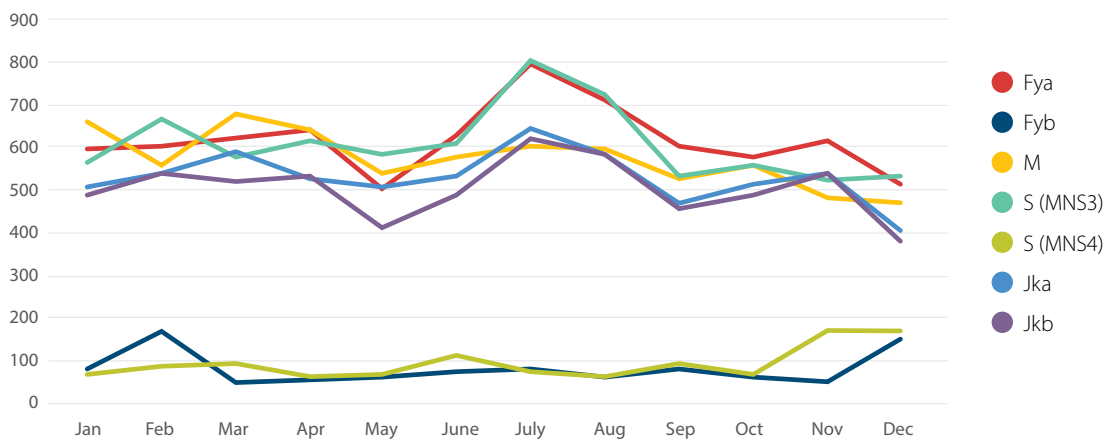
- Virology: The presence of antibody to Human Immunodeficiency viruses (anti-HIV 1 / 2), antibody to Hepatitis C virus (anti-HCV), antibody to Human T-Lymphotropic virus type I and II (anti-HTLV-I / II), antibody to Hepatitis B core (anti-HBc),

Hepatitis B surface Antigen (HBsAg), antibody to Treponema Pallidum (Syphilis).

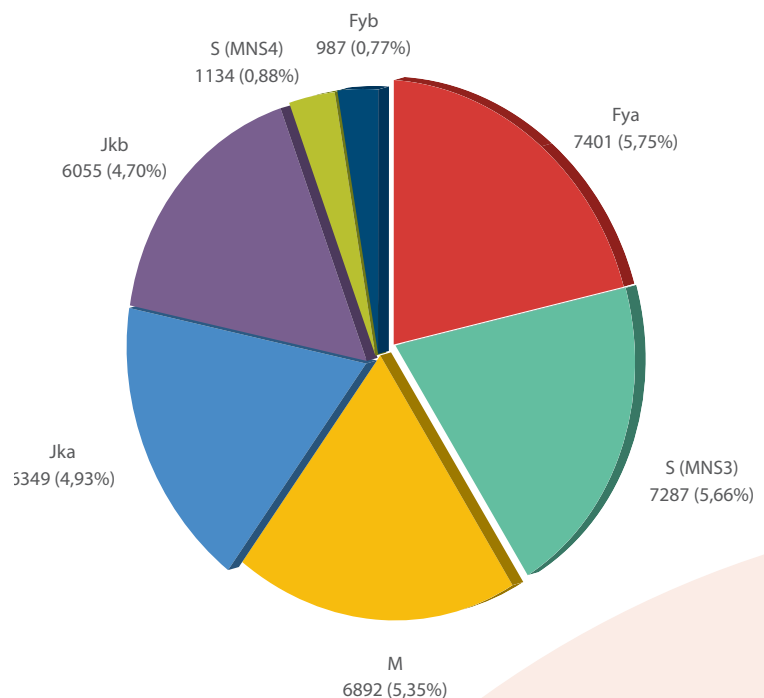
- NAT: Human Immunodeficiency Virus type 1 and 2 (HIV-1/2), Hepatitis C virus (HCV) and Hepatitis B virus (HBV), Hepatitis E Virus (HEV)
- Selected donations were tested for:

- ADG: Extended antigen types: haemoglobin S, neonatal antibody screen. Donors are typed for extended antigen types (Fya/b, Jka/b, M, S/s) for routine hospital orders and also to identify rarer phenotypes or combinations of antigen negative types. These are typically for patients with complex transfusion requirements such as sickle cell disease or multiple red cell antibodies and for prophylactically antigen-matched blood for intrauterine transfusions and certain patients who are known red cell antibody producers.

Number of extended antigen type tests performed



Percentage of donations typed for an extended phenotype



- Virology: Selected donations are tested for Cytomegalovirus (CMV) (approx. 80% of donations) in order to have a supply of CMV negative donations for those patients who are at risk of the complications of CMV infection e.g. immunocompromised patients.
- NAT: Selected donors were screened for West Nile Virus (WNV) from May to December 2022. This testing was performed for donors who had travelled to a WNV at risk area within the past 28 days.

ADG have two instruments in use: PK7400 as the primary blood group analyser and Ortho Vision as the secondary blood group analyser. Both instruments are immunohematology systems and utilise both hemagglutination and sensitisation techniques. The PK7400 is a high-throughput microplate system and the Ortho Vision tests using column agglutination technology. Manual techniques are used for antibody identification and sickle trait testing.

The Virology laboratory performs screening on the Abbott Alinity s System, which is a high-throughput, fully-automated immunoassay analyser designed to determine the presence of specific antigens and antibodies using chemiluminescent immunoassay (CMIA) technology.

The NAT laboratory performs Individual Donation testing (ID-NAT) using the Panther testing instruments with the Ultrio Elite (UE), HEV and WNV assays. The Panther instrument is a fully automated closed system for NAT testing. The Procleix UE assay is a multiplex Transcription Mediated Amplification (TMA) assay for the detection of HIV-1/2 RNA, HCV RNA and HBV DNA in human plasma. The Procleix HEV assay detects HEV RNA. The WNV assay reliably detects low level WNV RNA (lineage 1 and 2) in blood donations.

The laboratory also performs screening tests for viral markers for various departments within the IBTS, including stem cell donors, heart valve tissue donors and samples from recipient tracing testing programmes.

Participation in External Quality Assessment Schemes (EQAS)

NDSL participate in several EQAS. All departments within the NDSL had satisfactory results for their relevant EQA. ADG is a participant in 3 NEQAS schemes and 1 EDMS scheme annually. This consists of 19 separate serology exercises and 6 abnormal haemoglobin exercises.

The Virology department participates in three proficiency programmes: one circulated by the United Kingdom National External Quality Assessment Service (UK NEQAS) for Microbiology, the second by the NRL, Australia and one by the European Directorate for the Quality of Medicines & HealthCare (EDQM/NAT). Overall 25 proficiency exercises were completed in 2022 in Virology, assessing all Virology markers tested in the laboratory.

The NAT laboratory participated in seven proficiency programmes: two provided by the NRL, Australia, two by the European Directorate for the Quality of Medicines & HealthCare (EDQM), one by Quality Control for Molecular Diagnostics (QCMD), UK and two by the National Centre for the Control and Evaluation of Medicines (CNCF), Italy. Overall 13 proficiency exercises were completed in 2022 in the NAT laboratory. The laboratory also participates in the surveillance programme run by National Health Service Blood and Transplant (NHSBT) Epidemiology Unit/Health Protection Agency UK. The repeat reactive rates and the confirmed positive rates for testing kits using various lot numbers of reagents with the NHSBT are monitored. A notifying report is generated which details assay performance and trends in reactive rates.

NDSL Contingency Testing

As the NDSL is a national testing facility, the IBTS has an external testing plan with the Scottish Blood Transfusion Service in case of a critical failure of instruments or site. The NDSL succeeded in participating in 2 exercises in 2022 which involved sending samples from 24 donors for testing with favourable results. This plan has not had to be activated in a 'live' situation since the consolidation of testing at the National Blood Centre in 2010.

NDSL Audits

The NDSL Laboratory also participates in a number of Internal and External Audit programmes to ensure compliance within the Quality Management System (QMS). This auditing of the NDSL processes and procedures are undertaken by the Health Products Regulatory Authority (HPRA), the IBTS Quality Assurance (QA) department and the (NDSL) Laboratory.

Red Cell Immunohaematology (RCI) Laboratory

The RCI laboratory provides extensive pre-transfusion and antenatal referral services for hospitals nationwide.

Key achievements

Research and educational achievements

- RCI secured an agreement with the University of Minnesota and began participation in the BEST Study: D Alloantibody Titration Assessment (DATA) due to be rolled out in 2023.
- Poster presentation: "The Detection and Titration of Immune IgG Anti-A/B in ABO HDFN" was presented at BloodHIT.
- RCI began scoping phase for the validation and development of testing around the drug Magrolimab/anti-CD47.
- RCI continued to supply customer requests for samples which were used in projects across the country.

Laboratory Achievements

- The RCI laboratory achieved ISO15189 accreditation in December. Major developments and improvements were made in preparation for INAB inspection in May 2022 and subsequent ISO15189 accreditation in December 2022 such as:
 - Preparations for (INAB) Irish National Accreditation Board pre-assessment inspection and completed actions following pre-assessment report
 - Preparation of affiliated documents for assessment dates in May
 - Completion of necessary actions following assessment in May

Other key laboratory objectives achieved:

- Completion of customer satisfaction survey
- Review of Manual Grouping Process
- Creation of verification requirements in RCI
- Development of RCI policy around linkages and dependencies
- Development of the inter-laboratory comparison scheme to include DTT treatment technique
- Development of the equipment policy
- Software upgrade of the Ortho Vision automated analyser was completed in Q4 2022

Laboratory activity

The services provided by the RCI laboratory include:

- provision of crossmatched blood for patients with complex antibodies;
- investigation of red cell antibodies including serologically complex cases;
- investigation of haemolytic transfusion reactions;
- ABO/Rh typing, including the investigation of blood group anomalies;
- investigation of patients with positive direct antiglobulin tests;
- investigation of autoimmune haemolytic anaemia;
- investigation of monoclonal antibody interference;
- investigation of haemolytic disease of the fetus & newborn (HDFN);
- antenatal screening for red cell antibodies to identify at risk pregnancies; (antibody quantitation and / or antibody titration as appropriate);
- provision of suitable blood at delivery for at risk pregnancies;
- extended phenotyping for transfusion dependent patients and for patients with complex red cell antibodies;
- phenotyping of donor red cells when requested;
- clinical and scientific advice to hospital colleagues;
- importation of rare blood for named patients;
- out of hours emergency on-call service, and
- provision of hospital blood bank services for Our Lady's Hospice and Care Services and the Royal Victoria Eye and Ear Hospital.

A total of 2598 samples were tested in the RCI laboratory, a 4.3% decrease on 2021 figures, however 2022 saw a further increase in referrals from patients receiving the drug Daratumumab to treat multiple myeloma (21.5% increase). 2022 saw a marked increase in out of hours requests (9.3% increase).

