$\begin{array}{c} \bigcirc & \bigcirc & \bigcirc \\ \bigcirc & \bigcirc & \bigcirc \end{array}$



ANNUAL REPORT









Contents

Foreword Renewing our Vision, Mission and Values Executive Management Team	04 06 07
Chairperson's Report	08
Chief Executive's Report	20
Medical & Scientific Director's Report	22
Operations Key achievements in 2020 Donor Services Production, Hospital Services, Scientific	24 25 25
Support and Component Developments Testing Key achievements 2020 National Donor Screening Laboratory NHIRL BGGL RCI Dublin Diagnostics/Crossmatch Cork	32 39 39 44 45 46 50
Other services	54

Other services	54
Tissue	55
Therapeutic Apheresis	55
NHO	63
IUBMR	63

Quality & Compliance Key achievements 2020	66 67
Risk and Resilience Academic activities, Research and Innovation Publications, research, relevant	70 72
projects, teaching etc Human Resources Key achievements 2020	76 78 79
E,H&S	80
ICT	83
Green Agenda	84
Finance	85
Contact Details	87

4 | Annual Report 2020





Foreword

2020 was a year of extraordinary challenge and disruption for many organisations. The IBTS was no different in facing the serious challenges presented by managing the impact of COVID-19, but in addition we faced a change of leadership at the top of our organisation, as we said goodbye to our long-tenured CEO Andy Kelly and welcomed Orla O'Brien as his successor.

I would like to thank Andy for his immense contribution to the organisation as its leader for eighteen years. He saw our organisation through some difficult challenges. The true test of a leader is to leave the organisation in a stronger position than on joining, and that was definitely the case with Andy, as under his leadership the IBTS re-established its position of trust within Irish society. In his last few months in early 2020 he helmed the IBTS in his usual sure-footed way as it developed its plans to navigate through the challenges of collecting, processing and delivering blood and tissue products at a time of great uncertainty and logistical challenges. Andy is missed by his many colleagues inside the IBTS and in the broader healthcare community in Ireland, and we wish him a very good retirement, although we suspect he will not be slowing down just yet.

Orla O'Brien joined us in April and has brought immense energy to her new role. Orla was previously CEO of LauraLynn Children's Hospice and prior to that she had a thirty-year career in clinical and management roles within the Health Service. Through her various roles she has managed a number of complex change agendas in different environments and has developed strong networks in the Department of Health and the HSE which will, no doubt, be of great benefit to the IBTS. The year 2020, although challenging for a new CEO, was an opportune time to join our organisation as our previous four year strategy was coming to an end.

Orla approached the development of the new strategy with gusto and despite the limitations of virtual meetings she worked collaboratively with management, board colleagues and external stakeholders to develop a strategy for the next five years which is ambitious and is one to which the board and management are fully committed. The title of our new strategy - "Connections that Count" - provides a thematic umbrella that is easily understood and endorsed by everyone working within the Irish Health Service, as it is only in working together that we can achieve the quality and delivery of service to which we all aspire. We warmly welcome Orla into her new role and look forward to working with her in the years ahead.

Keeping staff and donors safe has been our main priority through the long months of the pandemic and this has involved more cumbersome work practices for a lot of our staff. We are extremely proud as a board of how our people have pulled together in difficult circumstances and we are grateful to them for the flexibility they have demonstrated to maintain a safe and sustainable blood supply on which the healthcare system can depend.

We accelerated our plans to fully roll out an appointment system for donors in March last year and this has been extremely well received. There is still some work to be done to fully automate this process which we hope will be completed in 2021 and in the meantime we are grateful to those staff members who have stepped up to manage this time-intensive process. Sadly, we have had to cancel our donor award ceremonies since last March. These have been a highlight for me in my role as Chair, as not only do I get to thank donors individually, but I also have the privilege of listening to recipients tell their personal stories of how the generosity of our donors and the work of our staff have changed their lives. Our gratitude to our donors is as deeply held as ever and we look forward to resuming these events when circumstances allow.

We made strong progress on our research agenda in 2020 by hiring a Lead Research and Development Facilitator and establishing a sub-committee of the board, made up of board members and domestic and international experts to oversee the governance and the prioritisation of research projects from 2021 onwards. The board is excited that we can support research to advance knowledge in blood and tissue transfusion; disease epidemiology and genetic susceptibility; donation and deferral policy; and applied diagnostics and technical advancement. We hope through this increased profile to foster a culture which will encourage medical residents and scientists to consider careers in the field of transfusion medicine.

We welcomed Dr. Sharon Sheehan to our board in 2020. Dr Sheehan served as Master of the Coombe Womens Hospital until 2019, and she brings a wealth of healthcare experience to the board. Finally, I would like to thank all my board colleagues for the support they showed to the management team and for their continued commitment to our organisation during a difficult year.

Linda Hickey

Chairperson

Renewing our Vision, Mission and Values

The core work of the IBTS has always been centred on the most precious of commodities, blood and blood components. We collect, test, package and distribute in an end to end process we refer to as 'vein-to-vein'. Our services also extend to other areas in blood transfusion and tissue. Our vision, mission and values have always reflected this, however, it was agreed that we should review and revise each of these areas. Our strategic direction has not altered greatly although there is a renewed emphasis on working closely with our donors, our peers and our colleagues across healthcare and education. We consulted with staff on the values they want to instil in the IBTS and these have been revised to reflect the feedback received.

Our Vision

Working together to deliver world class blood and tissue services for the people of Ireland.

Our Mission

We are 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.

Our Values



Executive Management Team



Orla O'Brien CEO



Dr. Stephen Field Medical & Scientific Director



Noel Murphy Finance Director



Idelle Hawkins HR Director



Paul McKinney Operations Director



Karen Byrne Quality & Compliance Director

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 2020 in accordance with Appendix 2 of the Code of Practice for the Governance of State Bodies 2016.

- 1. I, as Chairperson, 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.
- 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.

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 requirements. ii. Management 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 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, which is a subcommittee of the Board 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 2020 at its meeting on the 9th February 2021.

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 have been put 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 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.' 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 Finance Committee reviewed its terms of reference in 2020.The revised terms of reference were approved by the Board. The Board completed an internal effectiveness review in November 2020.

Workings of the Board

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

The Board met on 6 occasions for ordinary meetings during the year. Attendance by Board members was as follows:

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

Board Attendance in 2020

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

**Dr S Sheehan was appointed on 5th October 2020

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.

Members of the Board

Ms Linda Hickey (Chairperson) Mr Brian O'Mahony Ms Kate Williams Dr Elizabeth Kenny Dr Ronan Desmond Ms Deirdre Cullivan Mr John Malone Dr Satu Pastila Dr Sarah Doyle Ms Deirdre-Ann Barr Mr David Gray Prof Sharon Sheehan*

*Appointed on 5th October 2020

	Board	Medical Advisory Committee	Audit, Risk & Compliance Committee	Finance Committee	Performance Development Committee	Board Fees 2020 €	Expenses 2020 €
Number of Meetings							
Ms L Hickey (Chairperson)	6	-	-	-	3	21,309	-
Mr B O'Mahony	6	-	-	-	-	-	-
Dr E Kenny	6	6	-	-	-	-	104
Ms K Williams	5	-	-	5	-	12,430	-
Dr R Desmond	5	6	-	-	-	-	-
Ms D Cullivan	6	-	-	5	3	12,430	-
Mr J Malone	6	-	-	5	-	12,430	-
Dr S Pastila	6	6	-	-	-	11,970	630
Dr S Doyle*	0	0	-	-	-	-	-
Mr D Gray	5	-	4	-	-	12,430	209
Ms DA Barr	5	-	4	-	-	12,430	-
Dr S Sheehan**	2	-	1	-	-	-	-
Dr Y Traynor***	-	-	-	-	-	783	-
						96,212	943

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

** Board Term commenced 5th October 2020

*** Board Term Finished 31st December 2019 but Board members are paid two weeks in arrears

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

Board members expenses in 2020 amounted to €943 broken down €184 mileage, €69 subsistence and €690 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 Circulars 02/2016 – arrangements for Digital and ICT-related expenditure in the civil and public service.

The IBTS has also developed its own formal 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 senior 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 2020 was €142,421. The Performance and Development Committee met three times in 2020.

The former Chief Executive retired on 24/6/2020. He received a salary of €175,195 in 2020 which includes salary arrears and holiday pay (2019 : €165,828) and had the use of a company car with a benefit in kind value of €3.916. The retired Chief Executive is also entitled to a pension in line with the trust deed and rules of the Irish Blood Transfusion Service pension scheme, which provides on retirement at age 65, in respect of each year of service, a pension of 1/80th and a gratuity of 3/80th of final pensionable salary. The new Chief Executive commenced on 20th April 2020 and received a salary of €94,593 in 2020 and is entitled to a pension under the terms of the Single Public Service Pension Scheme. The two month overlap was provided for in the Board's business plan for 2020 submitted to the Department of Health and was considered necessary to ensure a smooth transition during the development of the Board's strategic plan 2021-2025.

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 2020. 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.

	February	April	June	September	November	December	Total 6 Meetings
E Kenny	\checkmark	~	\checkmark	~	\checkmark	~	6
R Desmond	\checkmark	\checkmark	\checkmark	~	\checkmark	\checkmark	6
S Pastila	\checkmark	\checkmark	\checkmark	~	\checkmark	Х	6
Sarah Doyle	Х	х	Х	Х	Х	Х	0
B O'Mahony **	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	~	6
S Field	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	~	6
D Ó Donghaile	Х	\checkmark	\checkmark	\checkmark	\checkmark	~	5
L Pomeroy	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	~	6
E McSweeney	Х	\checkmark	\checkmark	\checkmark	\checkmark	~	5
J Power	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	~	6
I Hann	Х	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	5
N O Flaherty	Х	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	5
N O'Connell	\checkmark	\checkmark	\checkmark	Х	\checkmark	\checkmark	5
C DeGascun	Х	Х	\checkmark	\checkmark	\checkmark	\checkmark	4
K Morris	Х	\checkmark	\checkmark	\checkmark	Х	\checkmark	4
R Hagan	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	6
S Thomas *	-	~	\checkmark	~	\checkmark	\checkmark	5 (only appointed for 5)

M&SAC Attendance 2020

* S Tomas, Assistant Director of Manufacturing Development for NHSBT appointed by Board to M&SAC in February 2020

** B O'Mahony is only in attendance at M&SAC 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, external audits by the Comptroller and Auditor General, financial and 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 regularly.

Finanace Committee Attendance 2020

Finance Committee Meetings 2020	January	Мау	July	September	October
Ms K Williams	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark
Ms D Cullivan	\checkmark	\checkmark	\checkmark	\checkmark	√
Mr J Malone	\checkmark	\checkmark	\checkmark	\checkmark	~

Audit, Risk & Compliance Committee

The Audit, Risk and Compliance Committee met four 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 Operations Director, Director of Quality & Compliance, the Internal Auditor, Risk and 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 financial statements, reports of the Internal Auditor, quality reports both internal and from the HPRA, the accounting policies, compliance with accounting standards and the accounting implications of major transactions. 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 regularly.

Board Members Attendance Audit, Risk & Compliance 2020	February	April	June	September	December
Mr D Gray	\checkmark	Cancelled	\checkmark	\checkmark	\checkmark
Ms D A Barr	\checkmark	Cancelled	\checkmark	~	\checkmark
Ms S Sheehan*					\checkmark

* Attended first ARCC meeting

Resarch & Development Committee

The Board approved the establishment of a Research and Development Committee to oversee the implementation of the IBTS Research and Development Strategy.

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. The Risk and Resilience Manager has responsibility for overseeing the risk register and contingency arrangements. A set of inherent risks have also 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, 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 this 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 Comptroller and Auditor General Guidance Document titled "OCAG Insights: The impact of COVID-19 on your control environment", received in October, assisted executive management in considering the impact that the COVID-19 pandemic has had on the internal control environment.

The Financial Statements for the year ended 31st December 2020 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 with the exception of procurement related to the purchase of PPE and the hiring of additional buses to ensure social distancing for clinic teams travelling to blood donation venues.

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. There were no protected disclosures in 2020.

Commercially significant developments

COVID-19

COVID-19 impacted on various income and cost headings with an estimated net impact of (\in 1.7m). The main impact was the drop in income with additional costs such as PPE, occupational health costs, transport costs and additional staff cover which was offset by savings in travel, training and advertising costs.

eProgesa Hardware

IBTS and its supplier commenced the building of the required new eProgesa and eRiskline environments (Test, Train, Validation and Production plus a DR environment externally hosted in the DR Site) for the new Semester Patch S1 2017. A new version of Oracle Database was updated to Oracle 19c which in turn had the knock on effect of needing a new mechanism for loading the required data from eProgesa to the BOSS application. The hardware has been installed and the application is installed and is currently in a validation state and has an expected delivery date of April 2021.

