



Irish Blood  
Transfusion Service  
Seirbhís Fuilistriúcháin na hÉireann

# ANNUAL REPORT 2019



IRON

**LIFE**  
enabling



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## Foreword

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Once again, the greatest achievement for our organisation in 2019 was the delivery of a *safe and sustainable blood supply*. A successful year for us is one where the blood supply is sufficient, and there are no unexpected adverse outcomes from blood transfusion. The sufficiency of our blood supply is achieved by ensuring that our donors have a positive experience when they donate and we keep this objective at the core of a lot of our decisions.

In 2019 we successfully rolled out a new process including new chairs at all our mobile clinics to make the experience of donating as comfortable as possible, and we completed the relocation work on a new centre in Tuam. We commenced the upgrade to our computer system which will allow for the introduction of an appointment system across all of our clinics further enhancing the donor experience. The board is indebted to all the staff who work in our clinics and are a welcoming, professional and friendly face to all of our donors. We are also indebted to the rest of our management and staff throughout the organisation who ensure that collected blood is safely

tested, processed, stored and transported to the hospitals and patients we serve. Our staff are our most important resource and in October we launched a Leadership Development Framework in conjunction with the Kemmy Business School in University of Limerick. This will develop existing leaders and grow the next generation who will drive the necessary changes required to stay at the forefront of best international transfusion practices.

Brexit planning dominated executive risk reviews in the early part of 2019 to ensure that contingencies were in place for suppliers, and to ensure that supply chain disruption, if it were to take place, would be mitigated to the best degree possible. Some of our costs will inevitably rise in the short term as a result of Brexit. The IBTS is a member of a European network of blood agencies which is an excellent group for sharing knowledge and procurement structures and we are delighted to be part of such a collaborative organisation as we deal with these changes. The IBTS is well placed to deal with a no-deal Brexit were it to occur.

In June we completed the roll out of our services for haemochromatosis patients to all of our mobile clinics, giving them the opportunity to become blood donors as part of the treatment of their condition. Until now, treatment was carried out at hospitals and GP practices, and the blood was discarded.



***“ The board is indebted to all the staff who work in our clinics and are a welcoming, professional and friendly face to all of our donors.”***

Now, many HH patients will be able to attend any blood donation clinic throughout the country and their blood will be collected and used as part of the national blood supply. While it will take time to maximise the full potential of this service, these donors are already contributing 2.5% of the national blood supply. This is a long-term project the IBTS is committed to, as it is the perfect example of what can be achieved when different parts of the health service work together to drive efficiency and it has the benefit of increased blood donations at the same time.

In October, the IBTS removed the permanent deferral policy for individuals that had been resident in the UK for a period of more than one year between 1980 and 1996 from donating blood. This deferral had been in place since 2002 to mitigate the risk to the blood supply from the transmission of vCJD. It was introduced as one of a suite of measures at a time when there was great uncertainty about the most effective measures that would reduce the transmission of this disease through the blood supply. The decision to remove the deferral followed a special meeting convened by our Medical and Scientific Director, Professor Stephen Field to consider the most up-to-date evidence and was attended by leading international experts in this area. The board is delighted to welcome donors, old and new, who have been unable to donate during this long period of deferral. As indicated last year, the board has

endorsed the expansion of its statutory research remit into a more co-ordinated activity and in 2019 we began the process of establishing the appropriate governance structures, and recruiting a manager to oversee this function and increase collaboration with other scientific and medical establishments. The field of Transfusion Medicine began in the early 20th century as a discipline to oversee all the complex areas of Blood Banking. Now the discipline is finding a niche in the area of Regenerative Medicine. We as a board are excited about the research opportunities we can support to advance knowledge in this area and to foster a culture which will encourage medical registrars and research scientists to consider careers in the field of transfusion medicine.

Our plans to build a new donor centre in Cork progressed toward agreeing a design brief last year and we look forward to working with our colleagues in the Cork hospitals, the HSE and the DoH to optimise transfusion services in Munster and ultimately to deliver a more streamlined national service. This commitment to delivering the best national service possible drives and motivates the management, staff, and board of the IBTS in all our work, and I would personally like to thank all my colleagues for their continued efforts in 2019.

**Linda Hickey**  
Chairperson

# Chairperson's Report

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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 2019 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.
3. The Board confirms that there is an ongoing process for identifying, evaluating and managing significant risks faced by the IBTS. This process is regularly reviewed by the Board via reports from the Chief Executive.

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 the 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 sub-committee 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 2019 at its meeting on the 4th February 2020.

## 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.

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 Medical Advisory Committee reviewed its terms of reference in 2019. The revised terms of reference were approved by the Board.

### 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:

### Board attendance 2019

Board Member	February	April	June	September	November	December
Linda Hickey	X	X	X	X	X	X
David Gray*	X		X	X	X	X
Kate Williams	X	X	X	X	X	
Deirdre Cullivan	X	X	X	X	X	X
Dr Liz Kenny	X	X	X	X	X	X
Dr Satu Pastila	X	X	X	X	X	X
Dr Ronan Desmond		X			X	X
Brian O'Mahony	X	X	X	X	X	
Dr Sarah Doyle		X		X	X	X
Simon Mills#						
Yvonne Traynor##	X	X	X		X	
John Malone	X		X	X	X	X
Deirdre-Ann Barr*		X	X	X	X	X

\* Appointed on 5th March 2019

# Resigned on 28th February 2019

# Resigned on 31st December 2019

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

Linda Hickey (Chairperson)

Mr Brian O'Mahony

Ms Kate Williams

Dr Elizabeth Kenny

Dr Ronan Desmond

Ms Deirdre Cullivan

Dr Yvonne Traynor\*

Mr John Malone

Dr Satu Pastila

Dr Sarah Doyle

Simon Mills\*\*

Deirdre-Ann Barr\*\*\*

David Gray\*\*\*

\*Resigned with effect from 31st December 2019

\*\*Resigned with effect from 28th February 2019

\*\*\*Appointed on 5th March 2019

	Board	Medical Advisory Committee	Audit, Risk & Compliance Committee	Finance Committee	Performance Development Committee	Board Fees 2019 €	Expenses 2019 €
<b>Number of Meetings</b>	<b>6</b>	<b>7</b>	<b>5</b>	<b>5</b>	<b>4</b>		
Ms L Hickey (Chairperson)	6	-	-	-	4	20,520	1,432
Mr B O'Mahony	5	-	-	-	-	-	-
Dr E Kenny	6	7	-	-	-	-	1,110
Ms K Williams	5	-	-	5	-	11,970	-
Dr R Desmond	3	5	-	-	-	-	-
Ms D Cullivan	6	-	-	5	4	11,970	1,718
Dr Y Traynor*	4	-	4	-	-	11,970	-
Mr J Malone**	5	-	2	3	-	11,970	-
Mr S Mills***	-	-	-	-	-	2,716	-
Dr S Pastila	6	6	-	-	-	11,970	5,250
Dr S Doyle	4	7	-	-	-	-	-
Mr DW Gray****	5	-	3	-	-	9,126	1,745
Ms DA Barr****	5	-	2	-	-	9,162	-
						<b>101,374</b>	<b>11,255</b>

\* Board Term finished 31st December 2019

\*\* Mr J. Malone switched from the Audit, Risk and Compliance Committee to the Finance Committee from May 2019

\*\*\* Board Term finished 28th February 2019

\*\*\*\* Board Term commenced 5th March 2019

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

Board members expenses in 2019 amounted to €11,255 broken down €3,374 mileage, €1,485 subsistence and €6,396 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 2019 was €165,828. The Performance and Development Committee met four times in 2019.

### Medical Advisory Committee

The Medical Advisory Committee is comprised of the medically qualified members of the Board and the medical consultant staff of the IBTS and met 7 times in 2019. 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.

### 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 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.

### MAC Attendance 2019

Name	Feb	Mar	Apr	June	Sept	Nov	Dec	Total 7 Meetings
E Kenny	Y	Y (audio link)	Y	Y	Y	Y	Y	7
R Desmond	X	Y	Y	X	Y	Y	Y	5
S Pastila	Y	X	Y	Y	Y (audio link)	Y	Y	6
Sarah Doyle	Y	Y	Y	Y	Y (audio link)	Y	Y	7
B O'Mahony**	Y	Y	Y	Y	X	Y	Y	6
S Field	Y	Y	Y	Y	Y	Y	Y	7
D Ó Donghaile	Y	X	Y	Y	Y	Y	x	5
L Pomeroy	Y	Y	Y	X	X	X	Y	4
E McSweeney	Y	Y	Y	Y	Y	Y	Y	7
J Power***	Y	Y	Y	Y	Y	X	X	5/7
I Hann****	X	X	X	X	X	Y	Y	2/2
N O Flaherty	Y	Y	Y	Y	Y	Y	Y	7
N O'Connell	Y	X	Y	Y	Y	X	Y	6
C DeGascun	X	Y	X	Y	Y	X	Y	4
K Morris*	—	—	—	—	—	Y	Y	2/2

\* K Morris only joined IBTS in November 2019

\*\* Brian O'Mahony is only in attendance at MAC meetings not a full member of the MAC

\*\*\* Joan Power is now 50% time in HSE and 50% time in IBTS

\*\*\*\* Ian Hann covering 50% of Joan Power's time in IBTS

Finance Committee Attendance	January	May	August	September	November
Ms Kate Williams	✓	✓	✓	✓	✓
Ms Deirdre Cullivan	✓	✓	✓	✓	✓
Mr John Malone	X	✓	✓	X	✓

### Audit, Risk & Compliance Committee

The Audit, Risk and Compliance Committee met five times during the year and is comprised of three members of the Board and two independent external members. 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 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.

### Going Concern

After making reasonable enquiries, the Board Members have a reasonable expectation that the IBTS has adequate resources to continue in operational existence for the immediate future. For this reason, they continue to adopt the going concern basis in preparing financial statements. In light of the pension deficit of €92.258 million, 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.

Audit, Risk & Compliance Committee Attendance	February	April	June	September	December
Dr Yvonne Traynor	X	X	X	X	
Mr David Gray			X	X	X
Ms Deirdre Ann Barr			X		X

### Risk Register

The risk register identifies various types of risks including strategic, reputational, clinical, IT, financial and operational risks to the organisation and the existing controls and further actions necessary to minimise the impact on the organisation, in the event of the risk occurring. A Risk and Resilience Manager has responsibility for overseeing the risk register and contingency arrangements. A set of inherent risks have 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 controlling measures put in place.

### 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 GRN and purchase order
- Payment verification checks of supplier invoices by staff independent of accounts payable staff

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

The Financial Statements for the year ended 31st December 2019 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.

### 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 2019.

## Commercially significant developments

### Histo Trac

HistoTrac is a Laboratory Information Management System (LIMS) specifically designed for use in Histocompatibility & Immunogenetics (H&I) laboratories where testing is performed for Haematopoietic Stem Cell and/or Solid organ transplantation. The system is composed of a core package and modules that can be added on depending on the testing services provided by the laboratory. The main functional aspects of HistoTrac are sample accessioning through to test reporting, database of test history for patients and donors, creation of billing files, management of workload, and tracking of tests. HistoTrac is interfaced with the analysis software for each of the testing platforms in the National Histocompatibility & Immunogenetics Reference Laboratory (NHIRL); these include the HLA antibody, HLA sequence based typing, HLA sequence-specific oligonucleotide probe typing, and DNA quantitation instrumentation. Implementation of the system was completed in 2019.

### eProgesa Hardware

The IBTS decided to upgrade its current IBM Host servers which host all of the current MAK Supplied applications such as eProgesa, eTraceline, TCS and eRiskline. The purpose of this upgrade was also to have the capacity to host the planned upgrade to eProgesa to take the 2017 S1 semester patch from MAK.

This entailed the installation of two new host servers at the NBC to replace the six current IBM host servers and one new host server at the IBTS DR site to replace the existing host server there. It included the installation of two new HMCs (Hardware Management Consoles) for managing the servers, 1 in each site. Migration from the existing Power7 hosts to the new Power 9 hosts was completed without too much impact on end users but where it did it was kept to a minimum.

### Linda Hickey

Chairperson





## Chief Executive's Report

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As I write my last annual review in early 2020 it is at a time when the world has changed dramatically and we are dealing with a pandemic caused by a novel coronavirus known as COVID – 19. As I write over 58,000 people worldwide have died from the virus. It has thrown the World upside down and much of the World's population is confined to their houses. The World economy has virtually shut down and the personal effect has been enormous and quite devastating in many countries. It has changed our World and society forever.

I would like to commend the hard work, dedication and commitment of all the staff of the IBTS in very difficult circumstances not only at work but on a personal level also.

The most worrying thing is that nobody can tell us when this is going to pass.

At the beginning of 2019 the dialogue was all about Brexit and how the country and IBTS were going to deal with the possibility of a no deal exit. The IBTS had undertaken extensive planning and taken appropriate measures to mitigate the impact of this scenario. These measures were maintained and have been very beneficial in dealing with (COVID – 19) the pandemic.

One of the issues that I have referred to in previous Annual Reports is the appropriate use of O negative blood. In the course of the year we had a very productive meeting with representatives of the Academy of Clinical Science & Laboratory Medicine (ACSML) on how we could, together, influence the management of this blood group. We discussed the carrying out of a survey to gather the necessary data. However, it was decided in light of the work being done by the National Transfusion Advisory Group, led by Dr Joan Power, not to progress the survey at this time.

This Group will play a major role in changing transfusion practice in the hospitals.

One of the most significant changes in donor deferral criteria happened in 2019. The IBTS lifted the ban on donating blood by people who had spent one year or more in the UK between 1980 and 1996 because of the risk of transmission of vCJD. This had been a very contentious issue with our donors. This project was led by Professor Stephen Field, Medical and Scientific Director, who organised a workshop with relevant international and national experts to provide the best advice on whether to lift the ban or not. I am sure that Prof Field will deal with this in his report.

The Health and Safety (HAS) of staff is very important and the IBTS over the past number of years have been trying to improve behaviours with a consequential improvement in health and safety practice. In 2019 we set the target of reducing HAS reportable accidents by 30%. The Environmental Health and Safety Manager came up with the idea of Good Catch / Bad Catch programme to achieve this target. It was an amazing success with staff really buying into it with the result that there was a 50% reduction in HAS reportable accidents. This was a great achievement and is something really positive to build on.

Risk Management is an intrinsic part of blood establishments and in 2019 the Board and Audit, Risk and Compliance Committee did an in-depth review of the top ten risks. This was done to deliver governance oversight on the on-going review by the Executive Management Team. We also carried out a desk top exercise of our Business Continuity Plan building on the previous exercises. On this occasion we used "Role Players" who inputted into the exercise using pre-prepared scripts unseen by the BCP Management Team. This proved a very worthwhile addition and brought a greater sense of realism to the exercise. There were lessons learned which have been used to improve the BCP.

In 2017 the IBTS launched an ambitious Learning and Development Strategy designed to support the business strategy and by embedding a culture of continuous improvement and leadership in the organisation. In October 2019 we launched our iLEAD programme designed in collaboration with the Kemmy Business School, University of Limerick. There are three levels and it has the potential to change the culture of the IBTS through the development of leaders across the Organisation who will drive change and innovation. Congratulations to the HR L&D team especially the L&D Manager Idelle Hawkins and Dr Nuala Ryan from the Kemmy Business School whose research in this area was critical to the content in this programme. The IBTS is always looking to raise awareness of blood donation in different sectors of the economy and society. Such an occasion arose during the year when an opportunity presented itself for IBTS to apply for accreditation as an

All-Ireland Business All-Star. The three pillars of All-Ireland Business All-Star accreditation are (i) Performance (ii) Trust and (iii) Customer Centricity and there are a number of steps involved in the registration process. These are centrally linked to elements within our Learning and Development Strategy. There was a detailed questionnaire to be completed which involved customer references and suppliers. Following evaluation of our submission the IBTS achieved All Star Accreditation. This means that IBTS will now form part of the AIBF TRIBE (The Register of Irish Business Excellence). This is a recognition of the impact the Learning and Development strategy is having on how we have rebuilt trust with our key stakeholders and our customer focus.