Comparison of 2021 and 2022 sample numbers

	Total No. of Samples tested	RhD Type Workup	Antibody ID	Anti-D Quant	Anti-c Quant	Monoclonal Interference	Total Compatibility Test	Complex Compatibility Test	On-call Samples
2021	2712	3	1844	394	171	312	1150	1140	215
2022	2598	8	1718	387	142	387	859	849	236
(%)	-4.3%	+90.9%	-7.1%	-1.8%	-18.5%	+21.5%	-29.0%	-29.3%	+9.3%

As in previous years, there was a continued high level of serologically difficult or rare samples received. The following complex samples, some with rare allo-antibodies, were identified by the RCI Laboratory:

Antibody Identified	No. of Samples	No. of Patient's
Anti-Ce	5	5
Anti-Ch/Rg	26	8
Anti-G	42	16
Anti-Kna	1	1
Anti-P1	5	5
Other HTLA Antibodies	5	4
Immune Anti-B	4	3
System Specific	37	28
CR1 Related	3	3
Anti-Wra	13	5
Anti-Leb	12	12
Anti-Lea	27	18
Anti-Kpb	2	1
Anti-Lua	13	7
Total	195	116

Many of these patients are antenatal and in conjunction with identification of the red cell antibody, the risk of HDFN and possible blood requirements for both mother and baby were managed. The outcome for both mother and baby were successful.

The laboratory continued to develop its inventory of Rare Reference Cells and Antisera (through membership of the International Serum, Cell and Rare Fluid (SCARF) Exchange network and the UK Cell Exchange) and optimised its testing methodologies to adapt to the changing demographics of the Irish population.

Importation of rare blood/products

A total of nine rare units were imported from abroad for RCI patients following the identification of rare antibodies anti-U and anti-Kpb. Seven U-units and two Kpb- were imported for two patients.

Participation in external quality assurance schemes

The RCI laboratory participates in three different quality assurance schemes; four exercises in IEQAS, four exercises in AQQAS and 10 exercises in NEQAS along with pilot NEQAS schemes in red cell phenotyping, DAT and antibody titration. In addition, the RCI laboratory is involved in Interlaboratory comparison schemes for elution techniques, antibody titrations, adsorption techniques, DTT treatment and neutralisation techniques. All results obtained were satisfactory.



Diagnostics laboratory Cork

The Diagnostics laboratory at the Cork Centre provides both routine and reference immunohaematology and laboratory services. The former to South Infirmary University Hospital (SIVUH), St. Finbarrs', Mater Private Cork and Marymount University Hospital & Hospice, and reference immunohaematology & laboratory Services to the Munster Region. Medical Scientists and despatch officers are on-site 24/7 supported by Specialist Medical Staff and Consultant Haematologist.

The services provided by the Diagnostics laboratory include;

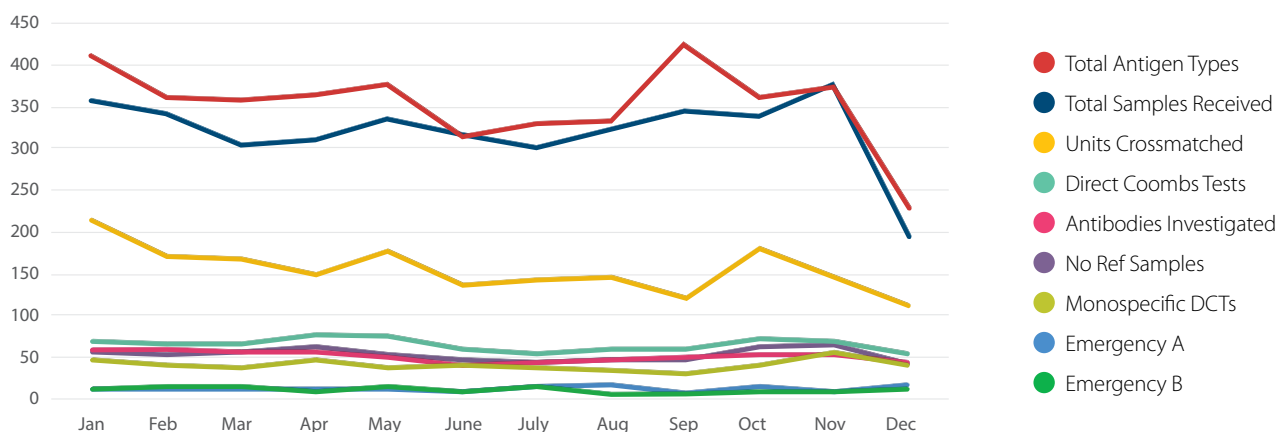
- Hospital Blood Bank for several city hospitals: the Cork Centre undertakes blood grouping, antibody screening, provides cross-matched red cells and other components for individual patients. Provides laboratory and clinical advice for these patients. Investigates possible transfusion reactions, participates in Patient Blood Management and transfusion practice planning and review through the hospital transfusion committees and audit, and manages component traceability.
- As a reference laboratory the Cork Centre investigates complex or anomolous red cell typing, extended typing for transfusion dependent patients, positive direct antiglobulin tests, auto-immune haemolytic anaemia, haemolytic disease of the fetus/newborn, and complex antibodies providing extended matched

(phenotyped) and crossmatched red cells for these patients. Individual samples in these cases may take several hours to investigate fully and may require donation screening where matching red cells are not available on the shelf. Five patient samples required further specialist referral to the international blood group reference laboratory (IBGRL) Bristol, and a further 96 samples were sent to the NBC for genotyping. Advice is provided to colleagues in the region.

- As a reference laboratory the Cork Centre investigates ante-natal patients with red cell antibodies and tracks their care through pregnancy to plan availability of matched blood for mother and baby at delivery.
- The Diagnostics' laboratory staff manage special component stock for the region. This includes all platelet components and all orders received by the electronic order system (EOS) for antigen typed red cells, irradiated blood components and blood components for babies.
- As the scientists on duty out of hours the diagnostics' laboratory contributes to the service by undertaking secondary processing of blood components, and are the first point of contact for clinical queries which are referred on to the medical staff.
- Performance in External Quality Assessment Schemes was satisfactory throughout the year.

Diagnostics Laboratory Activity 2022

Total samples received 2022: 3854 (2021: 3509). This increase in sample numbers was a direct result of increased activities in the hospitals.



National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL)

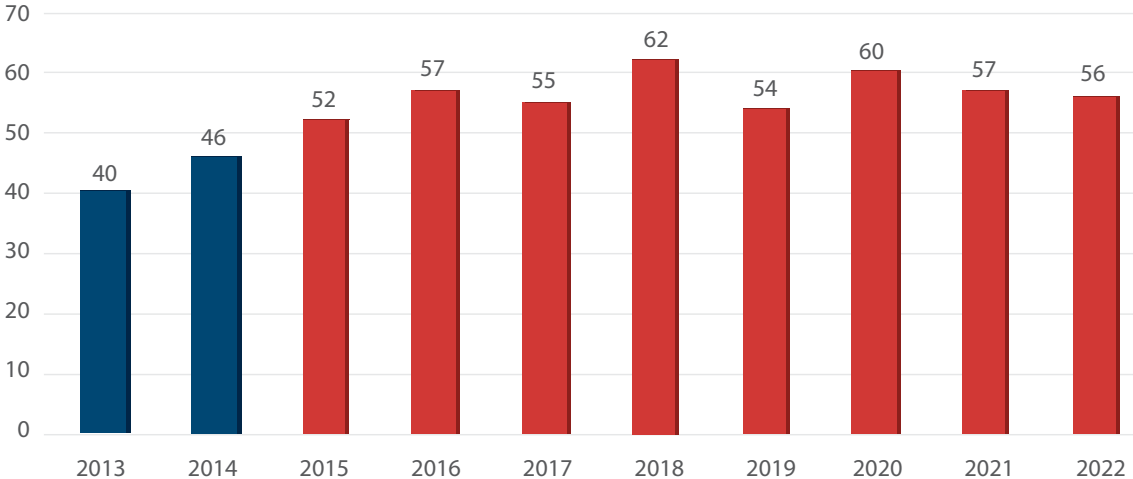
The National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL) provides a comprehensive range of clinical testing services designed to support the allogeneic haematopoietic stem cell transplantation (HSCT) programmes at St. James’s Hospital and Children’s Health Ireland at Crumlin. HSCT can be used in the treatment of leukaemias, bone marrow failure syndromes and inherited metabolic disorders.

The laboratory determines the human leucocyte antigen (HLA) type of all patients and donors (related or unrelated) prior to transplantation to aid donor selection. The laboratory uses exclusively molecular methods based on the polymerase chain reaction (PCR) to define the genes that encode the HLA molecules. This technology can achieve a high level of resolution that distinguishes between individual alleles of the HLA genes. The NHIRL performs high resolution HLA typing for 11 HLA loci (HLA-A, B, C, DRB1/3/4/5, DQA1, DQB1, DPA1, DPB1) by Next Generation Sequencing (NGS) using the Illumina MiSeq platforms.

The laboratory has an extensive quality assurance programme including participation in both internal and external proficiency testing programmes for HLA typing, human platelet antigen (HPA) genotyping and HLA antibody investigations. The NHIRL has been accredited by the European Federation for Immunogenetics (EFI) since 2001.

In 2022 samples from 260 Irish patients for potential haematopoietic stem cell transplants and 420 family members were HLA typed by the NHIRL. For those patients without a suitable family donor, an unrelated donor may be identified from the registry of volunteer unrelated donors. A total of 385 samples from possible unrelated donors were HLA typed for Irish patients in 2022. The NHIRL provides an immunogenetics support service for the Irish Unrelated Bone Marrow Registry (IUBMR). Since October 2019 the blood donor Health and Lifestyle Questionnaire (HLQ) includes a question for donors aged between 18-25 asking if they would like to join the bone marrow registry. This has resulted in a very significant increase in the number of donors registering, with 2,441 new donors joining in 2022.

Number of Irish Patients receiving a HSCT from an Unrelated Donor 2013–2022



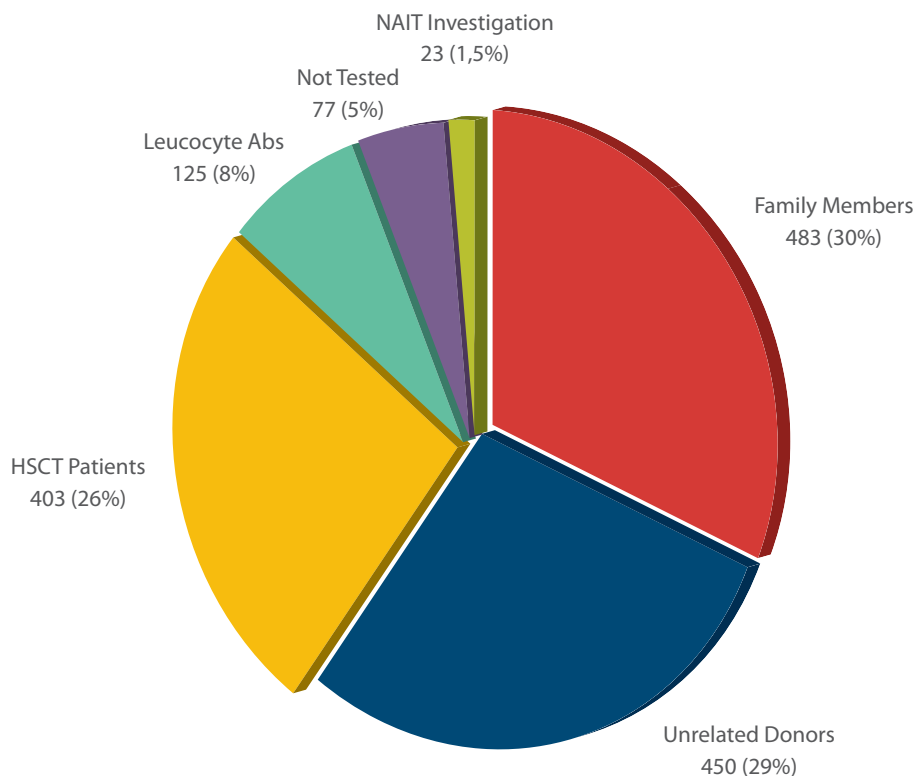
A total of 56 unrelated donor transplants were performed. In the last 10 years the IUBMR has facilitated 539 unrelated donor transplants for Irish patients.