Linda Hickey

Chairperson





Chief Executive's Report

It is with great pleasure that I write my first report as Chief Executive of the Irish Blood Transfusion Service (IBTS). 2020 proved not to be the year that anyone was expecting, yet the IBTS continued to provide its vital products and services to the Irish health service. COVID-19 tested us all, the IBTS had to respond quickly to a rapidly evolving situation, introducing an appointments system for donors virtually overnight and maintaining the national blood supply by continuing to operate donation clinics throughout the country in a manner that ensured the safety of our donors and our people. Internally we had to adapt to new ways of working, implementing new work rosters, mobilising hundreds of staff to work remotely, changing roles for some staff, sourcing volumes of PPE, developing and implementing guidelines to support staff, answering hundreds of queries and of course making sure everyone was kept up to date with all the necessary public health and organisation guidance. It was a significant effort and I want to thank all staff for playing their part. A special word of thanks needs to be extended to the volunteers who helped us to keep the clinics up and running, in particular the Civil Defence teams across the country who supported our clinic teams on a daily basis.

The IBTS had commenced the consultation process for our new strategic plan Connections that Count: Developing the IBTS 2021 - 2025 before COVID-19 arrived on our shores and notwithstanding the additional pressures on the organisation during the year to continue to maintain the blood supply and our other services through varying degrees of restrictions, work on our strategy development continued and was approved by the Board at its December meeting. Connections that Count sets the organisation's strategic direction for the next five years and will ensure that the IBTS remains at the forefront of transfusion medicine. The strategy development also provided the opportunity to renew our mission, vision and values through an extensive internal and external consultation process.

Another achievement in 2020 was the development of our first **Research and Development Strategy** (R&D) which will be implemented over a three-year period. The implementation of this strategy will be overseen by a Research Development Sub-Committee consisting of Board members and external experts from Ireland and abroad. This is an exciting opportunity for the IBTS to build collaborations with academic institutions as well as medical practitioners across the health sector. The research themes that we will focus on over the lifetime of this R&D Strategy are disease epidemiology and genetic susceptibility, applied diagnostics and technical advancement, donation and deferral policy and the clinical evaluation of blood and tissue transfusion.

COVID-19 tested our contingency planning arrangements in real time and we have learned a lot from it – these lessons will be incorporated into our Business Continuity Plan when it is reviewed again in 2021. During the year the IBTS also had to prepare for Brexit, which meant engaging with suppliers and ensuring that we had contingency stock for critical supplies and in some instances make arrangements with suppliers to bypass the UK land bridge and import directly from the continent.

Unfortunately, some traditions could not take place in 2020. Donor awards ceremonies had to be cancelled as a consequence of the COVID-19 public health restrictions. We hope to resume these events in the latter half of 2021 and celebrate the amazing achievement of our donors who have reached significant donation milestones.

The iLead programme, our leadership development programme for staff designed in collaboration with the University of Limerick had to switch to online learning in 2020 and this will continue to be the manner of delivery for the foreseeable future. 14 members of staff completed this programme and following positive feedback, we look forward to rolling this out organisation wide.

The outgoing Chief Executive Andy Kelly retired in June 2020. I was fortunate enough to have a handover period with Andy which was invaluable to me at a time of great uncertainty and rapid change, not just for the IBTS, but for us all.

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. They have all made significant contributions to the work of the IBTS in the best interests of patients and donors. I would also personally like to the Board, the Executive Management Team and all staff for their help and support throughout the year which presented us all with unexpected challenges, not least of which was taking over the leadership of the IBTS.

We will continue to innovate and bring new ideas to our work in the interests of the patients and donors we serve, our strategy outlines how we plan to go about it. Our renewed values show why we do what we do.

Orla O'Brien

Chief Executive



We strive for excellence



We lead by example



We love our donors



We improve patients lives, together



We are the IBTS



Medical & Scientific Director's Report

This year saw the arrival of the SARS CoV 2 pandemic in Ireland which has resulted in changes in the way we work as a result of the impact this disease (COVID-19) has had on hospitals and the wider public throughout the country. Our blood donors have responded magnificently and despite the protective measures put into place our bloodstocks have been stable and adequate to meet the demands, albeit with reduced red cells and platelets, throughout the whole year. The changes to donor clinics and the impacts on supply and demand are documented elsewhere in this annual report.

Convalescent plasma

With the advent of the pandemic we developed and validated a process for the collection of convalescent plasma. This was duly authorised for clinical use by the regulator, the Health Products Regulatory Authority (HPRA). It was intended that this component would be used for clinical trials, but unfortunately funding was not secured. Data available from clinical trials elsewhere indicated that for COVID-19 convalescent plasma did not have any therapeutic advantage over other treatment strategies.

However, it is imperative that IBTS is able to provide convalescent plasma in future

pandemics or epidemics as other blood borne viruses may be more susceptible to this treatment modality.

Research and development

The Lead Facilitator for Research and Development (R&D) was appointed in August. This enabled the development of the R&D strategy which will be published in 2021. The reorganisation of research at IBTS will enable staff to make significant contributions to the scientific literature in the field of transfusion medicine.

Laboratories

The laboratories at the IBTS have continued to function throughout the pandemic. Staff, where practicable, were split into teams as a measure to limit service disruption should any staff member need to isolate because of COVID-19 infection or close contact.

The tissue typing (HLA) laboratory introduced the next generation sequencing (NGS) methodology which provides better resolution of the highly polymorphic and complex HLA genes. This improved and state of the art tissue typing technology will provide for better matching of stem cell donors and patients requiring transplant. The Blood Group Genetics Laboratory continued to grow and the number of Rh-Negative mothers getting the Rh type of their babies determined is increasing. This service supplements the routine antenatal anti-D prophylaxis (RAADP) programme and identifies those cases in which the foetus is found to be Rh D negative thus not requiring anti-D injections.

The virology laboratory has implemented SARS CoV 2 antibody testing which allows characterisation of convalescent plasma. A seroprevalence study on donors throughout the pandemic has also been undertaken and will be published later in 2021. Tests for malaria antibodies have also been validated in this laboratory in readiness for a recruitment campaign for donors of African ancestry many of whom have lived in malaria endemic areas of the world. These donors are required to improve Rh matching of blood required for Sickle cell patients.

National Transfusion Advisory Group (NTAG)

NTAG is a wide representation of all relevant stakeholders, including clinical leads across a range of programmes, IBTS, national societies, Faculty of Pathology, HSE, national agencies including the National Haemovigilance Office (NHO), the Pre-Hospital Emergency Care Council (PHECC) and the National Office of Clinical Audit (NOCA), together with patient and donor representatives. The inaugural meeting of NTAG was hosted by the Royal College of Physicians of Ireland in January 2020.

National plans to manage shortages of red cells and platelets

With the emergence of SARS CoV 2 the

previous pandemic plan (from the bird flu pandemic of 2009) was reviewed. With the launch of NTAG and its broad membership, it was appropriate to update this plan and national red cell and platelet shortage protocols were approved and published on the HSE transfusion portal.

Review of social behaviours

In 2017 IBTS reduced a permanent deferral to 12 months for men that had sex with men (MSM) and other high risk activities including people with partners from areas with high prevalence of HIV (sub-Sahara Africa). With other blood establishments in Europe and America now making changes to their deferral for MSM it was felt that this needed to be reviewed in Ireland and a committee with independent members has been convened to review the evidence and make a recommendation to the IBTS. It is expected that this will be complete by late 2021.

Eye Banking

The IBTS presently imports all corneas and ocular tissue from the USA and planning commenced this year to reopen the eye bank in Ireland.

Plasma

For the past 20 years plasma for therapeutic use has been imported as a pooled pathogen reduced commercial product. However, with the 2019 risk assessment the evidence has shown that plasma derived from Irish donors is very low risk for vCJD and therefore should be reintroduced to Irish hospitals. Any plasma that is surplus to normal therapeutic use could be sent for production of protein fractions such as intravenous immunoglobulin. This will be a focus for the IBTS in 2021.

OPERATIONS



Donor Services & Collections

Key achievements

- Maintaining the blood supply in the face of many significant COVID-19 challenges
- Introducing appointment based clinics for all blood donation clinics
- Ensuring the safety of donors and staff while continuing community based blood donation clinics
- Launch of new marketing campaign "We Count on You."

Maintaining the blood supply during COVID-19

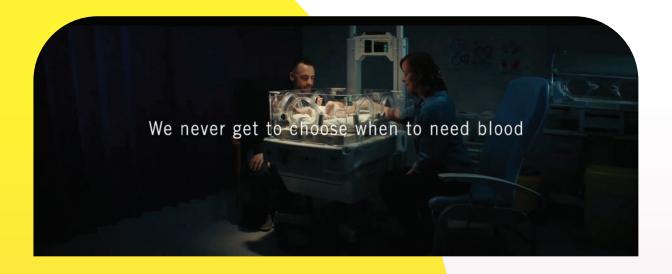
IBTS aims to have 7 days supply of blood to ensure it can maintain supplies to hospitals throughout the country. To do this it must undertake nearly 40 blood donation clinics countrywide each week. With the onset of COVID-19, this capability was significantly challenged. Clinics still had to be undertaken, venues secured, safety of staff, donors and blood guaranteed, and donors reassured. While initially from mid March the demand from the hospitals fell by nearly a quarter, by May hospital usage was back close to Pre Covid levels, and has generally remained at that level since then. All through this period, IBTS has maintained blood and platelets supply to the hospitals including, across the challenging negative blood groups like O negative and B negative, and in particular fulfilling twice weekly standing orders of rarer compatible blood to our neonatal hospitals.

Key to this response was the introduction of appointments for all blood donation clinics. By pre-booking donors into clinics, it meant IBTS could regulate the number of doors on clinic at any one time, thus ensuring social distancing. All of this had to be undertaken by phone as each donor needs to be prescreened regarding COVID-19 exposure prior to attending a clinic. From its introduction in mid March to the end of 2020, Donor Services made in excess of 150,000 pre-screenings and bookings, with many staff answering calls working remotely from home.

In addition, many changes were made on clinics including all staff wearing PPE, and social distancing maintained with new clinic layouts. To facilitate this, a number of changes had to be introduced including the use of larger venues which meant some donors had to travel longer distances than previously to attend clinics (blood donation being classified as essential travel). This was particularly challenging given IBTS is typically dependent on schools, local hotels and facilities for many of their community based clinic venues, many of which are unavailable during COVID-19. We are extremely grateful to those venues in 2020 and onwards into 2021, who continue to facilitate us.

In addition, to avoid delays on clinic, we needed to reduce and limit the number of appointment slots available for new donors, and ensure there were enough appointment slots for existing donors.

One significant positive outcome from all these changes, as commented by many donors on social media, has been the reduced time it now takes for donors to complete their full blood donation.



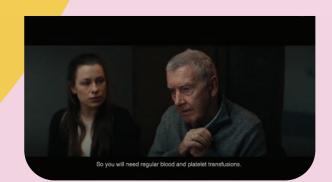
#WeCountOnYou Campaign

In January 2020, IBTS launched the next phase of our award winning Every One Counts donor recruitment campaign called "We Count On You". The focus of the campaign evolved to highlighting the uses of blood and platelet donations to treat patients in need, and why we count on our donors to give their donations in clinics throughout the year. A new series of advertising collateral was developed at the end of 2019 for the launch of the new campaign phase in January of 2020. The video "Diagnosis" illustrates the fact that 67% of donated blood goes to patients who receive transfusions while undergoing treatment for cancer. The second video "Newborn" highlights how 6% of donated blood is used in treating blood loss after childbirth, and help newborn and premature babies.

The "Diagnosis" advert aired across multiple communication channels in January and February 2020 including National TV, Video on Demand, national and local radio, Spotify and online advertising. The objective of the campaign is to educate and nudge donors from awareness to action. It is important to communicate to a large audience about the importance of blood donation throughout the year as part of every day life, and inspire and encourage donors to go to their local clinic when they can.

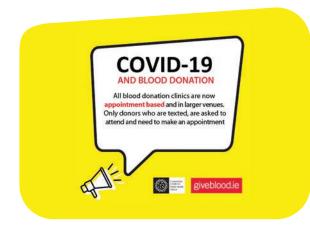
The campaign was due to run at key seasonal periods throughout the year across multiple channels but due to the COVID-19 emergency, plans were reviewed and communications adjusted to meet the new requirements for donors attending clinics during the pandemic.





Communication during COVID-19

With the onset of COVID-19 and the fear of gathering in social places, our communications with donors shifted away from awareness and developing motivation, to reassuring existing donors about the safety on clinic while giving blood, and the constant need for them to make an appointment and attend clinics, as hospital demand continued. From March to December 2020 communication was about updating donors about changes to the clinic process and our guidelines, as a result of COVID-19 via our social media platforms and website. The priority was to engage with and answer queries from donors in relation to eligibility and provide reassurance that giving blood, platelets and bone marrow is part of an essential service, and we still need our donors to attend the clinic, with every effort being made to ensure the safety of donors and staff at the clinics.



The website was updated with a COVID-19 pop up window, and dedicated page, featuring important information for donors to know prior to attending a clinic. Website carousels and social media page banners were also updated with key messages for anyone donating during the year. Social media information posts were created in response to the most frequently asked questions from donors on topics like safety and social distancing measures being taken in clinics, all clinics now being appointment based, and the policy on wearing masks in clinic etc.