In 2019 we saw major changes to the Executive Management Team with the retirement of the HR Director and the resignation of the Director of Quality and Compliance. I would like to express sincere appreciation to Nessan Rickard for his many years of dedicated and committed service to IBTS as HR Director and to Craig Spalding who, in his short time, made a significant contribution to the future direction of the Quality Function. In their place I welcome Idelle Hawkins as HR Director and Karen Byrne as Director of Quality and Compliance and wish them every success in their new roles. By year end my successor was appointed. Orla O'Brien was appointed as CEO Designate to take over in June 2020. I wish her well in the post and know that she will bring a wealth of experience to the role.

The IBTS is a critical service to the healthcare system and this is sometimes overlooked. Without the ready availability of blood, platelets and tissue much of modern medicine could not happen. The patient is front and centre to what we do and staff go the extra mile to make sure that we provide products as safe as we can make them. It has been an absolute privilege to be Chief Executive of the IBTS and the Irish public can be justly proud of the services we provide. My sincere thanks to the Board who have been very supportive of me and generous with their counsel, to all staff who have shown their willingness to change and adapt to an ever changing environment and for their dedication and commitment and finally to my colleagues on the Executive Management Team for their hard work, professionalism, support and camaraderie over the past eighteen years. I know that the organisation will continue to grow because of the willingness and enthusiasm of everyone to learn, to be the best you can be and provide patients and donors with the quality of product and service they deserve. It will be an emotional parting and while I will not miss the work I will miss all my colleagues and the many friends I have made along the journey.

**Andrew Kelly**  
Chief Executive



## Medical & Scientific Director's Report

During the year a major review was carried out on the measures implemented in 2002 to mitigate the effects of transmission of variant Creutzfeldt-Jakob disease (vCJD). At the time of the implementation of these measures there had been four reported cases of transmission of vCJD in the United Kingdom arising out of donations from 3 people subsequently found to have the disease. A measure implemented in 1999 to remove white cells by filtration from all blood components (Leucodepletion) appears to have been successful in preventing transmission of vCJD as no cases have been reported since this intervention. The Medical Advisory Committee met on 29 April 2019 to review the evidence and was assisted by invited experts from the fields of neurology, blood transfusion and veterinary health.

After considering the evidence presented at the special meeting a further deliberation of the Medical Advisory Committee made the following decisions:

- That the current deferral for individuals that had been resident in the UK, including Northern Ireland and the Channel Islands, for a cumulative period of one year or more between 1 January 1980 and 31st of December 1996, would be no longer applicable and donors will now be eligible to donate.
- That the surgical procedures which had previously resulted in deferral of donors was reduced to those involving the brain and breaches of the spinal-cord. Procedures involving the posterior part of the eye were considered for the purposes of this to be part of the brain.
- That Irish plasma recovered from whole blood could be used for therapeutic purposes (Fresh Frozen Plasma FFP).
- That the Irish Eye Bank should reinstate the collection of corneas from deceased Irish donors. Corneas for transplant are presently imported from Denver in the United States

- That the deferral with respect to root canal treatment in the UK be rescinded and that donors that have had this treatment should be eligible to donate.
- The tissues collected in the United Kingdom (in particular heart valves from Northern Ireland) that comply with the European Commission Tissue Directives could be used in the Republic of Ireland.

Ireland has a growing immigrant population, some of whom have transfusion-dependent sickle-cell anaemia. As many of these patients have a different Rh phenotype (RO) to that generally seen in Irish donors (R1) demand for Rh-negative blood has increased. In order to meet the demands of the RO patients it would be desirable to recruit donors from the Black community. However, many of this community have been exposed to malaria and this is potentially transmissible via blood. The IBTS will be introducing malaria antibody testing in 2020. This intervention will also serve to reduce the time that people are deferred on returning from holidays or business in countries with an endemic malaria risk.

As reported last year the IBTS was modernising its virology serology testing laboratory with a new generation of automated equipment. The IBTS continues to use state-of-the-art testing platforms to detect transfusion transmissible diseases. This along with appropriate screening of donor eligibility continues to ensure that the blood supply in Ireland remains safe.

A new consultant position, the Clinical Lead Advisor Transfusion Services, was appointed in conjunction with the HSE during 2019. This consultant would set up a National Transfusion Advisory Group which will serve to provide clinical guidelines for transfusion medicine for Irish hospitals. The NTAG will encompass all levels of transfusion practitioner in its deliberations thus making the guidelines it adopts truly national.

### **Professor Stephen Field MA, MMed(Haem) FCPATH (SA)**

Medical and Scientific Director  
Consultant Haematologist



# *Operations*





## Donor Services

### #EveryOneCounts Campaign

In 2019, IBTS continued the award winning EveryOneCounts campaign for its third year. The focus of the campaign this year was again focused on engaging donors with the added element of integrating the recipient story also. The campaign reached out to donors on all key communication touch points, with the objective to educate and nudge donors from awareness to action throughout the year. This marketing campaign uses real donor and recipient stories communicated via digital and social media; FB, Twitter, online advertising, Youtube, relevant social influencers, national and local radio ads, and online editorial on TheJournal.ie, Pundit Arena, Video on Demand and national TV advertising.

TV and Video on Demand advertising featured 3 of our original Skerries donors and their blood donation stories. This advertisement ran in January, April and during the Summer featuring on popular channels such as RTE, RTE 2, TV3, TG4, SKY, and C4. Adverts were also run on national radio stations, on Spotify and for the first time on Audio XI (Ireland's largest audio exchange). The media was planned to sync with challenging times of the year for blood and platelet donation clinics, as people break from their normal routine by going away on holidays and children are on their break from school.

The objective was to communicate to a large audience about the importance of blood donation throughout the year, as part of your everyday life, and inspire and encourage donors to go to their local clinic when they can.

In 2019, digital and social media was always on in order to further engage donors in their normal daily experiences, encourage them to engage with the Giveblood.ie pages and move them to action. Our online donor videos were shortened to 10 secs to further improve reach and completion. They were retargeted online to audiences, moving donors from awareness to education to action in attending clinics. The shorter, targeted stories surpassed their targets in terms of reach and impressions. There has been steady growth in our social media channels throughout the year, our Facebook page had 124k plus fans at the end of 2019, our Twitter page had 19.9k 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 launched in 2019, followers grew from 200 in January to 5.1k in December. 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 was refreshed in order to engage companies and donors interested in our Work Ferry programmes, we had 2k followers at the end of 2019.

There has been a high level of engagement on our social channels due to the emotive and inspiring stories from our Every One Counts donors, and this has in turn encouraged others to



share their own donor stories and promote the message and benefits of giving blood further. There have been some amazing stories and pictures taken by IBTS staff and donors in clinics across the country, using #BloodyLegend heart boards to make the EveryOneCounts campaign tangible in the clinics. This is to encourage donors to share their milestones on our social channels, helping inspire other donors to continue their donor journey and reach their own milestones, and celebrating their achievements in helping save lives.

## Partnership

Partnership is an important part of engaging with and spreading the importance of blood donation in the community. In 2019, IBTS partnered with a number of organisations such as the GAA, Macra na Feirme, FAI Referees, Vodafone and the many work ferry organisations who book in to attend the clinics.

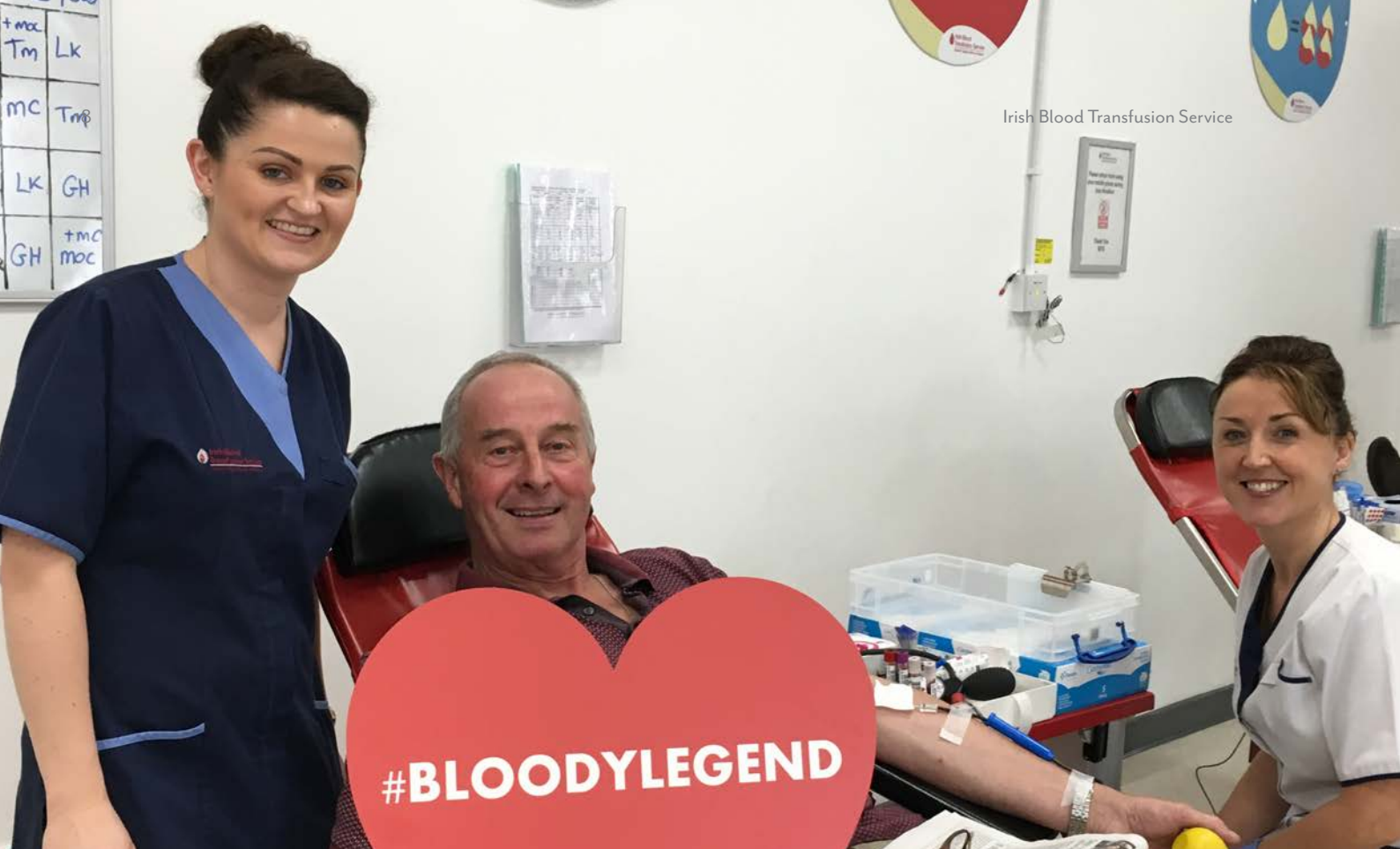
Skoda Ireland helped IBTS to promote blood donation clinics in 2019 via their nationwide dealer network of 32 outlets. As part of this partnership Skoda displayed the Giveblood.ie series of #EveryOneCounts donor video on screens in the waiting area of the dealerships. They displayed a 'know before you go' clinic information card in this waiting area and hung car mirror hangers with 'Give blood' messaging in all Skoda cars that received a service. The organisation also took part in a company wide blood drive and attended local clinics / work ferry groups to give blood. Together, Skoda and IBTS marketing created a series of videos for social media, one of which shows how one of Skoda's Blood Donors makes time in his life / work day to give blood,

he is shown how blood is processed in our laboratories and also explains how 'blood is the oil of the health system' and how this concept correlates to his day to day job as a Skoda expert mechanic.

Part of the strategy this year was to work with media partners such as the Journal.ie, Pundit Arena and Off The Ball that align with the interests of our target donors, and help us to communicate with them via channels they engage with on a daily basis with stories from the donor and the recipient side.

Off The Ball carried out on air blood drives via their daily radio show, social channels and website during 4 key times of the year for blood donation. As part of their shows they interviewed well known personalities who had received blood transfusions. Newstalk presenter Tom Dunne, Monaghan footballer Niall Kearns, Irish jockey Pat Smullen, and Irish international footballer Shane Duffy all spoke about their experience of receiving a blood transfusion and the importance of being a donor.

Throughout the year, Pundit Arena featured articles on their site and social channels and ran a sponsored interview series called the 'power of one more', illustrating the difference it makes to go to the clinic one more time, or bring one more person with you. The last interview ran in September featuring Dublin Hurler Peter Kelly, who spoke to Pundit Arena about the importance of being a donor and how his father received blood transfusions during his treatment for cancer.



Other featured interviews included were with Munster Rugby player Sam Arnold, his experience seeing his sister receive transfusions for her illness regularly, and Eimear Considine speaking about her experience as a donor and motivation for giving blood. Native article content was run on the Journal.ie throughout the year featuring articles about IBTS partnership with Skoda, Rugby player Sharon Lynch's story about being a platelet donor, and the roll out of the Hereditary Haemochromatosis programme across clinics nationwide. Two additional two long form videos were launched in September and October 2019, with the help of NetCast, featuring interviews with Professor Stephen Field, Medical and Scientific Director, IBTS, speaking about the criteria for Hereditary Haemochromatosis patients becoming donors and explaining the lift of the UK residency ban from 7th October 2019 for donors previously deferred who lived the UK including Northern Ireland for a year or more between the year 1980-1996.

### **College Outside Broadcast Activity**

It is important for IBTS to communicate with younger donors and engage with them to make them aware about blood donation and the importance it has in daily life for patients in hospitals across the country.

***“ In 2019, we ran washroom advertising to promote our college clinics on campus***

***and also featured outside broadcasts with local radio stations to educate students about what they need to know and do before becoming a donor, and where and when their college clinic was on campus. ”***

IBTS teamed up with Beat, Spin 103.8 and Red FM and held live broadcasts on campus close to the college blood clinics in DCU, UCD, DkIT, UCC and Waterford IT. The presenters spoke about checking eligibility to become a donor on giveblood.ie and how you need to be well and health, drink plenty of cold fluids and eat before attending the clinic on campus. Students were also asked to take a picture with the #BloodyLegend heart selfie board and share their pictures on social media to encourage their friends to also become donors.

### **World Blood Donor Day**

Every year on the 14th of June we celebrate World Blood Donor Day and thank donors for giving blood and raise awareness of the importance of blood donation. In 2019 we held our Dublin Donor Awards Ceremony on World Blood Donor day and celebrated the wonderful achievements of our donors. We had World Blood Donor Day selfie boards on clinic and social



media content featuring and celebrating our donors around the country. We ran one of the OTB on air blood drives and they spoke to Monaghan GAA football player, Niall Kearns, who received a blood transfusion, and spoke about the impact this has had on his life.

### Merchandise campaigns on clinic

IBTS aim to make the experience for our donors as special as possible when they come in to clinic to give their donation so that they are looking forward to returning. This year we ran a number of mini seasonal merchandise campaigns in addition to the regular items like pens and blood drop key rings. Donors were delighted to find special Chocolate hearts and giveblood.ie jelly bean treats in clinics across the country on Valentine, Easter and in the Summer. Monster Munch crisps were available on clinic at Halloween.

The Christmas campaign was particularly special this year. The objective of the EveryOneCounts strategy this year was to further engage with donors via the stories of fellow donors and recipients in the community. In December 2019, four new Giveblood.ie Christmas decorations were introduced on to the clinics for donors to take home with them as a thank you from IBTS for the amazing gift that they give to help patients in need. The wooden decorations were designed by four brave children who received transfusions and displayed on IBTS Christmas trees in clinic, adding some festive cheer to the clinic 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.

We'd like to thank Ciara, age 3, for her lovely Snowman; James, age 6, for his family drawing; Clodagh, age 3, for the lovely Christmas tree and presents; and Issy, age 9, for the beautiful drawing of her cat, Pig.

