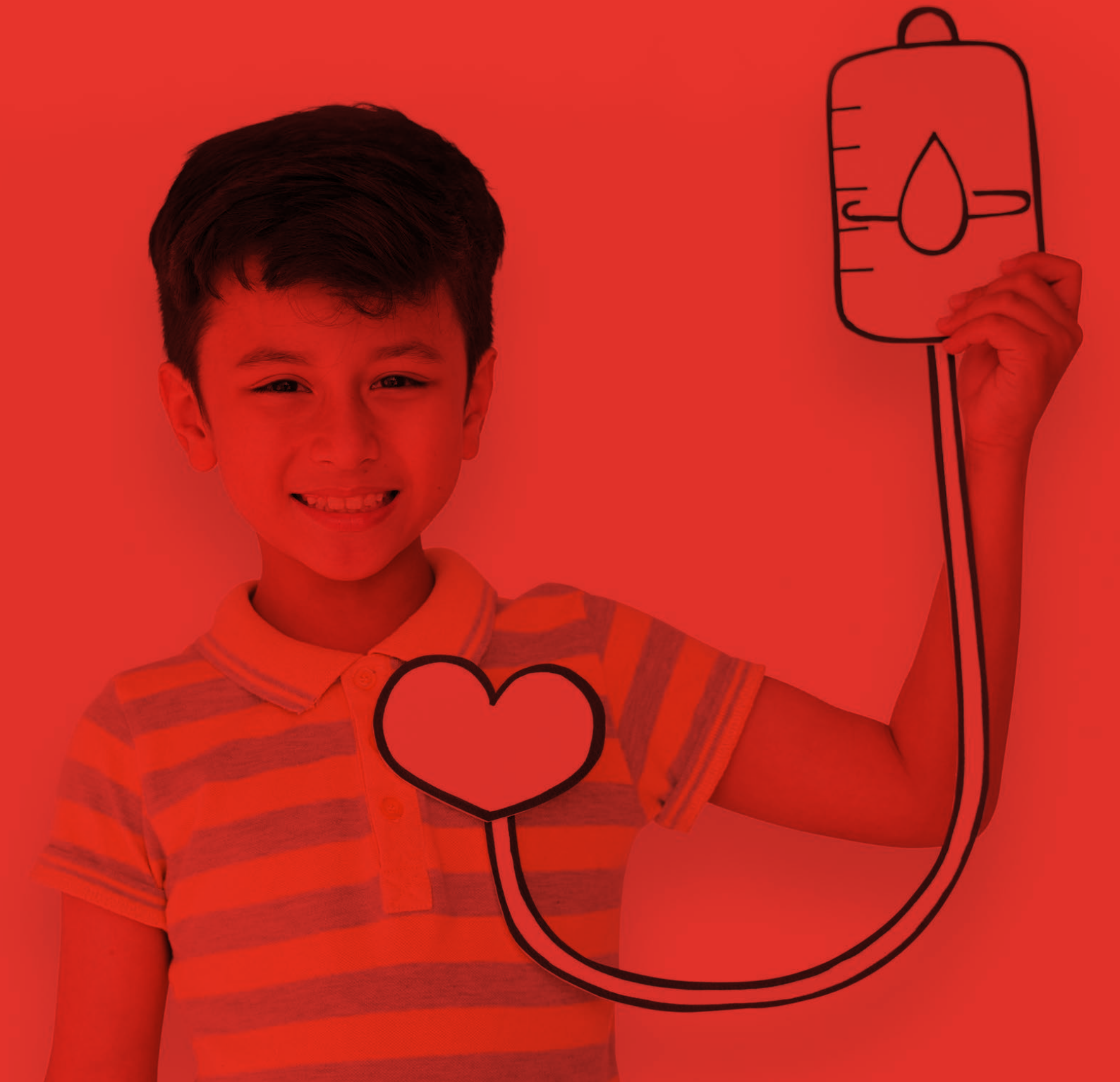
Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Annual Report
2017



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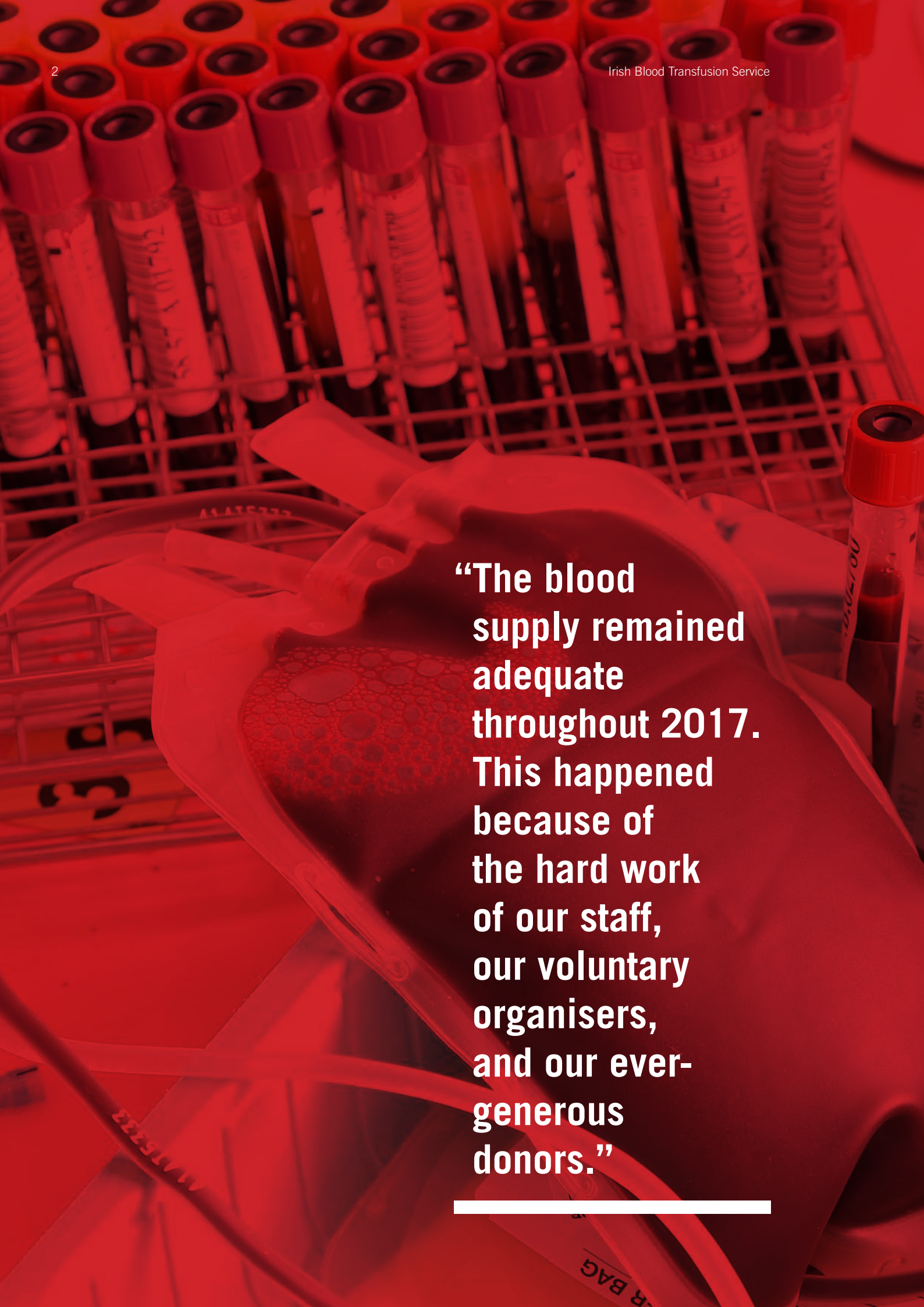


“The blood supply remained adequate throughout 2017. This happened because of the hard work of our staff, our voluntary organisers, and our ever-generous donors.”

Foreword

The IBTS, unlike many public sector bodies, has a single core task, expressed in our vision 'Our service delivers excellent, safe, secure and reliable blood transfusion services, and human tissue services, to the people of Ireland'. Delivering this is the mission of the organisation, but we have to deliver, while achieving excellence in meeting patients' needs. Our key resources to do this are the professionalism of our staff and the generosity of our donors.

This depends on the choreography of a supply chain running from our donors, who live in every parish in Ireland; our local voluntary organisers, who advertise our clinics, and mobilise our donors, our collection teams, who work in parish halls, hotels, sports facilities, and offices across the country; our processing, testing, and dispatch staff in Dublin, who receive every donation, test it to ensure patient safety, and dispatch the right unit to the right place, thousands of times each week; hospital blood bank and nursing staff, who deliver the blood, and give it to those who need it; our quality, safety, and haemovigilance teams, who monitor the process 'from vein to vein', and identify problems; our medical team; who advise colleagues, monitor safety, make decisions on donations, and lead Irish transfusion practice; our donor services and marketing teams, who manage our donors, and recruit new ones; and our administration and management teams, who keep us solvent, running, and open. All this is easier to describe, than to do.

In 2017, our blood supply was more stable than in 2016. We did not need to make a special call for donors. The blood supply remained adequate throughout 2017. This happened because of the hard work of our staff, our voluntary organisers, and our ever-generous donors. It also reflects, I believe, the success of our new marketing strategy, which is intended to encourage more young people to become donors, and to raise our profile on social media. Storm Ophelia, affected us significantly, and we activated our internal emergency plan. We had to be very mindful of the safety of our staff, and of our donors. Thanks to good planning, and high blood stocks, our operations were not significantly affected.

After several years of hard work, and considerable redesign of our own systems, we have expanded our program to offer routine therapeutic venesection for people with stable haemochromatosis, and to recruit people with this common genetic condition to our donor pool. Dr. Stephen Field, our Medical and Scientific Director, continues to make this project a high priority, and our intent is to make it available country wide during 2018.

The IBTS is looking to the future too. We are moving steadily to having a bigger role in stem cell therapy. Our limbal cell transplant scheme, run with the Eye and Ear Hospital, is now well established, and we expect to expand work in this area over the next few years. We are making more and more use of the most modern genotyping equipment, to offer a new service to maternity hospitals. We are reaching out to the new Irish, working with communities of recent migrants, to become blood donors, in part so that we can better meet the specific blood type needs of those communities. Following on from our revision of deferral rules for men who have sex with men, we have started a wider and more systematic review of our rules for deferral, to ensure that they remain

Foreword

fit for purpose, and based on updated formal risk assessments.

We faced one very challenging incident in 2017. We were notified that a donor had developed Hepatitis B, some time after donating. Unfortunately, one patient was infected with Hepatitis B by a donation. The clinicians treating the patient were informed immediately we became aware of this and the patient informed and commenced on appropriate treatment. We also informed our regulator. An extensive investigation, which has now been published in Vox Sanguinis, showed that this transmission was a 'window period' infection. Although we use the best tests for viral infections available, there is a short period between the infection, and the point at which there is enough virus in the donor's blood, for our test to detect it. This donation was taken during this time, well before the donor developed any symptoms. I have had the privilege of chairing the Board of the IBTS for the last six years. I will step down in July 2018. I want to thank three successive Ministers for Health James Reilly, Leo Vardakar, and Simon Harris, for putting their trust in me, and Mary Jackson and Michael Conroy, our civil service liaisons, for supporting us so well. I want to pay tribute to our donors and volunteers, without whom we would not exist; to our hard-working and dedicated staff, who have worked through good times, and bad, to ensure Ireland has a safe, and secure blood supply; to our senior management team, and especially our CE Andy Kelly, who have taught me so much; and to all my colleagues on the Board over the last six years, with whom I have faced the challenges, and the joys of Irish blood transfusion. It has been an honour to lead this remarkable organisation.

Prof Anthony Staines
Chairperson

Chairperson's Report

Report of the Chairperson of the Irish Blood Transfusion Service regarding the assessment of internal financial controls of a State body for the year ended 31st December 2017 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 financial 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 which is a sub-committee of the Board carried out a formal review of these systems in respect of 2017 at its meeting on the 24th January 2018.

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. These were reviewed in 2017. Terms of reference of all sub-committees of the Board were reviewed by the Board in 2017.

The Board has adopted a detailed travel and subsistence policy which complies with all aspects of Government travel policy.

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

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

Corporate Governance

The Board of the Irish Blood Transfusion Service was established under The Blood Transfusion Service Board (Establishment) Order, S.I.78/1965. The functions of the Board are set out in section four of this Act. The Board is accountable to the Minister for Health and is responsible for ensuring good governance and performs this task by setting strategic objectives and targets and taking strategic decisions on all key business issues. The regular day-to-day management, control and direction of the Irish Blood Transfusion Service are the responsibility of the Chief Executive (CE) and the senior management team. The CE and the Executive Management Team must follow the broad strategic direction set by the Board, and must ensure that all Board members have a clear understanding of the key activities and decisions related to the entity, and of any significant risks likely to arise. The CE acts as a direct liaison between the Board and management of the Irish Blood Transfusion Service.

The Board has a manual for Board members. The Board has reviewed its governance and compliance arrangements in 2017 against the Code of Practice for the Governance of State Bodies as published by the Department of Public Expenditure and Reform in August 2016 and amended those arrangements accordingly.

Chairperson's Report

Board Responsibilities

The work and responsibilities of the Board are set out in The Blood Transfusion Service Board (Establishment) Order, S.I.78/1965. Matters specifically reserved for Board decision are contained in the Board manual. Standing items considered by the Board include:

- declaration of interests,
- Chief Executive Report
- reports and minutes from Board sub-committees,
- performance reports, and
- reserved matters.