There has been steady growth in our social media channels throughout the year, our Facebook page had 129k plus fans at the end of 2020, our Twitter page had 20.9k followers and is used to reply to many donor comments and queries daily, as well as reaching out to mass media outlets and special interest groups to amplify our message.

The Giveblood.ie Instagram followers grew from 200 in 2019 to 8.7k in December 2020. This is a growing social media channel and the objective is to continue doing more on this platform to engage with our younger donors. The IBTS LinkedIn page is growing organically with a business audience; we had 2.8k followers at the end of 2020.

We have had a high level of engagement on our social media channels and feedback from donors about the new appointment system. We have also seen some amazing stories and pictures sent in from staff and donors in clinics across the country about the milestones they have reached and reasons why they are donors. We encourage anyone with a donor or a recipient story to share this with us and let us celebrate the achievements in helping save lives.

eblood.ie

Irish Blood Transfusion Servi

Seirbhís Fuilaistriúcháin mhi

Partnership

Partnership is an important part of engaging with and spreading the importance of blood donation in the community. In 2020, IBTS partnered with a number of organisations such as the GAA, Macra na Feirme, FAI Referees, and many community organisations who continued to support us through challenging times and help promote our clinics. for their on-going support, and we look forward to developing these relationships in 2021 particularly as we seek to increase our first time donor recruitment later in the year.

Of particular importance in 2020 was our partnership with Vodafone with over 6 million texts sent free of charge to donors about clinics and appointments.

IBTS is extremely thankful to all of these organisations

rough challenging a 2020 a 2

Merchandise campaigns on clinic

During the COVID-19 pandemic, each donor was given their own Giveblood.ie pen to fill out the Health and Lifestyle questionnaire and take home with them afterwards.

It is important to ensure that our donors enjoy their experience at our clinics. We aim to make their visit special so that they look forward to coming back again to donate blood and platelets. We ran a number of mini seasonal merchandise campaigns in addition to the regular items like pens and blood drop phone holders. Chocolate heart treats were available to donors in clinics around Valentine's Day and Easter.

This was the second year of our special Christmas merchandise campaign featuring four Giveblood.ie Christmas decorations for donors to take home with them. The wooden decorations were created to thank donors for the amazing gift they give to help patients in need. They were designed by four brave children who received transfusions and were displayed on IBTS Christmas trees in clinic, adding some festive cheer to the surroundings. Each decoration was accompanied by each child's recipient story explaining how they had received blood, platelet or bone marrow transfusions and how this has helped them in their recovery. Once again we'd like to thank Ciara, James, Clodagh and Issy for their beautiful drawings and sharing their inspiring stories with us.

Donor Awards

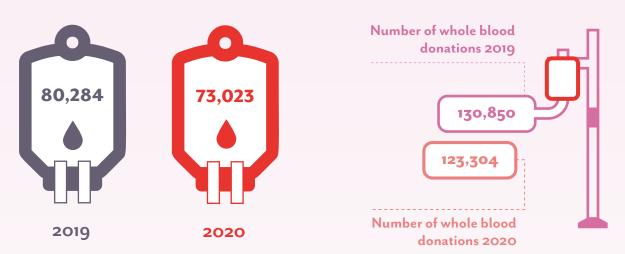
Unfortunately we were unable to hold donor award ceremonies in 2020. But a celebratory pack is being developed for 2021 and will be sent out to our 50 and 100 time donors to recognise their achievement on reaching a momentous donation milestone.





Donor statistics

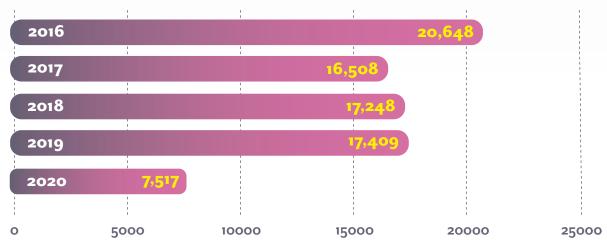
Donors 2019 vs. 2020

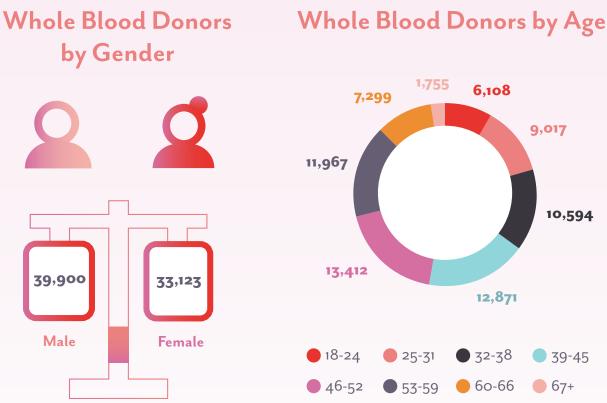


Whole Blood Donations by Donors

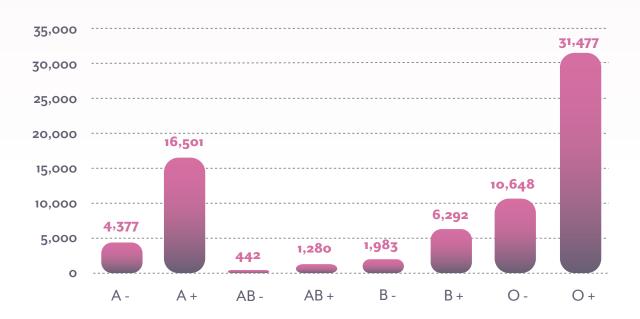


First time Donors





Whole Blood Donors by Blood Group



Production, Hospital Services, Scientific Support and Component Development

Key achievements:

- Maintained blood stocks across the supply chain, ensuring blood and blood product availability to meet patient's needs at all times.
- Maintained blood processing and frontline hospital service 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.
- Engaged with external healthcare partners ascertaining their needs and feedback through customer engagement and survey.
- Implemented optimal bacterial screening protocols with automatic 7 day shelflife for all platelets products, enhancing product safety and availability.
- Transition of blood processing and scientific roles to optimise skills and talent, ensuring day to day operational excellence, 24/7 customer support and future blood product development capability.

- Strategic replacement of blood processing equipment to maintain state of the art processing capability and operational best practice.
- Validated processes for the collection, processing and storage of convalescent plasma for the treatment of COVID-19.
- Introduction of new additive solution for washed platelets, with product shelf life increase from 6 hours to 24 hours.

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 Scientific Support and Component Development team are responsible for the management of all platelet products, nonroutine 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.

A total of 34,981 product orders were received electronically in 2020, a decrease of 1.1% on 2019. Of these, 28,119 (80%) were received in the NBC and 6,862 (20%) were received in the Cork Centre.

Blood Component Activity

There was a reduction in red cells (-5.2%) and platelets (-1.5%) issued to hospitals in 2020, compared to 2019, mainly due to the impact of COVID -19 on hospital activity. The impact on demand varied over the course of the year, with the most significant decrease in blood usage during the first wave of the pandemic. During this period red cell issues decreased by up to 43% and platelet issues decreased by up to 23% on a weekly basis, compared to average weekly issues for 2019.

Donor blood was processed to produce the following products:

Primary Product	Number prepared	Distributed						
Whole Blood and Red Cells								
1.411 mm	18	01						
Whole blood for neonatal use	1165	01						
Red Cell Concentrate	106,913	96,813						
Red Cell Concentrate for neonatal use	11,191	3,764 ¹						
Whole Blood Clotted	28	28						
Plasma Products								
Fresh Frozen Plasma for neonatal use	108	0						
Fresh Frozen Plasma for IVD use	117,556	84,876						
Plateletapheresis - Doses								
Apheresis platelets	19,344²	9,785 ³						
Secondary Product	Number prepared	Distributed						
Red Cells								
Red Cell Resuspended	793	762						
Red Cell Washed Irradiated	2	2						
Red Cells Thawed/Washed	0	0						
Red Cells for IUT	20	18						
Red Cells, Plasma Reduced	330	133						

Red Cells, Plasma Reduced, Irradiated	5	3			
Red Cells Split for Neonatal Use	617	600			
Red Cells Split for Neonatal Use, Irradiated	38	34			
Red Cell, Irradiated	14,733	14,244			
Red Cell, Neonatal Use, Irradiated	224	218			
Whole Blood Reconstituted	0	0			
Plasma Products					
Cryoprecipitate for neonatal use	119	93			
Platelet Products - Doses					
Platelets, Apheresis, Washed	15	13			
Platelets, Paediatric Dose	14	14			
Platelets, Hyperconcentrated	0	0			
Platelets, Apheresis, Extended Life	7,7984	6,100			
Platelets, Pooled	7,118	3,4875			
Platelets, Pooled, Extended Life	3.0556	2,7215			
Leucocytes Pooled					
Leucocytes, Pooled	2	2			
Leucocytes, Pooled, Red Cell Reduced	0	0			

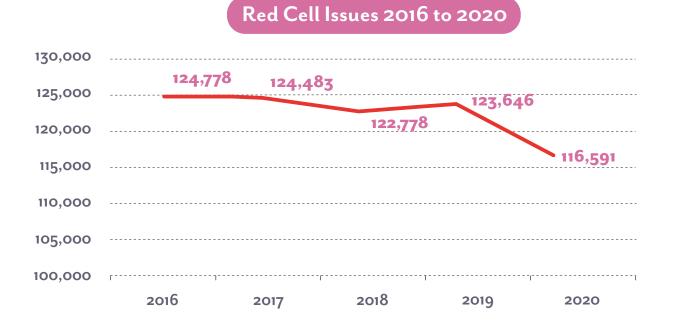
Footnotes:

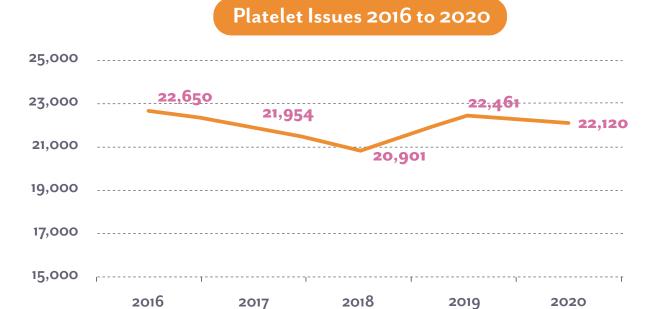
- ¹This is the number issued as whole blood, the remaining units prepared were reprocessed into adult use red cell products or red cells plasma reduced for neonatal use.
- $^{\rm 2}{\rm This}$ is the total number of plateletapheresis doses prepared in 2020.
- ³This is the number of plateletapheresis doses, with a 5 day shelf life only, issued for therapeutic use. This does not include doses that were extended to 7 day shelf life prior to issue.
- ⁴These are a subset of the total plateletapheresis doses prepared
- 5 The total number of pooled platelets issued for the rapeutic use is the sum of these figures (*i.e.* 3,487 + 2,721 = 6,208)
- ⁶ These are a subset of the 7,118 pooled platelets prepared

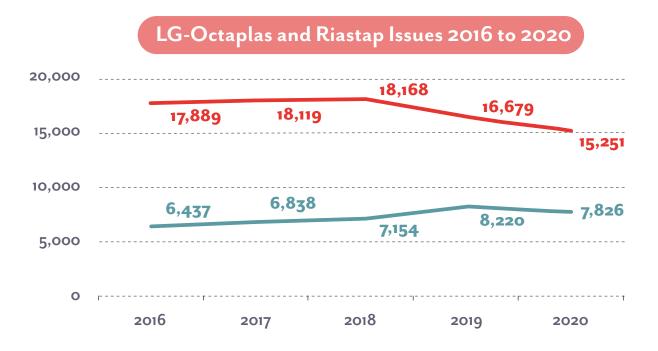
Please note that produced will not necessarily match distributed due to incoming stock available from 2019 and issued in 2020.

Medicinal Product Activity

There was a reduction in medicinal products issued in 2020, compared to 2019. There was an 8.6% reduction in LG-Octaplas issued and 4.8% reduction on Riastap issued.

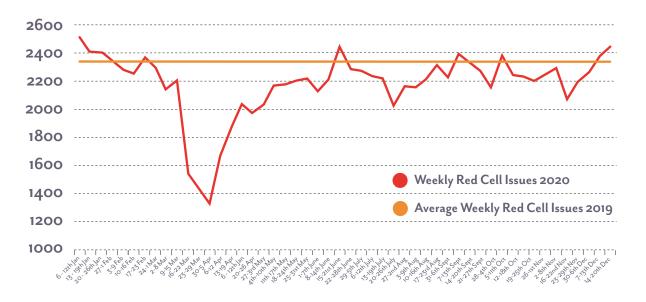


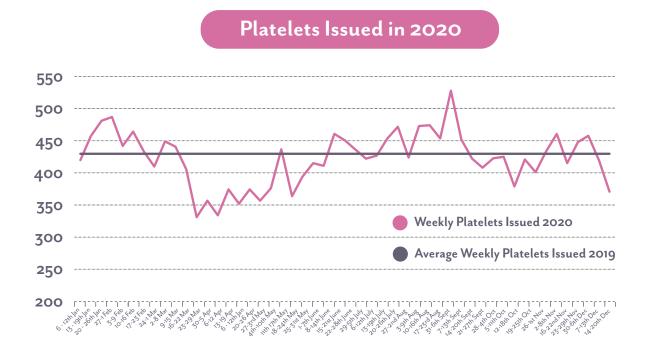






Red Cells Issued in 2020







TESTING



National Donor Screening Laboratory (NDSL)

The National Donor Screening Laboratory (NDSL) was formed in 2020 following the amalgamation of the three donor testing laboratories: Automated Donor Grouping (ADG), Virology, and Nucleic Acid Testing (NAT). Extensive collaboration between the three donor testing laboratories, workflow analysis, and international benchmarking with Blood Establishments facilitated this amalgamation. Key to this new structure is cross training of staff to allow rotation across all three departments. This will provide staff enrichment and also greater contingency for cover. The cross training project was initiated in 2020 with the central premise of an extensive educational programme for participants.