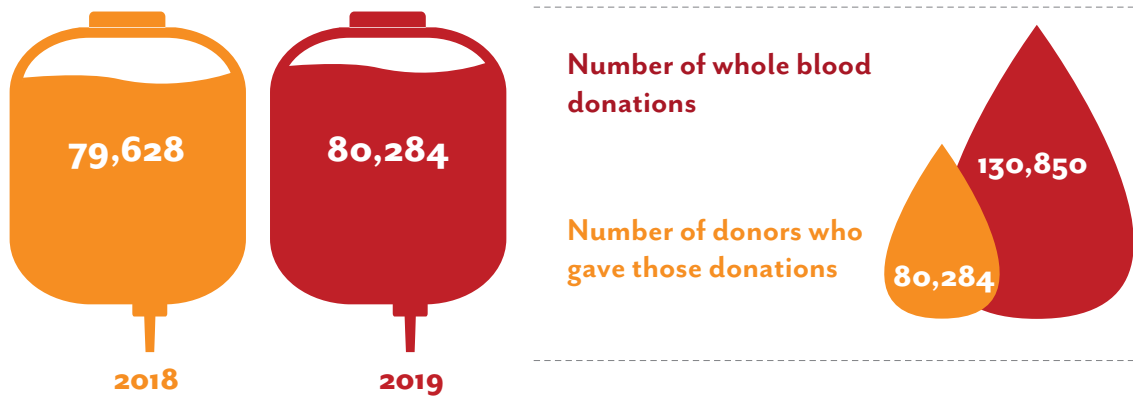
### Donor Awards Ceremony

Donor Awards ceremonies took place in Dublin, Carlow, Cork, Tuam and Ardee. A total of 956 donors received recognition for giving over 50 and 100 donations. These awards are an important part of the IBTS calendar year as it serves to recognise donors and their continued commitment to giving blood or platelets. It is an opportunity for the IBTS to thank donors for their long-standing loyalty and commitment to saving lives. At each of these events a patient who has received blood tells their story and brings real meaning to each donor of what their life saving gift means to others.

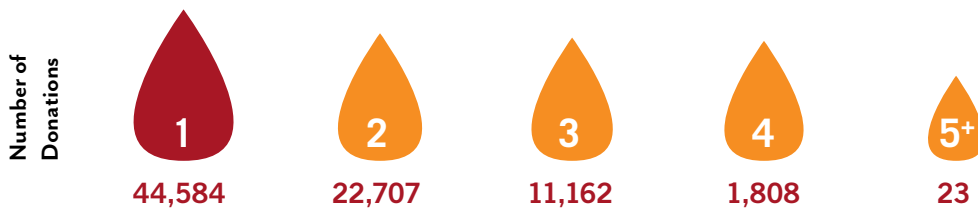
Donor Awards 2019			
	50s	100s	Ceremonies
Carlow	78	11	1
Donegal	69	2	1
Ardee	125	9	1
Dublin	159	77	2
Cork	271	73	2
Tuam	75	7	1
<b>Total</b>	<b>777</b>	<b>179</b>	<b>8</b>

# Donor Statistics

## Donors 2018 vs. 2019

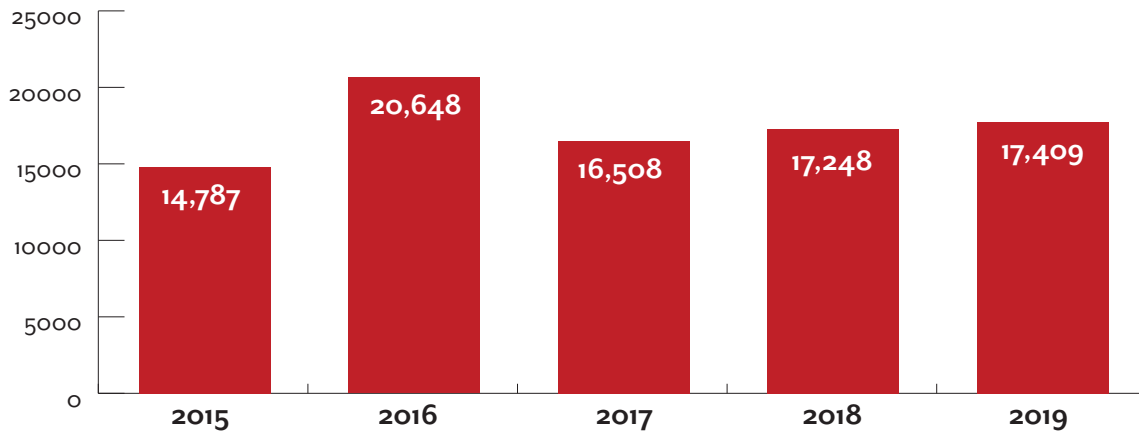


## Whole Blood Donations by Donors 2019

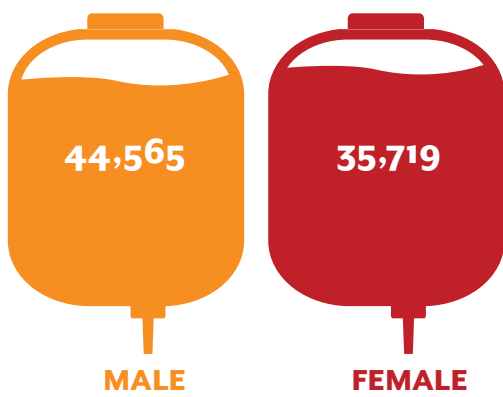


Number of Donors (Note: donors who gave 4+ times are on the HH panel)

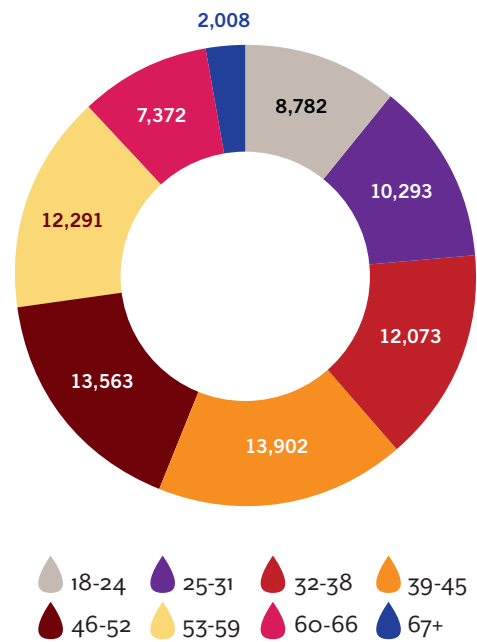
## First time donors



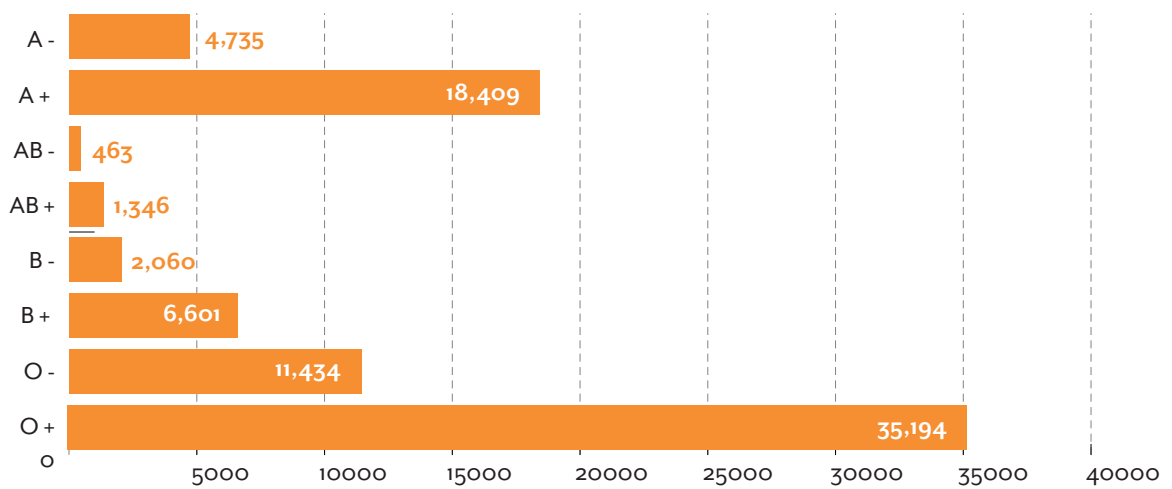
### Whole Blood Donors by Gender



### Whole Blood Donors by Age



### Whole Blood Donors by Blood Group



# Production, Product Development and Hospital Services

This report pertains to the Component Production Laboratories, the Product Development Laboratory, and the Hospital Services Departments.

The NBC Components Production Laboratory is responsible for processing, labelling and banking all whole blood donations collected nationally and platelet apheresis donations collected in the apheresis clinic located in the NBC. In addition, it is responsible for the preparation of pooled platelets nationally and for the issuing of non-routine whole blood and red cell orders and all platelet orders received in the NBC.

The Components Laboratory in Cork is responsible for processing, labelling, and banking the platelet apheresis donations collected in the IBTS cork Centre and also manages the stock holding unit based in the Centre. The Hospital Services Department in the NBC and Hospital Services Department in the Cork Centre are responsible for the receipt of electronic orders from the hospitals and for issuing products on foot of those orders.

The Hospital Services Department (HSD) in the NBC is responsible for receiving all electronic orders from hospitals supplied from the NBC and for issuing all products from the NBC. HSD staff select and issue all routine red cell products whilst the Components Laboratory Medical Scientists are responsible for selecting all platelet products and all non-routine whole blood and red cell products for issue by HSD NBC.

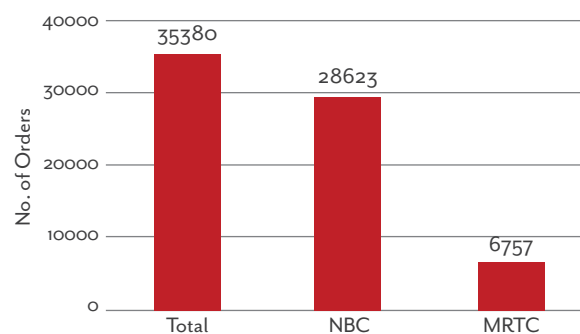
In the Cork Centre, Hospital Services is responsible for selecting and issuing all routine red cell products while the Diagnostics Laboratory in Cork is responsible for selecting for issue by Hospital Services all platelet products and non-standard whole blood and red cell products.

Following on from a peer review exercise completed in 2018, a project manager initiated a programme of change in 2019 relating to the Components, Hospital Services and Product Development areas. Key changes include the introduction of a

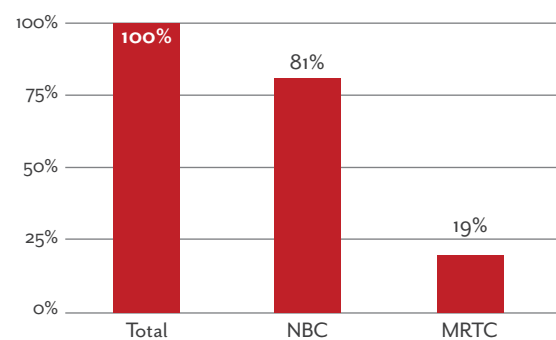
Production staffing model in the Components blood processing department including the introduction of a Production Manager, Production Supervisors and Production Operators. The production team are supported by Medical Scientists to produce a high performance production and component development dynamic.

A total of 35,380 product orders were received electronically in 2019, an increase of 6.4% on 2018. Of these, 28,623 (81%) were received in the NBC and 6,757 (19%) were received in the MRTC.

## Electronic Orders Received - 2019



## Percent Order Activity by Centre



On-Line Orders Received			
	2018	2019	Change
NBC	26,787	28,623	+1836 (+6.9%)
Cork Centre	6,461	6,757	+296 (+4.6%)
<b>Total</b>	<b>33,248</b>	<b>35,380</b>	<b>+2132 (+6.4%)</b>

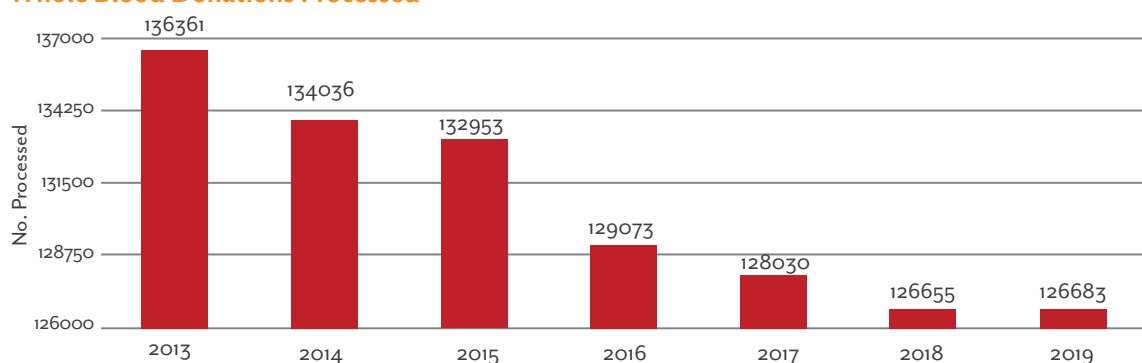


# Components Laboratory

## Whole Blood

A total of 126,683 productive whole blood donations were processed in 2019. This represents a 0.02% increase on the number processed in 2018.

### Whole Blood Donations Processed



The whole blood donations were processed to produce the following primary and secondary products:

Primary Product	Number prepared	Distributed
<b>Whole Blood and Red Cells</b>		
Whole blood	17	0
Whole blood for neonatal use	1268	2
Red Cell Concentrate	114,291	101,639
Red Cell Concentrate for neonatal use	11,083	3,765 <sup>1</sup>
Whole Blood Clotted	24	24
<b>Plasma Products</b>		
Fresh Frozen Plasma for neonatal use	240	0
Fresh Frozen Plasma for IVD use	124,852	76,626
<b>Buffy Coats</b>		
Leucocytes, Buffy Coat for pooled platelet production	40,075	N/A

Primary Product	Number prepared	Distributed
<b>Plateletapheresis - Doses</b>		
Apheresis platelets	18,489 <sup>2</sup>	9,711 <sup>3</sup>
<b>Secondary Product</b>		
<b>Red Cells</b>		
Red Cell Resuspended	833	783
Red Cell Washed	9	9
Red Cells Thawed/Washed	0	0
Red Cells for IUT	9	9
Red Cells, Plasma Reduced	393	226
Red Cells Split for Neonatal Use	714	648
Red Cell, Irradiated	15,130	15,007
Red Cell, Neonatal Use, Irradiated	304	296
Whole Blood Reconstituted	0	0

Plasma Products		
Cryoprecipitate for neonatal use	167	129
Platelet Products - Doses		
Platelets, Apheresis, Washed	12	12
Platelets, Paediatric Dose	20	19
Platelets, Hyperconcentrated	0	0
Platelets, Apheresis, Extended Life	7,864 <sup>4</sup>	6,522
Platelets, Pooled	6,908	3,918 <sup>5</sup>
Platelets, Pooled, Extended Life	2,485 <sup>6</sup>	2,270 <sup>5</sup>
Buffy Coats		
Leucocytes, Pooled	45	45
Leucocytes, Pooled, Red Cell Reduced	19	19

**Footnotes:**

- 1 This is the number issued specifically for neonatal use, the remaining units prepared were transformed into adult use products.
- 2 This is the total number of plateletapheresis doses prepared in 2019.
- 3 This 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.
- 4 These are a subset of the total plateletapheresis doses prepared
- 5 The total number of pooled platelets issued for therapeutic use is the sum of these figures (i.e. 3,918 + 2,270 = 6,188)
- 6 These are a subset of the 6,908 pooled platelets prepared

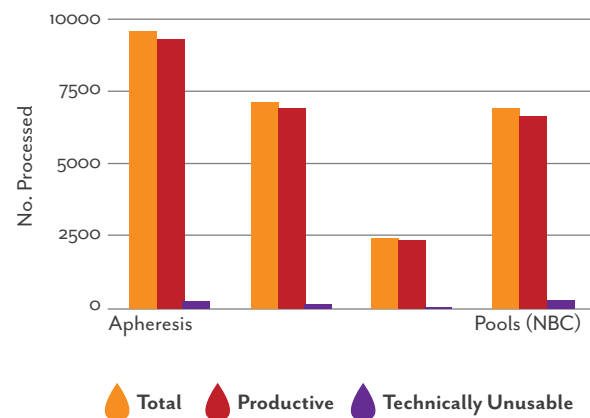
Please note that produced will not necessarily match distributed due to incoming stock available from 2018 and issued in 2019.