Section 20 of the S.I. 78/1965 requires the Board of the Irish Blood Transfusion Service to keep, in such form as may be approved by the Minister for Health with consent of the Minister for Public Expenditure and Reform, all proper and usual accounts of money received and expended by it.

In preparing these financial statements, the Board of the Irish Blood Transfusion Service is required to:

- select suitable accounting policies and apply them consistently,
- make judgements and estimates that are reasonable and prudent,
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that it will continue in operation, and
- state whether applicable accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements.

The Board is responsible for keeping adequate accounting records which disclose, with reasonable accuracy at any time, its financial position and enables it to ensure that the financial statements comply with section 20 of the S.I 78/1965.

The Board is responsible for approving the annual plan and budget. An evaluation of the performance of the Irish Blood Transfusion Service by reference to the annual plan was carried at the Board meeting on February 13th 2017 and against budget was carried out on the 12th June 2017. The Board also complies with guidelines on the payment of director's fees. The Chief Executive's salary in 2017 was €151,615.

The Board is also responsible for safeguarding its assets and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The Board considers that the financial statements of Irish Blood Transfusion Service give a true and fair view of the financial performance and the financial position of Irish Blood Transfusion Service at 31 December 2017.

Board Structure

The Board consists of a Chairperson and eleven ordinary members, all of whom are appointed by the Minister for Health. The members of the Board are appointed for a period of three years and are scheduled to meet six times per year and as required. The table below details the appointment period for current members:

Board Member	Role	Date Appointed
Prof. Anthony Staines Chairperson	Chairperson	1st June 2012
Mr B O'Mahony	Ordinary Member	11th June 2012
Ms L Hickey	Ordinary Member	14th February 2013
Dr J Heslin	Ordinary Member	21st May 2014 Term Expired 31st May 2017
Dr E Kenny	Ordinary Member	21st May 2014
Ms K Williams	Ordinary Member	21st May 2014
Dr J Georgsen	Ordinary Member	1st June 2014 Term Expired 31st May 2017
Dr R Desmond	Ordinary Member	20th July 2015
Ms D Cullivan	Ordinary Member	20th July 2015
Dr Y Traynor	Ordinary Member	20th July 2015
Mr J Malone	Ordinary Member	20th July 2015
Mr S Mills	Ordinary Member	20th July 2015
Dr S Pastila	Ordinary Member	7th June 2017

The Board has established four committees, as follows:

1. Medical Advisory Committee: comprises all medical Board appointees and IBTS Consultant staff and advises the Board on medical related matters such as virus surveillance, emerging infections and deferral policies. The Medical Advisory Committee is Chaired by Dr. Elizabeth Kenny and met ten times in 2017.

2. Audit, Risk and Compliance Committee: comprises three Board members and two independent members. The role of the Audit, Risk and Compliance Committee (ARCC) is to support the Board in relation to its responsibilities for issues of risk, control and governance and associated assurance. The ARCC is independent from the financial management of the organisation. In particular the Committee ensures that the internal control systems including audit activities are monitored actively and independently. The ARCC reports to the Board after each meeting, and formally in writing annually.

   The members of the Audit, Risk and Compliance Committee are: Dr Yvonne Traynor

Chairperson's Report

(Chairperson), Mr John Malone and Mr Simon Mills. There were four meetings of the Audit, Risk and Compliance Committee in 2017.

3. Finance Committee: comprises three Board members. The role of the Finance Committee is to assist the Board in its governance role with regard to financial matters including maintenance of proper books of account, preparation of annual accounts and budget, submission of annual accounts for audit and the presentation of audited accounts to the Minister for Health. The members of this committee are: Ms Linda Hickey (Chairperson), Ms Kate Williams and Ms Deirdre Cullivan. There were five meetings of the Finance Committee in 2017.

4. Performance Development Committee: comprises two Board members. The role of the Performance Development Committee is to support the Board in evaluating the performance of the Chief Executive and delivering the training and development strategy and performance development. The members of this committee are: Professor Anthony Staines (Chairperson), Ms Kate Williams. There were two meetings of the Performance Development Committee in 2017.

Schedule of Attendance, Fees and Expenses

A schedule of attendance at the Board and Committee meetings for 2017 is set out below including the fees and expenses received by each member:

	Board	Medical Advisory Committee	Audit, Risk & Compliance Committee	Finance Committee	Performance Development Committee	Board Fees 2017 €	Expenses 2017 €
Number of Meetings	**8**	**10**	**4**	**5**	**2**		
Prof. Anthony Staines (Chairperson)	8				2	-	848
Mr B O'Mahony	4					-	-
Ms L Hickey	7			3		11,970	-
Dr J Heslin	2*	5				-	187
Dr E Kenny	7	10				-	721
Ms K Williams	6			3	2	11,970	180
Dr J Georgsen	2*	3*				4,988	1,689
Dr R Desmond	6	6				-	183
Ms D Cullivan	8			5		11,970	1,324
Dr Y Traynor	4		4			11,970	-
Mr J Malone	8		4			11,970	257
Mr S Mills	3		3			11,970	-
Dr S Pastila	4**	4**				5,985	2,022

* Board term finished 31st May 2017

** Board term commenced 7th June 2017

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

Chairperson's Report

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.

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. After evaluation by the Board of the pension scheme asset valuations, the current funding plan including agreed changes to scheme benefits, the scheme actuaries revised recommended funding rate and the Board's projected cash flows for the twelve months from the date of approval of the financial statements, the Board is satisfied that the organisation has sufficient reserves to allow the preparation of the financial statements on a going concern basis.

Statement on Internal Control

Scope of Responsibility

On behalf of the Board of the IBTS I acknowledge the Board's responsibility for ensuring that an effective system of internal control is maintained and operated. This responsibility takes account of the requirements of the Code of Practice for the Governance of State Bodies (2016).

Purpose of the System of Internal Control

The system of internal control is designed to manage risk to a tolerable level rather than to eliminate it. The system can therefore only provide reasonable and not absolute assurance that assets are safeguarded, transactions authorised, and properly recorded and that material errors or irregularities are either prevented or detected in a timely way.

The system of internal control, which accords with guidance issued by the Department of Public Expenditure and Reform has been in place in the IBTS for the year ended 31st December 2017 and up to the date of approval of the Financial Statements.

Capacity to Handle Risk

The IBTS has established an internal audit function which is adequately resourced and conducts a programme of work agreed with the Audit, Risk and Compliance Committee.

The Audit, Risk and Compliance Committee has developed a risk management framework, the risk management processes in place and details the roles and responsibilities of staff in relation to risk. The framework sets out the role responsible for each risk, the review process in place to alert management on emerging risks and control weaknesses and the role with the assumed responsibility for risks and controls within their own area of work.

Risk and Control Framework

The IBTS has implemented a risk management system which identifies and reports key risks facing the IBTS and these have been identified, evaluated and graded according to their significance. The risk register identifies various types of risks including strategic, reputational, clinical, IT, financial and operational risks to the organisation and the existing controls and further actions necessary to minimise the impact on the organisation, in the event of the risk occurring. The register is reviewed and updated by the Executive Management Team on a quarterly basis and reviewed at the Audit, Risk and Compliance Committee meetings where an update on risk management and the risk register is provided by the Risk and Resilience Manager. The outcome of these assessments is used to plan and allocate resources to ensure risks are managed to an acceptable level.

The risk register details the controls and actions needed to mitigate risks and responsibility for operation of controls assigned to specific staff. I confirm that a control environment containing the following elements is in place:

- procedures for all key business processes have been documented,
- financial responsibilities have been assigned at management level with corresponding accountability,
- there is an appropriate budgeting system with an annual budget which is kept under review by senior management,
- there are systems aimed at ensuring the security of the information and communication technology systems,
- there are systems in place to safeguard the assets, and
- control procedures over grant funding to outside agencies ensure adequate control over approval of grants and monitoring and review of grantees to ensure grant funding has been applied for the purpose intended.

Ongoing Monitoring and Review

Formal procedures have been established for monitoring control processes and control deficiencies are communicated to those responsible for taking corrective action and to the Executive Management and the Board, where relevant, in a timely way.
I confirm that the following ongoing monitoring systems are in place:

- key risks and related controls have been identified and processes have been put in place to monitor the operation of those key controls and report any identified deficiencies,
- reporting arrangements have been established at all levels where responsibility for financial management has been assigned, and
- there are regular reviews by senior management of periodic and annual performance and financial reports which indicate performance against budgets.

I confirm that the IBTS has procedures in place to ensure compliance with current procurement rules and guidelines. Matters arising regarding controls over procurement are highlighted under internal control issues below.

Chairperson's Report

Review of Effectiveness

I confirm that the IBTS has procedures to monitor the effectiveness of its risk management and control procedures. The IBTS monitoring and review of the effectiveness of the system of internal financial control is informed by the work of the internal and external auditors, the Audit, Risk and Compliance Committee which oversees their work, and the senior management within the IBTS responsible for the development and maintenance of the internal financial control framework.

I confirm that the Board conducted an annual review of the effectiveness of the internal controls for 2017.

Internal Control Issues

Non-Compliant Procurement

In 2016 a HR consultancy was urgently appointed to carry out a formal investigation under our disciplinary and dignity at work procedures. Investigations of this nature are a routine part of employee relations. Such investigations normally cost less than the procurement requirement to tender amount threshold of 25K. At the point of entry into this investigation it was not contemplated that the investigation costs would exceed this threshold and accordingly an expert investigator was appointed on an urgent basis without a tender process. As the investigation progressed the complexity of the issues involved and the number of witnesses to be interviewed expanded considerably which had a consequential but unanticipated effect of costs. However, as the process was on-going it was impossible to discontinue the investigation already in train without taking unacceptable legal risk of High Court litigation from the numerous complainants, and the alleged perpetrator, and this would also have resulted in a duplication of some costs as the work completed would have had to be repeated.

In such circumstances and given the sensitivity of the matter the IBTS had no real option but to proceed with the investigation to conclusion, undesirable as the cost situation had become as to do otherwise would have totally undermined an independent investigation being undertaken into serious matters by an external consultant. These investigations require a very high standard on natural justice and experience of managing complex processes as well as the necessary independence of the investigator, any interference by the IBTS in the investigation once it had commenced would not find favour before the Courts. The total cost to date of the investigation amounted to €109,049 in 2017.

Expenditure was approved for the replacement of hand held scanners in order to address issues with the current scanners used on clinics. The company supplying the scanners with the correct firmware required is a sole supplier so it was agreed that a formal tender for the 100 replacement units required would not be held. The agreed price of this expenditure was €27,433 including VAT.

An online survey of donors and non donors was carried out during 2017. The organisation agreed to work with a recognised firm who had previously carried out work for the IBTS in this area and had the necessary experience and expertise of working with the various donor and non donor population groups targeted by the survey. This was building on

previous research work done by this company. The expenditure for the survey and report amounted to €32,134 including VAT.

The Financial Statements for the year ended 31st December 2017 have been prepared under FRS102.

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 2017.

Commercially significant developments

Nil.

Professor Anthony Staines
Chairperson

“We must continue to innovate and to bring new ideas to our work in the interests of the patients and donors whom we serve.”

Chief Executive's Report

The IBTS continues to supply blood, platelets, tissue and blood products to patients in Ireland within very high standards of quality. What is emerging is that like many developed countries we have difficulty in maintaining a consistent supply to hospitals. Consequently, our marketing and advertising must become more targeted and across many platforms.

We have very high deferral rates especially in haemoglobin and this has resulted in shortages in certain blood groups during the course of the year. We have particular difficulty in maintaining supply of O negative blood. There are some hospitals who are using this group inappropriately and we will have to manage this group more actively during 2018 and take whatever steps are necessary to protect our O negative donors. We launched a new creative campaign during 2017 called *Every One Counts* based on the principle of a few telling the many. This was designed for social media and we had a very good response to this campaign. It also dovetailed with the implementation of a new website. We also ran the international campaign *Missing Type* and this with the new creative campaign resulted in IBTS having a much more visible presence on digital platforms. While social media has seen very positive results we must also become more visible in other spaces to attract other donors who are not active on social media.

For the first time in a number of years we saw an increase in the use of blood and platelets which was unexpected. This was mainly due to increased transfusion to sickle cell patients and increased activity in oncology and haematology cases.

We carried out a Staff Survey in 2015 under the Great Place to Work banner. Arising from this we have worked with staff representatives known as the *Staff Matters Team* to develop a set of responses and actions with associated timelines to address the key issues raised through the survey. This action plan was published at the end of 2017 and will be implemented. We are committed to holding another survey in Quarter 4 2018.

The Strategic Plan 2017 – 2020 was approved by the Board and Minister in 2017 and was presented to staff across the organisation. The Plan will be operationalized within each area. It is vitally important that implementation is monitored closely to ensure that the momentum for change which became evident through the planning sessions is not lost. We will have a Strategy Review in mid 2018.

The IBTS implemented changes to the MSM criteria for donating in January 2017. This was a major change to our donation criteria and brought the IBTS in line with most international blood services. We will monitor the change to see what the impact on the deferrals might be and on the blood supply. Interestingly when we made the change we had a significant number of complaints from donors who are deferred because of vCJD and residence in the UK. The Medical and Scientific Director is committed to reviewing this criterion in 2018.

Risk management is a very topical subject across business. The IBTS carried out a lot of work during the year refining the risk policy, the framework for managing risk and cleaning up the risk register. It was also reviewed by the EMT, Audit, Risk and

Chief Executive's Report

Compliance Committee and the Board. We also carried out a desk top exercise on the Business Continuity Plan to find out if it worked as written. The exercise was very worthwhile and we discovered a number of issues that needed to be addressed and were addressed by year end. We appointed a new Risk and Resilience Manager towards the end of the year who will bring a lot of experience to this area.