In addition, a total of 303 platelet donors were HLA-A, -B typed and included on the panel of platelet donors to support the provision of an optimal platelet product to the hospitals.

The NHIRL received 1,561 samples as part of clinical investigations. As well as supporting the stem cell transplant programmes the NHIRL provides a platelet immunology service for the serological investigation of neonatal alloimmune thrombocytopenia (NAIT), post transfusion purpura (PTP), platelet refractoriness, alloimmune thrombocytopenias and adverse transfusion reactions. The number of investigations for NAIT in 2022 (n=23).

The NHIRL provides a routine disease association HLA typing service. This service represented 3,671 (44.5%) of the 8,243 samples received for testing by the NHIRL. The majority (79%) of samples are referred for determining the presence or absence of HLA-B27 which is associated with Ankylosing Spondylitis; a painful, progressive rheumatic disease mainly affecting the spine and sacroiliac joints. The service also provides HLA typing for Coeliac Disease (DQ2/DQ8, 1.7%), Behcet's Disease (B*51, 4.8%), Abacavir-induced hypersensitivity reaction (B*57:01, 10.4%), Narcolepsy (DQB1*06:02, 0.9%), Birdshot retinochoroidopathy (A*29, 1.2%), Acute severe Hepatitis in children (DRB1*04, 1.4%) and Metastatic Uveal Melanoma (A*02:01, 0.7%).

NHIRL Clinical Investigations





Blood Group Genetics Laboratory (BGGL)

Molecular Blood Group typing is performed by the Blood Group Genetics Laboratory of the Molecular Biology and Genetics Department at the National Blood Centre, with the purpose of providing a molecular diagnostic service for blood group determination.

The Blood Group Genetics Laboratory provides a service for:

- Fetal *RHD* Screen
- Weak D Genotype investigation
- *RHD* Variant investigation
- Full RBC Genotype investigation
- *RHCE* Variant investigation

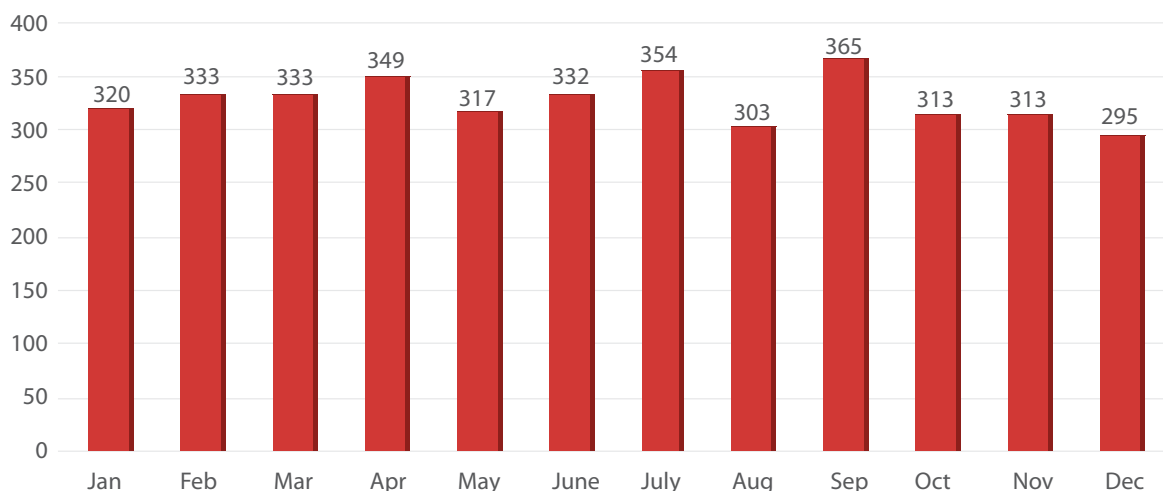
DNA-based testing is increasingly being used to predict a blood group phenotype to improve practices in transfusion medicine. Red blood cells carrying a particular antigen, if introduced into the circulation (through transfusion or pregnancy) of an individual who lacks that antigen, can elicit

an immune response. The resultant production of antibodies can have a significant effect on the patient's morbidity and even mortality.

Sensitive methods, such as quantitative polymerase chain reaction (qPCR), offer the ability to detect very low levels of DNA and are particularly applicable for the detection of fetal blood group genes in cell-free DNA extracted from maternal blood.

3,927 samples were received by the Blood Group Genetics Laboratory for Fetal *RHD* screening from 7 different hospitals nationally. The results for Fetal *RHD* screening identified 57.9% *RHD*-positive, 35.6% *RHD*-negative, and 5.8% Inconclusive. The referrals for Fetal *RHD* screening increased by 23.7% from 3,174 samples tested in 2021. The electronic transmission of Fetal *RHD* screening results through Medibridge is available to referring hospitals and was validated for use with the National Maternity Hospital, Holles Street.

Monthly Fetal *RHD* Screen Numbers 2022

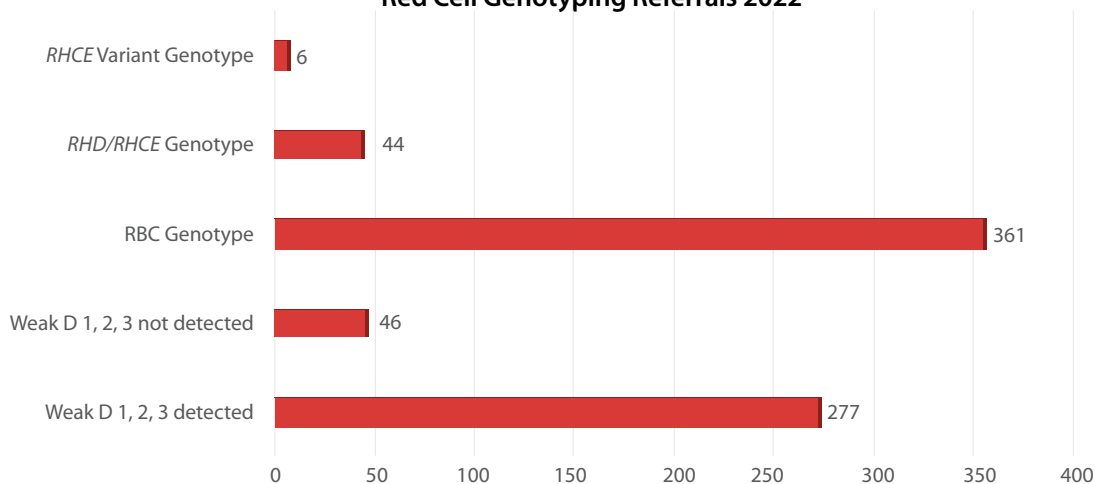


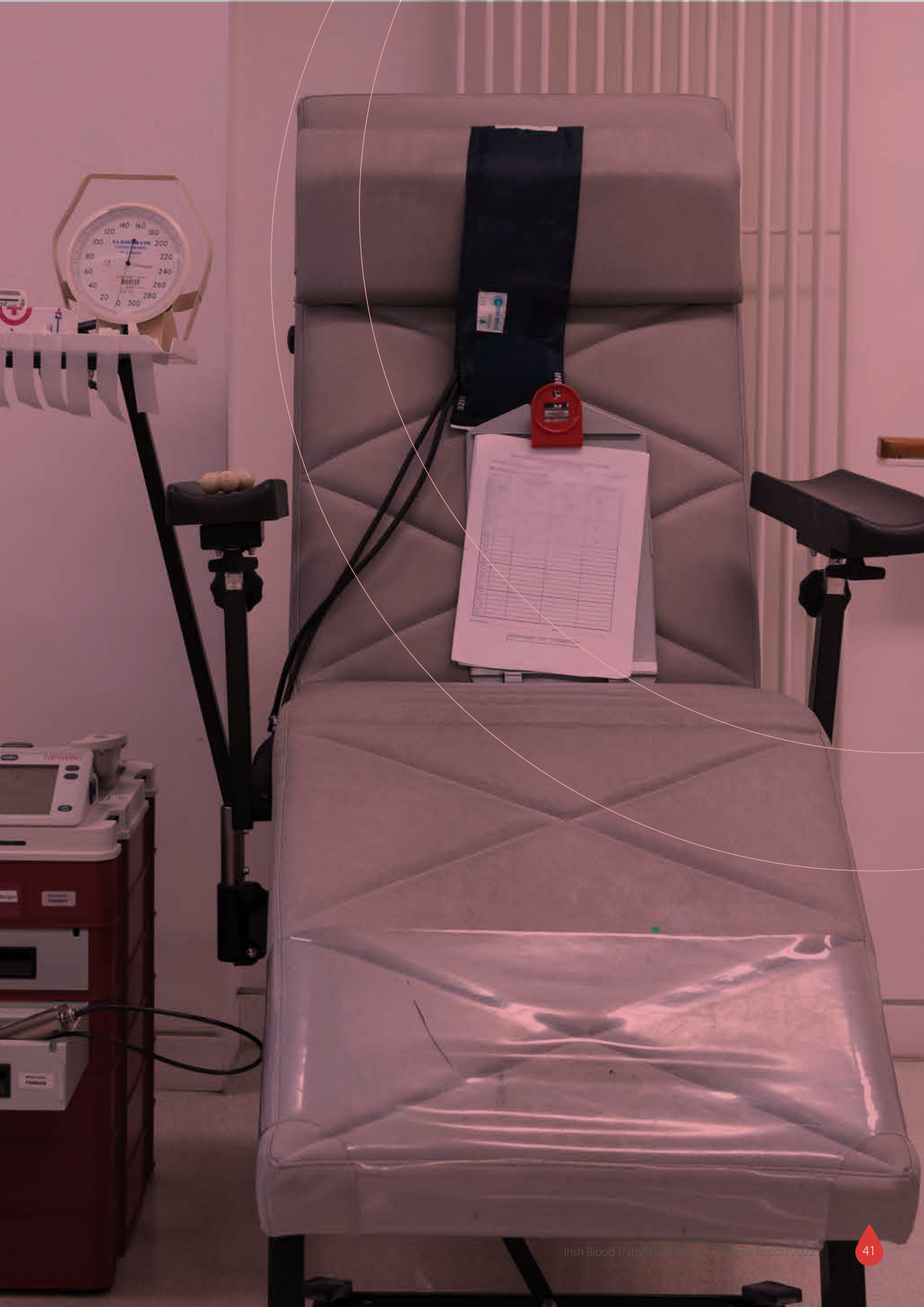
Molecular determination of blood groups offers a powerful method that overcomes many of the limitations of, and often offers higher resolution blood group typing than serological methods (e.g. *RHD* and *RHCE* variants, FY_{GATA} mutation).