**Platelets**

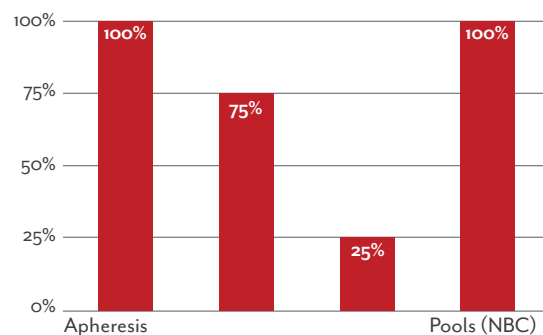
Platelet production consisted of 9,558 apheresis donations collected nationally and 6,908 pooled platelets prepared in the NBC.

The apheresis donations were collected and processed in the two centres, with 75% being processed in the NBC and 25% being processed in the Cork Centre.

**Platelet Production**



**Platelet Production by Processing Centre**



The total production of platelets suitable for issue increased slightly relative to 2018, with platelets via apheresis down by 131 doses (-0.7%), and platelets via pooling up by 206 doses (+3.2%), overall up 75 doses (+0.3%).

	Apheresis (Issuable doses)	Pooled (Issuable doses)	Total (doses)
2018	18,620	6,411	25,031
2019	18,489	6,617	25,106
Difference	-131	+206	+75
% Change	-0.7%	+3.2%	+0.3%

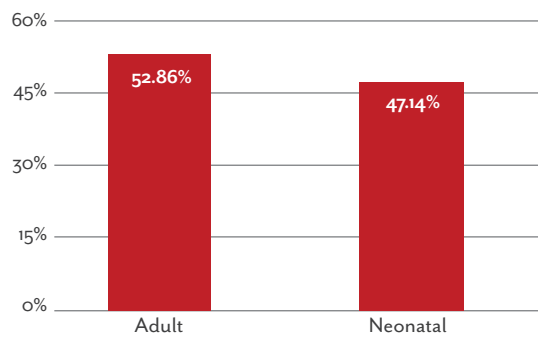
**Platelets, Apheresis**

Apheresis donations yield single, double or triple doses and the 9,558 platelet apheresis donations yielded a total of 18,489 issuable doses.

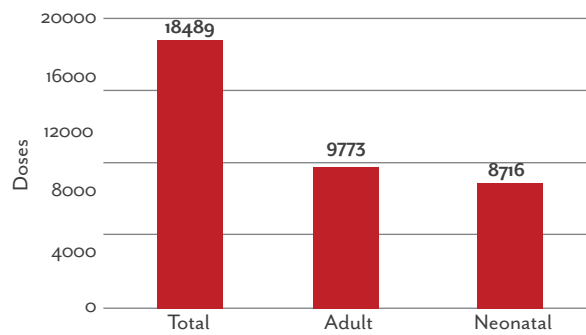
The equivalent 2018 figures are 9,657 platelet apheresis donations yielded a total of 18,620 issuable doses.

Of the total productive plateletapheresis doses collected in 2019, 9773 (52.9%) were suitable for adult use only and 8716 (47.1%) were suitable for both adult and neonatal use.

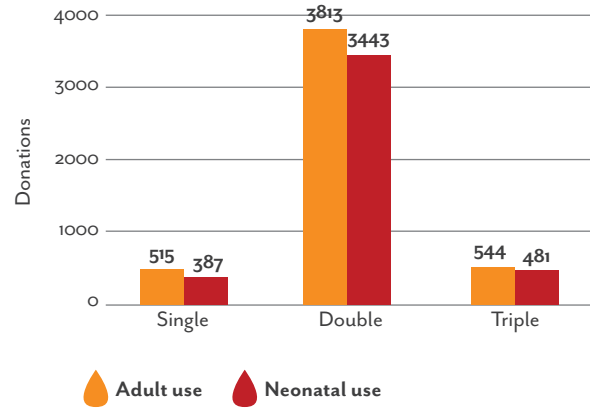
### Apheresis Donations by Phlebotomy Type



### Apheresis Doses by Phlebotomy Type



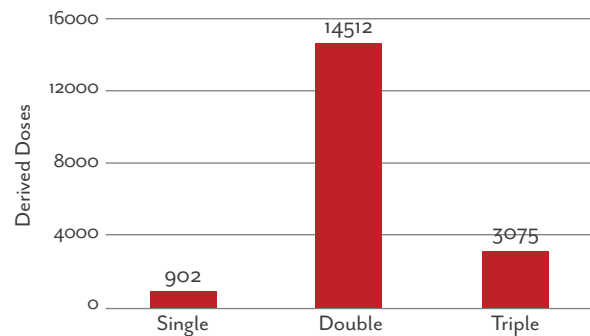
### Apheresis Donations by Donation Type



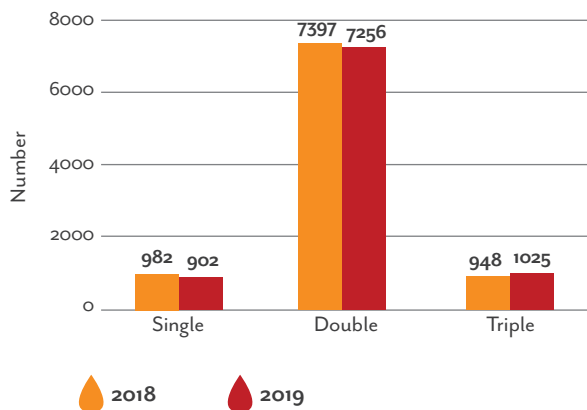
The proportion of single and double-dose donations decreased and the proportion of triple dose donations increased relative to 2018.

		Single	Double	Triple
2018	Adult Use	555	3921	503
	Neonatal Use	427	3476	445
	<b>Total</b>	<b>982</b>	<b>7,397</b>	<b>948</b>
2019	Adult Use	515 (-7.2%)	3813 (-2.7%)	544 (+8.1%)
	Neonatal Use	387 (-9.4%)	3443 (-0.9%)	481 (+8.1%)
	<b>Total</b>	<b>902 (-8.1%)</b>	<b>7256 (-1.9%)</b>	<b>1025 (+8.1%)</b>

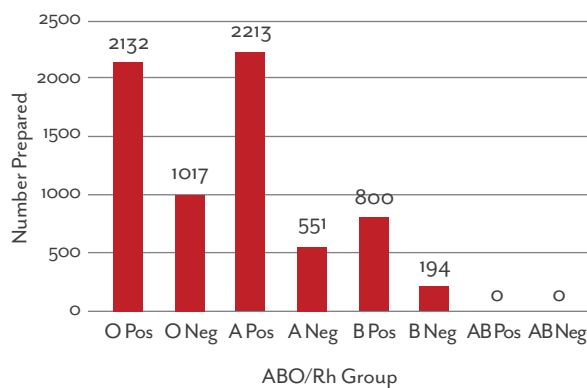
### Doses Derived from Various Donation Types (2019)



### 2018/2019 Comparison by Donation Type



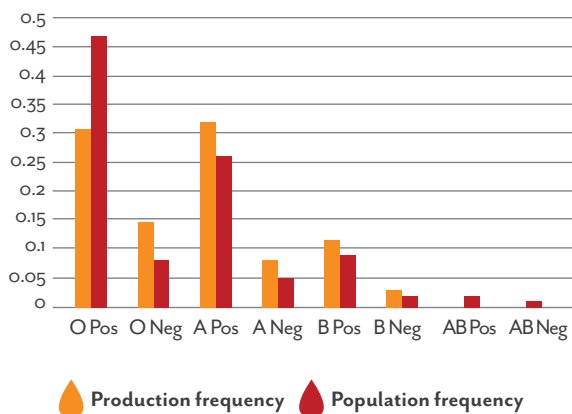
### Pooled Platelets by ABO/Rh Group



### Platelets, Pooled

A total of 6,908 pooled platelets were produced in the NBC in 2019, resulting in 6617 issuable doses. All ABO/Rh groups, except for AB were produced. The breakdown by group was:

### Pooled Platelet Production by ABO Rh



### Medicinal Products

The manufactured products distributed nationally in 2019 are shown in the table below:

Product	Distributed
Riastap 1g	8220
Octaplex 500	6 <sup>1</sup>
LG Octaplas O	8,106
LG Octaplas A	5,421
LG Octaplas B	2,036
LG Octaplas AB	1,116

<sup>1</sup> For stock management purposes

### Product Development Laboratory

A key recommendation of the 2018 peer review exercise was the resourcing of the Product Development Laboratory. This commenced in 2019 with the establishment of the Scientific Support and Component Development team, the remit of which is to provide day to day scientific support as well as the development of new processes, blood components and the validation of equipment.

The Product Development Laboratory worked on a range of projects during 2019, these included the validation of blood separators in the Components department, a review of processes to include the introduction of pathogen inactivation methodologies and the introduction of additive solution into platelet apheresis.



# Testing

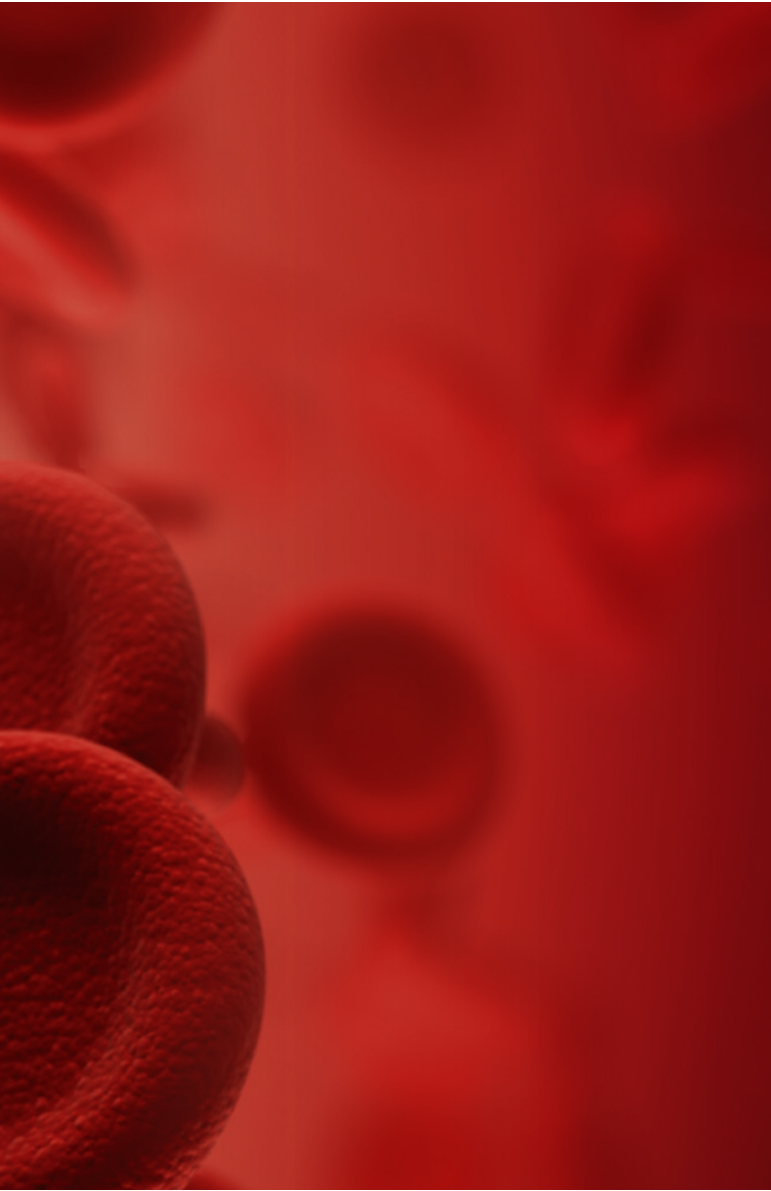
## Nucleic Acid Testing (NAT) Laboratory

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The Nucleic Acid Test or NAT laboratory is located at the NBC and provides molecular testing of all IBTS blood donor samples to reduce the risk of transfusion transmitted infections (TTIs) in recipients. The highly sensitive and specific assays used in the NAT laboratory screen directly detect the viral nucleic acid (RNA/DNA) of blood borne pathogens including Human Immunodeficiency Virus type 1 and 2 (HIV-1/2), Hepatitis C virus (HCV) and Hepatitis B virus (HBV), Hepatitis E Virus (HEV) and West Nile Virus (WNV). The NAT laboratory maintains the highest standards of quality while contributing to providing a safe and secure national blood supply.

The NAT laboratory performs Individual Donation testing (ID-NAT) using the Panther testing instruments with the Ultrio Elite (UE) and Hepatitis E virus (HEV) 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. During 2019 142,866 samples were ID-NAT tested for HIV1/2, HCV, HBV and HEV.

The Procleix West Nile Virus (WNV) assay reliably detects low level WNV RNA (lineage 1 and 2) in blood donations using the Panther platform. Prior to its introduction, donors travelling to a WNV at risk area within the past 28 days were deferred from donating. Selective testing of blood donations for WNV was introduced as an alternative to the 28 day geographical donor deferral from 1st May to 27th December 2019. During this time frame 3,642 donations (3.84%) were tested for WNV RNA.



Quality Control of NAT testing ensures accurate monitoring of the analytical sensitivity and reproducibility of NAT blood screening assays. External Quality Control samples (EQCs) are used to monitor technical proficiency and consistency in the sensitivity of reagent batches with the NAT Panther platform. The Grifols Procleix assays also include Calibrators and Internal Control (IC). The IC is used to control sample processing, amplification and detection steps and is used to ensure all manufacturer testing processes are operating correctly. Calibrator results must meet assay specifications. The NAT laboratory participated in multiple External Quality Assessment Schemes (EQAS) in 2019 with no discrepancies to report. Inter laboratory comparisons using EDCNet software (National Reference & Serology Laboratory, NRL, Australia, [www.nrlqa.net](http://www.nrlqa.net)) allow us to perform peer review with other Panther and Ultrio Elite users worldwide.

The NAT laboratory is committed to continuous improvement of the NAT process, maintaining up to date knowledge of emerging pathogens and potential new instruments and assays.

## 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.

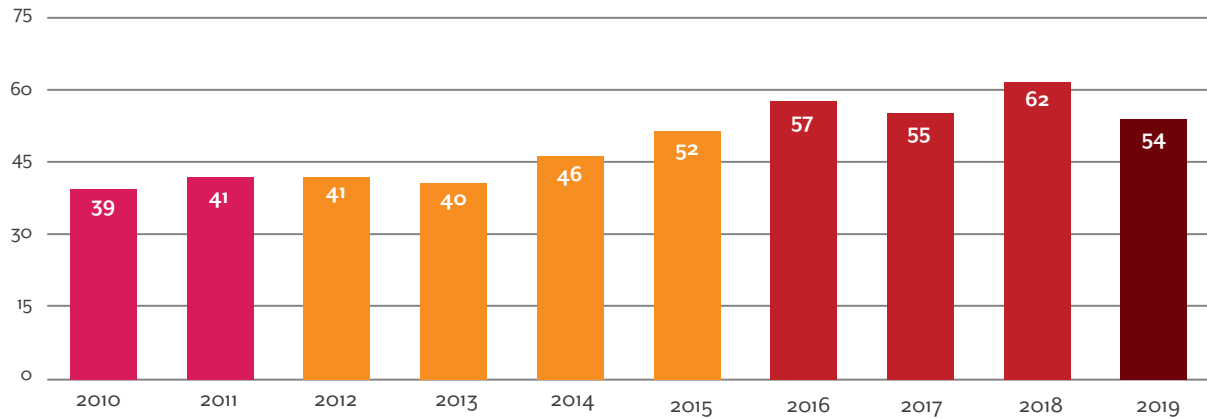
The laboratory determines the human leucocyte antigen (HLA) type of all patients and donors (related or unrelated) prior to transplantation to aid donor selection. The laboratory uses exclusively molecular methods based on the polymerase chain reaction (PCR) to define the genes that encode the HLA molecules. This technology can achieve a high level of resolution that distinguishes between individual alleles of the HLA genes.