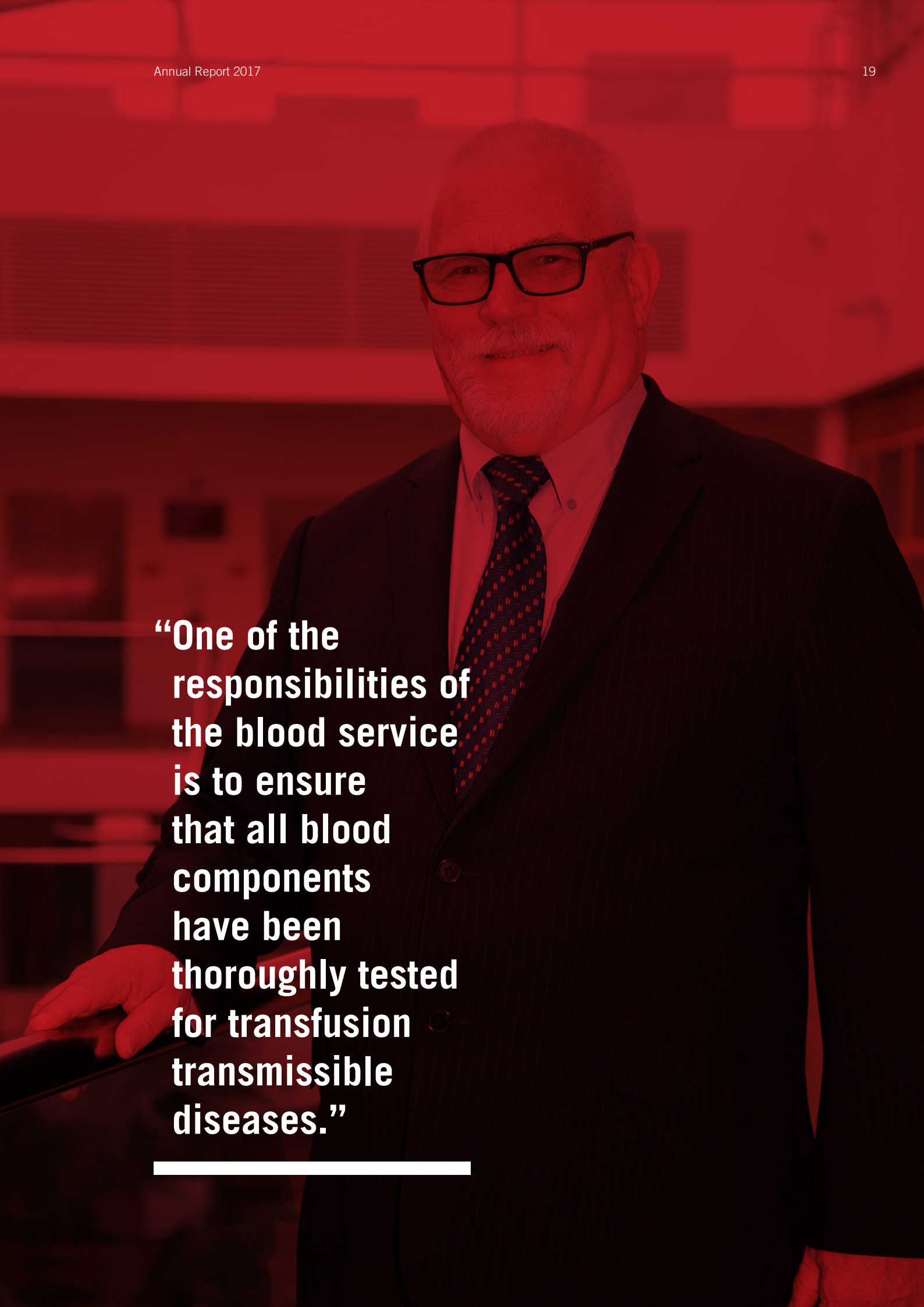
The Board decided to amend the plans for the new Centre in Cork. This would see the IBTS build the new Centre on the current site and if possible support the development of an integrated red cell immunahaemotology and reference serology laboratory on the campus of the major hospital in Cork. It is imperative that this solution which provides the best outcome for both parties is delivered as soon as possible.

There were a number of changes to key personnel in 2017. In January 2017 the Consultant responsible for testing retired after many years of dedicated service. She had a very high international standing with her peers which was invaluable to IBTS. There were a number of other key staff members retired who had a vast amount of experience and knowledge and had a broad network of peers in Ireland and internationally. I thank them most sincerely for their commitment, dedication and professionalism during their time with IBTS and wish them well for the future.

We welcomed Dr Stephen Field as the new Medical and Scientific Director. He brings many years of experience in blood transfusion and has shown clinical leadership across all areas since his arrival.

The IBTS is a people driven organisation and cannot operate without the dedication and professionalism of all staff. I would like to express my sincere appreciation to all staff who through their efforts ensured that we continue to supply blood and blood products to the highest standard. We must continue to innovate and to bring new ideas to our work in the interests of the patients and donors whom we serve.

Yours sincerely,
Andrew Kelly
Chief Executive



“One of the responsibilities of the blood service is to ensure that all blood components have been thoroughly tested for transfusion transmissible diseases.”

Medical and Scientific Director's Report

One of the responsibilities of the blood service is to ensure that all blood components have been thoroughly tested for transfusion transmissible diseases. To this end the IBTS does both molecular DNA/RNA testing (nucleic acid testing otherwise known as NAT) and test for the detection of antibodies or antigens (serology). This combination of techniques ensures that there is a very high sensitivity of detection for the viruses HIV, Hepatitis B,C and E. Despite this testing regime there is still a theoretical chance of infection being transmitted in the very early phase of donor infection otherwise known as the window period. This risk has been estimated to be one and 2 million donations for hepatitis B and one in 43 million donations for hepatitis C.

Travel constitutes another risk for transmission of disease and these include the parasite that causes malaria, tropical viruses such as the Zika, Chikungunya and Dengue. There have been recent epidemics of haemorrhagic fever such as Ebola Virus in Africa. Travel history is therefore important and donors that have been in affected areas are deferred for a period of time to exclude the possibility of transmission of any of these diseases. The one exception is West Nile virus which is prevalent in the United States and other countries during the summer months. Donors that have travelled to these countries are selectively tested using NAT. A subcommittee of medical consultants meets regularly to assess any global infectious diseases threats to the blood supply that may be emerging.

In January 2017 the IBTS changed the rules for Men that have Sex with Men (MSM) from a permanent deferral to a one-year deferral from the time of the last MSM encounter. This is in keeping with the practice in many other countries and given the state of the art testing facilities is considered to be a safe practice. This will be reviewed in 2018.

In an effort to reduce the incidence of fainting, especially in young people, new rules were introduced to ensure that females under the age of 25 of a low blood volume were not selected for donation, this being calculated on the basis of their height and weight.

European regulations have made it mandatory for blood establishments to ensure that donor identity is verified by the examination of appropriate identification documents. IBTS will be introducing requirements for donors to produce such documents in 2018.

The immuno-haematology molecular laboratory has developed and validated this method for the extraction of fetal DNA from maternal serum and is now able to establish the Rh status of the unborn child thus making possible for those carrying Rh -negative babies to avoid the injection of prophylactic anti D immunoglobulin. It is hoped that this technique will be available to all maternity hospitals in 2018.

Stephen Field MA, MMed(Haem) FCPath (SA)
Medical and Scientific Director
Consultant Haematologist

Operations

Donor Services

#EveryOneCounts Campaign

IBTS launched the EveryOneCounts campaign in April 2017, the objective of the campaign was to educate and nudge donors from awareness to action throughout the year. This digital marketing campaign used 9 donor stories communicated via digital & social media; FB, Twitter, online advertising, Youtube, relevant social influencers, national radio ads, and online editorial on Independent.ie, TheJournal.ie, Her.ie, Joe.ie.

The campaign has been successful and has been received well by donors. All stories exceeded their targets in terms of reach and impressions. There has been steady growth in our social media channels throughout the year, our Facebook page now has 110k plus fans (from 60k at start of campaign), our Twitter page has 17.5k 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. We have had a high level of engagement on our social channels due to the emotive and inspiring stories from our Skerries donors, and this has in turn encouraged other people to share their own donor stories and promote the message and benefits of giving blood further.

New Schools Education Pack

A new School's Education Pack was created and sent out in October 2017 to over 700 secondary schools nationwide. The pack includes a 40 minute lesson plan, Blood Education DVD, and student blood facts quiz. A soft copy of the pack is also available to download on the new giveblood.ie website.
The launch of the School's pack was supported digitally with Every One Counts themed school's pack video content, featuring Pobalscoil Neasáin Principal, Pat McKenna, Teacher, Thérèse Glennon, and her senior cycle students talking about how they have become involved in giving blood and their aspiration to inspire other school's to also take action. Students from Pobalscoil Neasáin came into D'Olier street to donate blood as part of school spirit week and inspired other schools to do the same.

The video content was advertised on IBTS social media to help promote education about blood donation with teachers, students and their parents.

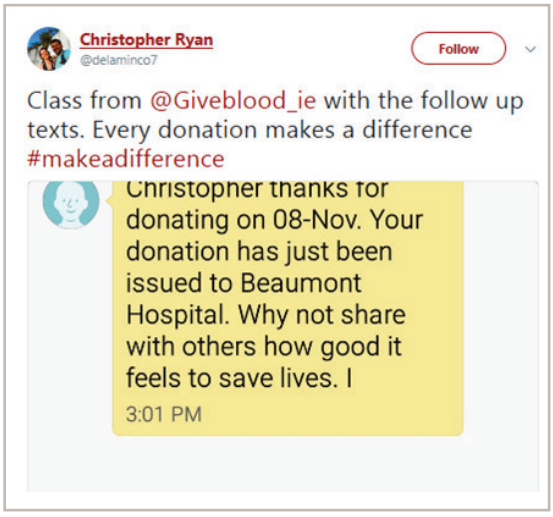
Donation Used Texts

IBTS were very pleased to announce the launch of blood donation used texts in February 2017. Donors now receive text messages after they have given

blood thanking them and also letting them know what hospital their donation was sent to. Over a quarter of a million issue texts were sent out in 2017. The texts have been very well received, with many donors frequently sharing their texts on social media and tagging Giveblood.ie, extending our reach and visibility online and inspiring others to go to their local clinic and receive their own issue text afterwards.

Website re-launch/Mobile Responsive

Due to the increasing change in behaviour of our donor base using their mobile phones as their primary information source, the IBTS website, Giveblood.ie, was re-launched in August 2017. The website was upgraded to make it mobile-responsive and improvements included the clinic finder application, so as to facilitate quicker and more efficient searches for donation information like clinic times, locations, blood donation eligibility, and general blood, platelet, bone marrow registry information.



Seasonal Campaign – #Wheresdrac

Bank holidays and school mid-term break periods are a challenging time of year for IBTS to ensure that we have a steady blood supply to keep up with the demand from hospitals as people go away on holidays and break their regular routine.

In the lead up to the October bank holiday and school mid-term break we ran a seasonal Halloween themed campaign in association with the National Wax Museum Plus called #Wheresdrac in order to remind and recruit donors. The campaign ran from Monday 23rd to Tuesday 31st October 2017 and was promoted on social media to target current fans of our page and recruit new followers.

The content featured pictures from 6 well known locations around Dublin: The National Wax Museum, Croke Park, Heuston Station, Penny's, Molly Malone and D'Olier St Blood Clinic. People were asked to guess #Wheresdrac each day and share the post to be in with a chance to win a family pass to the National Wax Museum Plus. The campaign linked back in to the clinic as on the last day of the competition Dracula was finally revealed to be in the D'Olier St Blood clinic.

Donor Services

We ran a native article on Joe.ie that followed up on the story behind our partnership with the National Wax Museum Plus. The article contained an interview with Laoise (the Wax Museum Marketing Manager) and her Dad, John, both donors themselves. The article told the story of John and how he reached his 94th donation before he had to stop due to illness, but he inspired his children to continue the tradition of giving blood!

The campaign drove strong results for awareness and engagement before and after the mid-term break as clinic attendance was strong throughout this period.

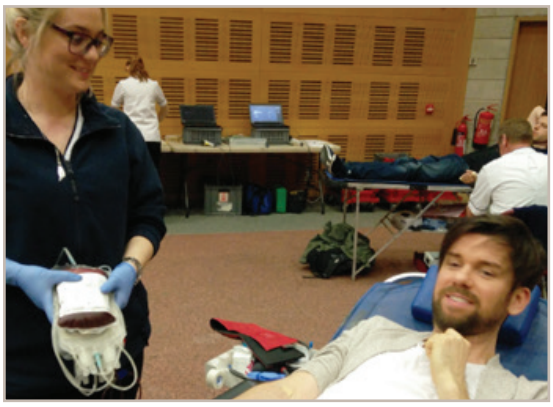
2FM Colleges Link Up

2FM and IBTS linked up to promote blood donation with the Eoghan McDermott radio show in the roadcaster outside the student clinic in UCD on the 6th November. Eoghan attended the UCD clinic and gave a donation, he documented the experience, including that of other donors and one of our nurses at the clinic and shared it with his listeners on the live show that afternoon. The show is broadcast nationwide and targets the younger demographic, helping IBTS to reach out to a younger profile of donors and spread the message about the importance of giving blood.