Currently 44 Human Blood Group Systems have been identified, their genes cloned and the molecular

basis associated with individual antigens determined; there are 354 red cell antigens represented in the 44 Blood Group Systems. The Blood Group Genetics Laboratory tested 734 samples in total for Weak D Genotype investigation; *RHD* variant investigation; Full RBC Genotype investigation; and *RHCE* Variant investigation. An increase of 11.7% from the previous year.

Red Cell Genotyping Referrals 2022





Other Services

Tissue services

The IBTS tissue bank is located at the National Blood Centre in Dublin. This is a licensed tissue establishment and also holds a GMP license for the production of serum eye drops under the classification of an exempt medicinal product.

The facilities consists of a suite of clean rooms, mandatory for the processing and testing of donated human tissue and the production of serum eye drops. The service provides human tissue nationwide to a variety of hospitals. Some tissue is donated by Irish donors but other tissue needs to be obtained from tissue banks in Europe or imported from the USA. Tissue products available include ocular, cardiovascular, musculoskeletal and skin.

The highlight of 2022 was the granting of a Manufacturer's Authorisation by the HPRA, to produce allogeneic serum eye drops as an exempt medicinal product. This was the result of a positive report following a 3 day inspection in April. Serum eye drops are prescribed as a treatment of last resort when conventional treatment has failed to work. They are prescribed for a number of conditions both immune and non immune which has resulted in dry eye.

Production of the drops commenced in September and the clinical demand for the product has been high, as anticipated by the Ophthalmic Director of the bank. The team has commenced the implementation of the plan to re introduce a cornea bank in Ireland. This will once again allow Irish donors to donate their corneas and in time reduce the demand for imported corneas with an ultimate aim to be self sufficient. Supply of ocular tissue was up 20% on 2021 while cardiovascular, musculoskeletal and skin tissue remained constant with the previous year.

Irish Unrelated Bone Marrow Registry (IUBMR)

2022 key Achievements:

- Addition of 2,441 donors to the registry
- Transformation of donor recruitment, enriching the registry with younger donors to further enhance the chances for IUBMR patients to receive a bone marrow transplant

Haematopoietic progenitor cell transplantation is a lifesaving therapy for certain patients with leukaemia, bone marrow failure syndromes, and for particular inherited metabolic disorders. For the many patients who do not have the preferred option of a fully matched sibling, an unrelated donor from one of the forty million volunteer donors available worldwide can provide a suitable alternative.

To meet the need for haematopoietic progenitor cell donors for both Irish and international patients, the Irish Unrelated Bone Marrow Registry (IUBMR) was set up in 1989.

The Irish Registry searches and selects donors for patients in need of a transplant in Ireland. It also hosts a database of donors in Ireland who are willing to donate blood stem cells.

Tissue typing of donors registered on the unrelated panel is performed by the National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL). The registry is licenced by the HPRA under the EU Tissue Directive 2004/23/EC.



National Activities

The IUBMR searches for suitable donors on the Irish Bone Marrow Panel and through the World Marrow Donor Association (WMDA) database, on behalf of the Irish transplant centres at St. James's Hospital, Dublin and Children's Health Ireland at Crumlin. In 2022, the number of patients referred to the IUBMR for unrelated searches was 105.

Fifty-Six Irish patients received stem cell transplants from an unrelated donor in 2022. The majority of these were from international donors with 4 of these from IUBMR donors. Of the 56 transplants performed 15 were of bone marrow, 38 were peripheral blood stem cell, and 3 were Donor Lymphocyte Infusions.

International Activities

The IUBMR is connected to European Marrow Donor Information System (EMDIS), a communication system which allows international registries to search each other's panels and select donors for extended testing with ease. In 2022, 125 IUBMR donors were requested for additional testing. From some of the testing results 7 work up requests were received. We had a total of 5 PBSC donations completed on behalf of international patients in 2022.

Irish Donor Recruitment

During the year, 2,441 new volunteers gave blood samples to join the IUBMR, which will be added to the current registry of over 23,000 potential donors.

National Haemovigilance Office (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 Irish Blood Transfusion Service (IBTS). Since the programme commenced in 1999 a total of 8,586 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 and Ireland Blood Transfusion Network (UK & IBTN).

Serious Adverse Events (SAEs) — mandatory and non-mandatory

Mandatory SAEs relating to the quality and safety of blood under EU Blood Directive 2002/98/EC and non-mandatory SAEs relating to the clinical aspect of blood transfusion are reviewed by the NHO. These reports come from blood establishments, hospital blood banks and facilities. During 2022, 153 mandatory SAEs were reported (48% of all SAEs). In addition, 168 non-mandatory SAEs, (52% of all SAEs) primarily relating to errors in clinical areas, were also reported. This figure includes Wrong Blood in Tube events (WBIT) (n=57) which were collected by the NHO.

Serious Adverse Reactions (SARs) — mandatory and non-mandatory

A total of 134 SARs that meet the criteria have been reported in 2022. Mandatory SAR (82) reported to date is an increase on those recorded in 2021 (78).

Annual Notification of Serious Adverse Reactions and Events (ANSARE)

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 ANSARE form to the NHO. 211 mandatory reports were reported by the NHO in 2022 (for the reporting year 2021), with the compilation of 2022 ANSARE report on-going at time of writing.

Health Products Regulatory Authority (HPRA)

The Competent Authority for implementation of all aspects of the EU Blood Directive is the HPRA and, as in previous years regular case review meetings were held with the NHO to discuss reported incidents.

Education, promotion and developments

The NHO supports the on-going development of hospital in-service training programmes by working closely with hospital based HVOs. On-going education of undergraduate and post graduates, medical scientists and specialist registrars also continued during the year.

NHO Virtual Conference 2022

The National Haemovigilance Office hosted a virtual conference on Tuesday 15th February 2022 with just over 300 delegates with various disciplinary backgrounds in attendance.

The virtual event was opened by Professor Stephen Field, Medical and Scientific Director of IBTS and featured speakers from Ireland, United Kingdom, Norway and USA presenting on topics ranging from the 'National Transfusion Advisory Group in Ireland; to SHOT UK Human & Systems errors; Patient Blood

Management in Norway; Paediatric transfusion in Ireland and Blood Track update.

The NHO staff presented the findings and analysis on serious adverse reactions and events of reports accepted during 2020/21.

A poster competition coincided with the conference with 7 entrants received; the subject of the winning entry was on Implementation of the Haemobank™ in University Maternity Hospital Limerick.

The virtual event generated much interest with lively online discussion during the three question and answer sessions.

The presentations are available on the IBTS website (where permission was given by the presenter).

Annual report

The NHO have compiled the 2021 annual report which provides information on adverse events and reactions reported to the NHO in 2021.

The Annual report has been made available on the giveblood.ie website.

e-Learning

The IBTS continued to provide 'Learnbloodtransfusion' e-learning programme under licence to hospitals via LearnPro NHS.

The majority of Irish hospitals and a number of third level institutions are registered on the programme. This includes hospital staff and health care undergraduates in several universities undertaking the modules as a mandatory course requirement.

Therapeutic Apheresis Service

The Cork Centre, Therapeutic Apheresis Service (TAS) provides therapeutic apheresis for patients in the Munster region at Cork University Hospital (CUH), Mercy University Hospital (MUH) and Bon Secours Hospital Cork (BSHC). Patients in other hospitals in the region requiring TAS are transferred to these facilities, as appropriate.

TAS is led by a consultant in transfusion medicine, supported by Specialist Medical Officer (SpMO), Specialists Registrars (SpRs) and nurses trained in therapeutic procedures. Procedures are carried out at the patient's bedside using mobile apheresis equipment; Terumo Spectra Optia. Individualised apheresis protocols are prepared for each patient in conjunction with the requesting clinical hospital team, guided by the American Society for Apheresis 'Guidelines and Indications for Treatment' (ASFA-2019), and cognisant of the other guidelines including those from the British Society of Haematology (BSH-2015).

TAS operates within the quality management system, with trained personnel, controlled docu-

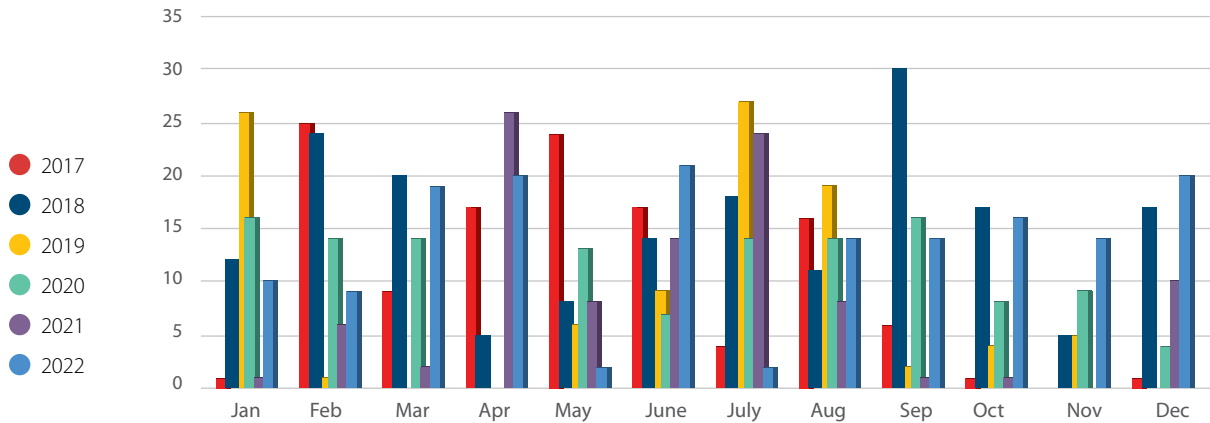
mentation, standard operating procedures (SOPs), validated technology and adverse event monitoring, subject to HPRA inspection. Adverse events are subject to on-going review and changes are incorporated into the IBTS Therapeutic SOPs, relevant hospital policies and procedures. TAS staff attend national and international meetings and comply with continuing professional development (CPD) including audits. During 2022 there were 28 patient referrals and 161 procedures undertaken. This included Therapeutic Plasma Exchange (TPE) and Red Cell exchange (RCE) mostly in CUH with one patient in BSHC and one patient in MUH. The demand for TAS is varied and unpredictable. The trend in increasing neurology referrals is balanced by a reduction in haematology and to a lesser extent, renal referrals over recent years.

Service demand trend

The service from 2017 to date typically provides 97 to 181 procedures per annum. Trends and variability in service demand over recent years are shown below.