Key achievements 2020

- The NDSL team faced and adapted to the challenge of the COVID-19 pandemic and have maintained testing of donations, processing of results to consistently high standards of quality and training of new staff members. This involved a huge amount of dedication and flexibility from the teams by adapting to split team working and / or working from home when required and significant changes to work practices to keep the teams safe, and in turn maintain the service of the NDSL.

- Successful amalgamation of the three departments, Automated Donor Grouping (ADG), Virology and Nucleic Acid Testing (NAT) into the national Donor screening Laboratory.
- The launch of a significant National donor Screening laboratory education and training upskilling programme has been developed and the academic course in Immunohaematology and transfusion transmitted infectious disease screening is currently being delivered on-line due to COVID-19 restrictions The cross-training programme was developed with support from the Training and Education Officer to provide cross functional support between staff in the three departments.
- ADG moved to perform an extended Rh type (C, c, E, e) on all donors. This provides a greater selection of units in the hospitals for patients with commonly occurring red cell antibodies.
- ADG continued their programme to identify rare red cell donors. In response to a patient with anti-Jra ADG identified donors to be tested, and, in conjunction with RCI, a compatible donor was identified. There was a probability of 3 in 10 million for finding this donor; such was the rarity of the type.
- The Virology laboratory introduced and validated two Malaria screening assays the Captia[™] Malaria Total Antibody EIA and the Diapro Malaria Antibody ELISA to facilitate the introduction of selective malaria testing of donors in 2021.

- In order to be more adaptable to meet current and future challenges the Virology laboratory added two viral serology analysers the Abbott Architect i2000 and the Dynex DS2 2-Plate ELISA Processing System thereby adding capability to the laboratory to screen for 100+ additional disease markers.
- The Virology laboratory introduced and evaluated two SARS-CoV-2 antibody screening assays, the EuroImmun Sars CoV 2 IgG assay and the DiaPro IgG Sars CoV 2 IgG on the Dynex DS2 platform for convalescent plasma screening.
- SARS-CoV-2 seroprevalence study. The Virology laboratory began investigating the prevalence and distribution of antibodies to SARS-CoV-2 in a healthy adult population of blood donors in Ireland. The unlinked and anonymised anti-SARS-CoV-2 antibody testing of donor was carried out on plasma test tubes from IBTS donations selected and stored (frozen) between January and September 2020. This will be the largest such study completed to date in Ireland.
- An archive sample of each blood donation tested at the IBTS is stored at <-20°C. In line with other blood centres this retention period has been reduced to 10 years. The NAT laboratory has project managed this change and has overseen the destruction of the Virology sample archive of approximately 2,000 boxes of archive trays leading to significant cost savings and efficiencies for the IBTS. The project is due for completion in 2021.
- A review of NAT external quality controls (EQCs) used to ensure the quality of NAT results was undertaken. This review of EQCs including monitoring processes and usage has lead to the implementation of

significant efficiencies and cost savings for managing and monitoring our Go/Nogo EQCs.

- A review of NAT HEV initial reactive testing algorithm was undertaken which has lead to the implementation of more efficient testing.
- A new delivery system for NAT reagents was introduced making the process more efficient, greener and safer for staff.
- Successful performance of a contingency testing exercise with the Scottish Blood Transfusion Service (SNBTS) under extremely challenging COVID-19 restrictions
- 'A snapshot of ABO, RhD, Rh phenotype and Kidd profile in Modern Ireland' was presented as a poster presentation at ISBT 2020.

In 2020 the NDSL tested 133,229 donations, with 127,434 coming from repeat donors (96%) and 5,795 (4%) of these donations coming from first time donors. In addition, 761 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
- 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:

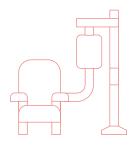
- ADG: Extended antigen types, haemoglobin S, neonatal antibody screen. Donors are typed for extended antigen types (Fya/b, Jka/b, M, S/s) for routine hospital orders and also to identify rarer phenotypes or combinations of antigen negative types. These are typically for patients with complex transfusion 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.
- 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: Routinely, West Nile Virus (WNV) testing is performed in the NAT laboratory on selected donors who have travelled to a WNV at risk area within the past 28 days. This testing is usually performed from May to December each year. Due to the Covid pandemic and associated travel restrictions, WNV testing was not implemented in 2020.

ADG have two instruments in use: PK7300 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 PK7300 is a high-throughput microplate system and the Ortho Vision tests using column agglutination technology.

The Virology laboratory performs screening on the Abbott Alinity s System, which is a highthroughput, 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 Qulaity Assessment Schemes

NDSL participate in both UK National External Quality Assessment Scheme (UK NEQAS) and European Directorate for the Quality of Medicines & Healthcare (EDQM) external quality assurance (EQA) schemes. All departments within the NDSL scored 100% accuracy for their relevant EQA.

ADG is a participant in 4 NEQAS schemes and 1 EDMS scheme annually. This consists of 19 separate serology exercises and 6 abnormal haemoglobin exercises. In 2020 ADG participated for the first time in the Extended Red Cell Phenotyping Scheme.

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 (EDQMNAT)

NAT participated in 4 EQAS schemes in 2020. This consisted of 8 separate exercises.

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 contingency plan was modified in 2020 due to COVID restrictions. However, NDSL succeeded in participating in 2 exercises which involved sending samples from 24 donors for testing. In 2020 the contingency was tested 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

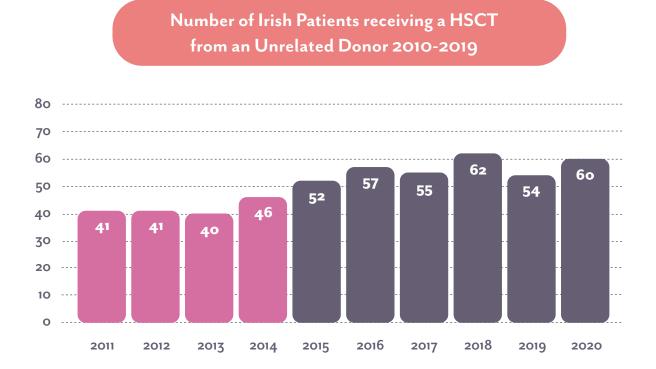
The laboratory also participates in a number of Internal and External Audit programmes to ensure compliance within the Quality Management System (QMS). This auditing of the NDSL processes and procedures are undertaken by the Health Products Regulatory Authority (HPRA), the IBTS Quality Assurance (QA)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

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 Our Lady's Children's Hospital, 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. On the 15th June 2020 the NHIRL commenced 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.

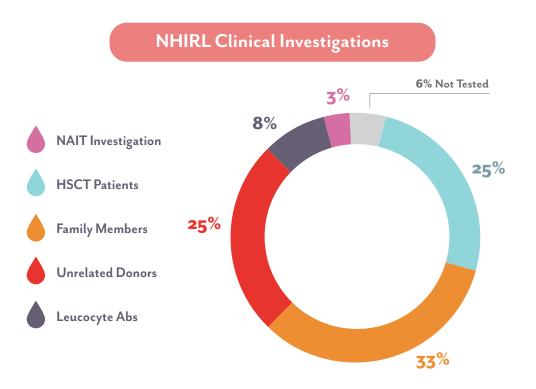
The laboratory has an extensive quality assurance programme including participation in both internal and external proficiency testing programmes for HLA typing, human platelet antigen (HPA) genotyping and HLA antibody investigations. The NHIRL has been accredited by the European Federation for Immunogenetics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

In 2020 samples from 230 Irish patients for potential haematopoietic stem cell transplants and their relatives 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. The NHIRL provides an immunogenetics support service for the Irish Unrelated Bone Marrow Registry (IUBMR). From October 2019 the blood donor Health and Lifestyle Questionnaire (HLQ) included 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 a total of 4,663 new donors joining in 2020.



In 2020 a total of 60 unrelated donor transplants were performed. In the last 10 years the IUBMR has facilitated 508 unrelated donor transplants for Irish patients.

In addition, a total of 373 platelet donors were HLA-A, -B typed and included on the panel of platelet donors in order to support the provision of an optimal platelet product to the hospitals. The NHIRL received 1,381 samples as part of clinical investigations in 2020. 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 is provided. The number of investigations for NAIT in 2020 (n=46) increased significantly as compared to 2019 (n=32).



The NHIRL provides a routine disease association HLA typing service. This service represented 2,676 of the 9,443 samples received for testing by the NHIRL in 2020. The majority (88%) 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), Behcet's Disease (B*51), Abacavirinduced hypersensitivity reaction (B*57:01), Narcolepsy (DQB1*06:02) and Birdshot retinochoroidopathy (A*29).

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:

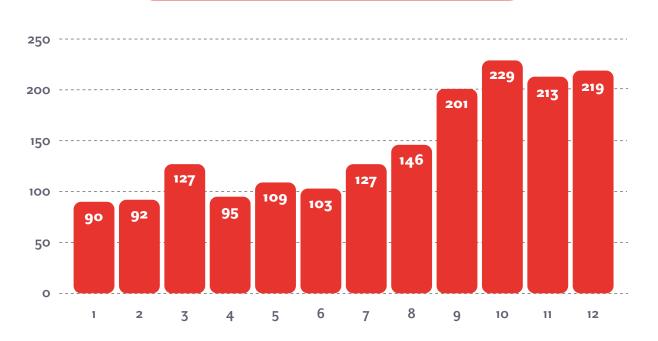
- Fetal RHD Screen
- Weak D Genotype investigation
- RHD Variant investigation
- Full RBC Genotype investigation
- RHCE Variant investigation

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.

In 2020 1,751 samples were received by the Blood Group Genetics Laboratory for Fetal *RHD* screening. The results for Fetal *RHD* screening identified 59% *RHD*-positive, 37% *RHD*-negative, and 4% Inconclusive. The electronic transmission of Fetal *RHD* screening results through Medibridge is available to referring hospitals and was implemented with the Rotunda Hospital from August 2020.

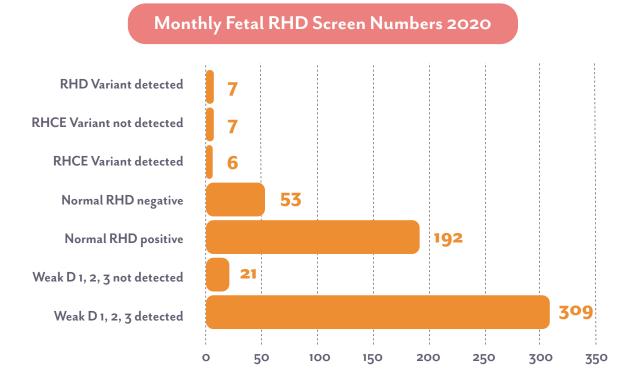


Monthly Fetal RHD Screen Numbers 2020

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 38 Human Blood Group Systems have been identified, their genes cloned and

the molecular basis associated with individual antigens determined; there are well over 300 individual blood groups recognised in the 38 Blood Group Systems. In 2020 the Blood Group Genetics Laboratory tested 595 samples in total for Weak D Genotype investigation; *RHD* variant investigation; Full RBC Genotype investigation; and *RHCE* Variant investigation.



Red Cell Immunohaematology (RCI) Laboratory

The RCI laboratory provides extensive pretransfusion and antenatal referral services for hospitals nationwide.

Key Achievements for 2020

Research and Educational Achievements

The staff in the RCI laboratory are passionate about research and education and despite the challenges posed by the pandemic, 2020 saw a number of achievements in this area.

- RCI laboratory staff presented at both the National Haemovigilance Conference and at the BioMedica Conference in 2020.

- RCI Laboratory staff were invited to present two webinars for the Academy of Clinical Science & Laboratory Medicine in August and October 2020.
- The RCI laboratory contributed to the following paper '*Two novel antithetical KN blood group antigens may contribute to more than a quarter of all KN antisera*' which was published in the journal 'Transfusion' in October 2020.
- The RCI laboratory values user engagement and customer relationships. A Customer Liaison Day was held in March 2020. Scientists from three Blood Transfusion Laboratories in the R.O.I came to the RCI laboratory and participated in a day of both theoretical and practical red cell serology activities.
- For the first time the RCI laboratory held a half day User Symposia in November 2020. The subject matter was a range of interesting cases that the laboratory has dealt with over the year, along with a Q&A session to allow users of the laboratory to interact with the RCI staff. The event was well received and the feedback from the day was extremely positive.