As part of the broadcast Eoghan interviewed Ex UCD student/donor Padraig & UCD student/ recipient Marianna who shared their own personal experiences and stories about the significance of giving and receiving blood in their lives. Eoghan & 2FM retweeted Giveblood tweets to their combined 320,000+ twitter followers and the show received a high level of engagement via text and WhatsApp during the broadcast. Total UCD clinic attendance was +8.24% and donations was +14.51%. The clinic attendance in the following weeks after the live radio show was also very good.

Blood For Life Week

IBTS ran Blood For Life week in June 2017 to raise awareness of the importance of blood donation. We supported World Blood Donor day on the 14th June with promoted posts on social media. The Dublin Fire Brigade and Joe Duffy also teamed up to help promote this year's theme highlighting the imperative use of blood in the treatment of recipients involved in emergency situations.



Missing Type 2017

Due to the popularity of #Missingtype campaign in 2016, IBTS ran the campaign for a second year with repeated levels of success during a traditionally challenging time of year for blood donation attendance in the month of August. The premise of the campaign was that by removing A,B and Os from brand names and signage, we were able to pose the question what would happen if there was no A, B or O blood group supplies available. With fantastic support from companies and organisations such as the GAA, Fáilte Ireland, Dublin Tourism, Tayto, Dundrum shopping centre, The Journal, Irish Rail and lots of other companies, we trended as the number 2 topic on social media on the launch day.

The campaign ran across online platforms, national radio stations and radio street teams, and was a great success in bringing our message to younger people in particular. It also gave donors a chance to let others know they gave blood by posting selfies with a selfie blood group board at canteens on our clinics.

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 coming back soon to give blood and platelets again! This year we ran a number of mini seasonal merchandise campaigns in addition to the regular items like pens and trolley key rings. Donors were delighted to find special giveblood.ie jelly bean treats in clinics across the country on St. Patrick's Day and again in the Summer.

We did a seasonal drop of Halloween themed 'pumpkin' oranges in October as eating vitamin C and iron rich foods can help with haemoglobin levels. In December we launched the #BlingUpYoBauble campaign. Giveblood.ie baubles were displayed on IBTS Christmas trees in clinic, adding some additional festive cheer to the clinic surroundings and donors were encouraged to take home a giveblood.ie bauble, personalise it and share their designs with us on our social media pages bringing the experience from the clinic to the donor's home.

Donor Award Ceremony

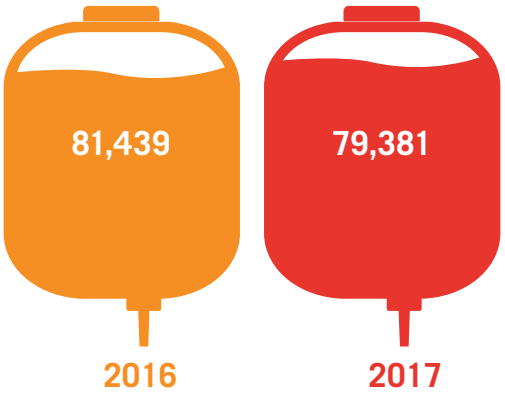
Donor awards ceremonies took place in Dublin, Carlow, Cork, Tuam and Ardee. A total of 536 donors received recognition for giving over 50 and 100 donations. These awards are an important part of the IBTS calendar year as it serves to recognise donors and their continued commitment to giving blood or 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 2017

	50 time donors	100 time donors	Ceremonies
Carlow	42	4	1
Ardee	78	7	1
Dublin	124	56	2
Cork	136	29	1
Tuam	49	11	1
Total	**429**	**107**	**6**

Donor Statistics

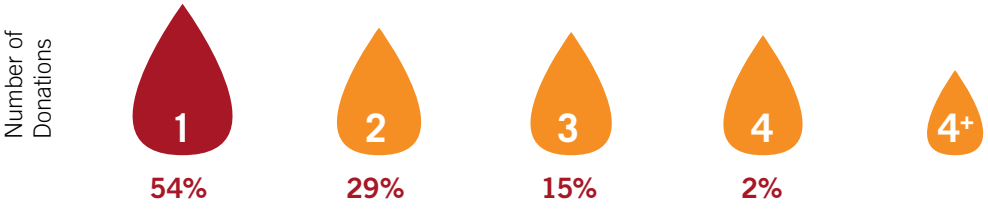
Donors 2016 vs. 2017



Number of whole blood donations 130,566

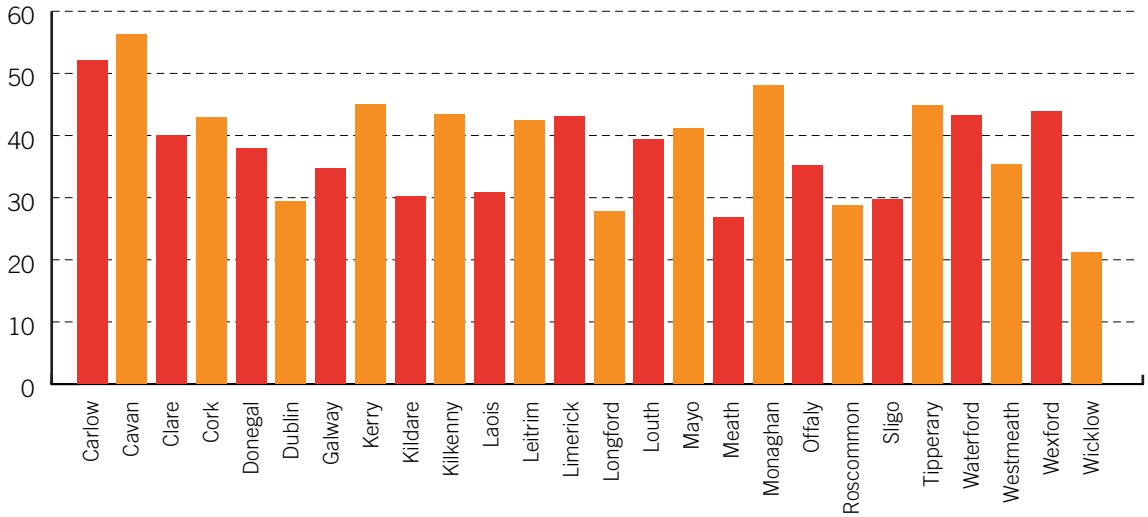
Number of donors who gave those donations 79,381

Whole Blood Donations by Donors 2017

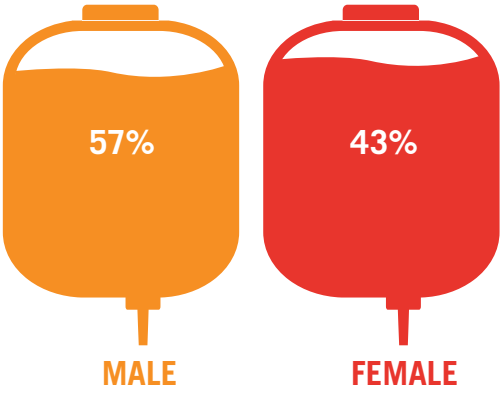


Number of Donors (Note: donors who gave 4+ times are on the HH panel)

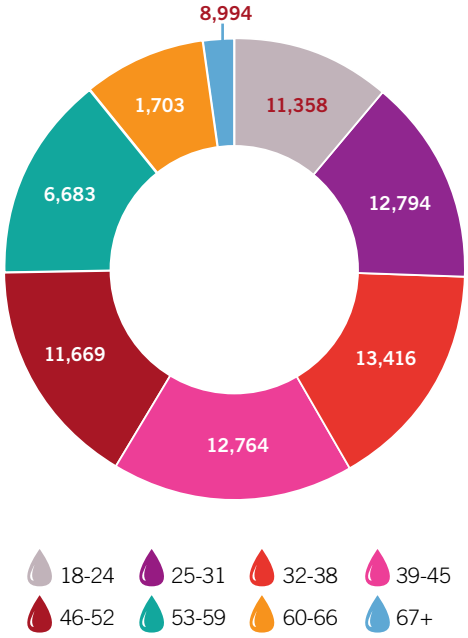
Attendance per thousand of population 2017



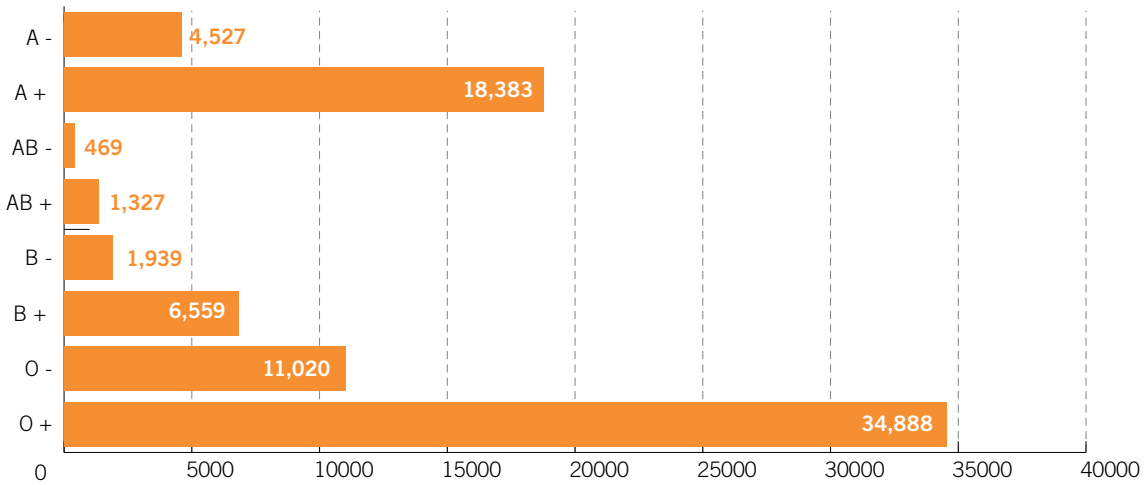
Whole Blood Donors by Gender



Whole Blood Donors by Age



Whole Blood Donors by Blood Group



Processing and Hospital Services

The Processing and Hospital Services section of the Irish Blood Transfusion Service (IBTS) consists of the Components Laboratory, the Product Development Laboratory, and the Hospital Services Department. It is based in the National Blood Centre (NBC) in Dublin and IBTS Cork.

The NBC Components Laboratory is responsible for processing, labelling and banking all whole blood donations collected nationally and plateletapheresis donations collected in the apheresis clinic located in the NBC. In addition it is responsible for the preparation of pooled platelets and for the issuing of non-routine whole blood and red cell orders and all platelet orders received in the NBC. The Cork Centre Components Laboratory is responsible for processing, labelling, and banking the plateletapheresis donations collected in the Cork Centre and also manages the stock holding unit based in Cork. The Hospital Services Department in the NBC and Despatch Department in Cork are responsible for the receipt of electronic orders from the hospitals and for issuing products on foot of those orders.

Hospital Services

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 Cork, hospital services is responsible for selecting and issuing all routine red cell products while the Red Cell Immunohaematology Laboratory in the Cork Centre is responsible for selecting for issue by hospital services all platelet products and non-standard whole blood and red cell products.

A total of 32,935 product orders were received electronically in 2017. Of these, 26,360 were received in the NBC and 6,575 were received in the Cork Centre.

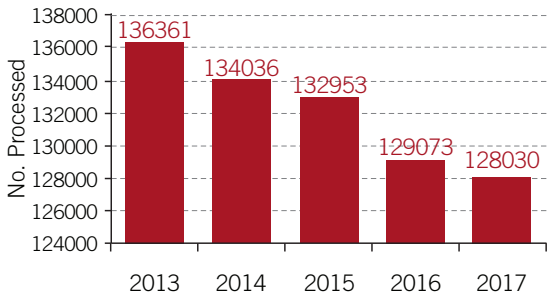
On-Line Orders Received			
	2016	2017	Change
NBC	27,275	26,360	-915 (-3.35%)
Cork Centre	6,157	6,575	+418 (+6.79%)
Total	**33,414**	**32,935**	**-479 (-1.43%)**

Components Laboratory

Whole Blood

A total of 128,030 productive whole blood donations were processed in the NBC in 2017. This represents a 0.81% reduction on the number processed in 2016.

Whole Blood Donations Processed



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

Primary Product	Number prepared	Distributed
Whole Blood and Red Cells		
Whole blood	9	0
Whole blood for neonatal use	1,396	0
Red Cell Concentrate	115,396	102,897
Red Cell Concentrate for neonatal use	11,001	3,725
Red Cells, Clotted	2	0
Plasma Products		
Fresh Frozen Plasma, Filtered	1	0
Fresh Frozen Plasma for neonatal use	119	0
Fresh Frozen Plasma for Cryoprecipitate Production	0	N/A
Fresh Frozen Plasma for Cryoprecipitate for neonatal use	482	N/A
Serum for Tears	2	2
Fresh Frozen Plasma for IVD use	125,795	72,622
Buffy Coats		
Leucocytes, Buffy Coat for pooled platelet production	36,977	N/A
Leucocytes, Buffy Coat	4,005	N/A
Plateletapheresis		
Apheresis platelets	19,148[1]	9,841[2]

Secondary Product	Number prepared	Distributed
Red Cells		
Red Cell Resuspended	836	807
Red Cell Washed	16	7
Red Cells Thawed/ Washed	0	2
Red Cells for IUT	24	24
Red Cells, Plasma Reduced	548	356
Red Cells Split for Neonatal Use	953	814
Red Cell, Irradiated	16,223	15,851
Plasma Products		
Cryodepleted Plasma	244	0
Cryoprecipitate for neonatal use	244	153
Platelet Products		
Platelets, Apheresis, Washed	79	78
Platelets, Paediatric Dose	9	9
Platelets, Hyperconcentrated	0	0
Platelets, Apheresis, Extended Life	7,961[3]	6,201
Platelets, Pooled	6,909	3,520[4]
Platelets, Pooled, Extended Life	2,610[5]	2,314[4]
Buffy Coats		
Leucocytes, Pooled	4	4
Leucocytes, Pooled, Red Cell Reduced	2	2

Please note that produced will not necessarily match distributed due to incoming stock available from 2016 and issued in 2017.