***“ 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 2019 samples from 204 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 2,367 new donors joining in 2019.

### Number of Irish Patients receiving a HSCT from an Unrelated Donor 2010-2019



In the last 10 years the IUBMR has facilitated 487 unrelated donor transplants for Irish patients. In 2019 a total of 54 unrelated donor transplants were performed. Forty-five by St. James’s Hospital and nine by Our Lady’s Children’s Hospital, Crumlin.

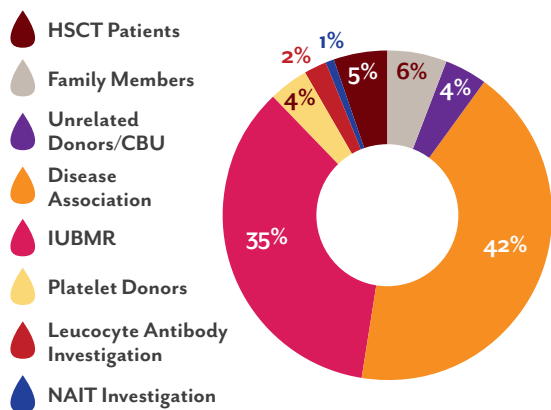
A total of 245 platelet donors were HLA-A, -B typed and included on the panel of platelet donors in order to support the provision of an optimal platelet product to the hospitals.

The NHIRL also provides a routine disease association HLA typing service. This service represented 42% of the investigations performed in 2019. The majority 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.

In addition, 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 has remained at the same level as compared to 2018.

In July 2019 the National Histocompatibility & Immunogenetics Reference Laboratory (NHIRL) merged with the Blood Group Genetics Laboratory (BGGL) to form the Molecular Biology & Genetics (MBG) Department. The BGGL provides Fetal RHD screening, as well as Weak D genotyping, and RBC genotyping services.

### NHIRL Investigation Distribution





# Virology Laboratory

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The function of the IBTS Virology Laboratory is the mandatory screening of all blood donations for 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). 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.

The Virology laboratory receives a clotted serum sample from each donor taken at the time of donation which is identified with a unique bar code identifier. All samples from the blood donor clinics are transported to the NBC overnight and tested the following day. 140, 274 donation samples and 2,177 sample only new donor samples were tested in 2019. The blood components from the donor are labelled for issue provided the test results for each and every donor are negative and satisfactory results can be issued by all the IBTS testing laboratories.

The Virology laboratory performs screening on the Abbott Alinity s System, which is a high-throughput, fully-automated immunoassay analyser designed to determine the presence of specific antigens and antibodies using chemiluminescent immunoassay (CMIA) technology. The Abbott Alinity s System is in routine use to test Irish blood donors and can simultaneously process seven assays which include HIV Ag/Ab Combo, HTLV I/II, Anti-HCV, HBsAg, Anti-HBc, CMV IgG and Syphilis. All assays are CE marked. The system processes up to 500 CMIA tests per hour. Results generated from the Abbott Alinity s System are managed using the Abbott AlinIQ AMS software.

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.

The Virology laboratory is also responsible for the referral and reporting of repeat reactive samples (including NAT) from the donor and non-donor programmes to the National Virus Reference Laboratory (NVRL) and the Central Pathology

Laboratory (CPL) St James Hospital for confirmatory/ supplementary testing. Occasionally samples from the Virology laboratory are shipped for additional Virology testing abroad to agencies such as the SNBTS Scotland and the National Transfusion Microbiology Laboratory (NTMRL) in Collindale UK (eg. Malaria testing).

The Virology Laboratory must ensure that the expected performance of assays is achieved by using appropriate batch pre acceptance testing and by using standards from the 'National Institute of Biological Standards and Controls U.K.', and a multimarker control from the National Serology Reference Laboratory Australia (NRL, Australia) "Acrometrix Q Connect Blue" as 'go/no go' controls on all testing runs. These quality control standards are used to monitor the consistency of test performance using statistical process control on a daily basis and, over a period of time, as a retrospective monitor of batch performance. The laboratory participates in a monitoring programme which allows IBTS to compare results to Blood Centres in the UK.

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.

The Virology laboratory participates in three proficiency programmes, one circulated by the United Kingdom National External Quality Assessment Service (UK NEQAS) for Microbiology, the second by the NRL, Australia and one by the European Directorate for the Quality of Medicines & HealthCare (EDQM).

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

The IBTS has an External Contingency testing plan with the Scottish National Blood Transfusion Service (SNBTS). This process is tested four times each year by sending a small number of samples to the SNBTS for Virology testing. There was no requirement to invoke the SNBT External Contingency testing plan in 2019.

# Red Cell Immuno-haematology Laboratory

The RCI Laboratory at the National Blood Centre provides extensive pre-transfusion and antenatal referral services for hospitals nationwide.

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 titration as appropriate).
- Provision of suitable blood at delivery for at risk pregnancies.
- Extended phenotyping for transfusion dependant patients and for patients with complex red cell antibodies.
- Phenotyping of donor red cells.
- Clinical and scientific advice to hospital colleagues.
- Importation of rare blood for named patients.
- Out of hours emergency on-call service.

The RCI also provides hospital blood bank services for Our Lady's Hospice and Care Services and the Royal Victoria Eye and Ear hospital.

## Comparison of 2018 and 2019 Sample numbers

	Total No. Samples tested	RhD Type Workup	Anti-body ID	Quantitation anti-D	Quantitation anti-c	Mono-clonal interference	Total Compatibility Test	Complex Compatibility Test	Total No. of Out of Hours
<b>2018</b>	2403	4	2244	503	144	207	865	837	185
<b>2019</b>	2168	2	2049	455	171	227	741	717	143
<b>(%)</b>	<b>-9.78%</b>	<b>-50%</b>	<b>-8.69%</b>	<b>-9.54%</b>	<b>+18.75%</b>	<b>+9.66%</b>	<b>-14.34%</b>	<b>-14.34%</b>	<b>-22.70%</b>

## Laboratory Activity

In 2019 a total of 2168 samples were tested in the RCI laboratory, a 9.78% decrease from 2018.

Even though 2019 marked a reduction in overall sample numbers across antibody identification and compatibility testing. There was a notable increase in the number of anti-c quantitation samples and samples received for monoclonal antibody interference investigation. Anti-c quantitation samples increased by 18.75% compared to 2018 and monoclonal antibody interference increased by 9.66%.

As in previous years, there was a continued high level of serologically difficult or rare samples received. In 2019 the following complex samples some with rare allo-antibodies were identified by the RCI Laboratory:

Antibody	Patients	Referrals
Anti-Ch/Rg	8	16
Other HTLA-type	9	25
Anti-Wra	11	12
CR1-related	1	3
Immune Anti-A	1	1
Anti-Ce	3	4
Anti-cE	5	11
Monoclonal Interference	57	227
System Specific	12	22
Anti-Jk3	1	7
Anti-Jra	1	2
Anti-P1	7	8
Anti-Vw	1	1
Anti-Yta	1	1
<b>Total</b>	<b>118</b>	<b>340</b>

Many of these patients were antenatal. In conjunction with identification of the red cell antibody, the risk of HDFN and possible blood requirements for both mother and baby were managed. Outcomes have all been successful to date.

2019 saw an increase in referrals from patients receiving the drug Daratumumab to treat multiple myeloma. This drug was licenced for use in Ireland in April 2018.

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.

The RCI laboratory actively contributes literature to the field of blood transfusion science. The following posters were presented at either national or international conferences as listed below:

- **BBTS:** An example of the Matuhasi-Ogata Phenomenon in a patient with no recent transfusion history. Ruth Cleary, Barry Doyle, Edel Scally, Diarmaid O'Donghaile.
- **EQAS:** The identification and management of Anti-Jk3 in pregnancy. Presented by Cait Geaney
- **Sure Conference:** Improving the process of mitigating DARA interference in pre-transfusion compatibility testing. Awarded: Institute of Biomedical Science - President's Prize Ciara Liptrot, Helen Cregg, Edel Scally

## Importation of rare blood/products

A total of 2 red cell units of rare phenotype and 2 HLA matched platelets were imported from abroad in 2019.

## Participation in External Quality Assurance Schemes

The RCI laboratory participates in 3 different quality assurance schemes; 4 exercises in IEQAS, 4 exercises in AQQAS and 10 exercises in NEQAS along with pilot NEQAS schemes in red cell phenotyping, DAT and antibody titration. In addition to this, the RCI laboratory is involved in Interlaboratory comparison schemes for elution techniques and antibody titrations. All results obtained were satisfactory.

# Diagnostics laboratory Cork

The diagnostics laboratory at the Cork Centre provides both routine and reference immunohaematology and laboratory services. The former to South Infirmity University Hospital (SIVUH), St. Finbarrs', Mater Private Cork and Marymount University Hospital and 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 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 Diagnostics laboratory Cork investigates complex or anomalous 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. 4 patient samples required further specialist referral to the international blood group reference laboratory (IBGRL) Bristol, and a further 53 samples were sent to the NBC for genotyping. Advice is provided to colleagues in the region.

As a reference laboratory Diagnostics laboratory Cork 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 order system (EOS) for antigen typed red cells, irradiated blood components and blood components for babies.

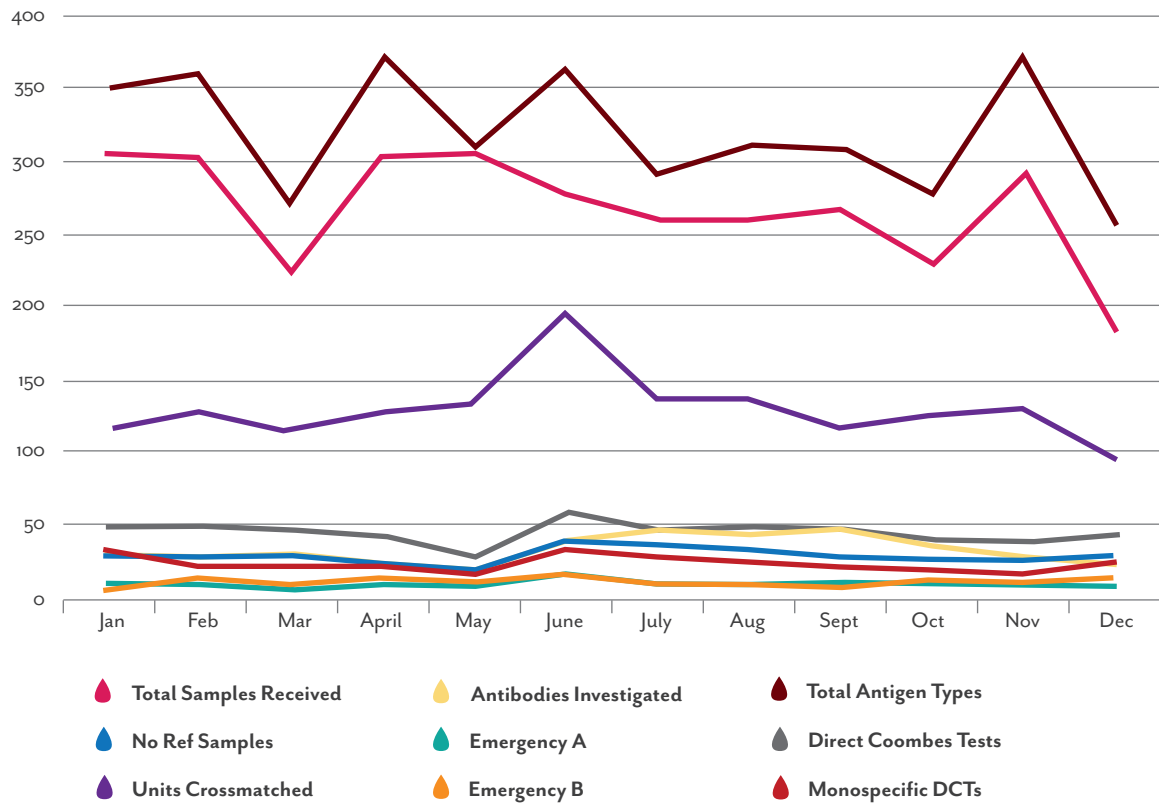
As the scientists on duty out of hours the diagnostics' laboratory contributes to the service by undertaking secondary processing of blood components, and are the first point of contact for clinical queries which are referred on to the medical staff.

Performance in External Quality Assessment Schemes was satisfactory throughout the year and staff attended the British Blood Transfusion Society (BBTS) UKNEQAS and IEQAS meetings.

### Diagnostics Laboratory Activity 2019

Total samples received 2019: 3690 (2018 : 3714)

### Diagnostics Cork Activity 2019



## Automated Donor Grouping

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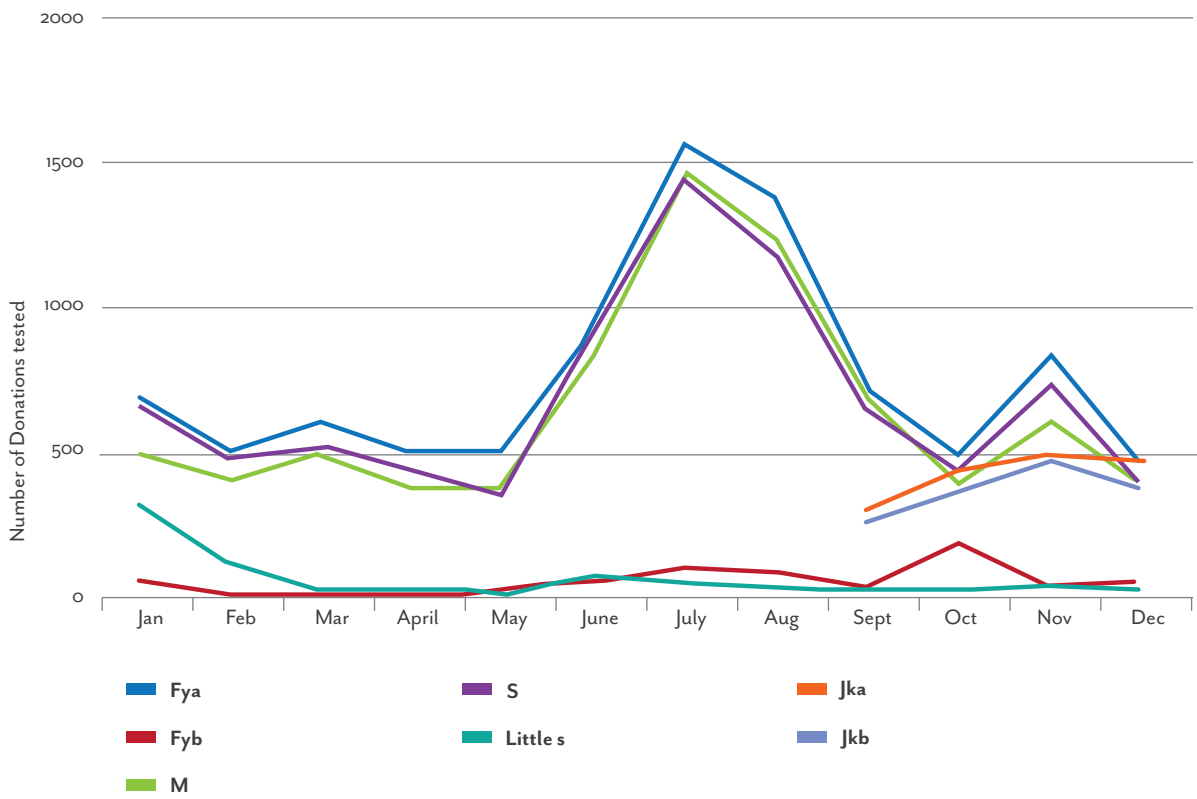
The Automated Donor Grouping laboratory (ADG) is responsible for the ABO blood group and the Rh D typing which must be determined on each blood donation. In addition, all donations must be tested for the presence of red cell antibodies by performing a routine antibody screen. Selected donations are tested for the presence of high-titre A/B antibodies, neonatal antibody screen, haemoglobin S and extended antigen types. The laboratory utilises the PK 7300 as a primary blood group analyser and the Ortho Vision as a secondary blood group analyser. In 2019 all Jka/Jkb typing was moved from the PK 7300 to the Ortho Vision.