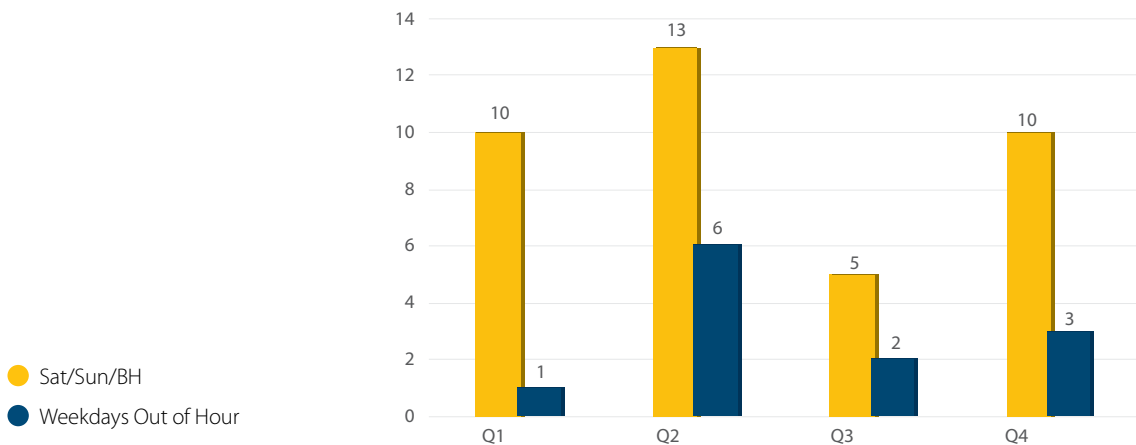


Service demand 2017–2022 by month



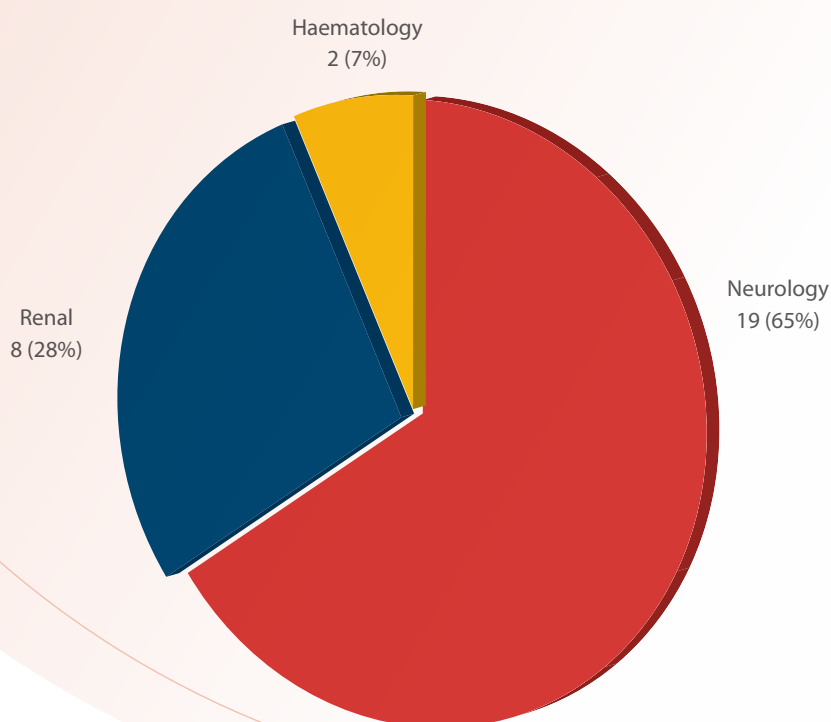
Patients may present for emergency, out of hours care when their diagnosis is acutely life or organ threatening. Daily/alternate day protocols also require weekend service. Of the 161 procedures carried out in 2022, 38 (26.6%) were performed at the weekend and 12 (7.4%) were commenced out of regular hours during the week. The trend in demand (by quarter year) for weekend/bank holiday and out of hour's service is set out below.

Weekend, Bank Holiday, Out of hours 2022



1.1 In line with recent trends the majority of referrals were for patients presenting with neurological conditions 19 (68%), followed by renal 7 (25%) and haematology 2 (7%).

Patients by Speciality



Sickle Cell Disease

TAS continued an elective Red Cell Exchange programme for a patient with sickle cell disease (SCD) from 2020, guided by laboratory and clinical parameters. In 2022 a total of 11 red blood cell exchanges were performed. It is anticipated that this demand will increase as the regional paediatric patient cohort matures into adulthood.

CUH had the greatest demand for TAS referring 26 patients in 2022. BSHC and MUH had 1 referral each.

The American Society for Apheresis (ASFA) guidelines

ASFA guidelines are the basis of planning individual patient treatment protocols. These are based on both quality of supporting evidence as well as the strength of the recommendation derived from that evidence. The most recent guidelines (8th Ed.) were published in 2019.

Category I — Disorders for which apheresis is accepted as first-line therapy, either as a primary standalone treatment or in conjunction with other modes of treatment.

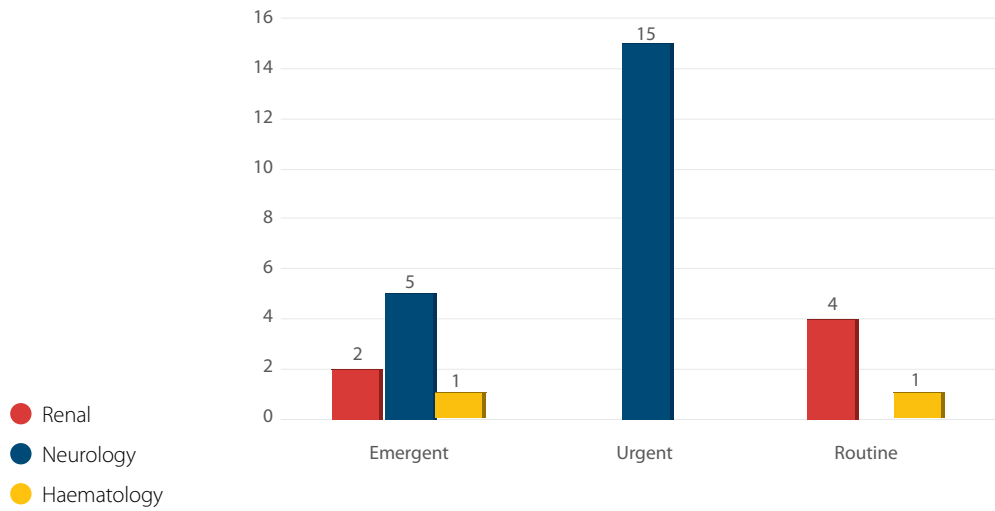
Category II — Disorders for which apheresis is accepted as second-line therapy, either as standalone or in conjunction with other treatments.

Category III — Optimum role of apheresis is not established — decision making is individualised.

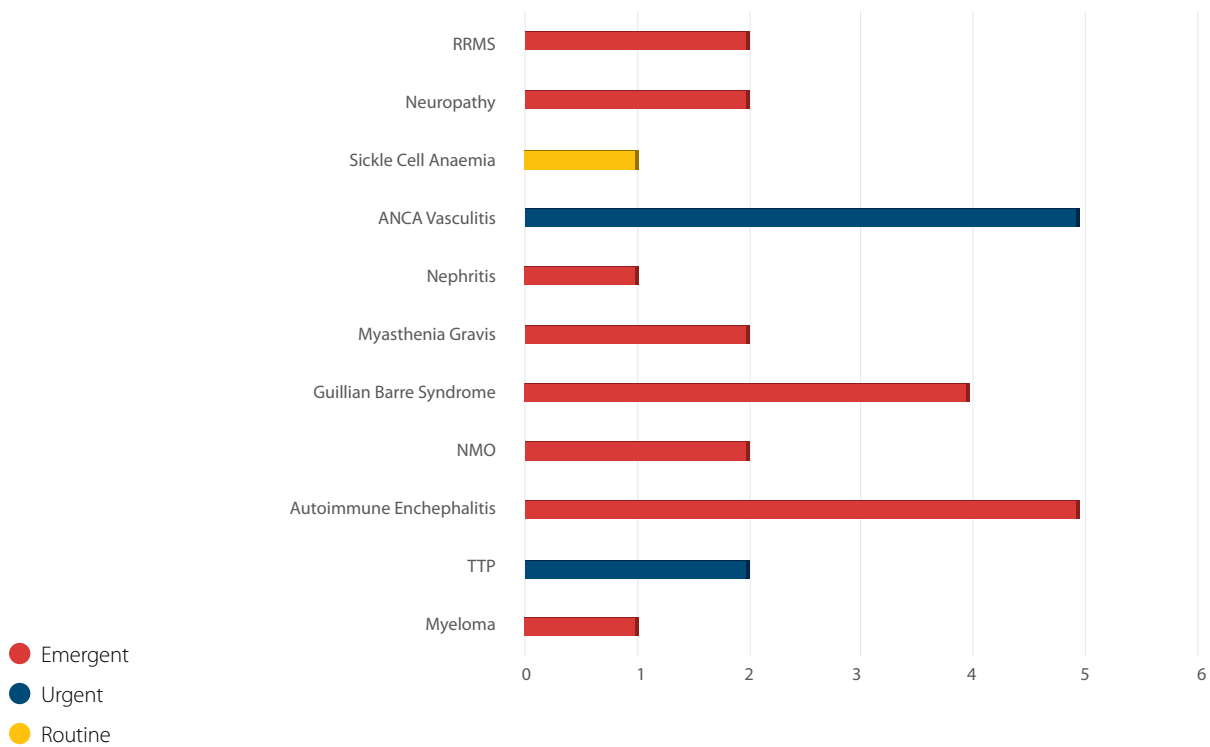
Category IV — Disorders in which published evidence demonstrates or suggests apheresis to be ineffective or harmful.

Therapeutic Apheresis may, in some conditions, form part of the urgent clinical response to patient's presentation. Early apheresis can reduce the threat to life or organs. 68% of patients presented as urgent, 29% as emergent and 3% presented as routine in 2022.

Degree of Urgency of patients by speciality 2022

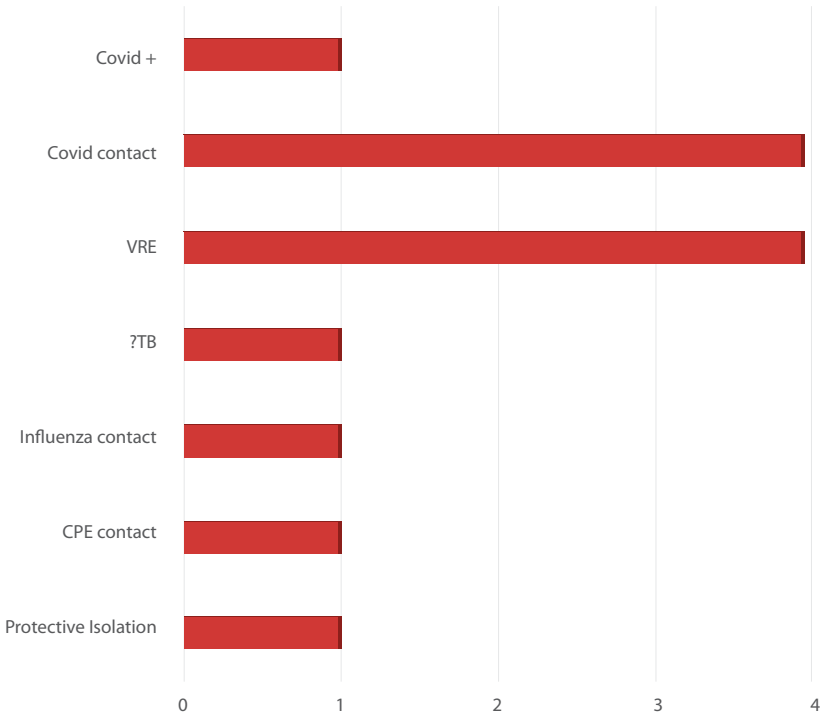


Patients by diagnosis and degree of urgency



In 2022 a number of patients needed to be treated with isolation precautions.