1 This is the total number of plateletapheresis doses prepared in 2017.
2 This is the number of plateletapheresis doses, with a 5 day shelf life, issued for therapeutic use
3 These are a subset of the total plateletapheresis doses prepared
4 The total number of pooled platelets issued for therapeutic use is the sum of these figures (i.e. 3,520+2,314 = 5,834)
5 These are a subset of the 6,909 pooled platelets prepared

Processing and Hospital Services

Platelets

Platelet production consisted of 10,025 apheresis donations collected nationally and 6,909 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 MRTC.

While total platelet production was down slightly relative to that in 2016, the production of platelets via apheresis was down by 2,095 doses (-9.86%) relative to that in 2016, while pooled platelet production was up by 1,270 doses (+ 22.52%).

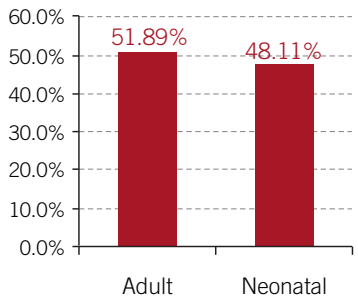
	Apheresis (doses)	Pooled (doses)	Total (doses)
2016	21,243	5,639	26,882
2017	19,148	6,909	26,057
Difference	-2,095	+1,270	-825
% Change	-9.86%	+22.52%	-3.07%

Platelets, Apheresis

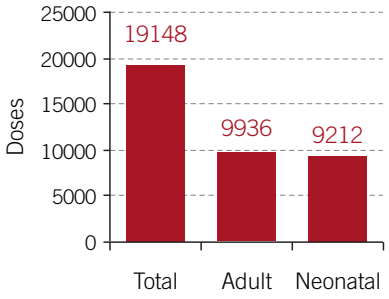
The 10,025 plateletapheresis donations yielded a total of 19,148 issuable doses. This is a dose per donation rate of 1.91, increasing to 1.97 when technically unusable donations (320 donations) are excluded. The equivalent 2016 figures are 10,763 plateletapheresis donations collected, yielding a total of 21,243 issuable doses. This was a dose per donation rate of 1.97, increasing to 2.03 when technically unusable donations (313 donations) are excluded.

Of the total productive plateletapheresis donations collected in 2017, 9,936 (51.89%) were suitable for adult use only and 9,201 (48.11%) were suitable for adult and neonatal use.

Apheresis Donations by Phlebotomy Type



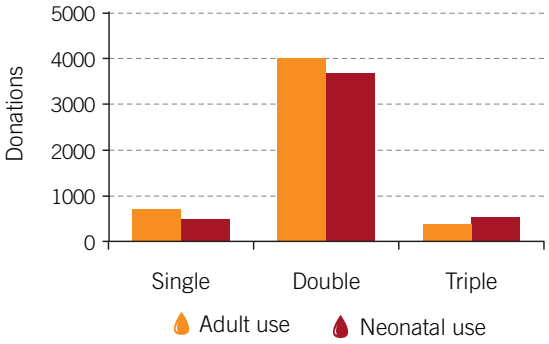
Apheresis Doses by Phlebotomy Type



Plateletapheresis donations were collected as single dose, double dose, or triple dose donations.

The proportion of multi-dose donations decreased and the proportion of single dose donations increased relative to 2016.

Apheresis Donations by Donation Type

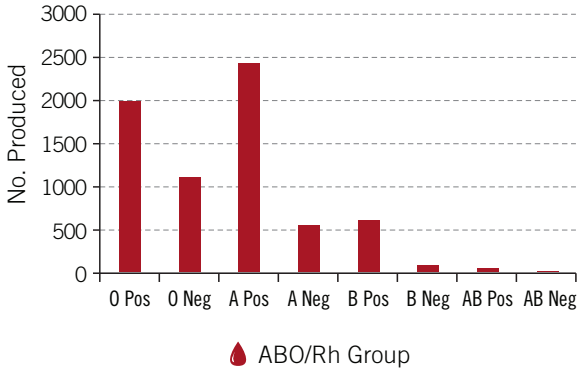


		Single	Double	Triple
2016	Adult Use	432	4249	701
	Neonatal Use	366	3821	734
2017	Adult Use	643 (+48.8%)	4000 (-5.9%)	431 (-38.5%)
	Neonatal Use	528 (+44.3%)	3625 (-5.1%)	478 (-34.9%)

Platelets, Pooled

A total of 6,909 pooled platelets were produced in the NBC in 2017. All ABO/Rh groups, except for AB Negative, were produced. The breakdown by group was:

Pooled Platelets by Group



The production level by ABO/Rh group was adjusted relative to the incidence of those groups in the population in order to address the order pattern for platelets.

The manufactured products distributed nationally in 2017 are shown in the table below:

Product	Distributed
Riastap 1g	6,838
Octaplex 500	18[1]
LG Octaplas O	9,372
LG Octaplas A	6,070
LG Octaplas B	1,740
LG Octaplas AB	937
Rhophylac	0

1 For stock management purposes

Processing and Hospital Services

Product Development Laboratory

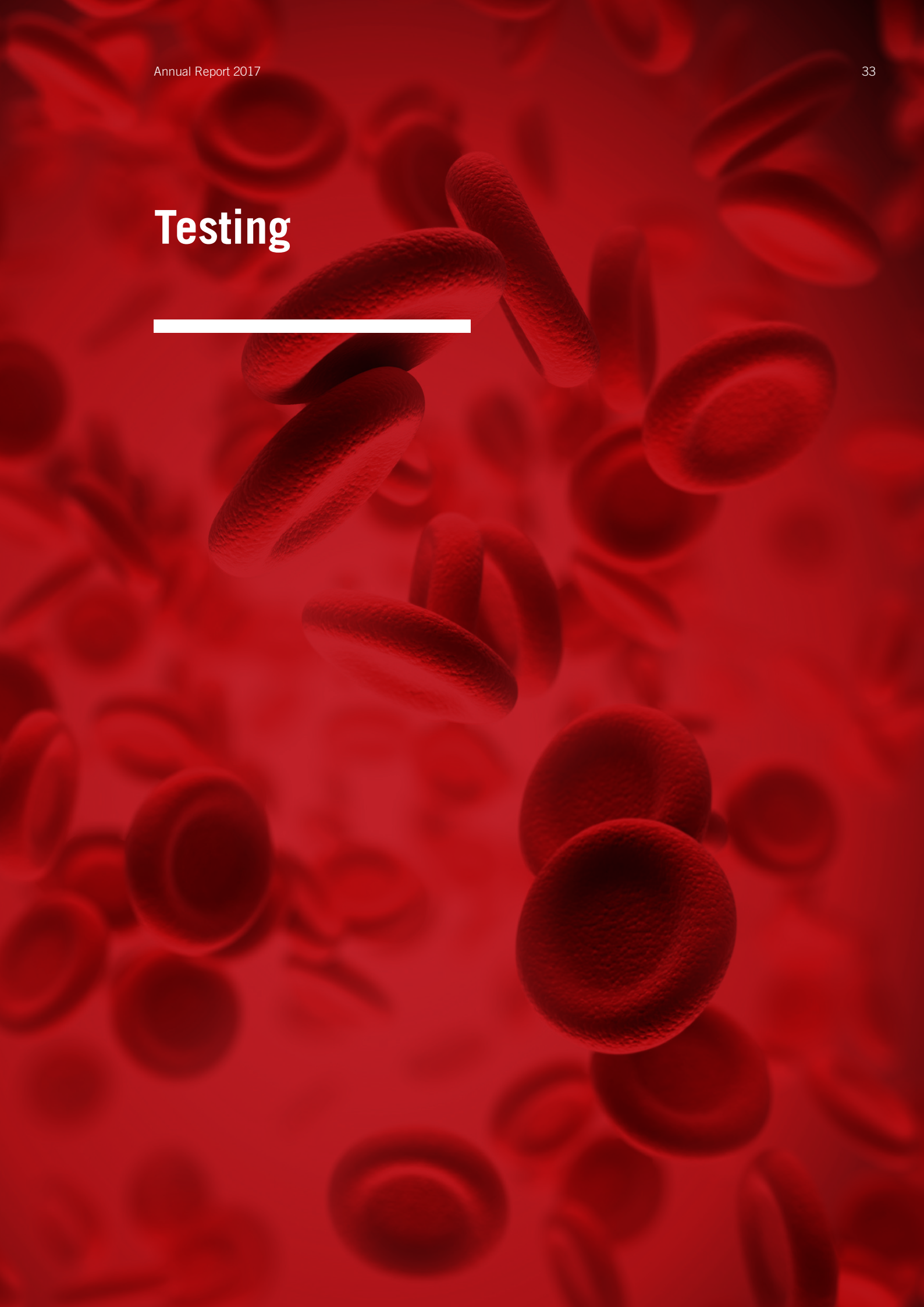
The Product Development Laboratory had two major projects during 2017:

- The validation and implementation of Terumo Automated Centrifuge and Separator Integration (TACSI) devices, and
- Validation of blood packs offered via the EuroBloodPack II tender.

The TACSI devices are used in pooled platelet production. Previously, all pooled platelets were prepared using the OrbiSac system which became obsolete in 2017. The TACSI system was successfully validated and was fully implemented during September 2017.

Validation of the EuroBloodPack II packs commenced in 2017 and the packs are expected to be fully implemented, following successful validation, in 2018.

Testing



NAT

Nucleic Acid Testing (NAT) Laboratory

The Nucleic Acid Testing (NAT) laboratory is located at the NBC and provides national molecular testing of blood donations from all IBTS centres. NAT detects viral RNA/DNA and is used to identify blood-borne pathogens which may not be detectable through current approved serological assays i.e. during the very early stages of an infection.

The NAT laboratory performs Individual Donation (ID)-NAT using the Panther platform in conjunction with the Ultrio Elite (UE) assay. The Panther instrument is a fully automated closed system for NAT testing with multiple assays. The Procleix Ultrio Elite assay is a multiplex Transcription Mediated Amplification (TMA) assay for the detection of Human Immunodeficiency Virus type 1 and 2 (HIV-1/2) RNA, Hepatitis C virus (HCV) RNA and Hepatitis B virus (HBV) DNA in human plasma. The IBTS was notified by the Public Health Service of a blood donor who presented with acute HBV infection. At the time of their most recent donation, the donor screened negative for all HBV markers (HBsAg, anti-HBc and DNA). Although the archive sample from this donation tested non-reactive with the UE assay (S/CO=0.08), the UE discriminatory (d) HBV DNA assay was reactive (S/CO=24.04). Viral load estimation was not possible. The donor was compliant with all donation guidelines on the index and preceding donations. The recipient was transfused with a unit of red blood cells from the only component of the implicated donation. The recipient was recalled post-transfusion when HBsAg, anti-HBc (IgM & total, Abbott Architect) were negative. However, HBV DNA was detected and Genotype sequences were identical in samples from the donor and recipient. This is the first reported case of a TT-HBV in which the UE assay was used for screening blood donations (O'Flaherty et al. 2018).

The Procleix West Nile Virus (WNV) assay reliably detects low level WNV RNA 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 8th May 2017 to 29th December 2017.

In 2014 the NAT laboratory performed a research study to evaluate the performance of the Procleix Hepatitis E virus (HEV) assay on the Panther instrument and to determine the incidence of HEV RNA in Irish blood donors. Based on IBTS research studies, the seroprevalence of anti-IgG HEV is 5.3% indicative of past infection, and the prevalence of HEV viraemia is 1 in 5,000 Irish donations. Universal screening of IBTS donations for HEV RNA was implemented on Monday 4th January 2016 for an initial period of three years (funding approved by the Department of Health).

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 also used to monitor technical proficiency and consistency in the sensitivity of reagent batches. The Grifols Procleix assays 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 2016 with no discrepancies to report. Inter-laboratory comparisons using EDCNet software (National Reference & Serology Laboratory, NRL, Australia, www.nrlqa.net) allow us to perform peer review with other Panther/Ultrio Elite and WNV users worldwide. The NAT laboratory is committed to continuous improvement of the NAT process.

Virology Laboratory

The function of the Virology laboratory at the NBC is the screening of all blood donations for transfusion transmissible disease. 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 and all samples from the blood donor clinics are transported to the NBC overnight and tested the following day. The sample is tested for the presence of specific viral markers that may be transmitted by transfusion. Approximately 140,570 donation samples and 1,746 sample only new donor samples were tested in 2017.

The following serology tests are carried out in the virology laboratory and are mandatory for all donations.