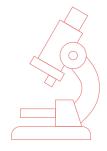
Laboratory Achievements

- The RCI team rose to the challenge in the face of the global COVID-19 pandemic, with ensuring continuity of service and testing samples from COVOID-19 positive patients. The team adapted to split team working and / or working from home when required.

- The validation and introduction of a new analyser for antibody quantitation of Anti-D and Anti-c in pregnancy.
- The tender was awarded for a new blood grouping automated analyser and the validation of this analyser began in 2020, with a target go live date of Q1 2021.
- The validation of a neutralisation technique for the inhibition of Anti-Ch/Rg in patient's plasma was also completed.

Quality Achievements

- The RCI laboratory began the process of achieving ISO 15189 accreditation in earnest in 2020. This involved the development of an internal audit programme specifically for the RCI laboratory and a review of quality risk management. Failure Mode Effect Analysis was identified as the key tool to develop quality risk assessments for the laboratory and these were completed for both analysers in the laboratory.
- A customer satisfaction survey was distributed to all hospital blood banks at the end of 2019 to obtain feedback on the service provided and to help shape the RCI laboratory strategic plan for 2020.



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, and
- out of hours emergency on-call service.
- provision of hospital blood bank services for Our Lady's Hospice and Care Services and the Royal Victoria Eye and Ear Hospital

In 2020 a total of 2,274 samples were tested in the RCI laboratory, a 4.89% increase on 2019 figures.

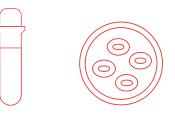


	Total No. of Samples tested	RhD Type Workup	Antibody ID	Anti-D Quant	Anti-c Quant	Monocional Interference	Total Compatibility Test	Complex Compatibility Test	On-call Samples
2019	2168	2	2049	455	171	227	741	717	143
2020	2274	5	2071	426	134	256	927	880	185
(%)	+4.89%	+150%	+1.07%	-6.37%	-21.64%	+12.78%	+24.70%	+22.73%	+29.37%

Comparison of 2019 and 2020 sample numbers

2020 saw a further increase in referrals from patients receiving the drug Daratumumab to treat multiple myeloma. This drug was licenced for use in Ireland in April 2018.

As in previous years, there was a continued high level of serologically difficult or rare samples received. In 2020 the following complex samples some with rare allo-antibodies were identified by the RCI Laboratory:



Antibody Identified	No. of Samples	No. of Patients
Anti-Ch/Rg	10	9
Other HTLA-type	10	10
Anti-Wra	8	5
CR1-related	4	4
Immune Anti-A	1	1
Immune Anti-B	1	1
Anti-Ce	4	3
Anti-cE	3	3
System Specific	14	14
Anti-G	18	15
Anti-H	1	1
Anti-P1	3	3
Anti-Yta	1	1
Anti-k	1	1
Anti – IH	2	2
Total	81	73

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 to date.

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 two red cell units of rare phenotype were imported from abroad in 2020.

Participation in External Quality Assurance Schemes

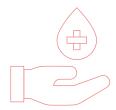
The RCI laboratory participates in three different quality assurance schemes; four exercises in IEQAS, four exercises in AQQAS and 10 exercises in NEQAS along with pilot NEQAS schemes in red cell phenotyping, DAT and antibody titration. In addition, the RCI laboratory is involved in Interlaboratory comparison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

Diagnostics/ Crossmatch 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;

As 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.

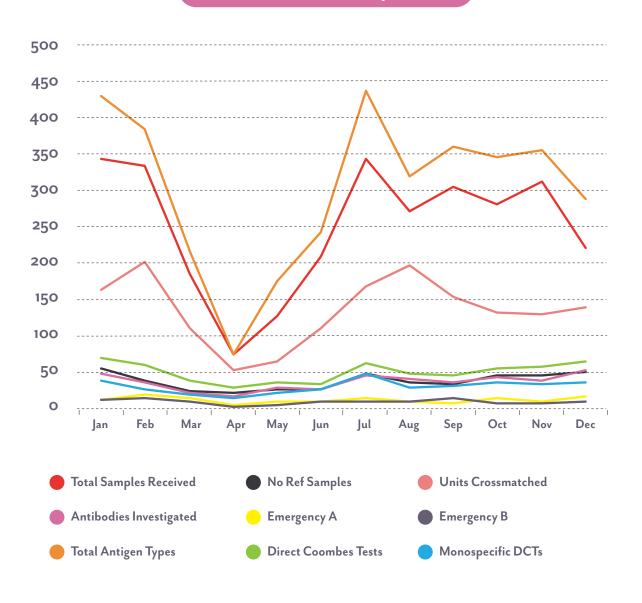




- As a reference laboratory the Cork Centre investigates complex or anomolous red cell typing, extended typing for transfusion dependant patients, positive direct antiglobulin tests, auto-immune haemolytic anaemia, haemolytic disease of the fetus/newborn, and complex antibodies providing extended matched (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. 2 patient samples required further specialist referral to the international blood group reference laboratory (IBGRL) Bristol, and a further 59 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 the 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 Ordering 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.

Crossmatch Activity 2020



Diagnostics Laboratory Activity 2020 (see table above)

Total samples received 2020: 3,007 (2019 : 3,690) This decrease in sample numbers was a direct consequence of COVID-19 lockdowns which resulted in cancellation of hospital procedures and subsequent blood requirements.

OTHER SERVICES



Tissue

The IBTS tissue bank is located at the National Blood Centre in Dublin. The facilities include a suite of clean rooms essential for tissue processing. In 2020, an IT system, MAK, TCS was implemented, to manage the processing and labelling of cardio vascular tissue. The team worked very closely with the Ophthalmic and Cardiothoracic units throughout the country and maintained a constant supply of tissue during the challenges of 2020.

For over 30 years the tissue bank has been supplying patients throughout Ireland with corneas for the treatment of ocular diseases. In 2004, measures were introduced to mitigate the potential risk of vCJD, and as a consequence we stopped collecting corneas from donors in Ireland. Since then, all ocular tissue has been imported. 2020 saw the IBTS revise it's position on vCJD, and the feasibility of re-opening the eye bank and once again collecting corneas in Ireland is being explored.

Due to the pandemic, all but emergency surgeries were cancelled for March, April and May 2020. Once elective surgery resumed, the demand for tissue was met but there was an approximate 25% reduction in corneas distributed in 2020. Apart from corneas, the tissue bank supplies sclera, amnion, fascia lata and pericardium – all human tissue products used in ocular surgery. The demand for certain tissue products, fluctuates from year to year, depending on clinical need, new technologies and surgical techniques. 2020 saw a significant increase in the demand for DMEK (manually pre cut tissue) from 12% to 22% of corneas distributed. The tissue bank also operates the Irish Heart Valve bank, in conjunction with the MMUH. Donations were down on previous years due to the pandemic but recovered later in the year. Paediatric surgery was not affected and the IBTS was able to maintain supply and fill requests from tissue collected prior to 2020.

Cryopreserved human skin is also stored in the tissue bank and is the gold standard for the treatment of severe burns. This tissue is imported from the BST Tissue bank in Barcelona, Spain. The skin is mainly supplied to the burns unit in St. James's Hospital.

Therapeutic Apheresis

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 are transferred to these facilities as appropriate.

TAS is led by Consultants in Transfusion Medicine, supported by Specialist Medical Officers (SpMOs) and Nurses trained in therapeutic procedures. The procedures are carried out at the patient's bedside using mobile apheresis equipment - Terumo OPTIA Spectra. The procedures performed in 2020 were Therapeutic Plasma Exchange (TPE) and Red Cell exchange (RBCX). Software will be enabled on the second Optia to facilitate the latter and the Optia software has also been enabled for White Blood Cell Depletion (WBCD). TAS provides individualised apheresis protocols for each patient in conjunction with the requesting attending 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 IBTS quality management system, with trained personnel, controlled documentation, SOPs, validated technology and adverse event monitoring. Adverse events are subject to on-going review and changes are incorporated into the IBTS Therapeutic SOPs and relevant Hospital policies and procedures. TAS staff attend UK and international meetings, and comply with Continuing Professional Development (CPD), including audits. However, international meetings and access to CPD were restricted due to the COVID-19 pandemic, with remote access only from March 2020. The service intends to participate in international data gathering, once available.

During 2020, there were 18 patient referrals and 129 procedures undertaken, over three hospital sites. The demand for TAS is varied and unpredictable. Variability in demands includes requesting hospitals, specialities, consultants, degree of urgency, ASFA category and trends by month, weekend and out of hours.

The pandemic necessitated significant changes to the delivery of our TAS. With several local hospital infection outbreaks, clinicians were advised by TAS consultants that the service would be restricted to failure of other therapy in life threatening conditions. This, together with delayed presentation to hospital for patients with COVID-19 infection concerns, lead to a reduction in referrals. Each patient referred was assessed on an individual basis. All staff completed online PPE training on HSELanD and attended in person training in BSHC and had active liaison with hospital infection control. A referred patient in February 2020 had recently returned from China and before testing was completed staff attended to them in full PPE, as potentially the first COVID-19 positive patient in Ireland. They subsequently tested negative.

In addition, IBTS blood donation clinics changed from walk in to appointment only clinics with a pre-appointment selection process. To support this, TAS nurses were the first line referral for medical queries that ensued for clinics. This process subsequently led to a reduction by 50% in deferral rates at donor clinics. TAS nurses were technologically enabled to facilitate undertaking this work remotely, in rotation, where TAS demand allowed.



2020

The trends and variability in service demand over recent years are shown below

Weekend, Bank Holiday and Out of Hours Service

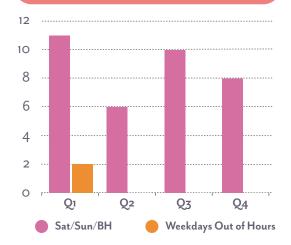
2018

2019

2017

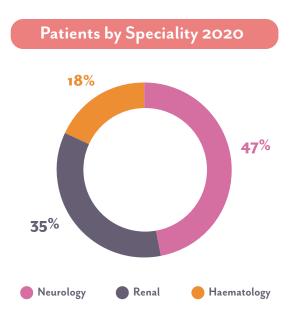
Patients may present for emergency, out of hours care when their diagnosis is life or organ threatening. The treatment programme may extend throughout a weekend period. Of the 129 procedures carried out in 2020, 35 (27%) were performed at the weekend and 2 (2%) were commenced out of regular hours during the week. The trend in demand (by quarter year) for weekend/bank holiday and out of hour's service is below.

Weekend, Bank Holiday, Out of Hours Service Provision 2020



Clinical speciality by patient and procedure

In line with recent trends the majority of referrals were for patients presenting with neurological conditions (47%), followed by renal (35%) and haematology (18%).



Sickle Cell Disease

TAS commenced an elective Red Cell Exchange programme for a patient with sickle cell disease (SCD) during 2020, guided by laboratory and clinical parameters. It is anticipated that this demand will increase as the regional paediatric patient cohort matures into adulthood.

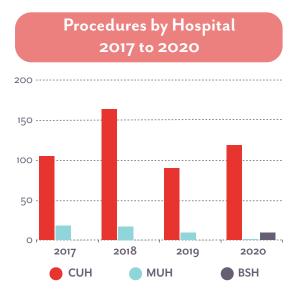
Service Provision to hospitals

CUH had the greatest demand for TAS referring 15 patients in 2020, MUH and BSH both referred a single patient.

Below is a comparison of service provision to CUH, MUH, BSHC over the past 3 years by patients and procedures.

Service provision patients by hospital 2017 to 2020





The American Society for Apheresis (ASFA) guidelines

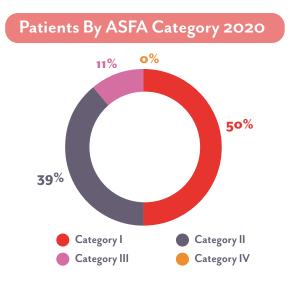
ASFA guidelines are the basis of planning individual patient treatment protocols. These are based on both quality of supporting evidence as well as the strength of the recommendation derived from that evidence. The most recent guidelines (8th Ed.) were published in 2019.

Category I – Disorders for which apheresis is accepted as first-line therapy, either as standalone or in conjunction with other treatments.

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.

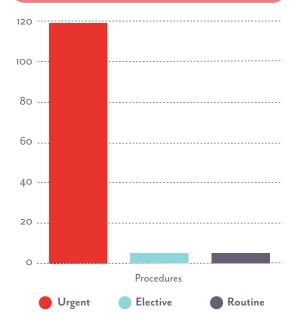


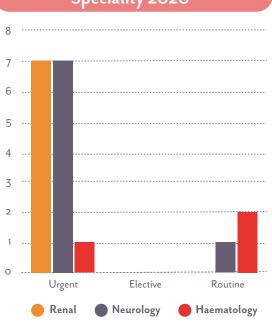
Degree of urgency of Therapeutic Apheresis Service required

Therapeutic Apheresis may, in some conditions, form part of the urgent clinical response to patients' presentation. Early apheresis can reduce the threat to life or organs. 82% of patients presented with urgency, 6% as elective and 12% presented as routine in 2020.