Isolation requirements 2022 (No. of patients)



Therapeutic Apheresis requires excellent blood flow which, especially for an intensive programme over a short number of days, may require support by the placement of a central line by anaesthesiology or radiology services at the referring hospital. Most patients required a central line.

Quality Framework

A quality management system is defined as a formalised system that documents processes, procedures and responsibilities for achieving quality policies and objectives. TAS is compliant with the American Society for Apheresis (ASFA) guidelines (2019) and the British Society of Haematology (2015) and undertakes internal audits and continuous professional development to assure good practice. Communication with other apheresis services and attendance at UK and international conferences also ensures that the service is evidence based.

Facilities and technology

TAS uses two Spectra Optia machines which are stored in the CUH and can be transported to either the MUH or the BSH as required. The machines are validated and have a bi-annual routine preventative maintenance.

The TAS team are licensed medical practitioners and registered general nurses who undertake all mandatory training and continuous professional development to ensure practice is current and evidence based.

Quality

The Quality function remains committed to delivering the highest standards of quality by making this part of everything we do. Processes in place continue to meet regulatory requirements to ensure safe, high-quality products and services for customers.

Quality is a key enabler which underpins strategic goals to support better healthcare, achieve operational excellence and improve customer service. The IBTS aims to be an industry leader in implementing and supporting a culture of quality which supports the organisation and continually meets its objective of delivering value to donors and patients.

Our Key Objectives

- Support IBTS medical laboratories and other departments in meeting international standards
- Improve efficiencies across a range of quality activities
- Introduce a flexible risk based approach



Key Achievements

- Supported the Red Cell Immunohematology laboratory with achieving award of accreditation by the Irish National Accreditation Board (INAB), to conformity with EN ISO 15189:2012.
- Update of the non-conformance process for management of Incident Reports to include significant changes such as an improved risk based approach, which incorporates international guidelines on Quality Risk Management (ICH Q9). This aims to ensure that the level of investigation is now commensurate with the level of risk.
- To further enhance embedding risk based principles, the area of Risk and Resilience moved to the Quality function.
- The Quality team also supported implementation of key changes to the Health and Lifestyle Questionnaire (HLQ) and introduction of the new Individual Donor Risk Assessment (IDRA) process.
- Development of an Electronic Quality Management System (EQMS) requirement specification was also completed, in line with the IBTS strategy. This involved a fresh review of Software as Service (SaaS) requirements by IT and Quality for incorporation in all future IBTS tenders. To further streamline and standardise our systems, Quality also collaborated with the HR department in an aim to implement a combined EQMS and Health & Safety system.
- Throughout the year a strong focus on recruitment, retention and cross functional up skilling continued in order for the Quality function to maintain a sustainable workforce.
- A new online location for quality information launched for Health Professionals and Customers.

Supporting Products and Services

Over the last year the Quality department supported collection, production and laboratory teams to ensure the IBTS continues to maintain the highest standard in blood collection, production and testing systems and services. During 2022 a significant amount of equipment and systems were validated which included the successful introduction of the PK 7400 Automated Blood Grouping System, a Fast Plasma Freezer, replacement of the Biological Safety

Cabinets, Flow Cytometers, Coagulation and Blood Gas Analysers. New Haemoglobin screening devices also went live on donor clinics (Hemocue 301) which was followed by upgrade of all the Trima Apheresis collection equipment and software. Significant upgrade to the Laboratory Water Systems was completed during the year, including revalidation of our state-of-the-art Alinity screening platform.

2022	Preventative Maintenance/Calibrations	Corrective Maintenance	Supplier Level Agreements	Re-qualifications
Total Number	2,061	258	32	519

Other IBTS projects and initiatives supported during the year include:

- Quality support provided for the feasibility assessment of the pathogen reduction process for platelets in the IBTS.
- Implementation of new and improved documentation processes such as a more efficient 'read and understand' system for document certifications, a new process for management of documents of external origin and new template documents, instructions and eForms which will improve efficiencies across the organisation.
- Participation in and leading strategic initiatives in the IBTS Culture Audit, Innovation and Lean 6-Sigma pilot.

- Supported implementation of structural changes across the organisation such as introduction of the new National Donor Screening Laboratory.
- Revision of the Quality Risk Management FMEA process and Tissue Establishment Manual.
- Review of the Donor Guidelines to create a more user friendly web browser format.
- Implemented a new IBTS training policy with the Learning and Development team.
- Introduction and facilitation of new Manager Training workshops for all mandatory training tasks.

Meeting Regulatory Requirements

The Health Products Regulatory Authority (HPRA) is the main regulatory body who authorise the IBTS to manufacture Blood and Tissue products. It is responsible for administering the provisions under relevant EU Directive and legislation for blood and tissue products.

During 2022 the HPRA continued their comprehensive inspection programme with the following areas completed:

Authorisation/Licence Type	Inspection Site/Area	Inspection Days	Compliance Actions
Blood Establishment (BE)	Limerick Centre (& Caherdavin Clinic)	1	3
	Ardee Centre (& Dunleer Clinic)	1	4
	Cork Mobile (& Midleton Clinic)	1	1
	Dublin Mobile (& Clane Clinic)	1	5
	D'Olier Street Clinic	1	7
	Stillorgan Clinic	1	5
	National Blood Centre	5	6 ¹
	Munster Regional Transfusion Centre	3	5
Good Manufacturing Practice (GMP)	Tissue Bank (Allogeneic Serum Eye Drops)	3	16 ²
Total	9	17	52

The Irish National Accreditation Board (INAB) is a national body with responsibility for the accreditation of Laboratories in Ireland. During 2022 the IBTS Red Cell Immunohematology laboratory was successfully awarded accreditation to conformity with EN ISO 15189:2012 by INAB assessors.

INAB Accreditation	Assessment Site/Area	Assessor Days	Compliance Actions
EN ISO 15189:2012	Red Cell Immunohematology Laboratory	3	19

- 1 Four Major Deficiencies reported
- 2 One Major Deficiency reported

Quality Assurance Summary

2022	Number
Incident Reports	524
Change Controls	374
Change Control Plans	83
Quality Complaints ³	956
Internal/External Audits	30
Document Change Orders	447
Product Recalls ⁴	480
Serious Adverse Events	47
Serious Adverse Reactions	36
Tissue Vigilance (Incl. IUBMR)	22

Risk

Risks that could impact and the opportunities that could enhance, our *'Connections that Count'* Strategy are actively managed in the IBTS. This is done under the IBTS Risk Management Framework.

The IBTS continued to navigate the risks and potential threats to business continuity from the on-going COVID-19 pandemic and international factors such as the invasion of Ukraine in 2022. COVID-19 and internationally factored risks were continually managed through the corporate risk register and quarterly risk reporting to the Executive Management Team, Audit, Risk and Compliance Committee and the IBTS Board. As the year drew to an end, the impact of COVID-19 began to minimise. The IBTS ran winter flu and COVID-19 booster vaccine campaigns to support staff.

The IBTS COVID-19 Recovery Taskforce implemented in 2021, with the mandate to put together a "Roadmap to Recovery" for the organisation continued its operations into 2022. The group

identified which measures were positive changes to be maintained in the long term post-pandemic, and the remainder to be removed when safe to do so. An unwinding of measures began in the spring of 2022, with a return to the workplace for staff working remotely. A new IBTS Blended Working Policy was introduced permitting suitable roles to avail of a combination of remote and on-site working.

The Emergency Blood Management (EBM) Group established in 2021 continued to utilise the IBTS Emergency Blood Management (EBM) Plan for Managing Shortages of Red Cell Components. This plan dovetails with the National Transfusion Advisory Committee (NTAG) Plan for IBTS, HSE and Hospitals in the Republic of Ireland to address Red Cell Shortages. These plans were put to the test throughout 2022, as COVID-19 pressures continued to place strain on the blood supply. The IBTS went to national appeal twice in 2022 to assist with the national blood stock. In addition, a risk-based decision making approach was employed when assessing the option to import blood products from NHSBT on two occasions in 2022. The Alliance of Blood Operators (ABO) Risk-Based Decision Making Model was utilised to assess all options available to ensure the continuity of the blood supply.

The electronic risk management solution procured in 2021 was further embedded in the organisation in 2022. This software allows risk reports to be generated in a format which allows for easily digestible content across the multi disciplines that play a role in effective risk mitigation in the organisation. This electronic risk management software was of benefit to the IBTS in examining the risk of fuel shortages in 2022 as a result of international factors including the invasion of Ukraine, and ensuring effective business continuity plans were in place for the IBTS.

3 Product, Hospital Services Complaints and Defects Reported. During 2022 approximately 60% were related to the incidence of Covid-19 in the community and 9% were for quality or service.

4 A recall is such that it promptly and effectively removes from potential use, products known or suspected to be defective. During 2022 approximately 80% of product recalls were related to the incidence of Covid-19 in the community.

Academic activities, Research and Innovation

Key achievements

- Hosted a very successful first-ever research conference, BloodDHIT, which showcased leading experts in all the fields allied with the blood service.
- Contributed to 9 peer-reviewed academic publications and gave 18 presentations at numerous national and international conferences.
- Successfully recruited two post doctorate researchers and a PhD candidate, greatly expanding our capacity and capabilities to perform fundamental platelet research.
- On-going and varied representation on European Blood Alliance (EBA), Biomedical Excellence for Safer Transfusion (BEST) and European Haematology Association (EHA) working groups which progressed our leadership on and contribution to issues impacting blood services.

Research Activities & Strategic initiatives

The IBTS expanded @IBTS_Research social media profile and used the platform to promote research activities through infographics, videos and posts during European Research & Innovation week. In October, the Health Professionals portal on giveblood.ie which delivers information on our Clinical Services, Education programmes and Research activities was launched. This provides, for the first time, a direct platform to showcase IBTS research and researchers with service users and collaborators. Website users are given the opportunity to sign up to our newsletter, #BloodDrop, which will communicate high-level updates to health professionals on a quarterly basis.

In November 2022, the IBTS hosted alongside our clinical partners, our first-ever research conference, BloodDHIT. The conference targeted professionals working in the fields of haematology and transfusion as well as medical scientists, and research partners. Expert speakers were a mix of local and international industry leaders covering a range of topics from transplantation, bone marrow research, Sickle Cell Anaemia and Iron Management. The IBTS continues to meet its strategic commitment to provide the evidence base from which to build future improvements to blood and tissue services. The main research and development activities are summarized below:

- Publication on the very low detection rate of Human T-Lymphotropic Virus antibodies in Irish blood donors provided the evidence for recommending a selective donor screening strategy (Williams *et al*, 2022).
- IBTS continued to play a vital role in COVID-19 antibody testing as part of the National Serosurveillance Programme (NSP) — Seroepidemiology of COVID-19 in Ireland. A testing algorithm to differentiate between vaccination and prior infection and using this, tracked the progression of the epidemic across Ireland throughout 2020 and 2021.
- Blood donor satisfaction was evaluated following a survey of donors that gave blood during COVID-19 public health restrictions. We are delighted to report that the majority of donors reported feeling safe donating during the pandemic.
- Collaborative research determined that African survey respondents reported that a lack of

information and malaria as their primary barriers to blood donation. An awareness of sickle-cell disease was higher among African respondents compared to Caucasians (Fogarty *et al*, 2022).