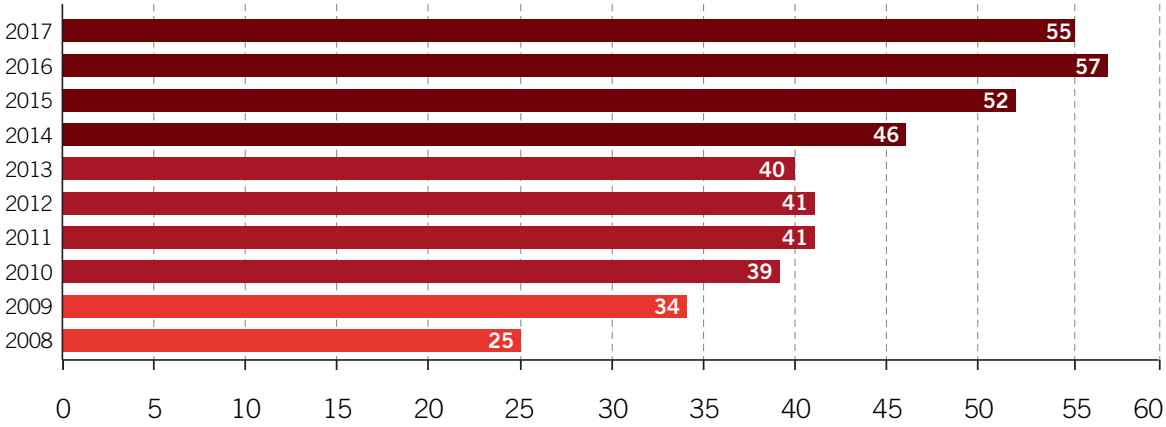
- Hepatitis B surface antigen (HBsAg) and antibody to Hepatitis B core
- Human Immunodeficiency Virus 1/2 antigen/ antibody
- antibody to Hepatitis C virus
- antibody to Human T-Lymphotropic Virus I & II
- antibody to *Treponema Pallidum* the causative agent of Syphilis

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 need it e.g. immunocompromised patients.

The blood components from the donor are labelled for issue provided all tests are complete and satisfactory results are obtained in all the IBTS testing laboratories.

These tests are performed using automated cGMP (good manufacturing practice) compliant equipment. Screening for most of these viruses takes place on the Abbott Prism using Abbott Prism test kits and the Prism system is in use in the IBTS since June 1997. The Abbott Prism is a fully automated, high-

Number of Irish Patients receiving a HSCT from an Unrelated Donor 2008-2017



volume, multi-channel blood screening instrument designed specifically for the blood donation screening market. It offers full GMP compliance and is capable of processing 180 samples per hour. Screening for Syphilis and Cytomegalovirus (CMV) takes place on the DiaSorin ETImax processor.

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.

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 Purple" 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 IBTS has an External Contingency testing plan with the Scottish National Blood Transfusion Service (SNBTS) in the event of a critical failure whereby the Virology laboratory is unable to provide some/all of the current mandatory Virology results. This plan 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 2017.

NHIRL

National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL)

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

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

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 2017 samples from 203 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 donors. The NHIRL provides an immunogenetics support service for the Irish Unrelated Bone Marrow Registry (IUBMR) and in 2017 the laboratory HLA typed 404 new volunteer donors to add to the registry.

In the last 10 years the IUBMR has facilitated 430 unrelated donor transplants for Irish patients. In 2017 a total of 55 unrelated donor transplants were performed. Fifty-two by St. James's Hospital and three by Our Lady's Children's Hospital, Crumlin.

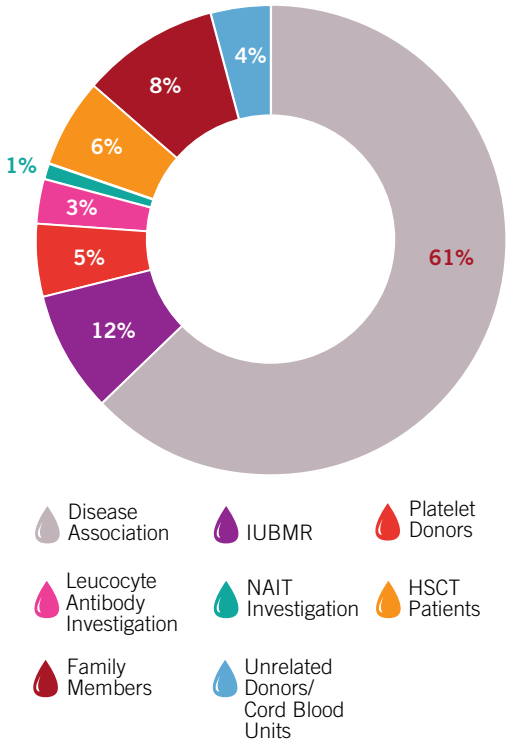
The NHIRL also provides a routine disease association HLA typing service. This service represented 61% of the investigations performed in 2017. The majority of samples are referred for determining the presence or absence of HLA-B27 which is associated with Ankylosing Spondylitis; a painful, progressive 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 2016.

A total of 277 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.

On behalf of the European Federation for Immunogenetics, the NHIRL hosted the 13th International Summer School on Immunogenetics in Trinity College Dublin between the 23rd July and the 26th July 2017. Eight guest speakers were invited from the Histocompatibility & Immunogenetics community worldwide to give educational talks and forty-eight students were selected from around the world to give presentations based on their research studies.

NHIRL Investigation Distribution



RCI Laboratory

Red Cell Immunohaematology Laboratory

On the 1st March 2017, the Diagnostics Laboratory NBC changed its name to the Red Cell Immunohaematology (RCI) Laboratory. The RCI Laboratory 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 haemolytic disease of the fetus & newborn (HDFN).
- Antenatal screening for red cell antibodies to identify at risk pregnancies. (antibody quantitation or titration as appropriate).
- Provision of suitable blood at delivery for at risk pregnancies.
- Phenotyping of donor red cells.
- Clinical and scientific advice to hospital colleagues.
- Extended phenotyping for transfusion dependent patients and for patients with complex red cell antibodies.
- Importation of rare blood for named patients
- Out of hours emergency on-call service
- Investigation of monoclonal antibody interference

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

Laboratory Activity

In 2017 a total of 2780 samples were referred to the RCI Laboratory, a 13.7% increase on 2016 and the highest number of samples tested since current statistics have been recorded in 2009.

There was an increase in sample numbers in all categories except anti-D quantitation. Molecular testing to differentiate between types of weak D was introduced by the IBTS in April in 2017 and there was a notable increase in the number of samples referred in this category. The RCI Laboratory continues to perform the investigation of RhD type serologically on cord/baby's samples, to inform the requirement for anti-D prophylaxis administration.

Comparison of 2016 and 2017 Sample numbers

	Total No. Samples tested	RhD Type Workup	Antibody ID	Quantitation anti-D	Quantitation anti-c	Total Compatibility Test	Complex Compatibility Test
2016	2444	199	2243	752	188	490	445
2017	2780	379	2322	607	229	645	625
(%)	13.7%	90.4%	3.5%	-19.3%	21.8%	31.6%	40.4%

As in previous years, there was a continued high level of serologically difficult or rare samples received. In 2017 the following complex samples some with rare allo-antibodies were identified by the RCI Laboratory:

Antibody	Patients	Referrals
Anti-Chido/Rogers	5	10
Anti-f	1	1
Anti-Kpb	1	2
Anti-Coa	1	1
Anti-Jk3	1	1
Anti-Jra	1	1
Anti-Wra	3	7
Cr1-related	2	2
Anti-Lub	1	1
Other HTLA-type	15	23
Anti-Yta	2	5
Anti-JMH	2	2
System specific	23	29
Daratumumab Interference	46	248
Total	**104**	**333**

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.

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 made two offerings to the SCARF exchange in 2017.

In 2017 the RCI laboratory received 228 samples from 47 patients who have been administered the drug Daratumumab. This drug was first used in Ireland in 2016 to treat patients with Multiple Myeloma, however, it interferes with key pre-transfusion serological tests. Suitable blood was provided for these patients using a method involving the DTT treated of reagent red cells.

The RCI laboratory actively contributes literature to the field of blood transfusion science and in 2017 two posters were presented at international conferences;

- ISBT Copenhagen - Ryan C, Doyle B, Scally E, NiLoingsigh S. Identification of 'stored red cell antibodies' in the plasma of four patient's referred to the RCI Laboratory at the IBTS. Vox Sanguinis 2017:112 (Suppl.1)
- AABB San Diego - Scally E, Doyle B, Long J, Sheehan K, Ryan C, NíLoingsigh S. Laboratory management of patients treated with Daratumumab: the Irish experience. Transfusion 2017:57 (Suppl.3).

Importation of rare blood/products

A total of 7 red cell units of rare phenotype were imported from abroad in 2017.

Participation in External Quality Assurance Schemes

The RCI department participates in 3 different quality assurance schemes; 4 exercises in IEQAS, 4 exercises in AQQAS and 10 exercises in NEQAS.

Diagnostics/ Crossmatch Cork

Diagnostics/Crossmatch Laboratory Cork

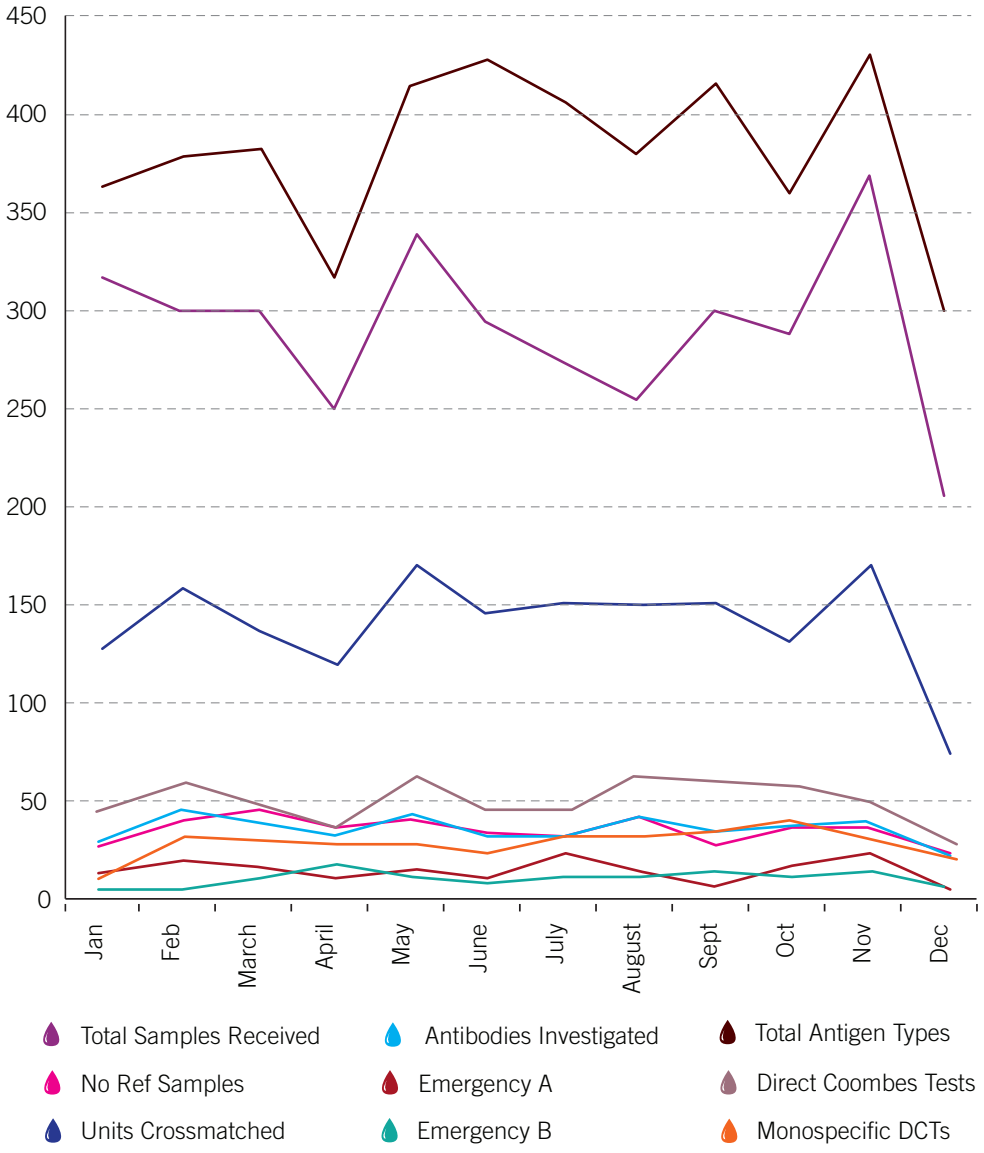
The diagnostics laboratory at the Cork Centre provides both routine and reference immunohaematology and laboratory services. The former to South Infirmary University Hospital (SIVUH), St. Finbarrs', Mater Private Cork and Marymount University Hospital & Hospice, and reference immunohaematology and laboratory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

The services provided by the Diagnostics laboratory include;

- As hospital Blood Bank for several city hospitals: the laboratory 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 which investigates complex or anomolous red cell typing , extended typing for transfusion dependant patients, positive direct antiglobulin tests, auto-immune haemolytic anaemia, haemolytic disease of the fetus/newborn, and complex antibodies providing extended matched (phenotyped) and crossmatched red cells for these patients. Individual samples in these cases may take several hours to investigate fully and may require donation screening where matching red cells are not available on the shelf. 22 patient samples required further specialist referral to the international blood group reference laboratory (IBGRL) Bristol. Advice is provided to colleagues in the region.
- As a reference laboratory which 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, undertaking recalls 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) and IEQAS meetings.