Service Urgency by patients & Procedures					
Urgency	Patients 2020	Procedures 2020			
Urgent	14	119			
Elective	1	5			
Routine	2	5			
Total	17	129			

Degree of Urgency by Procedures 2020

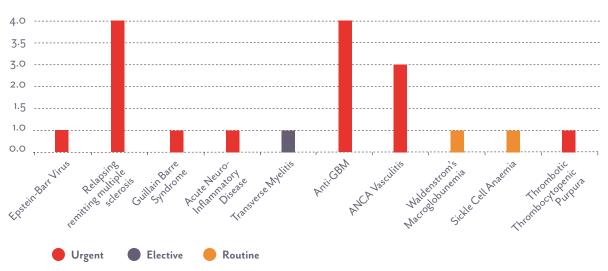




Degree of Urgency of Patients by Speciality 2020

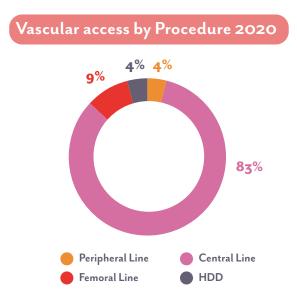


Number of conditions treated by urgency 2020



Vascular access for patients and procedures

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 in 2020. Some had a combination of vascular access types such as; peripheral lines, femoral lines or haemodialysis devices.



Quality Framework

A quality management system is defined as a formalised system that documents processes, procedures and responsibilities for achieving quality policies and objectives. The Therapeutic Apheresis Service 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 a service is evidence based.

Due to the COVID-19 pandemic, during 2020, all interaction with other apheresis services were remotely enabled by technology.

Facilities and technology:

TAS uses two Spectra Optia machines which are stored in CUH and can be transported to either the MUH or the BSHC as required. The machines are validated at regular intervals and with preventative maintenance twice last year.

Training: TAS staff 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. Post pandemic declaration this was remote access enabled by technology.

Outcome communication

In compliance with the British Society for Haematology guidelines that "The clinical outcome of apheresis procedures should be documented (Recognising that this may require clinical data collection days or weeks after the apheresis procedure)", Cork Centre TAS requests outcome details from service users.

Speciality	Patients referred (N)	TAS overview letters sent to referring physicians (N)	Patients where outcome status received from referring physician (N)	Compliance (%)
Neurology	13	13	6	43%
Haematology	1	1	0	0
Renal	3	3	3	100%

Clinical data communication by speciality:

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 7,750 serious adverse transfusion reactions and events have been reported.

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

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 aspects of blood transfusion are reviewed by the NHO. These reports come from blood establishments, hospital blood banks and facilities. During 2020, 118 mandatory SAEs were reported (42% of all SAEs). In addition, 163 non-mandatory SAEs, (58% of all SAEs) primarily relating to errors in clinical areas, were also reported. This figure includes Wrong Blood in Tube events (WBIT) (n=79) which were collected by the NHO.

Serious Adverse Reactions (SARs) mandatory and non-mandatory

At the time of writing, a total of 106 reactions that meet the criteria have been reported in 2020. Mandatory SAR (62) reported to date is an increase on those recorded in 2019 (54).

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. 174 mandatory reports were reported by the NHO in 2020 (for the reporting year 2019), with the compilation of 2020 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 scientist and specialist registrars also continued during the year.

The NHO held a conference on the 4th March 2020 entitled 'The Evolving Landscape of Blood Transfusion'. The conference featured both national and international speakers with an attendance of close to 300 delegates. A poster competition coincided with the conference with 12 entrants received from 8 reporting establishments.

e-Learning

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

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. The NHO have seen an increase in use of LearnProNHS as a result of the COVID-19 pandemic.

Irish Unrelated Bone Marrow Registry (IUBMR)

2020 key Achievements:

- Provision of stem cell products continued despite COVID-19 restrictions on international travel.
- Donor Assessments and international sample shipments continued despite COVID-19 restrictions.
- Recipient safety maintained in unpredictable situations through implementation of cryopreservation of stem cell products upon arrival at Cryobiology Laboratory SJH, or when necessary cryopreserved prior to travel at country of collection when available.
- Bone Marrow Donor recruitment continued when possible at all blood donation clinics – donor and staff safety maintained through implementation of COVID-19 safety measures and donor appointment system.

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 thirty eight 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 Panel and through the Bone Marrow Donors Worldwide (BMDW) database, on behalf of the Irish transplant centres at St. James's Hospital, Dublin and Children's Health Ireland at Crumlin. In 2020, one hundred and five patients were referred to the IUBMR for unrelated searches.

Sixty Irish patients received stem cell transplants from an unrelated donor in 2020. The majority of these were from international donors (57).

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. Thirty Irish donors were selected for additional testing in 2020.

Irish Donor Recruitment

For many years, potential stem cell volunteers have been recruited through blood donation clinics. Until recently donors had to specifically make a request to join the registry. In the fourth quarter of 2019, the blood stem cell donor recruitment pathway was changed. Now, all blood donors of appropriate age are invited to join the registry, when they attend clinic to donate blood. This has resulted in a significant increase in donor interest to become blood stem cell donors. In 2020, 3,968 new volunteers gave blood samples to join the IUBMR, which will be added to the current registry of over 21,000 potential donors.

Irish Donor Donations

Donations (peripheral blood stem cell and bone marrow) from 3 Irish donors were facilitated in 2020, for national patients.



QUALITY & COMPLIANCE



Key Achievements

- Revised IBTS Quality Manual
- Successful implementation of changes to improve bacterial testing of platelet products
- HPRA Authorisation variation to include collection of Convalescent Plasma
- Implementation of electronic review and approvals by QA
- Launch of online Quality System training
- Initiation of departmental Quality Business Partner meetings
- On-going project support for key organisational initiatives, such as, upgrade of our Blood Management System and ISO 15189 Laboratory Accreditation.

Quality & Compliance

The safety and quality of our products and processes are maintained by complying with legislative requirements under the EU directives for blood and tissue products, which are subject to regulation by the Human Products Regulatory Authority (HPRA). We meet our regulatory obligations through maintaining a Quality Management System (QMS) so that we are always in control of the quality of our biological products.

Our QMS is based on the requirements of the Blood Establishment Good Practice Guidelines (EU Directive 2016/1214), the code of Good Manufacturing Practice (cGMP) (EU Directive 2017/1572) as well as relevant standards and requirements for quality. It ensures that, wherever possible, products and services meet or exceed the best practice standards for guality, efficacy and safety. In 2020 our on-site regulatory inspections were impacted due to the COVID-19 pandemic and we swiftly moved to facilitating remote inspections. The HPRA completed 2 inspections which included 1 clinic and a combined annual NBC/MRTC inspection. The IBTS achieved compliance for all inspections, so our customers and patients know that our products are safe for use and meet high quality standards. The Triennial Good Distribution Practice (GDP) inspection was postponed until 2021 due to the pandemic.

During 2020 our HPRA authorisation was updated with a variation to include the collection of Convalescent Plasma. Annual reports were also filed on the associated activities of the Blood and Tissue Establishments as per HPRA requirements.

A key initiative in 2021 will be to support the medical laboratories in attaining ISO 15189 accreditation from the Irish National Accreditation Board (INAB). This will ensure that we continue to meet the highest international standards in the quality and safety of our products and services for our donors and patients. Our main efforts during 2020 were to support the organisation in meeting regulatory requirements, alongside the challenges faced due to the COVID-19 pandemic. Throughout the year the team continued to implement and support all elements of the QMS ensuring that appropriate decisions and actions were captured, relative to their risk and impact.

Having learned and listened to our customers, our focus will be to continue improving efficiencies across a range of quality activities to achieve operational excellence. We will also embed an improved risk based approach, in order to provide a more agile and proactive quality system. We will continue to drive a culture of quality by improving our partnerships, to achieve better healthcare outcomes.

During 2020 key achievements under the pillars of the Quality Strategy were:

Modern Quality Systems

Through key stakeholder engagement the IBTS Quality Manual was revised by the Quality Systems Development Team. This high level policy now provides an improved framework for document development within our quality system. Review of our current systems for Change Control, Incident Reporting, Customer Complaints and Documentation Management also commenced in 2020 and implementing improvements in these elements will be a main focus for the function in 2021.

In response to the pandemic the QA team also moved to electronically manage elements of the QMS to ensure continuity of core operational activity. This supported the team in continuing to meet regulatory requirements while safely working from home. It also highlighted the criticality of implementing a single electronic Quality Management Solution which is compliant, effective and efficient. This is a key initiative of the quality strategy further work is planned in 2021.

Stakeholder Engagement

Partnering with our stakeholders is critical to ensure we successfully understand the needs of our internal and external customers. To strengthen our existing relationships, the QA team commenced quality business partner meetings with various departments in 2020. This is the first step to ensure we build on existing relationships to become a trusted advisor in providing quality guidance to all our stakeholders.

Networking with our international partners also continued with membership of the Blood Quality Program for the European Directorate of Quality of Medicines in Healthcare (EDQM). Conferences were virtually attended this year, some of which included; *Keeping up with Reality and Quality* (EDQM), *Quality and Regulatory* (PDA) and *Strengthening Blood Systems* (WHO). In advance of the pandemic travel ban, the National Quality Assurance Manager joined the operations team to visit the Belgian Blood Establishment in February.

Sustainable Quality Workforce

To ensure that an effective management structure remains in place, developing optimum succession plans for the Quality and Compliance function will be a key area of focus for the Quality Leadership Team in 2021. This will also address any single points of dependency within the function in order to drive enhanced organisation performance. To support implementation of an organisational training programme which meets our regulatory requirements, engagement with the Learning and Development team continued. The first online Quality Systems GMP training module was also rolled out to the organisation. Key training sessions attended this year by the quality team were; *Internal Quality Auditing to ISO 15189, Advanced GDP training* and *Project Management – PRINCE2®*. Quality staff also attended various Leadership and Management programmes.

Key Quality Data

The IBTS records, investigates and actions internal incidents or issues that have a potential to impact donor or product safety, or which represent a departure from approved procedures, through the Incident Report (IR) system. In 2020, 567 IRs were raised, compared to 708 raised in 2019. The percentage closed was 45%, compared to 65% in 2019. The IBTS records, investigates, and responds to customer complaints through the Blood Complaint system. In 2020, 765 complaints were reported, compared to 797 in 2019. The percentage closed was 79%, compared to 65% in 2019. Associated with IRs and Complaints, the IBTS undertook 293 product recalls in 2020. This compares to 300 product recalls in 2019. As in previous years, the majority of product recalls are precautionary due to post-donation notification.

The IBTS proactively manages changes to processes and procedures through a Change Control system. This system allows us to assess the risks and benefits of a change before implementation. In 2020, 373 change controls were raised, of which 37 were temporary changes. This compares to 399 change controls and 48 temporary changes raised in 2019. In addition, 530 Change Orders, which are used to update documents where no significant process change is required, were raised in 2020, with a close out rate of 72%. This compares to 363 change orders raised in 2019, with a close out rate of 80%.

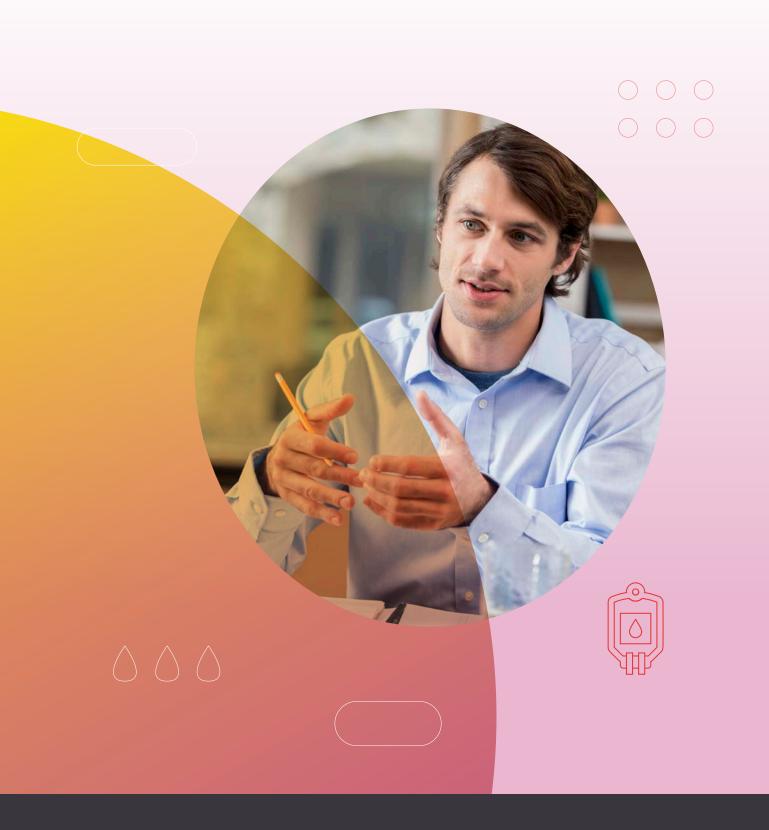
The IBTS monitors and reports Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs) to the National Hemovigilance Office (NHO). During 2020 there were 62 Serious Adverse Events (SAEs) and 39 Serious Adverse Reactions (SARs) accepted as reportable by the NHO.