In 2019 130,850 red cell and 9453 platelet apheresis samples were tested and of these 14,044 (10.7%) were from first time donors. In addition 1,867 sample only new donor samples were tested in 2019. A project was undertaken in ADG during the summer of 2019 to look at the blood group and extended antigen type of Irish first time donors and compare this to the blood group and extended antigen type of non-Irish donors to assess the impact of changing demographics on our donor population. From the results obtained from testing new donors it is possible to estimate the frequencies of ABO/Rh/K/Fya/M/S blood types in the Irish population.

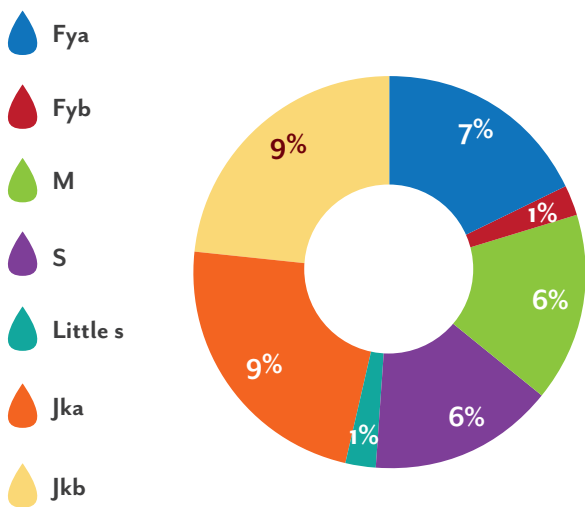
In addition to performing the mandatory serological tests, the laboratory routinely phenotypes donors for antigens in the Duffy, Kidd and MNS blood group systems. This is for routine hospital orders and also to identify rarer phenotypes or combinations of antigen negative types. These are typically for 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. A stock of extended typed units is also made available for emergency issue. The laboratory screened thousands of donors for Rh phenotypes (C,c,E,e) and Fya/b, Jka/b S/s types in 2019. (See table 1 and table 2).

In 2019 ADG began to look at better ways to serve all of our patient population by looking to our own donors for rarer blood types. In response to a patient with rare antibody anti-Jk3, a search for donors born in Polynesia, Finland and New Zealand was initiated and 84 donors were tested for the rare Jk3-phenotype. This will be expanded in 2020.

**Total number of extended phenotyping performed on Ortho Vision**



**Percentage of red cell donations tested for extended antigen types**



The laboratory participates in three types of external quality assessment schemes, which involves the submission of 15 separate serology exercises per year, 6 abnormal haemoglobin exercises and 1 large international survey covering all aspects of the laboratories serologic testing. Staff competency is monitored by the use of these schemes and involves the testing of samples by both automated and manual techniques. The laboratory staff have scored 100% accuracy in the UK National External Quality Assessment Scheme (UK NEQAS), since the laboratory's first registration in 2008. Satisfactory results were obtained for all NEQAS exercises performed in 2019. The second scheme is performed once a year and covers all aspects of donor serology, ABO grouping, RhD typing, antibody screening / identification and other antigen typing. This European Directorate for the Quality of Medicines & Healthcare scheme (EDQM) is an international survey of Blood Establishment laboratory standards.

As the Automated Donor Grouping Laboratory is a national testing facility, the IBTS has an external testing plan with the Scottish National Blood Transfusion Service in case of a critical failure of instruments or site. The contingency plan is tested 4 times a year (3 by air and 1 by sea) by sending twenty four samples for testing. In 2019 the contingency was tested with favourable results and this plan has not had to be activated in a 'live' situation since the consolidation of testing at the National Blood Centre in 2010.

## IBTS Staff Articles in PubMed 2019

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### **Blood Donor Screening for Hepatitis E Virus in the European Union.**

Boland F, Martinez A, Pomeroy L, O'Flaherty N.

Transfus Med Hemother. 2019 Apr;46(2):95-103. doi: 10.1159/000499121. Epub 2019 Mar 14. Review.

### **International Forum on Occult hepatitis B infection and transfusion safety.**

Seed CR, Allain JP, Lozano M, Laperche S, Gallian P, Gross S, Kwon SY, Oh EY, Kim JN, Chua SS, Lam S, Ang AL, Tsoi WC, Hewitt PE, Davison KL, Tettmar K, O'Flaherty N, Boland F, Williams P, Pomeroy L, Wendel S, Fachini R, Scuracchio P, Carminato P, Fearon M, O'Brien SF, Delage G, Kiely P, Hoad V, Matsubayashi K, Satake M, Taira R, Stramer SL, Sauleda S, Bes M, Piron M, El Ekiaby M, Vermeulen M, Levicnik Stezinar S, Nograšek P, Jarvis LM, Petrik J, Charlewood R, Flanagan P, Grabarczyk P, Kopacz A, Łetowska M, Seifried E, Schmidt M.

Vox Sang. 2019 May;114(4):e1-e35. doi: 10.1111/vox.12743. Epub 2019 Apr 10.

### **Is platelet gel safe enough for neutropenic patients?**

Piccin A, Bacigalupo A, Zini G, Hamidieh AA, Bianchi M, Sica S, Valentini CG, Wolf D, Dazzi F, Fontanella F, Krampera M, Field S, Smith OP.

Transfus Apher Sci. 2019 Apr;58(2):190-191. doi: 10.1016/j.transci.2019.02.004. Epub 2019 Mar 19.

### **Insight into the complex pathophysiology of sickle cell anaemia and possible treatment.**

Piccin A, Murphy C, Eakins E, Rondinelli MB, Daves M, Vecchiato C, Wolf D, Mc Mahon C, Smith OP.

Eur J Haematol. 2019 Apr;102(4):319-330. doi: 10.1111/ejh.13212. Epub 2019 Feb 21. Review.

### **A personal dedication to Sir David J Weatherall GBE, FRS (9 March 1933-8 December 2018).**

Cotter FE, Hann I.

Br J Haematol. 2019 Feb;184(3):319-320. doi: 10.1111/bjh.15755



# Other Services

## Tissue Bank

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The Tissue bank at the NBC is a licensed tissue establishment (TE-12) under the Tissue and Cells Directive 2004/23/EC which sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. The bank is inspected every 2 years by the Health Products Regulatory Authority. The tissue bank manages all ocular tissue, heart valves, skin and some musculoskeletal tissue on a national basis. Products supplied include corneas, both for PK, DSAEK and DMEK procedures, sclera, amnion, pericardium and fascia lata. These ocular products are all imported from the US. The threat of transmission of vCJD via corneal tissues has been significantly downgraded over the past 16 years and we are now actively exploring the possibility of reopening the eye bank. The IBTS also provides autologous serum eye drops for patients with severe dry eye on receipt of a request from an ophthalmologist. Approval has just been granted to start the validation work to provide allogeneic serum eye drops and it is hoped this service will be available to Irish patients by Q4 of 2020. The tissue bank also has a GMP licence for the production of Limbal Stem cells. These grafts are used to successfully treat patients with Limbal stem cell deficiency. Human skin is available for the treatment of severe burns and is imported from the BST Tissue bank in Barcelona, Spain. The skin is mainly supplied to the Burns unit in St. James Hospital.

The IBTS is a third party contractor to the MMUH for the processing, cryopreservation and distribution of human cardiovascular tissue. The majority of the valves donated are used in OLCHC for the repair of congenital heart defects. 2019 saw a 33% increase in the number of valves processed for clinical distribution.

## Therapeutic Apheresis Service

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The Therapeutic Apheresis Service (TAS) in Cork 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 a Consultant 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, specifically the Terumo OPTIA Spectra. The procedures performed in 2019 were Therapeutic Plasma Exchange (TPE) and Red Cell Exchange (RBCX). 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 “Guideline on the clinical use of apheresis procedures for the treatment of patients and collection of cellular therapy products” (BSH-2015).

TAS operates within the IBTS quality management system, with trained personnel, controlled documentation including SOPs, validated technology and adverse event and reaction monitoring. Adverse events are subject to on-going review and changes are incorporated into the IBTS Therapeutic SOPs/ documentation, relevant hospital policies and procedures as appropriate. TAS staff attend UK and international meetings and comply with Continuing Professional Development (CPD), including audits. The service intends to participate in ASFA international data gathering, once available.

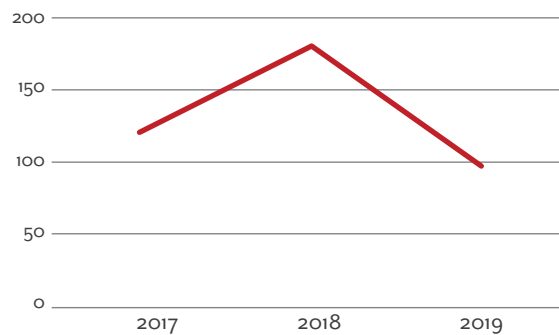
In 2019 the TAS received 17 patient referrals and performed 99 procedures for 16 patients, over two hospital sites. As displayed in the following tables and figures, the demand for TAS is varied and unpredictable. Variability in demand includes requesting hospitals, specialities, consultants, degree of urgency, ASFA category and trends by hospital, month, weekend and out of hours. Clusters of demand are not uncommon.

In 2019 TAS nurses also supported Blood and Platelet Donor clinical queries management.

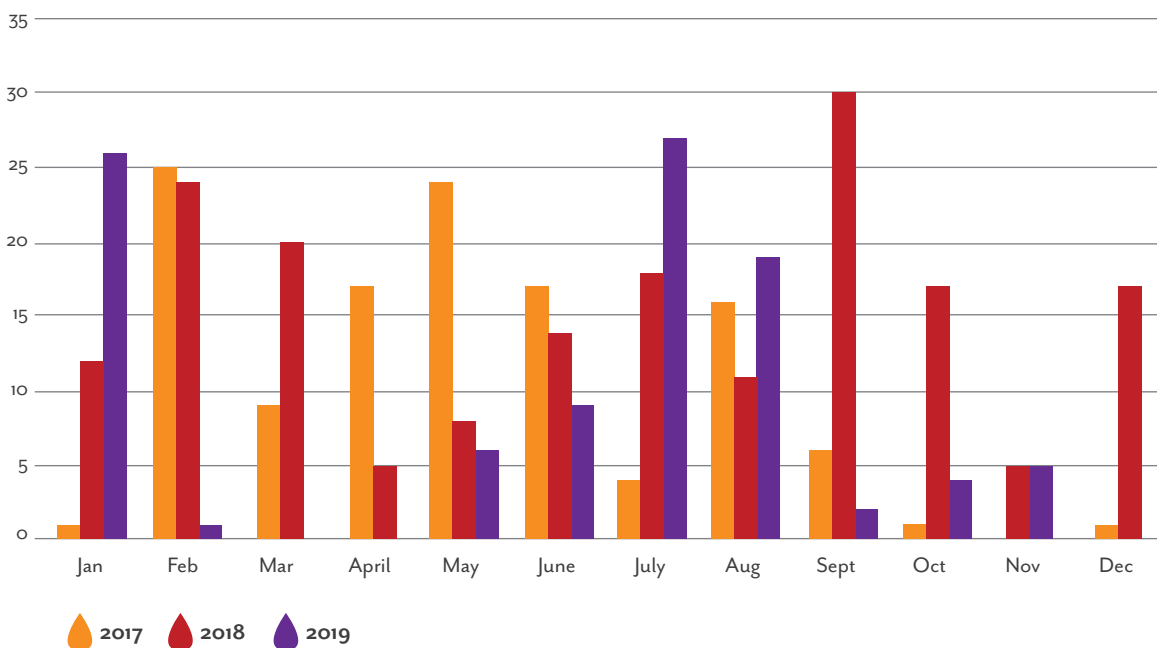
### Service demand trend

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

#### Total Annual Procedures 2017 - 2019



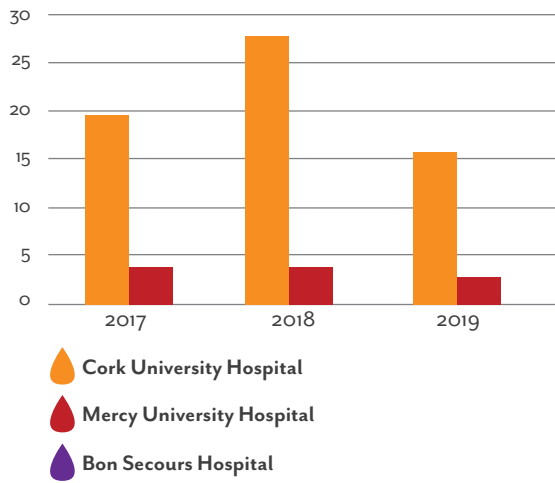
#### Service demand 2017 - 2019 by month



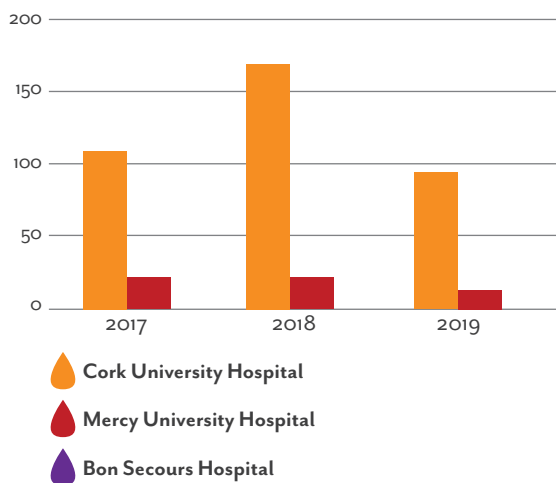
### Service demand by hospital

CUH had the greatest demand for TAS, referring 88% of patients treated in 2019. MUH referred 12% of patients. Figures 3 and 4 shows a comparison of service provision to CUH, MUH, BSHC over the past 3 years by patients and procedures.

#### Service Provision to Patients by Hospital 2017 to 2019



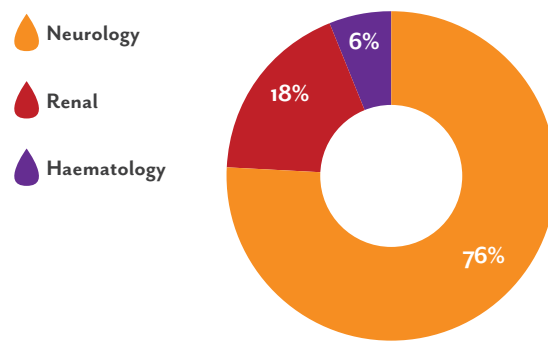
#### Procedures by Hospital 2017 to 2019



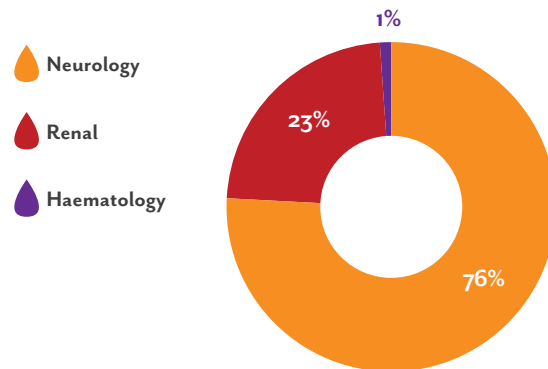
### Clinical speciality by patient and procedure

The majority of referrals were for patients presenting with neurological conditions (76%), followed by renal (18%) and haematology (6%) as per Figure 5 and Figure 6

#### Patients by Speciality 2019



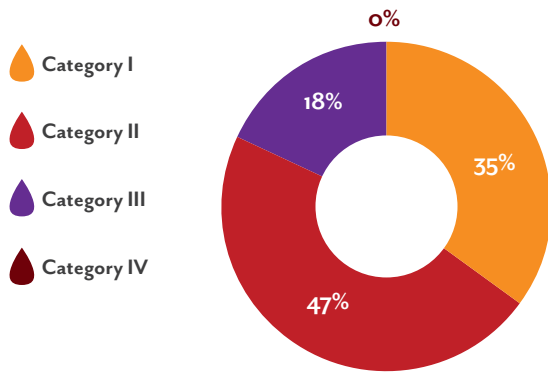
#### Procedure by Speciality 2019



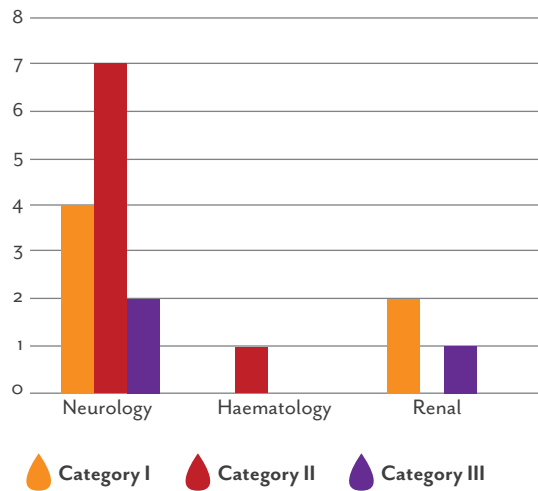
### Service delivered by The American Society for Apheresis (ASFA) categories

Figure 7: Patients treated by ASFA category 2019 (%), Figure 8: Patients by speciality & ASFA category 2019.