Total samples received 2017: 3491 (2016: 3201)

Diagnostics MRTC Activity 2017



Automated Donor Grouping

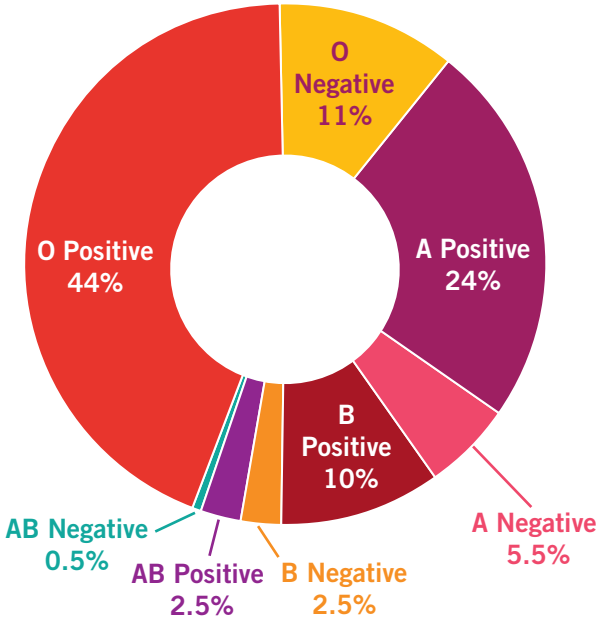
Automated Donor Grouping is continually striving to introduce the most up to date and sensitive testing techniques available. This is achieved by individual research or by way of projects performed as part of further study. These changes not only improve the safety of blood products, but also increase the efficiency of providing red cell products of rare or complex phenotypes, in response to specific requests from hospitals.

In 2016 tenders were sought to replace the QASAR blood typing platforms, with more up to date technology and this will see the implementation of sickle cell screening using the high performance liquid chromatography method, a very precise method of testing for this condition. During 2017 the new automates were installed and the validations plans were written and executed. The 2 QASAR IV machines are replaced by the OrthoVision and the Sickle cell testing is performed on the BioRad Variant II. It is planned that the OrthoVisions will be 'Live' by the end of January 2018 and the Variant II went into routine service in November 2017.

In 2017 over 142,500 donations were tested and of these 12,983 (9.1 %) were new donors. From the results obtained from testing new donors it is possible to estimate the frequencies of blood types in Ireland.

Apart from performing the mandatory serological tests (ABO, RhD and antibody screening) the laboratory routinely screens and types donors in order to find the rarer phenotypes or combinations of types, which may be requested in an emergency. The laboratory performed over 97,000 Rh phenotypes (C,c,E,e) and over 190,000 other antigen types in 2017. These are

Blood Groups in New Donors 2017



to provide typed blood for routine hospital orders, intrauterine transfusions and emergency requests for more complex antigen negative units.

The laboratory in 2017 saw an increase in demand for typed and screened units for patients with sickle cell disease, as the age group of these patients increases there is a corresponding increase in the demand for HbS negative units for use in their treatment. The use of the variant II will not only ensure there is sufficient stock for this programme, but will also identify donors with other rarer haemoglobin opathies.

The project to screen the donor population to find new k negative donors is now nearly complete. The

panel of k (cellano) negative donors (frequency 1:1000) now stands at over 300 and this means any requests for k negative blood can now be dealt with on an off the shelf basis or specific donors of the appropriate ABO group and Rh phenotype can be called in to donate specifically to cover the request.

In 2013 the laboratory began screening certain donors with a new partial RhD typing kit to detect donors carrying a variant RhD type. This was in response to the finding of a previously typed Rh D negative donor that was found to be a very rare weak RhD variant (type 10). This meant that this donor was very weakly RhD positive and could have consequences if that unit was transfused to a true RhD negative recipient. These rare weak RhD types usually also possess the Rh C or even rarer the Rh E antigen. So all RhD negative which are also positive for the RhC or RhE antigens were targeted for screening. This project is now almost complete and new donors with this Rh phenotype continue to be investigated. So far there have been 21 donors with rare weak RhD types identified.

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 2017.

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 is an international survey of laboratory standards.

As the Automated Donor Grouping Laboratory is a national testing facility, the IBTS has an external testing plan with the Scottish Blood Transfusion Service in case of a critical failure of instruments or site. The contingency plan is tested 4 times a year (3 by air and 1 by sea) by sending twenty four samples for testing. In 2017 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.

Other Services

“During 2017, the configuration and validation of a computer system for the tissue bank was completed.”

Tissue Services

Tissue Services

The Tissue bank at the NBC operates as 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. During 2017 the tissue bank had a HPRA inspection and received no citations.

The tissue bank manages all ocular tissue, heart valves, cord blood, skin and some musculoskeletal tissue on a national basis.

Products supplied include corneas, both for DSAEK, DMEK and PK procedures, sclera, amnion, pericardium and fascia lata. These products are all imported from the US. Human skin is imported from Barcelona, Spain. The IBTS also provides autologous serum eye drops for patients with severe dry eye on receipt of a request from an ophthalmologist. Secondary processing of the drops is carried out by the NBS in Speke, Liverpool. Demand for products was consistent with 2016.

The IBTS is a third party contractor to the MMUH for the processing, cyropreservation and distribution of human cardiovascular tissue. The majority of the valves donated are used in OLCHC for the repair of congenital heart defects. During 2017, there was a 63 % increase in valve donations which will help meet the clinical requirement for homograft tissue. Two further limbal stem cell transplants were successfully performed with more scheduled for 2018.

During 2017, the configuration and validation of a computer system for the tissue bank was completed. This system is specific for Tissue, cells and stem cells and was developed by the supplier. The system is up and running for all ocular products.

Therapeutic Apheresis

Therapeutic Apheresis Service Cork

The Therapeutic Apheresis Service (TAS) provides therapeutic apheresis for patients in the Munster region at Cork University Hospital (CUH), Mercy University Hospital (MUH) and Bon Secours Hospital Cork (BSHC). Patients in other hospitals in the region are transferred to these facilities as appropriate. The TAS is led by a Consultant in Transfusion Medicine, supported by Specialist Medical Officers 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. All procedures performed in 2017 were Therapeutic Plasma Exchange (TPE). The OPTIA software has been enabled for Red Cell Exchange (RBCX) and 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- 2016), and cognisant of other guidelines including those from the British Society of Haematology (BSH).

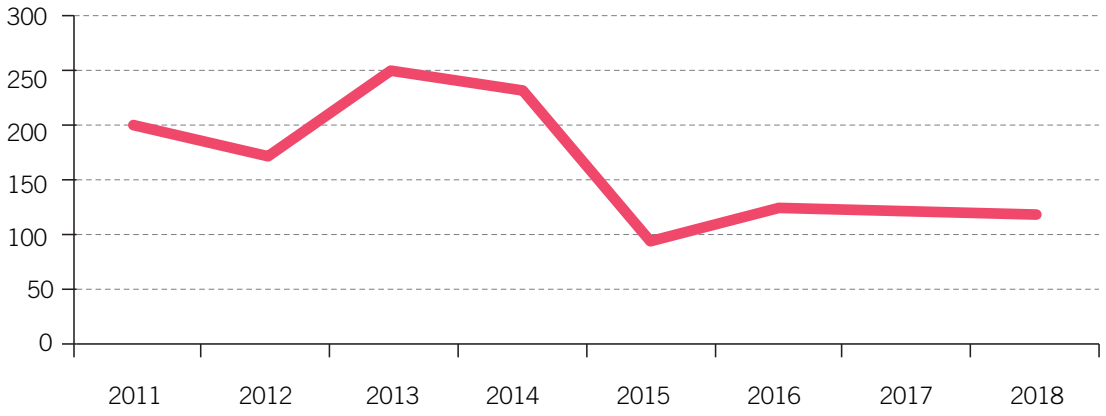
The TAS operates within the IBTS quality management system, with trained personnel, controlled documentation, SOPs, validated technology and adverse event monitoring. Adverse events are subject to on-going review and changes are incorporated into the IBTS Therapeutic SOPs, relevant Hospital policies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

In 2017 the TAS received 25 patient referrals and performed 121 procedures for 22 patients, over two hospital sites. As displayed in the following tables, the demand for TAS is varied and unpredictable.

Service demand trend

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

Total Annual Procedures 2011-2017



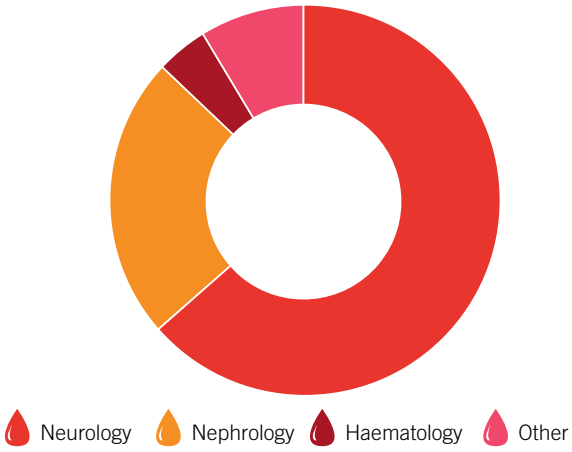
Weekend, bank holiday and out of ours service

Patients may present for emergency, out of hours care when their diagnosis is life or organ threatening. The treatment programme may extend throughout a weekend period. Of the 121 procedures carried out in 2017, 23 (16%) were performed at the weekend and 3% was performed out of regular working hours during the week.

Clinical speciality by patient and procedure

The majority of patients (64%) presented with neurological conditions, followed by renal (23%) and haematology (4%). Nine per cent of patients presented under other specialities.

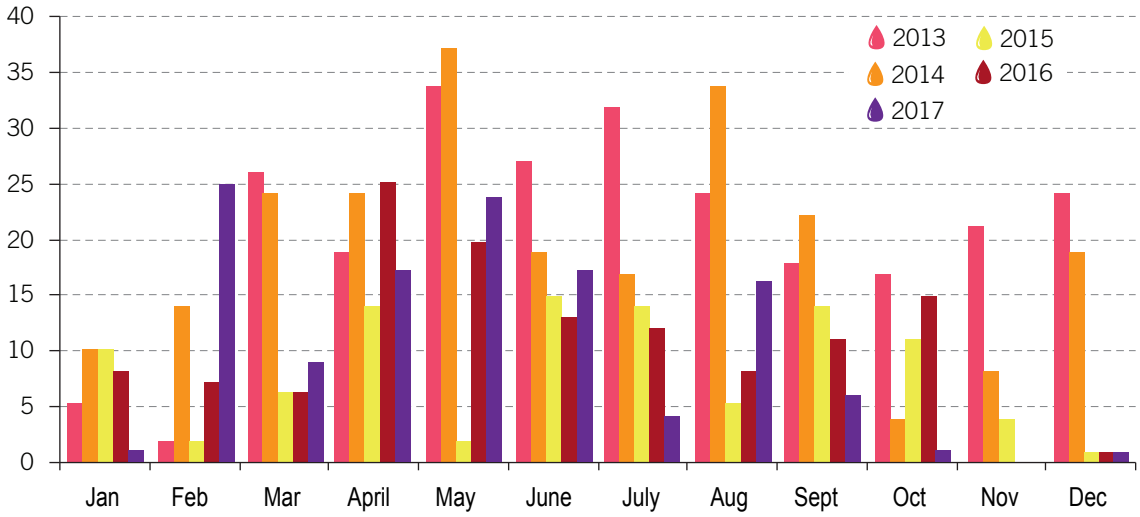
Patients by Speciality 2017



Service Provision to hospitals

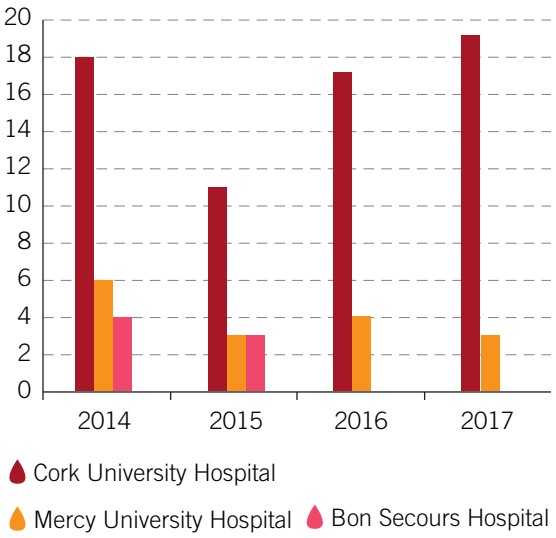
CUH had the greatest demand for TAS accounting for 86% of patients treated in 2017.

Service demand 2013 - 2017 By Month



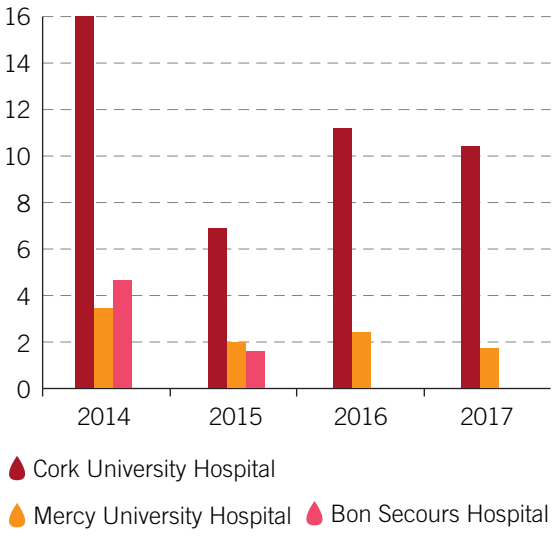
Therapeutic Apheresis

Patient by Hospital 2014 - 2017



MUH accounted for 14% of patients.