The quality audit programme carried out 9 internal audits and 4 external audits in 2020.

18 validation plans were closed out which included the upgrade to our Document Control System, SmartSolve. 228 change controls were raised which required validation input.

Implementation of an improved Quality Management Review (QMR) framework is planned for 2021 to provide greater efficiency and control of business processes, enhanced risk management and increased customer satisfaction.

RISK AND RESILIENCE



Risk Management is an intrinsic part of blood establishments, and the IBTS' capabilities to ensure business continuity in times of crisis was truly put to the test in 2020. In early 2020, as the risk of COVID-19 becoming a pandemic and impacting Ireland became ever more real, a cross-functional team was brought together. This team worked through the Pandemic Response Plan and put measures in place to prepare for what would become one of the greatest challenges that the organisation, and indeed the country, has faced in modern times. The risk of COVID-19 impacting on critical operations was added to the corporate risk register, and each area of the organisation completed risk assessments to identify vulnerabilities and mitigate accordingly. These risk assessments are living documents and updated regularly as the situation evolves. Early response measures included sourcing personal protective equipment and moving to an appointment-only blood donation system. The IT team spearheaded a huge effort to equip staff to work from home in order to comply with social distancing measures. This was a major undertaking, as working from home was not previously part of the IBTS culture. COVID-19 has been a standing agenda item at Executive Management Team meetings throughout 2020, which ensured a mechanism to appropriately escalate issues as they arise. This risk was also included in the Chief Executive Officer's reports to the Board.

The response to the pandemic throughout the year was led at a strategic level by the Business Continuity Group. This group, comprising of the Executive Management Team, Senior Managers and Medical Consultants, meet on a weekly/ fortnightly basis to ensure that all risks are identified and managed in a timely manner. The implementation of ever-evolving measures on the ground to keep our donors, staff and recipients safe has been coordinated by the COVID-19 Coordination Group. This group meets on a weekly basis and includes "Lead Worker Representatives" as key members, which has ensured that staff can communicate the effectiveness of new measures, and indeed suggest their own ideas from experience on the ground. This has contributed to the organisation as a whole being actively involved in risk management and business continuity activities throughout this challenging year.

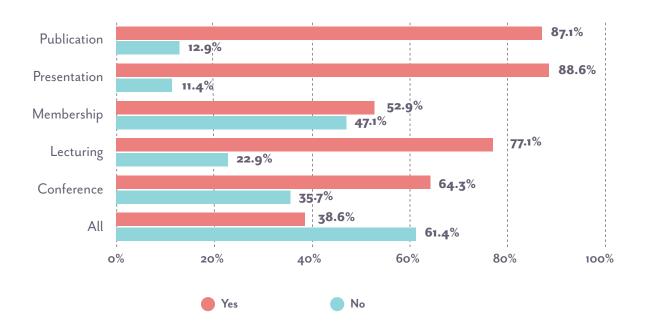
COVID-19 wasn't the only major risk that the organisation faced in 2020, as the Brexit Transition Period ended on December 31st. Two years of meticulous planning, led by the IBTS Brexit Team, ensured that key areas of the organisation were equipped to deal with the changes that occurred. Extensive work was carried out to evaluate our supply chain and identify potential vulnerabilities, and additional stock was procured to minimise the impact of any delays. Key risk areas including Data Protection, Human Resources, Finance and Operational issues were managed and mitigated, which ensured a smooth transition into 2021. The IBTS Risk and Resilience Manager worked closely with our UK Blood Establishment colleagues to ensure that our contingency plans were still viable. The Brexit Team, in conjunction with international partners, continues to monitor the situation as it unfolds.

A project to move our established risk management system from a paper-based activity to an electronic solution commenced in 2020. The new system will be implemented over the coming year and will help to further embed an already engrained culture of risk management at all levels within the IBTS.

Academic activities, Research and Innovation

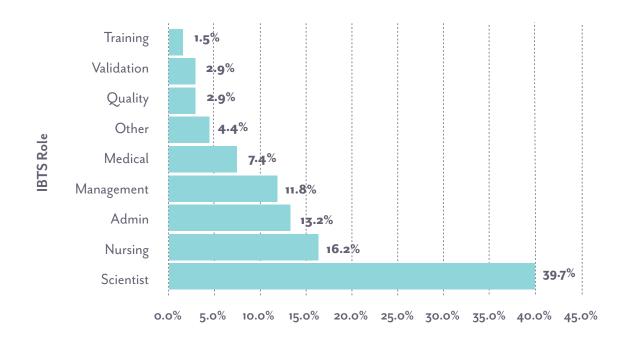
The majority of all staff which responded to a Research output and Engagement survey were actively involved with the academic and professional communities through teaching, research and membership in 2020. The IBTS contributed to 13 peer-reviewed academic publications last year and was engaged both locally and internationally with its academic and clinical partners. Nationally, we are key contributors to the Academy of Clinical Science and Laboratory medicine as well as to the National Transfusion Advisory Group, which provides clinical guidance on blood transfusion and product administration. In addition, staff are members of a widevariety of transfusion and transplant related societies and associations, notably the International Society of Blood Transfusion (ISBT), British Society for Histocompatibility & Immunogenetics (BSHI), European Blood Alliance (EBA) and the Biomedical Excellence for Safer Transfusion (BEST) collaborative. Research study data describing donor red cell antigen profiles and donor Hepatitis B virus core antibody screening was presented at ISBT 2020. The IBTS continues to contribute at both the undergraduate and postgraduate level to biomedical, scientific and medical third-level teaching and training.

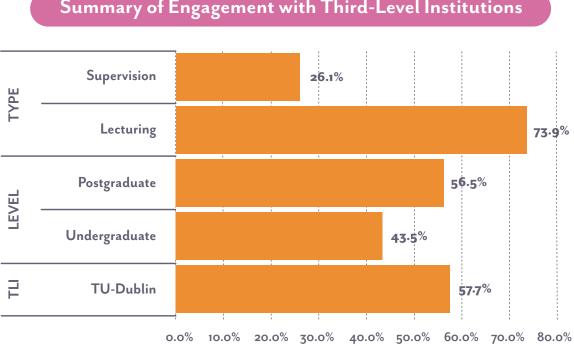




Research Output and Engagement Survey Summary Data

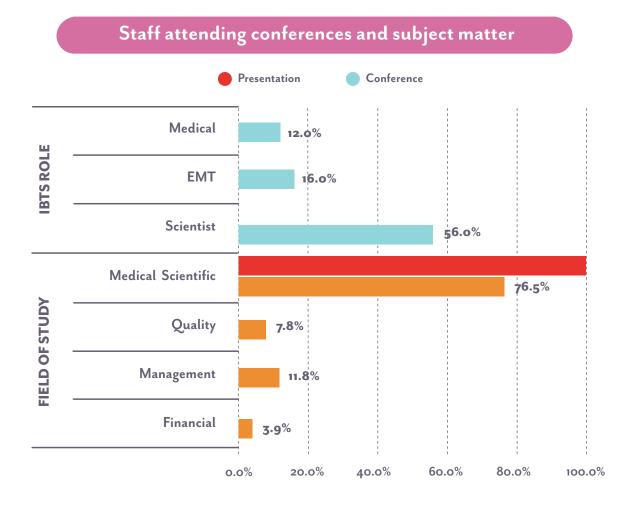
Research Output and Engagement Survey Respondants





Professional Membership RCPI 4.2% EEAA 4.2% BBTS 4.2% 5.6% EFI 5.6% PDA **5.6**% **RCPath** 7.0% EBA **BSHI** 8.5% 21.1% ACSLM 5.0% 0.0% 10.0% 15.0% 20.0% 25.0%

Summary of Engagement with Third-Level Institutions





Publications

1. Major obstetric haemorrhage: Incidence, management and quality of care in Irish maternity units.

Greene RA, McKernan J, Manning E, Corcoran P, Byrne B, Cooley S, Daly D, Fallon A, Higgins M, Jones C, Kinsella I, Murphy C, Murphy J, Bhuinneain MN; Maternal Morbidity Advisory Group

Eur J Obstet Gynecol Reprod Biol. 2021 Feb;257:114-120. doi: 10.1016/j. ejogrb.2020.12.021. Epub 2020 Dec 23.

2. Establishment of Transfusion-Relevant Bacteria Reference Strains for Red Blood Cells.

Prax M, Spindler-Raffel E, McDonald CP, Bearne J, Satake M, Kozakai M, Rojo J, Hanschmann KO, Lambrecht B, Grundmann U, O'Flaherty N, Klimek A, Bekeredjian-Ding I, Gathof BS, Störmer M, Süßner S, Renke C, Lee CK, Knabbe C, Vollmer T, Keil SD, Shipps ME, Wagner SJ, Jentsch U, Mpumlwana X, Cloutier M, Bringmann P, Lu T, Ramirez-Arcos S, Kou Y, Krut O; ISBT Transfusion-Transmitted Infectious Diseases Working Party, Subgroup on Bacteria.

Vox Sang. 2020 Dec 20. doi: 10.1111/ vox.13057. Online ahead of print. Residual red cells in blood components: A multisite study of fully automated enumeration using a hematology analyzer.

Cavagnetto C, Alejo Blanco R, McKenna H, Willmott L, Aydogdu E, Akinyemi N, Standring H, Procter S, Lagerberg JW, Johansson E, Croxon H, de Korte D, Garner SF, Shirakami A, Saker J, Linssen J, Cardigan R.

Transfusion. 2020 Nov 17. doi: 10.1111/ trf.16196. Online ahead of print.

4. The genesis of paediatric haematology in the UK.

Roberts I, Hann I.

Br J Haematol. 2020 Nov;191(4):593-603. doi: 10.1111/bjh.17163.

5. Expresser phenotype determines ABO(H) blood group antigen loading on platelets and von Willebrand factor.

O'Donghaile D, Jenkins PV, McGrath RT, Preston L, Field SP, Ward SE, O'Sullivan JM, O'Donnell JS.

Sci Rep. 2020 Oct 27;10(1):18366. doi: 10.1038/s41598-020-75462-2.

6. Donor oocyte-facilitated reproduction: Time to revisit the BSH antenatal guidelines?

Quigley J, Sweetman D, Allen C, Higgins MF, Cantwell C, Doyle B, Downey P, Fitzgerald J.

Transfus Med. 2020 Dec;30(6):525-526. doi: 10.1111/tme.12731. Epub 2020 Oct 23. 7. Persistent Hepatitis E virus infection across England and Wales 2009-2017: Demography, virology and outcomes.

Ankcorn M, Said B, Morgan D, Elsharkawy AM, Maggs J, Ryder S, Valliani T, Gordon F, Abeysekera K, Suri D, McPherson S, Galliford J, Smith B, Pelosi E, Bansal S, Bethune C, Sheridan D, Vine L, Tedder RS, Ijaz S; enhanced persistent HEV surveillance group.

J Viral Hepat. 2021 Feb;28(2):420-430. doi: 10.1111/jvh.13424. Epub 2020 Nov 2.

8. Partial compliance with symptom-based testing pathways reveals asymptomatic carriage of SARS-CoV-2 in Ireland.

Chan GY, Rajan L, De Gascun C, O'Flaherty N.

Ir J Med Sci. 2020 Sep 28:1-5. doi: 10.1007/s11845-020-02375-4. Online ahead of print.

9. Transfusion requirements in patients with COVID-19.

Worrall AP, Kelly C, O'Neill A, Reidy N, O'Doherty M, Griffin L, Quinn J, Thornton P, Fitzpatrick F, Curley GF, Morgan R, Glavey S, McNally C, McConkey S, Murphy P, de Barra E, Lavin M.

Eur J Haematol. 2021 Jan;106(1):132-134. doi: 10.1111/ejh.13521. Epub 2020 Oct 9.

 Changing trends in corneal transplantation: a national review of current practices in the Republic of Ireland.

Iselin KC, Greenan E, Hynes C, Shaw S, Fulcher T, Power WJ, Quill B, Guerin M, Lee WH, Murphy CC. Ir J Med Sci. 2020 Sep 4. doi: 10.1007/ s11845-020-02340-1. Online ahead of print.

11. Two novel antithetical KN blood group antigens may contribute to more than a quarter of all KN antisera in Europe.

Grueger D, Zeretzke A, Habicht CP, Skaik Y, Wagner FF, Scharberg EA, Costelloe A, Martens J, Verboom M, Bugert P, Schneeweiss C.

Transfusion. 2020 Sep 1. doi: 10.1111/ trf.16039. Online ahead of print.

 Anti-D immunization rates may exceed 50% in many clinically relevant settings, despite varying widely among patient cohorts.

Flegel WA, Wagner FF, Ó Donghaile DP.

Transfusion. 2020 May;60(5):1109-1110. doi: 10.1111/trf.15788.