- A range of stakeholders, all reported the Blood Establishments which have a key role in Advance Therapy Medicinal Product (ATMP) development

and production were surveyed. The blood service may enhance ATMP research through the provision of components, GMP production and extensive donor management experience.

- Blood components helped support and progress the research of 90 academic Irish researchers.

BloodHIT 2022 conference

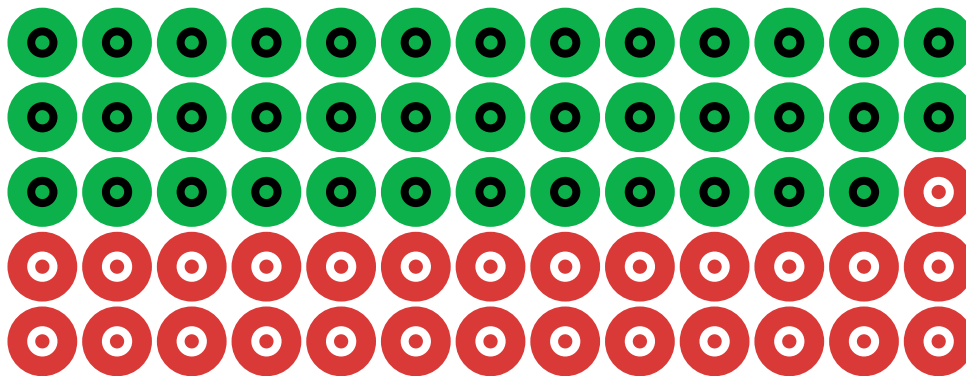




Strategy

The IBTS strategy 'Connections that Count — Developing the IBTS 2021 to 2025' was approved by the Board in Q4 2020. Every year the strategy implementation group considers proposed projects and initiatives that will support the delivery of the ambition statements in our strategy and develops

a strategy implementation plan. The strategy implementation plan for 2022 identified **65 strategic initiatives** to be delivered over the course of the year. The image below provides an overview of the progress made during the year, green indicates completed or closed and red indicates delayed.



The strategy implementation group monitor and track delivery of the strategy. In 2022 the IBTS progressed a number of complex and significant projects. Some of our successes include:

- The implementation of Individualised Donor Risk Assessment
- The Implementation of new PK analysers
- The production of allogeneic serum eye drops
- The introduction of new haemoglobin tests on clinics

- The plasma project reintroduction approach approved
- The inaugural BloodHIT conference
- INAB accreditation

We also dedicated time and effort to progressing significant multi-year projects such as pathogen reduction, plasma utilisation, and other projects that involved developing and implementing technical solutions that will improve how donors interact and share information such as the new donor web portal were progressed.

Human Resources

People Services

Aligned with the strategic priorities outlined in *'Transforming Together – People, Culture, Connections'* we advanced the strategic workforce plan ensuring that we had the necessary talent to support the delivery of overall strategic ambitions. In a very challenging and competitive market for health care and administrative resources there was a total staff turnover rate of 16.81%

representing an increase of 3.54% on the previous year. Consequently, a targeted recruitment and retention work plan was developed and commenced in quarter 3 to support proactive talent acquisition and talent management with complimentary wellbeing and socialisation actions.

621 employees
(535 full time equivalents)



17 staff retired
in 2022



240 retired staff
receiving pensions





161
recruitment
campaigns
activated



1109
applicants



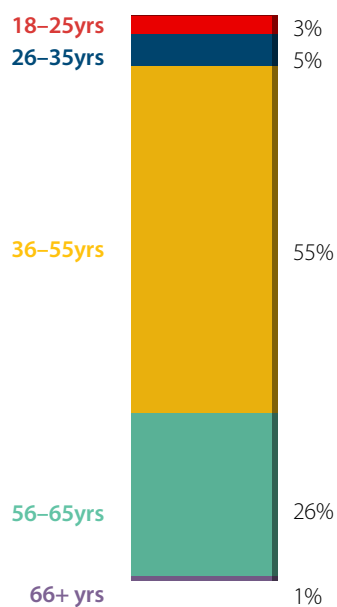
169
new
appointments



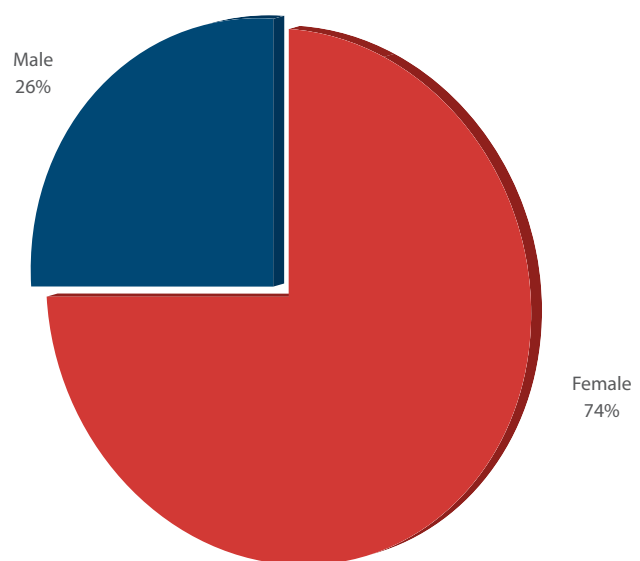
99
leavers

While the total sick leave absence rate was 7.24% (v 6.36% HSE average rate), absence due to COVID-19 related absence made up 1.60% of the total rate.

Age profile



Gender split



Organisation Structure Review

The review of our Tier 1 and Tier 2 leadership and management structures and Project Management Office was completed and with Board approval in March for the recommended changes, the implementation work plan commenced in Quarter 2. Key improvements included the split of the Operations Directorate into two directorships, Production and

Hospital Services and Donor Services and Logistics. There was a reorganisation of Facilities & Estates, Risk & Resilience and Data Protection. Also the development of four governance groups for Supply and Demand; Clinical; Quality, Regulatory and Safety and Workforce Planning and Co-Ordination.

Governance Group	Chair
Supply and Demand	Director of Supply and Logistics and Director of Processing and Hospital Services
Clinical	Medical and Scientific Director
Quality, Regulatory and Safety	Quality and Compliance Director
Workforce and Financial Planning Governance Group	Human Resources Director and Finance Director

Implementing Public Sector Equality & Human Rights Duty

Development of the IBTS 'Public Sector Equality & Human Rights Duty' (PSEHRD) Implementation Plan progressed during the year. The plan includes an annual framework to assess needs, action plan and report progress. Both the Equality, Diversity and Inclusion policy and the PSEHRD implementation plan are now accessible on giveblood.ie. Notable activities during the year included a social media programme on being an employer that proactively supports Women in STEM and International Women's day; Employee assistance aligned to national Neuro-diversity supports and partnering with community groups to progress development and work opportunities to support people with disabilities commenced.

The IBTS is an active member on the Department of Health Disability Monitoring Committee to support improvements and provide stakeholder input on enhancing disability monitoring in the public health sector. In conjunction with the National Disability Association, our corporate website was audited in relation to the EU Web Accessibility Directive and all audit recommendations were implemented to ensure on-going compliance.

Employee Engagement

Our annual all staff survey was conducted at the end of 2022. 256 responses were received representing a response rate of 43%. We measured promotion scores, staff satisfaction rates and pride scores.

- Average organisational promotion scores were 6.7 and team/department promotion scores were 7. This reflects a moderate to moderately high rate of promotion of the IBTS as a great place to work.
- Staff satisfaction levels varied depending on the factors assessed. Total satisfaction levels averaged a moderately high 60%. The highest satisfaction rates were recorded for satisfaction with managers 74.91% and ability to apply skills in the role. The lowest satisfaction score reported were for career progression opportunities 35.06%
- Staff reported extremely high levels of pride working in the IBTS with a total average score of 83.
- The top 3 recommendations for improvement based on the results include, recruitment and retention, training and development, and appreciation and recognition. Plans will be reviewed to address the areas for improvement in 2023.

Internal Communications

The Internal Communications Group launched the Internal Communication Work Plan during the year. The action plan includes short-term to longer term communication goals. The longer term actions will happen in line with the overall organisation's strategic plan and require support from outside of this group. However the immediate activities included:

- Reviewing and collating current communication tools, defining what each tool does and developing a clear objective for the use of each one.
- Promoting Plain English as the basis for all IBTS communications including providing Plain English training sessions.

Learning & Development Services

Leadership

A key strategic item for the IBTS is the continued investment in the formation of leaders across all areas of the organisation. Partnering with Dr. Nuala Ryan from University of Limerick (UL) the LEAD programme is now in its fourth year. Part of the work with UL is to ensure that the organisational systems that support and strengthen leader formation in the IBTS are in place. The Leadership Charter was developed, setting out the vision and objectives for how IBTS leaders are identified, behave and how they are supported in the organisation.

Talent Management

Implementation of initiatives identified in the IBTS talent management framework commenced. To examine specific deliverables of the bespoke framework Learning and Development partnered with University College Cork (UCC) MSc students who undertook applied research projects in some critical areas of talent management including attraction and selection, training and development, exit interviews and staff workplace wellbeing needs. The results and recommendations of the applied research projects have provided the ONEHR team with evidence and recommendations to support improvements in practices.

Performance Development

Integrating and aligning Performance Development into operational activities is a priority. A new bespoke e-learning module on the IBTS performance cycle was created and launched to support staff to

participate and engage in the process effectively. The L&D team concentrated its efforts on the role of the manager in proactively initiating PD conversations and promoting PD as an opportunity for staff. Consequently support tools and bespoke training for all Managers was developed.

Lean/Agile

Improving people experiences by responding in an agile way to customer needs is one of the ambitions set out in the ONEHR People and Culture Strategy. The ONEHR team completed a certified programme in AgileHR, enabling the team deliver high quality people and culture services which will attract, develop, reward and retain talent. In addition investment in a Lean programme of work also commenced with the delivery of a Lean Six Sigma Yellow Belt pilot programme to introduce Lean methodology and support the delivery of four key projects throughout the IBTS. Learnings from the pilot programme are being used as the basis to develop a sustainable lean and agile framework that will provide a roadmap for the delivery of an organisational wide programme of work.

30% Club

The IBTS became members of the 30% club, demonstrating our commitment to incorporating diversity ambitions within our ONEHR strategy and aiming to achieve a minimum of 30% gender balance at most senior levels in our organisation.