Procedure by Hospital 2014 - 2017

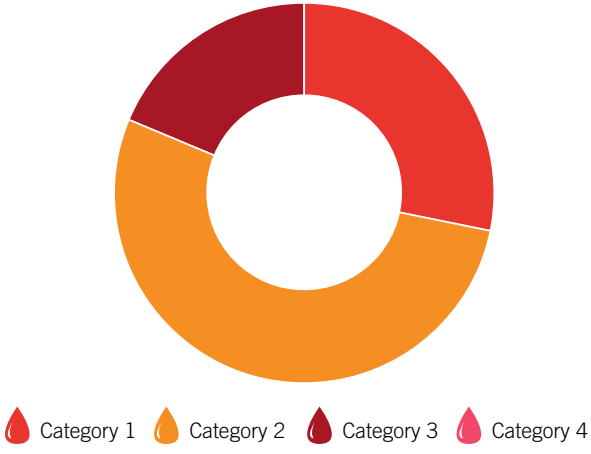


The American Society for Apheresis (ASFA) guidelines are used to plan individual patient treatment protocols.

The ASFA guidelines are based on both quality of supporting evidence as well as the strength of the recommendation derived from that evidence. The most recent Guidelines were published in 2016.

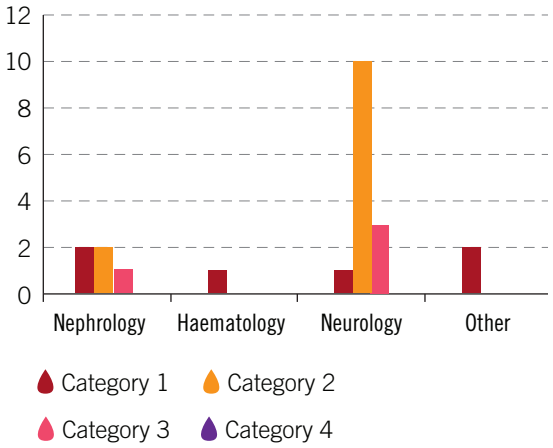
- Category 1 – Disorders for which apheresis is accepted as first-line therapy, either as standalone or in conjunction with other treatments.
- Category 2 – Disorders for which apheresis is accepted as second-line therapy, either as standalone or in conjunction with other treatments.
- Category 3 – Optimum role of Apheresis is not established – Decision making is individualised.
- Category 4 – Disorders in which published evidence demonstrates or suggests apheresis to be ineffective or harmful.

Patients by ASFA Category 2017



NHO

Number of Patients under each Speciality by ASFA Category 2017



Degree of urgency of service required

Therapeutic Apheresis may, in some conditions, form part of the urgent clinical response to patients' conditions. Early apheresis can reduce the threat to life or organs. Eighty two per cent of patients presented as urgent and 18% presented as elective in 2017.

Urgency of Service Required by Patients and Procedures

Urgency	Patients 2017	Procedures 2017
Urgent	18	104
Elective	4	17
Total	**22**	**121**

In 2017 no procedures were cancelled by the TAS service.

National Haemovigilance Office (NHO)

Haemovigilance collects and assess 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). The programme commenced in 1999 with a total of 6253 serious adverse transfusion reactions and events reported since then. 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 2017, 140 mandatory SAEs were reported (65% of all SAEs). In addition, 76 non-mandatory SAEs, (35% of all SAEs) primarily relating to errors in clinical areas, were also reported. (Figures correct at the time of writing).

NHO

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

At the time of writing , a total of 151 reactions that meet the criteria have been reported in 2017. Mandatory SAR (58) reported to date is a slight decrease on those recorded in 2016 (60).

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. 213 mandatory reports were reported by the NHO in 2016, with the compilation of 2017 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 ongoing development of hospital in-service training programmes by working closely with hospital based HVOs. On-going education of undergrads and specialists registrars also continued during the year.

In keeping with its remit to support hospital based staff, the NHO provided an ‘open day’ for newly appointed HVOs covering aspects of the reporting system, together with familiarisation with the workings of the IBTS and NHO. 19 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.

IUBMR

Irish Unrelated Bone Marrow Registry

Haematopoietic progenitor cell transplantation is a lifesaving therapy for certain patients with leukaemias, 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 32 million volunteer donors available worldwide provides 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. Since 2001 all donors registered on the unrelated panel are typed exclusively by DNA methods, 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

The IUBMR searches for suitable donors on the Irish Panel and through the Bone Marrow Donors Worldwide (BMDW) database, on behalf of the Irish transplant centres at St. James' Hospital (SJH) and Our Lady's Children's Hospital Crumlin (OLCHC). In 2017, 86 patients were referred to the IUBMR for unrelated searches. Fifty Five Irish patients received stem cell transplants from an unrelated donor in 2017. The majority of these were from international donors (52).

International Activities

In 2017 the IUBMR 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. 85 Irish donors were selected for additional testing in 2017.

Irish Donors

Potential stem cell volunteers are recruited through blood donation clinics, where they can request to join the registry. In 2017 404 new volunteers joined the IUBMR, there are now over 22,000 potential donors listed on the IUBMR.

Donations from 5 Irish donors were facilitated in 2017, for national and international patients. There was 1 additional Donor Lymphocyte Infusion (DLI) collected from an Irish donor.

“The programme for change within the Quality Management System proceeded during 2017.”

Quality & Compliance

The programme for change within the Quality Management System proceeded during 2017 . The Quality Improvement Project was started as part of the overall IBTS strategy and interim changes to manual systems for management of incident reports and complaints were introduced. Phase 1 of the Quality improvement project (QIP) was started and this focused on the planned upgrade to electronic quality management systems (EQMS) for document control and training record management. This upgrade will allow future introduction of other electronic quality system modules such as non conformance, CAPA and audit management.

The annual HPRA programme of inspection covered 9 inspections during 2017 including 4 clinics and 5 site visits. These covered the Blood Establishment activity, Tissue establishment activity and Good Distribution Practice operation.

There was one major non-compliance raised for the BE System elements and one major raised under the GDP authorisation. Annually the licences are updated, maintained and annual reports filed on the associated activities.

There were 2 Limbal Stem Cell products releases for clinical application during 2017, with a total of 5 products released for clinical application since the IBTS acquired the manufacturing authorisation in 2015.

Changes in the Quality Management System are captured through the Change Control system. There were 593 Change Controls raised during 2017, with 53% closed by end of year. There were 538 Change Orders raised to effect change to documents, policy and procedures, with 78% closed by 2017 year end. These figures are comparable to 2016.

On a quarterly basis, metrics are presented to the EMT and close out rates reported end of year. Close out rates for incident reports (IRs) achieving a disappointing 70% for 899 IRs raised during 2017. There was a large decrease in the total number of IRs captured during 2017, down from 1475 in 2016. This was due in the main to the reassignment of certain categories of technically unusable donations so that they would be captured as donation losses by Practice development rather than as incident reports.

The Complaint handing system processed 1026 individual complaint files in 2017 with a close out rate of 70% achieved, this represents an increase of approximately 10% over 2016 figures.

Associated with these complaints a total of 364 recalls were investigated during 2017, with the majority due to post donation information from donors. A total of 140 Donor Services complaints were captured at clinics/ post clinic during 2017. A close out rate of 96% was achieved for the year.

Both Complaints and IRs are continually analysed throughout the year to ensure Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs) are captured.

There were 72 SAEs accepted by the NHO from the IBTS as a Blood Establishment during 2017, and a

Quality & Compliance

total of 60 SARs were reported to NHO. The majority of SAEs from the IBTS as a BE are due to processing and distribution errors.

In all cases the reporting of SARs to the NHO is directly from the hospital based blood banks to the NHO office. There were no reported cases of deaths associated with the SARs reported.

Human Resources

Human Resources

As Learning and Growth is a key pillar of the IBTS Strategy 2017-2020, organisational development continues to be area of significant emphasis for Human Resources. Following on from the successful development of the first Learning and Development Strategy in 2016, (IBTS Learning and Development Strategy 'Working, Learning & Growing Together 2017-2020) 2017 saw the organisation wide launch of this strategy and implementation plan, with full Board and Executive Management approval and support.

The first step in implementing the ambitious 3 year strategy involved the review and re launch of an improved Performance Development (PD) process, previously known as Performance Measurement Development System (PMDS). With a continuous improvement and collaborative approach the L&D team engaged/consulted with employees across the organisation to gather valuable feedback and information which helped reshape PD for the IBTS.

Performance Development covers both performance management and employee development. It focuses on Managing Myself, Getting the Job Done and Working With Others. It is a vehicle to grow all employees to achieve greater levels of performance and ultimately provide an even better service for all donors and transfusion patients.

A robust training plan was designed, promoted and delivered across the organisation which resulted in exceptional attendance levels signifying organisational readiness to embrace a culture of learning and help deliver on the Great Place to Work survey. In June of 2017 PD was successfully launched with our Executive Management Team. PD conversations continue to cascade throughout the organisation with the support of our in-house PD Subject Matter Experts.

Continuing on our journey to become a Great Place to Work has also driven Human Resource activity in 2017. A great deal of work behind the scenes, across a number of groups, has taken place over the last year. We have now consolidated all the various strands of this work together in an action plan. We believe that the actions set out in this document will help improve our workplace and in doing so it will in turn improve our rating as a GPTW when our next survey is carried out in 2018.

Environmental, Health and Safety

Environmental Health and Safety (EHS) provides both an advisory and support role within the organisation. In order to maintain compliance and continuous improvement and development of EHS within the organisation, environmental health and safety programmes continue to be reviewed and developed.

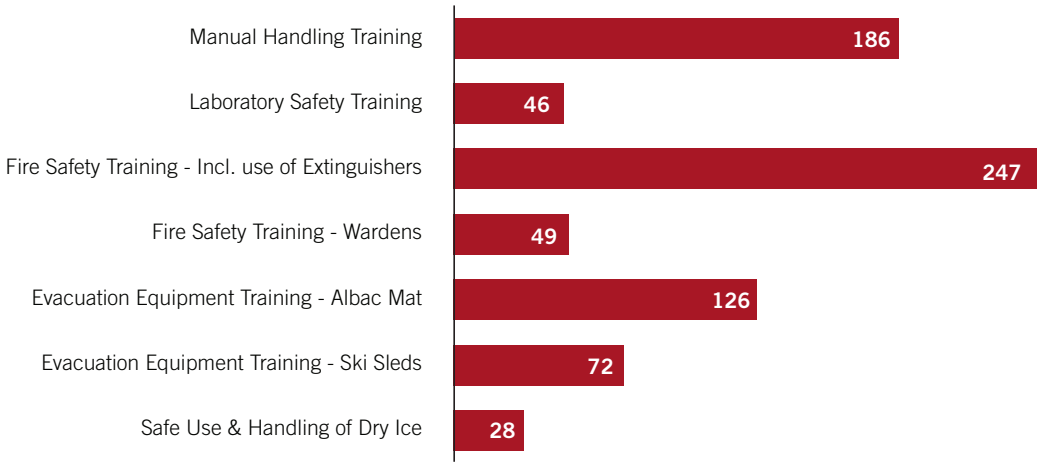
Dangerous Good Safety Advisory services

A review of Dangerous Good Safety Advisory services was undertaken. To fulfil the duties outlined in the European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 (S.I. No. 349 of 2011) and associated amendments a new Dangerous Goods Safety Advisor was appointed and will work with the IBTS into 2018.

Fire Safety Programme

As part of the fire safety programme an emphasis was placed on training including the use of emergency evacuation equipment. A review of fire evacuation drawings across all IBTS centres also took place.

Mandatory H&S Staff Training



Number Of Staff Who Completed Training

Finance

Draft Summary Accounts for the year ended 31st December 2017

	2017 €'000	2016 €'000
Income		
Recurring income	67,482	64,825
Non-recurring income	1,389	11,175
Total income	**68,871**	**76,000**
Expenditure		
Total expenditure	**70,865**	**69,436**
Surplus / (Deficit) for year	(1,994)	6,564
Actuarial gain / (loss) on pension schemes	7,224	(23,639)
Transfer to Capital Reserves	(17)	(70)
Transfer to Research Reserve	124	(449)
Accumulated Deficit at 1st January	(60,569)	(42,975)
Accumulated Deficit at 31st December	**(55,232)**	**(60,569)**

Income

The Board's total income for 2017 of €68.87 million (2016 €76.0 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 €67.48 million (2016 €64.83 million). Non-recurring income of €1.39 million (2016 €11.18 million) includes both grants from the Department of Health and interest on bank deposits. The increase in recurring income represents increased volumes in 2017 for Red Cells while the decrease in non-recurring income is due to a once of grant of €10m in 2016 in relation to the IBTS Pension scheme.

Expenditure

Expenditure for 2016 amounted to €70.9 million (2016 €69.4 million). The increase in expenditure mainly arises due to research payments to NUIG.

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 2017 was €8.60 million.

In 2006 the Board set up a research reserve. In 2017 the balance of research funds was €1.6 million. (2016 €1.76 million).

Capital Expenditure

The Board invested €1.7 million in capital projects and equipment during 2017 (€1.4 million 2016).

The main investments during the year included further investment in ICT infrastructure including a wireless network upgrade, laboratory testing equipment and an I.T. system for Tissue, Cords and Stem cells.

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 2017, under the terms of applicable legislation, invoices to the value of €208,165.74 were late, by an average of 18.79 days. These invoices constituted 1.1% by number and 0.55% 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 €7,578.86

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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Annual Report 2017

Irish Blood Transfusion Service
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