 Trends in platelet distributions from 2008 to 2017: a survey of twelve national and regional blood collectors.

Yazer MH, Shaz B, Seheult JN, Apelseth TO, de Korte D, Devin G, Devine D, Doncaster C, Field S, Flanagan P, Huet J, Mendrone A Jr, O'Brien C, Pink J, Rashleigh M, Shinar E, Takanashi M, Tian E, Tiberghien P, van den Berg K, Schmitt C.

Vox Sang. 2020 Nov;115(8):703-711. doi: 10.1111/vox.12917. Epub 2020 Apr 13.

HUMAN RESOURCES

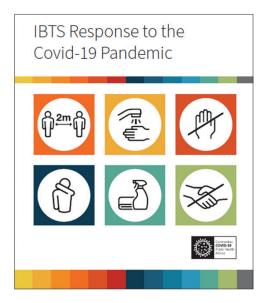


an a

Key achievements

- Successfully responding and navigating through COVID-19 and enabling everyone to work safely
- Delivering the Learning and Development Strategy
- 'Credit to the Crew'

COVID-19



The IBTS has continued to work safely throughout the COVID-19 pandemic. During this time and in conjunction with key internal IBTS stakeholders, internal COVID-19 working groups and our Occupational Health Providers, the IBTS has developed and implemented control measures to mitigate the risk of COVID-19 infection in line with ever evolving guidance. Our Human Resources function concentrated on ensuring that all IBTS staff were supported and enabled to continue to work safely throughout the pandemic ensuring there was no negative impact to the blood supply. This required agility, collaborative teamwork and a partnership approach with the business. We delivered organisation-wide communications, advice and information and developed protocols and guidance to ensure all COVID-19 requirements were implemented and monitored.

The management of Occupational Health referrals, case management and contract tracing saw a 477% increase in Occupational health activity. Consequently, this resulted in a deficit of resources. However this was managed very successfully and resulted in no significant negative impact on the provision of our service.



In response to the learning challenges presented by COVID-19 we worked with internal and external partners to transition from traditional classroom based training delivery to developing digital and blended learning and development offerings. A total of 19 bespoke learning programmes were designed and delivered to meet mandatory and core business skills needs.

In Quarter 4 2020 we launched the '*IBTS Response to the COVID-19 Pandemic*' Booklet. The information booklet which is available in electronic and hard copy formats consolidates IBTS policy, procedures and associated control measures put in place by the organisation and supports the Government's Work Safely Protocol to minimise the risk of infection in the workplace.

Environmental Health and Safety

'Making Safety Visible' Campaign

The 'Making Safety Visible' campaign was successfully introduced across the organisation with final roll out to all mobile teams in June 2020. Staff engagement and improved reporting of Good Catches/Safety Observations by teams has contributed to a 26% reduction in accidents since the campaign was launched in Quarter 1 2019, particularly in the area of slips, trips and falls.

In response to the COVID-19 pandemic, Good Catch/Safety Observation Cards were supported by the development and introduction of Hygiene Control Check Sheets. This initiative supported by the COVID-19 Co-Ordination Group and Team Leaders on IBTS clinics, helped the IBTS to monitor COVID-19 compliance with public health requirements and hygiene measures. The information gathered through the Hygiene Control Check Sheets also assisted in the targeting of COVID-19 staff communication proactively maintaining compliance and awareness in this area across the organisation.

Human Resources Operations

KPIs

In supporting Talent Management in the IBTS, the Human Resources Operations team provides a range of programmes and services, as well as qualified and expert advice and guidance on a multitude of staff employment situations. The team provides organisation-wide support to employees and managers throughout the employment lifecycle. This support starts at strategic workforce planning and the hiring process and continues throughout employment and into retirement. At the close of 2020 the IBTS had 585 employees (524 full time equivalents) and 215 retired staff receiving pensions.

Attracting, hiring and retaining top talent is important to maintain and future proof our service while promoting the evolution of the IBTS. There were 75 leavers in 2020, representing a reduction of 8.53% from the previous year, and representing a turnover rate of 10.5%. The number of recruitment campaigns posted was 130 resulting in 98 new hires. This represented an increase in recruitment activity of almost 9.25% on the previous year while navigating the complexities of the global pandemic. The average time to hire was 9.5 weeks against a standard target of 12 weeks.

HR Policy and Procedure Manual and Circulars

Maintaining compliance and delivering exemplary HR services is supported by the IBTS HR Policy & Procedure manual, which underwent a comprehensive review, was modernised and re launched. This guaranteed HR documentation and information was fully compliant with employment legislation, HSE and Public sector guidance, was document controlled and designed to be adaptable for a variety of online platforms and channels. A record number of applicable Department of Health, HSE and DPER circulars were published for interpretation into IBTS policy & procedures, in particular for managing COVID-19. There were a total of 57 Corporate Employee Relations memos (HSE Cers) to be interpreted also.

Learning and Organisational Development

2020 was the final year of implementation of the IBTS's first dedicated L&D strategy 'Working, Learning & Growing together' 2017 – 2020 and saw the successful completion of the majority of the strategic objectives, despite the impact of COVID-19. As a result of the work completed during the lifetime of the strategy the IBTS was shortlisted for three awards in 2020. One from the Irish Institute of Training & Development (IITD) Awards for **Best Large Learning and Development Organisation** and two from the HR Leadership and Management Awards for **Best Public Sector HR Initiative & Best L&D Strategy**.

The L&D department continued to work in partnership with Dr. Nuala Ryan from University of Limerick to develop management and leadership capabilities through the delivery of the iLEAD programme. iLEAD was delivered in a blended format with great success and feedback from the pilot group led to an increased demand in applications for the roll out.



L&D developed further academic partnerships and commissioned work with the HR Research Centre at University College Cork to assist in the development of an evidence-based talent management framework. The purpose of this work is to understand perceptions of talent within IBTS and what influences how talent is managed in order to develop a holistic talent management framework that encompasses the employee life cycle, builds people capability and maximises employee potential which results in improved organisational performance. Following a review of the Performance Development (PD) it was agreed to move to one designated PD cycle. The modifications will allow for increased alignment of individual personal development goals with work plans and activities. Work also continued on the development of learning pathways for all roles with this work being fully completed.

Work was also completed in identifying a suitable Learning Management System (LMS) for the IBTS. As a result of liaising with HSeLanD colleagues, the IBTS has become a HSELanD Health eLearning Management (HeLM) adopter. HeLM is a targeted HSELanD offering which provides health and social care organisations, such as the IBTS with their own tailored version of the HSELanD LMS in order to directly support learning, compliance and reporting. Availing of this option will facilitate opportunities to partner and collaborate with the wider health service/hospitals to develop and share transfusion related learning.





ICT Remote Access

The initial stage of the pandemic brought about challenges to meet the demands to allow people work from home; IT set up remote access for over 300 personnel to their required applications through a Citrix Receiver Gateway. There was no need to change any of the access controls to the required applications as access once remotely logged in was from the internal IBTS network. IT did have to increase the licences for Citrix users and also for the remote tokens used as part of the remote access authentication. In light of the expected longevity of the period of working from home IBTS supplemented remote access with a Health and Safety questionnaire to ensure staff were working ergonomically.

IT also had to purchase, setup and provide laptops and mobile phones to some users who did not have access from home; any such users requested and were approved for a laptop which were purchased under the OGP framework. The new laptops were set up solely for remote access and had a separate login to the laptop from which the user then authenticated themselves as normal by using their token and network password.

Identification and Configuration of the solution to allow Donor Services make Donor appointments

As the longevity of the pandemic increased it was clear that the IBTS required to change it's model of walk in blood collection clinics to appointments based clinics. In order to facilitate this IT identified a solution which allowed us breakout our donor information 1850 number to route to a number of mobile phones. This facilitated Donor Services to make the necessary appointments and is provided by Vodafone free of charge.

Selection of and start of on-boarding of Managed Services Provider

With the ever growing need to meet the demands on IT, it was agreed to tender for a managed service provider for provision of IT support. A tender process was run and a successful provider was identified and the project started by the end of the year to transition over the required services by mid 2021. This is a critical element for IT delivery to the IBTS and will assist in reducing current delays in both operational day to day support and IT project delivery.

IT Security Awareness

IT launched a series of short IT security videos using Metacompliance to help raise awareness to all users of possible IT security risks we all face on a daily basis. This was on the back of an internally ran and controlled phishing campaign which highlighted a number of breaches of users entering personal information in response to a bogus email. A physical security exercise was carried out in both NBC and the Cork Centre which also highlighted potential security risks and a detailed report was issued where all items are being addressed.

GREEN AGENDA

The new regional centre in Tuam opened in early 2020. At an early stage in the design IBTS opted for heat pump technology for temperature control which is the green solution and avoids fossil fuels being used in the building.

The first of four main refrigeration systems was changed onto a refrigerant with lower global warming potential, with the remaining systems to be migrated over in due course.

IBTS achieved an energy saving of 41% compared to our 2008 baseline year, exceeding the public sector target of 33% energy saving. This was achieved by optimising the way the buildings were operated, and replacement of some equipment at end of life with lower energy types. Energy Management is an important responsibility of the Facilities team. The 2030 target the Public Sector will be tasked to meet has not been published yet, but the expectation is that it will be more onerous and mean some fundamental changes to how our buildings operate. A Green Energy team comprised of Facilities and the laboratories is currently being set up to look at further opportunities.

The IBTS is scoping the installation of electric vehicle charging points so that staff, visitors and donors will have the facility to charge their electric vehicles while at the National Blood Centre. Separately we began assessing commercial electric vehicles currently available to see if these would be suitable for the IBTS van fleet.



FINANCE

Summary Accounts for the year ended 31st December 2020		
	2020 €'000	2019 €'000
Income		
Recurring income	64,760	67,450
Non-recurring income	2,138	1,613
Total income	66,898	69,063
Expenditure		
Total expenditure	70,304	67,520
Surplus / (Deficit) for year	(3,406)	1,543
Actuarial gain / (loss) on pension schemes	(15,632)	(6,878)
Transfer to Capital Reserves	(2)	(2,009)
Transfer to Research Reserve	(443)	(481)
Accumulated Deficit at 1st January	(63,974)	(56,149)
Accumulated Deficit at 31st December	(83,457)	(63,974)

Income

The Board's total income for 2020 of €66.9 million (2019 €69.1 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 €64.76 million (2019 €67.45 million). Non-recurring income of €2.1 million (2019 €1.6 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 decrease in recurring income represents reduced volumes in 2020 as a result of the impact of COVID-19 with reduced demand from hospitals particularly in relation to Red Cell demand.

Expenditure

Expenditure for 2020 amounted to €70.3 million (2019 €67.5 million).

The increase in expenditure is due to an increase in staff costs including an increase in employer pension costs and also an increase in staff numbers as a result of COVID-19. Additional costs for personal protective equipment, transport costs were matched by savings in foreign travel costs and training costs.

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 2020 was €10.60 million.

At the 31st December 2020 the balance of research funds was €2.7 million. (2019 €2.3 million).

Capital Expenditure

The Board invested €1.2 million in capital projects and equipment during 2020 (€3.1 million 2019).

The main capital investments during the year were new and replacement equipment in our testing and processing laboratories and various IT upgrades including our data storage infrastructure.

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 31 December 2020, under the terms of applicable legislation, invoices to the value of €346,631 were late, by an average of 17.37 days. These invoices constituted 1.49% by number and 1.01% 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 €10,210.

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.

Contact Details

Auditors

Comptroller and Auditor General Treasury Building Lower Castle Yard Dublin Castle Dublin 2

Solicitors

Byrne Wallace 88 Harcourt Street Dublin 2

Bankers

Allied Irish Bank Dame Street Dublin 2

Irish Blood Transfusion Service

National Blood Centre

James's Street, Dublin 8 t: 01 4322800 e:contactus@ibts.ie D08 NH5R

www.giveblood.ie

Donor infoline 1850 731137 www.facebook.com/giveblood www.twitter.com/giveblood.ie

Cork Centre

St Finbarr's Hospital Douglas Road Cork t: 021 4807400 T12 Y319

Dublin Blood Donor Clinic

2-5 D'Olier Street Dublin 2 t: 01 4745000 D02 TK51

Stillorgan Blood Donation Clinic

6 Old Dublin Road Stillorgan Co Dublin t: 1850 808 808 A94 NX47

Ardee Centre

John Street Ardee Co Louth t: 041 6859994 A92 HCP4

Carlow Centre

Kernanstown Industrial Estate Hackettstown Road Carlow t: 059 9132125 R93 AC82

Tuam Centre

Unit 2 Beechtree Business Park Weir Road Tuam Co Galway t: 093 70832 H54 P229

Limerick Centre

Carrig House Cloghkeating Avenue Raheen Business Park Limerick t: 061 306980 V94 AH97



National Blood Centre James's Street, Dublin 8. D08 NH5R

Tel: 00 353 1 4322800 Fax: 00 353 1 4322930 Email: contactus@ibts.ie

www.facebook.com/giveblood www.twitter.com/giveblood.ie www.giveblood.ie Donor Infoline 1850 731 137

Registered Charity Number: RCN 20006280