### Patients treated by ASFA Category 2019



### Patients by speciality & ASFA category 2019



The ASFA guidelines are used to plan 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.

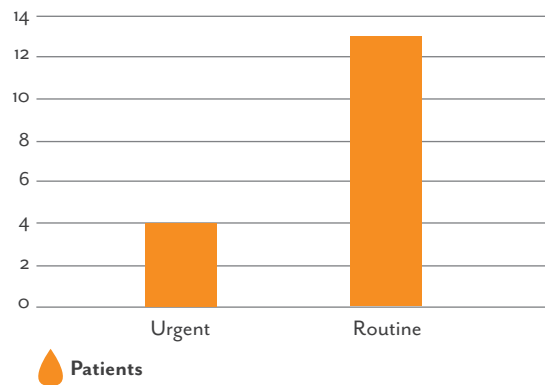
**Category IV** – Disorders in which published evidence demonstrates or suggests apheresis to be ineffective or harmful.

### Degree of urgency of Therapeutic Apheresis Service required

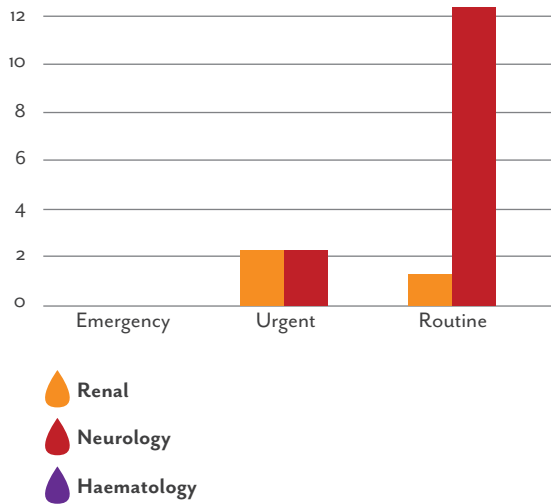
TAS may in some conditions, require the emergent initiation of an apheresis procedure. Emergency cases should start within 4 hours; urgent cases should start the same day within 4-8 hours. In routine cases the first procedure should start within 24 hours or as per physician arrangement (ASFA standard operating procedures manual 1st Ed 2019). Early apheresis can reduce the threat to life or organs. In 2019, 24% of patients presented as urgent and 76% presented as routine to Therapeutic Apheresis Service.

Service Urgency by patients	
Urgency	Patients 2019
Emergency	0
Urgent	4
Routine	13

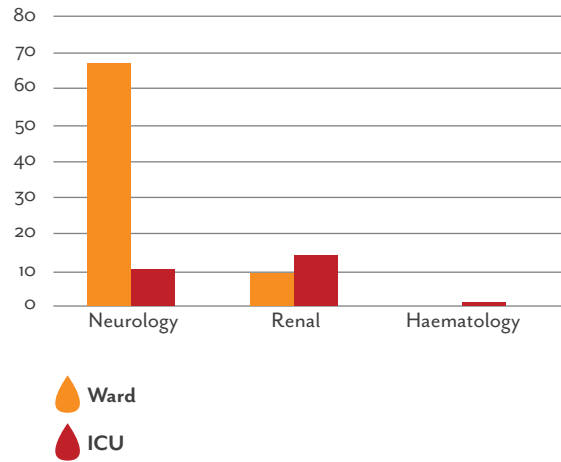
### Urgency by Patients 2019



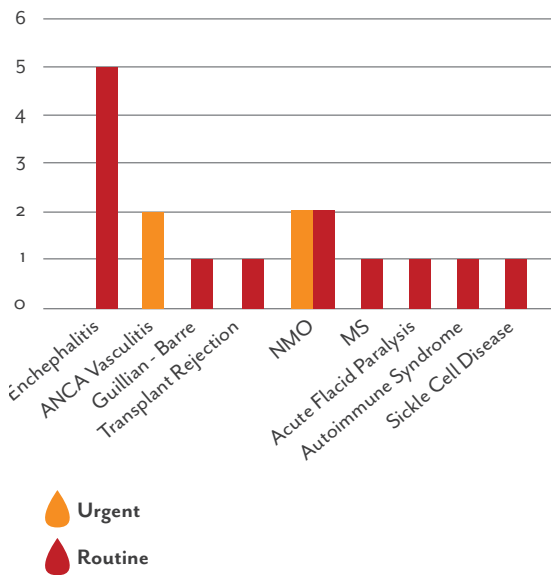
### Urgency by Patients and Speciality 2019



### Service by patient care support by procedures and speciality 2019



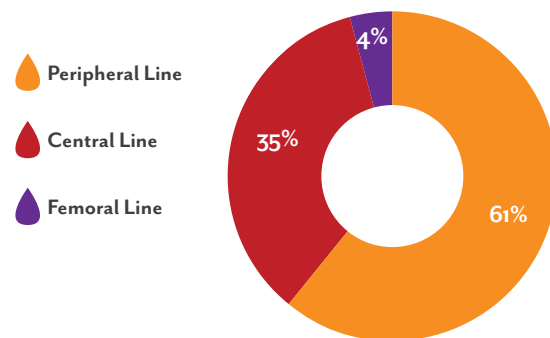
### Number of conditions treated by urgency 2019



### 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. While four procedures were attempted by peripheral access all patients required a central line or femoral line in 2019. Some patients had a combination of vascular access types.

### Vascular access by Procedure 2019



Therapeutic apheresis is required for patients with varying levels of care support. TAS programmes may commence when the patient referred requires ICU support and with improvement, these patients, may be transferred to general wards. Patients by diagnoses and degree of urgency

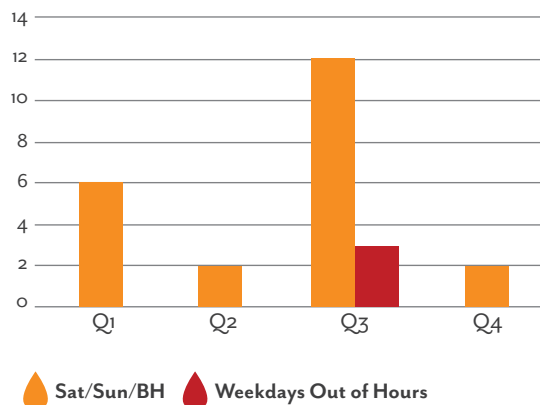
## Staffing

The service is led by a Consultant Haematologist supported by Specialist Medical Officers (SpMOs). Nursing is resourced by 2 staff nurses including scheduled agency support. However this was not available after September 2019. Out of hours is resourced on a roster system.

## Weekend, Bank Holiday and Out of Hours Service

Patients may require emergency and out of hours care when their diagnosis is life or organ threatening. The treatment programme may extend throughout a weekend period. Of the 99 procedures carried out in 2019, 22 (22%) were performed at the weekend and 3 (3%) were performed 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 displayed in Figure 14.

### Weekend, Bank Holiday, Out of Hours Service Provision 2019



## 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 “Guideline on the clinical use of apheresis procedures for the treatment of patients and collection of cellular therapy products” (2015). TAS undertakes internal audits and continuous professional development to assure good practice. Communication with other apheresis services and attendance at Terumo and ASFA conferences is on-going. “Audit of calcium use during plasmapheresis in an Irish Therapeutic Apheresis Service” was presented 2019 (Poster).

In 2019 all SOPs were revised to support current practice. A new patient information leaflet was developed and an audit on its effectiveness was undertaken. The 2018 audits on Calcium and Fibrinogen were measured against current practice and a good outcome was reported.

# National Haemovigilance Office (NHO)

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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 7360 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 aspect of blood transfusion are reviewed by the NHO. These reports come from blood establishments, hospital blood banks and facilities. During 2019, 119 mandatory SAEs were reported (49% of all SAEs). In addition, 121 non-mandatory SAEs, (51% of all SAEs) primarily relating to errors in clinical areas, were also reported. This figure includes Wrong Blood in Tube events (WBIT) (n=48) which were collected by the NHO for the first time in 2019.

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

A total of 119 reactions that meet the criteria have been reported in 2019. Mandatory SAR (54) reported to date is an increase on those recorded in 2018 (41).

## 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 2019 (for the reporting year 2018), with the compilation of 2019 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 specialists registrars also continued during the year. In keeping with its remit to support hospital based staff, the NHO provided an 'open day' in February for newly appointed HVOs covering aspects of the reporting system, together with familiarisation with the workings of the IBTS and NHO. Twenty newly appointed HVOs attended this event.

## e-Learning

The IBTS continued to provide '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. Over 19,300 users have completed one or more of the 'Learnbloodtransfusion' modules.

# Irish Unrelated Bone Marrow Registry (IUBMR)

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 millions of 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. 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.

## International Accreditation

Since 1991 the IUBMR has been affiliated to the World Marrow Donor Association (WMDA), an organisation which sets operational standards for bone marrow registries worldwide. In 2012 the IUBMR was awarded full registry accreditation. All search coordinators working in the IUBMR are certified through the WMDA education programme.

## National Activities

Since 1991 the IUBMR has been affiliated to the World Marrow Donor Association (WMDA), an organisation which sets operational standards for bone marrow registries worldwide. In 2012 the IUBMR was awarded full registry accreditation. All search coordinators working in the IUBMR are certified through the WMDA education programme.

## 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. Forty nine Irish donors were selected for additional testing in 2019.

## 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 the 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 2019, 2758 new volunteers gave blood samples to join the IUBMR, which will be added to the current registry of over 21,000 potential donors. This represents a 7-fold increase in recruitment compared to the previous year.

## Irish Donor Donations

Donations (blood stem cell and donor lymphocytes) from 6 Irish donors were facilitated in 2019, for national and international patients.

**“ 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. ”**

# Quality & Compliance

## Quality & Compliance

As implementation of the revised Quality Strategy progresses, the Quality and Compliance function continued to see a number of significant changes during 2019 which included new appointment of the Director of Quality & Compliance, Quality Control Manager, National Quality Assurance Manager and Biovigilance Officer. During 2019 the objectives and initiatives of the Quality Strategy were translated into the IBTS Strategic Plan 2017-2020 via introduction of the Product Quality internal process. This is designed to ensure successful delivery of strategic quality objectives and initiatives, which will enable us to achieve good quality outcomes across the business and support fully embedding a quality culture.

### 2019 key achievements under the three pillars of the Quality Strategy

#### Modern Quality Systems

Most notably in 2019 was the successful version upgrade of our electronic Document Control system, SmartSolve. This has improved the user experience and process efficiencies and is a step forward towards modernising our Quality System. A comprehensive self-assessment of the Quality System also commenced across the three dimensions of compliance, effectiveness and efficiency. This has enabled the first phase towards developing targeted plans to improve our quality practices.

Training sessions for staff were held in relation to the principles of Quality Risk Management in the context of the International Conference on Harmonisation (ICH) guidelines, Q9. This is a systematic process for the assessment, control, communication and review of risks to the quality of product across the product lifecycle. The next step will be to ensure this approach is translated across all elements of the Quality System.

Other key initiatives in this area continue such as the development of better quality measures in order to provide greater insight into the effectiveness of our Quality Management System and, in particular, Corrective and Preventive Actions. Significant work in this area is planned for 2020.

#### Stakeholder Engagement

To ensure the quality team continues to meet and understand the needs of our customers, partnering with stakeholders has commenced and continues to grow with feedback and communication sessions being held. The next step will be to deploy the Quality Business Partner model within the Quality Assurance (QA) team. This model is designed to build more effective relationships, ensuring our operational teams are well supported by designated QA staff. Introduction of a quality stakeholder feedback programme is also planned which will continually measure the effectiveness of our service provided and support identifying opportunities for improvement.

#### Sustainable Quality Workforce

Efforts persist to ensure that an effective management structure remains in place. In conjunction with this, the Quality Leadership Team continues to review current capabilities and resource requirements within all areas of the Quality and Compliance function. During 2019 a critical single point of dependency was addressed within the IT Quality Function with successful recruitment of an IT Quality Specialist.





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An emphasis on recruiting and resourcing for success, including effective succession planning, will remain a key area of focus in 2020. This will ensure we have the appropriate skill set in all areas of the Quality and Compliance function, which will enable us to achieve our desired vision.

## Regulatory Update

The annual HPRAs programme of inspection covered 7 inspections during 2019 which included 4 clinics and 2 site visits. These inspections covered Blood and Tissue Establishment activities, including that of the Irish Unrelated Bone Marrow Registry and Limbal Stem Cells. One major non-conformance was raised for a Tissue Establishment system element. Throughout the year the Manufacturing Authorisations are also regularly updated and maintained to reflect the current nature of the IBTS. Annual reports were filed on the associated activities of the Blood and Tissue Establishments as per HPRAs requirements. 19 Internal Audits were conducted in 2019 under the Internal Audit Programme.

## Key Quality Data

The IBTS records, investigates and actions internal incidents of 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 2019, 708 IRs were raised, compared to 618 raised in 2018. The percentage closed was 65%, compared to 78% in 2018. The IBTS records, investigates, and responds to customer complaints through the Blood Complaint system. In 2019, 797 complaints were reported, compared to 942 in 2018. The percentage closed was 62%, compared to 79% in 2018. Associated with IRs and Complaints, the IBTS undertook 300 product recalls in 2019. This compares to 312 product recalls in 2018.

As in previous years, the majority of these recalls are a result of post-donation notification of illnesses by donors. 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 implementing it. In 2019, 399 change controls were raised, of which 48 were temporary changes. This compares to 385 change controls and 64 temporary changes raised in 2018. In addition, 363 Change Orders, which are used to update documents where no significant process change is required, were raised in 2019, with a close out rate of 80%. This compares to 406 change orders raised in 2018, with a close out rate of 81%.

The IBTS monitors and reports Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs) to the National Hemovigilance Office (NHO). During Q1 & Q2 2019 there were 27 Serious Adverse Events (SAEs) and 1 Serious Adverse Reaction (SARs) accepted by the NHO from the IBTS. At the time of this report, Q3 and Q4 reports for 2019 were being compiled. Both the Complaint and IR systems are continually analysed throughout the year to ensure SAEs and SARs are captured. The majority of SAEs reported by the IBTS for this period were due to testing, issue and distribution errors.

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 implementing it. In 2018, 385 change controls were raised, with 50% being closed out. This compares to 593 change controls raised in 2017, with 53% being closed out at the end of that year. In addition, 406 Change Orders, which are used to update documents where no significant process change is required, were raised in 2018, with a close out rate of 81%. This compares to 538 change orders raised in 2017, with a close out rate of 78%.

# Human Resources



## Human Resources

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### Building a High Performance Organisation

The IBTS mission is to meet the transfusion needs of patients, through the professionalism of our staff and the generosity of our donors and the IBTS strategic plan 2017-2020 has committed to sustaining, growing and developing the service and people. We have embarked on significant transformation programmes across the organisation which have been driven in part by workforce development needs and changing expectations, technological advances and the 'war for talent'. All of these factors have contributed to a continued focus on people and building a high performance organisation.