Environmental, Health and Safety

Health & Wellbeing Supports

The establishment of a team of Mental Health First Aiders across the organisation is a key objective in the People and Culture Statement of Strategy 2021 to 2025. In line with this commitment, expressions of interest from staff were sought for the volunteer role of Mental Health First Aider. Fourteen staff from across the organisation successfully completed training with Mental Health First Aid Training in quarter 3. This is the first time the IBTS has run this training for staff.

The IBTS also introduced quarterly IBTS Health and Wellbeing bulletins aimed at providing staff with access to information on health and wellbeing initiatives and supports.

IBTS Staff Safety Recognition Award

To coincide with European Week for Safety and Health at Work, the EHS department launched the IBTS Safety Recognition Award to recognise and share positive safety practices undertaken by staff and departments within the IBTS to keep colleagues and friends safe and maintain a safe working environment for all.

IBTS COVID-19 Pandemic Plan

In Quarter 3 the IBTS Response to COVID-19 Pandemic Plan booklet was revised to take account of the evolving nature of the pandemic and guidance available. This informative booklet which is accessible to staff in electronic and hard copy formats consolidates the organisations policy and procedures to minimise the risk of infection in the workplace.





Information Communication Technology

2022 was the first full year of implementation of the IT Strategy 2021–2025 which underpins and enables delivery of many of the organisation's corporate strategic objectives.

The appointment of a Chief Information Officer to oversee and drive this strategy was a key milestone during the year. The IT Function also added additional skills which will be a crucial part of the strategy delivery with the recruitment of two business analysts and a transformation manager.

From a technology perspective, projects focused on modernisation of our IT estate as the first phase of implementation of the IBTS IT Strategy. In 2022 we focused on improving the foundations, specifically with a focus on core infrastructure and end-user tools. Achievements during the year included numerous server and software upgrades.

Cybersecurity threats continued to be an area of concern. Work during the year on improving our security included upgrades to security infrastructure and software, additional security monitoring as well

as ongoing programmes to raise awareness across all IBTS staff.

Work continued on projects to improve our donors' experience by leveraging new technologies and tools. As part of this a project to implement a new online booking system and portal was initiated. The new system, which will launch in 2023, will enable donors to manage their own bookings, as well as view their donation history.

Work also commenced on the *Self-Assessed Health History* ("SAHH") project which is aimed at improving and digitising the donor experience in clinics. This will also be deployed in 2023.

A new phone system for Donor Services who are responsible for donor bookings was implemented in 2022. The new system which is a cloud-based softphone solution provides us with improved resilience and also improves flexibility for Donor Services who can log in from anywhere connected to the IBTS network. It also provides improved reporting allowing a tailored service to donors.

Sustainability

The organisation's energy consumption is collected automatically from all energy providers from all sites onto SEAI's Public Sector Monitoring and Reporting (M&R) system. It takes a number of months post year-end for this information to be collated. The most recent information available is for 2021.

The figures for 2021 show:

- 34.8% energy efficiency saving was achieved compared to baseline year (2008).
- electricity consumption increased 1% on 2020 due to extra ventilation required in some areas.
- gas consumption increased 20% on 2020 due to performance issues with boilers which are approaching end of life.

The significant energy users are the laboratories and clinical areas, and these were fully operational and staffed at all times during the COVID-19 pandemic.

The National Donor Testing Laboratory achieved My Green Lab accreditation after auditing their processes and energy and utility use with reference to best practice provided by My Green Lab.

The IBTS has significant refrigeration load. The refrigerant in the central blood storage refrigeration system was replaced with a newer one which has a lower Global Warming Potential. This extended the useful life of the refrigeration system and delivered some energy savings.

A complete review of clinical waste from all laboratories with reference to guidelines from the Health Service Executive was completed. This process (which was approved by an external expert in this field) meant that the legacy requirement for onsite steam sterilisation of waste ceased and also clarified that many waste blood products (*bi-products of blood component production*) which had been historically sent overseas for incineration could now be heat-treated in the approved waste contractor's Irish facility. This led to significant carbon reduction through avoiding the need for generation of steam which is energy intensive and avoiding the transport of waste overseas for incineration.

In Autumn 2022, the Government communicated the new Climate Action Mandate to reduce energy related greenhouse gas emissions by 51% by 2030. IBTS has commenced its Climate Action Roadmap and list of proposed projects to meet this target.

Finance

Summary Accounts for the year ended 31st December 2022

	2022 €'000	2021 €'000
Income		
Recurring income	71,394	69,166
Non-recurring income	3,629	3,347
Total income	75,023	72,513
Expenditure		
Total expenditure	80,009	74,779
Surplus / (Deficit) for year	(4,986)	(2,266)
Actuarial gain / (loss) on pension schemes	73,052	13,024
Transfer to Capital Reserves	–	–
Transfer to Research Reserve	(264)	(164)
Accumulated Deficit at 1st January	(72,863)	(83,457)
Accumulated Deficit at 31st December	(5,061)	(72,863)

Income

The Board's total income for 2022 of €75 million (2021 €72.5 million) is analysed into recurring and non-recurring income. Recurring income consists of revenue generated from sales of products and services provided to hospitals of €71.4 million (2021 €69.2 million). Non-recurring income of €3.6 million (2021 €3.3 million) includes a grant from the Department of Health in respect of HEV testing and deferred funding for the single public service pension scheme. The increase in recurring income represents increased volumes in 2022 over 2021 levels and testing volumes also increased on the previous year.

Expenditure

Expenditure for 2022 amounted to €80 million (2021 €74.8 million).

The increase in expenditure is due to an increase in staff costs from public sector pay increases and significant increases in energy costs. There were also higher inflation costs generally reflected in some of the non staff cost items while some of the increases in direct costs were directly driven by the increases in sales volumes such as testing reagents due to the higher demand.

The Board accounts for pensions in accordance with financial reporting standard 102.

Reserves

The Board has a Capital reserve for the development of new facilities in Cork. The balance in the fund at the year ended 31st December 2022 was €10.60 million.

At the 31st December 2022 the balance of research funds was €3.1 million. (2021 €2.9 million).

Capital Expenditure

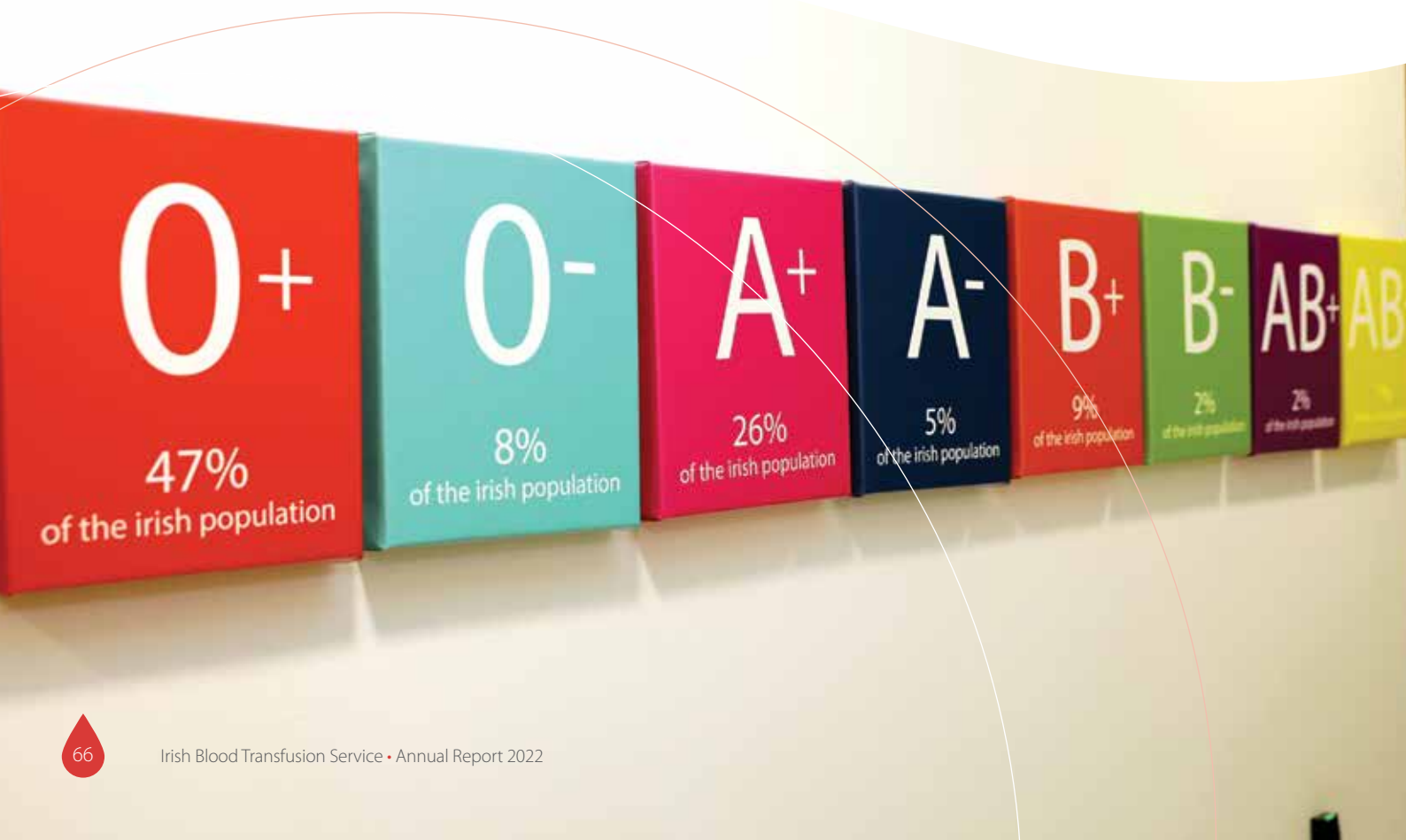
The Board invested €1.4 million in capital projects and equipment during 2022 (€1.3 million 2021).

The main capital investments during the year were the replacement of our main blood group analysers and also our blast plasma freezer along with the upgrade of our IT firewalls.

Prompt Payment Legislation

The Board complies with the requirements of Prompt Payment Legislation except where noted below. The Board's standard credit taken, unless otherwise specified in specific contractual arrangements, are 30 days from receipt of the invoice or confirmation of acceptance of the goods or services which are subject to payment. It is the Board's policy to ensure that all accounts are paid promptly. During the year ended 31st December 2022, under the terms of applicable legislation, invoices to the value of €321,377.09 were late, by an average of 18.74 days. These invoices constituted 1.87% by number and 0.78% by value of all payments to suppliers for goods and services during the year. Total interest and fines paid in respect of all late payments amounted to €12,074.87

The Board continuously reviews its administrative procedures in order to assist in minimising the time taken for invoice query and resolution and the approval and payment process.



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Allied Irish Bank
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Dublin 2

Irish Blood Transfusion Service

National Blood Centre

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e:contactus@ibts.ie

www.giveblood.ie

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www.twitter.com/giveblood.ie

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DO2 TK51

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A94 NX47

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WE LOVE OUR DONORS



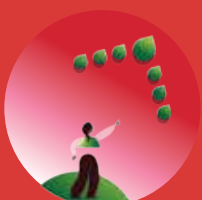
WE IMPROVE
PATIENTS LIVES, TOGETHER



WE LEAD BY EXAMPLE



WE STRIVE
FOR EXCELLENCE



WE ARE THE IBTS