Our HR department continues to transform and enable the growth of people and the service. This is achieved through the provision of strategic and operational support to the business via our Human Resources, Environmental, Health and Safety, Learning and Development and specialist Library services.

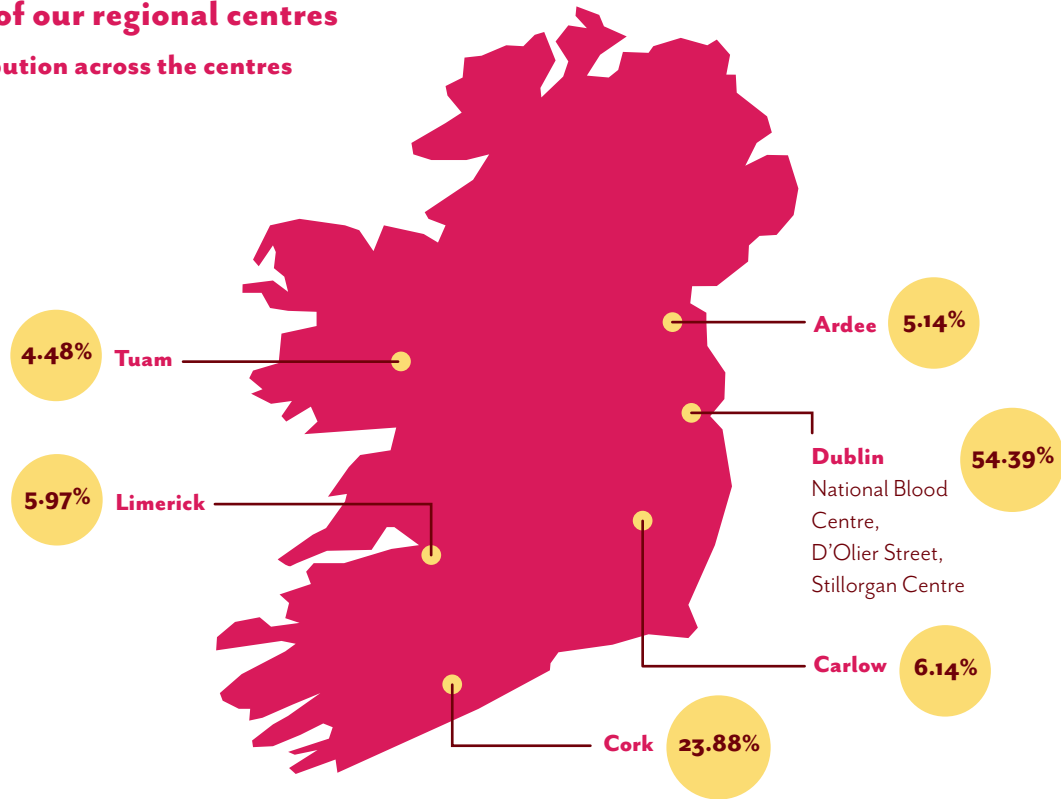
### Environmental, Health and Safety

As outlined in the Strategy 2017 – 2020, our aim is to “Embed Environmental Health & safety in the organisation”. With this at the core, EHS continued the development and implementation of an Occupational Health and Safety (OHS) Software System and successfully delivered on incident, risk and document control modules across the organisation. Delivery was supported by a number of staff/departmental training and support sessions.

The culture we aspire to is one where EHS becomes part of the day to day role of all within the organisation. With this in mind, the IBTS launched the 'Making Safety Visible' campaign in quarter 1, 2019 in Dublin and Cork centres with a view to evaluating its success and rolling the campaign out nationally. The main aim of the campaign was to promote a positive safety culture and encourage all departments and employees to report both safe and unsafe conditions/acts and to make safety visible within their own department/team. This was instigated through the introduction of a Good Catch/Safety Observation reporting programme with a view to empowering IBTS staff and others to take responsibility for identifying and addressing issues within their department and the broader working environment. In 2020 we will evaluate the success of this campaign and seek to build on it.

## Location of our regional centres

### Staff distribution across the centres



## Learning and Development

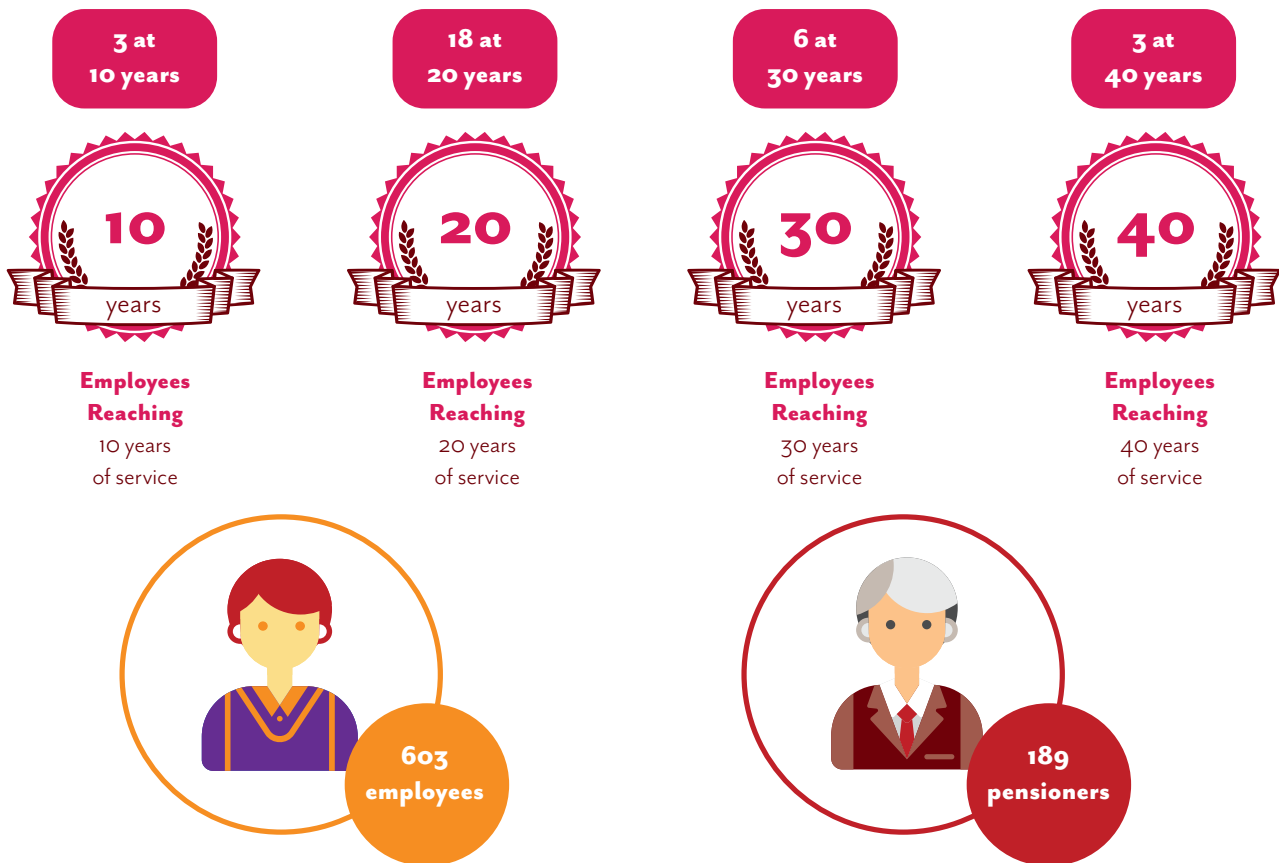
The implementation of our first dedicated L&D strategy 'Working, Learning & Growing together' 2017 – 2020 has achieved further strategic success across the organisation. We have continued to build a collaborative learning culture that develops the necessary expertise, supports growth opportunities and offers more innovative delivery methodologies for all staff.

The development of our leadership and management capabilities were a critical focus of our L&D efforts this year. We partnered with Dr Nuala Ryan from University of Limerick, adopted an evidenced based approach to programme design and development and launched LEAD (Leadership Education And Development). We know that leaders are formed as opposed to developed. Therefore the aim of this innovative framework is to develop support structures that allow leaders to emerge and form throughout all levels in the organisation. 16 learners commenced iLead at the end of 2019. We also designed our coaching framework and associated policy with the goal of supporting development around new competencies, qualities and ways of being as leaders and team members delivered through the establishment of our first external coaching panel.

Key investments were made in building change management, human resource and people management capabilities with 70 learners participating across all of our leadership and management initiatives. The investment in our people through L&D is on the rise with a total of 145 courses held incorporating orientation, mandatory and non-mandatory training.

1715 people attended training, with an average of 3 training attendances per person, and an average of 12 attendees per course. We also embarked on a collaborative review and revision of our Corporate Orientation Programme (COP) to enhance the employee experience to ensure that new recruits have the necessary skills and knowledge to kick start their career with IBTS.

Our commitment to progress in Performance Development (PD) has seen the completion of the second cycle of our employee led PD which was enabled by the successful implementation of technology (Talentev) to create a more efficient online experience for everyone. Training pathway development for all roles has been achieved by adopting a partnership approach with our key stakeholders and is 80% complete.



Finally, cultural development saw the establishment of our Values Team. This cross functional team diagnosed the current state of our core values and developed a 3 year plan to be implemented in three phases; Build Awareness, Embed our Values and Live our Values, which will commence early in 2020. Our learning culture has been enhanced with the introduction of volunteer learning champions across all areas of the IBTS. This has contributed to increased collaboration and the development of more innovative training and learning solutions to meet the ever changing needs of staff and the service.

### Human Resources Management

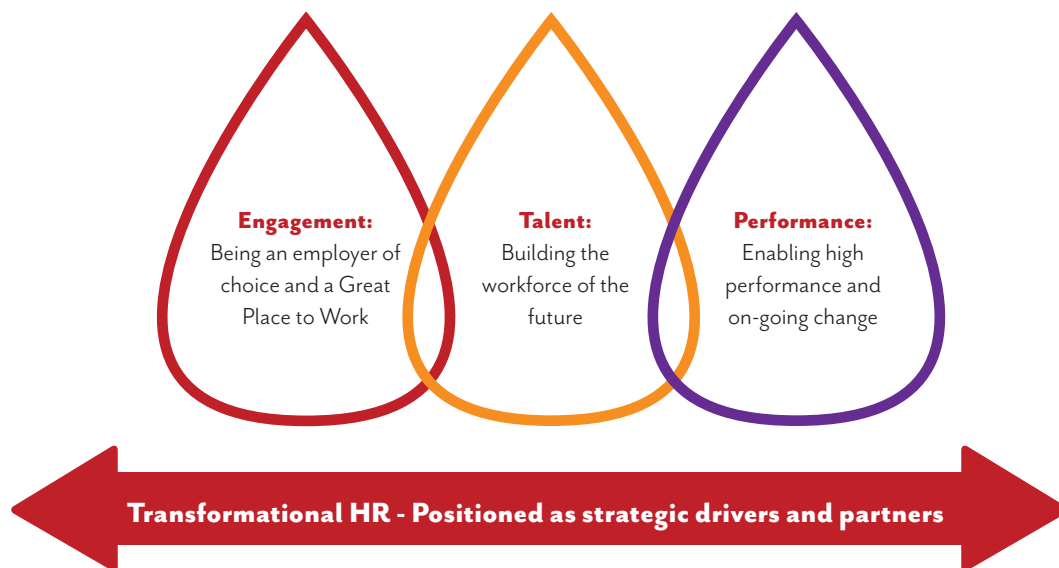
The Human Resources Management (HRM) team in the IBTS provides a range of programmes and services, as well as qualified and expert advice and guidance on a multitude of staff employment situations. The team provides organisation-wide support to employees throughout their employment life-cycle. This support starts at the hiring process, continues throughout employment and goes into retirement. At the close of 2019 the IBTS had 603 employees (525.65 full time equivalents) and 189 retired staff receiving pensions.

While the HRM team works from the Dublin-based National Blood Centre, employees are nationwide and situated in six locations.

The IBTS community of employees has a diverse range of specialities that support and drive the organisation’s mission and strategic objectives. Attracting, hiring, and retaining the best talent is important for current operations but also for the development and growth of the IBTS. The number of recruitment campaigns posted in 2019 was 119, resulting in 105 new hires, an increase in recruitment activity of 23.5% on the previous year. There were 82 leavers in 2019, representing 13.6% of the employee population.

The IBTS employs people at all stages of their careers and while the average age of an IBTS employee is 47 years, 12 people retired in 2019, which represents 2.3% of the employee population.

Employees are recognised by service milestones with either, 10, 20, 30 or 40 years of service recognised formally by the Chief Executive. Special congratulations were extended this year to one employee in recognition of their 50 years of service.



## Transformational HR

During 2019 the HRM team continued to focus on our strategic themes of: Employee Engagement, Managing Talent and Enabling Performance, through Transformational HR.

- A key outcome within the Employee Engagement theme was the collaboration between the IBTS HR team and the IBTS Marketing team in the redevelopment of our LinkedIn page, which saw an increase in traffic to our vacancy advertising by 55%.
- A key outcome within the Managing Talent theme was the re-versioning of job descriptions.
- A key outcome within the Enabling Performance theme was the review of HRM processes with a view to making them LEAN© and more agile and responsive to service needs.
- A key outcome within the Transformational HR theme was the successful upgrade of the HR IT/IS system, which will enable the department to further automate current processes and also provide self-service functions through Manager and Employee portals.

# Finance

Draft Summary Accounts for the year ended 31st December 2019		
	2019 €'000	2018 €'000
<b>Income</b>		
Recurring income	67,450	66,430
Non-recurring income	1,613	1,463
<b>Total income</b>	<b>69,063</b>	<b>67,893</b>
<b>Expenditure</b>		
<b>Total expenditure</b>	<b>67,520</b>	<b>70,572</b>
Surplus / (Deficit) for year	1,543	(2,679)
Actuarial gain / (loss) on pension schemes	(6,878)	1,926
Transfer to Capital Reserves	(2,009)	(9)
Transfer to Research Reserve	(481)	(155)
Accumulated Deficit at 1st January	(56,149)	(55,232)
Accumulated Deficit at 31st December	(63,974)	(56,149)

## Income

The Board's total income for 2019 of €69.1 million (2018 €67.9 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 €67.45 million (2018 €66.43 million). Non-recurring income of €1.6 million (2018 €1.46 million) includes a grant from the Department of Health in respect of HEV testing and deferred funding for the single public service pension scheme. The increase in recurring income represents increased volumes in 2019 for Platelets.

## Expenditure

Expenditure for 2019 amounted to €67.5 million (2018 €70.6 million).

The decrease in expenditure is due to a fall in depreciation costs, along with legal and financial expenditure.

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 2019 was €10.60 million.

At the 31st December 2019 the balance of research funds was €2.3 million. (2018 €1.8 million).

## Capital Expenditure

The Board invested €3.1 million in capital projects and equipment during 2019 (€1.0 million 2018).

The main capital investments during the year were new infrastructure hardware for the blood bank computer system and also additional licence costs along with the fit out of a new premises in Tuam.

## 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 2019, under the terms of applicable legislation, invoices to the value of €441,852 were late, by an average of 20.75 days. These invoices constituted 1.9% by number and 1.08% 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 €14,406.

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

# Contact details

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## 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  
D08 NH5R  
t: 01/4322800  
e:contactus@ibts.ie

[www.giveblood.ie](http://www.giveblood.ie) Donor infoline 1850731137  
[www.facebook.com/giveblood](https://www.facebook.com/giveblood)  
[www.twitter.com/giveblood.ie](https://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  
H54P229



## Irish Blood Transfusion Service

Seirbhís Fuilaeistriúcháin na hÉireann

### **National Blood Centre**

James's Street, Dublin 8.

**Tel:** 00 353 1 4322800

**Fax:** 00 353 1 4322930

**Email:** [contactus@ibts.ie](mailto:contactus@ibts.ie)

[www.facebook.com/giveblood](http://www.facebook.com/giveblood)

[www.twitter.com/giveblood.ie](http://www.twitter.com/giveblood.ie)

[www.giveblood.ie](http://www.giveblood.ie)

Donor Infoline 1850 731 137