ANNUAL REPORT 2016





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"Our aim is to keep a stock of 5 to 7 days worth of blood in each of the eight major blood groups at all times."

DVR 4

Chairperson's Foreword

Our job might seem simple, to provide a safe, secure, and reliable supply of blood products for patients using the Irish health services, but it has its challenges. In 2016, we have achieved a reliable supply, but only thanks to the generosity of our donors, the support of the media, and our partners, such as the GAA, Óglaigh na hÉireann, Vodafone, and many businesses, and the hard work of our staff. Over 2016, we had regular periods when the blood supply fell below the levels we set ourselves. Our aim is to keep a stock of 5 to 7 days worth of blood in each of the eight major blood groups at all times. From late 2015, through much of 2016, we regularly had to run extra clinics to ensure the continued availability of blood for Irish patients. This happened because, as we predicted last year, the deferral rate for donors attending our clinics rose, and stayed high throughout 2016. This reflects the relatively low haemoglobin levels in the Irish population.

This has an impact on our costs, but more importantly it has affected our staff, our team of local voluntary organizers, and our donors. During this period, we have taken three actions, intended to bring blood supply and demand into better balance. We have developed a new marketing strategy, intended to encourage more young people to become donors; we have worked closely with hospitals to use blood products more effectively; and our donor teams have worked over the year to provide more opportunities for convenient and accessible donation. By the end of 2016, the blood supply had become more stable, and we hope over 2017 to keep our service on an even keel. Over the course of 2016 we worked with patient organisations, our donors, our medical and scientific staff, national and international experts, and staff in HSE, and the Department of Health, to prepare a proposal to change our existing rule which gave a lifetime deferral from donation to all men who have sex with men. We had an extensive consultation process, leading to an international meeting in mid-2016, effectively chaired by Prof John Bonnar. A proposal was prepared, and accepted by the Minister for Health, and in early January 2017, the lifetime deferral was removed. This challenging process was led by Dr Willy Murphy, our former Medical Director, and Mr Andy Kelly, our CE.

We have stepped up our program to provide therapeutic venesection for people with stable haemochromatosis, and to give those who wish, and are eligible, the opportunity to donate. A recent upgrade in our IT systems will allow us to develop this important service further during 2017.

We continue to face financial challenges. Our proposal to link the prices we charge for our products, to our Activity Based Costs, has now been accepted by the Minister for Health. I appreciate the effort of the Minister and the civil servants in the Department of Health, to achieve this. We appreciate this, as it makes our finances more stable, and it is encouraging to recognition for our innovation in public sector financial control, which represents a great deal of hard work by Mr Noel Murphy, our CFO, and the finance team. We continue to seek every opportunity to control our costs. In the latter half of 2016, our executive management team, and my colleagues on the Board, put a very large amount of time and effort into our new strategy. Some pieces of this are already visible, notably a new marketing campaign, and a much greater emphasis on social media than before. Other parts are less obvious, for example, we have a further significant increase in the resources and effort going into staff training and development, especially training staff to take on mid-level and senior roles in the IBTS.

This year also marked the end of an era. Dr Willy Murphy, our Medical and Scientific Director has retired. He came into the IBTS in the wake of the crises which led to the Finlay and Lindsay tribunals, and was the rock on which the IBTS held firm over those very difficult years. His impact on our organisation, and on the Irish health services, was immense, and we all owe him a debt of gratitude. Characteristically, he has gone to New Zealand to work there. We wish him all the best in his Antipodean endeavours.

As always, I have to thank our staff. It is a real privilege to lead such a dedicated group of people. Our staff perform difficult and exacting work, with no room for error, and need to work well and effectively with people, both our donors, and our clients – the Irish hospitals. Thank you all very much.

Finally I wish to give my thanks to our senior management team, and my colleagues on the board. The IBTS is a complex organization, with a very specific history, and a strong culture. Our executive management team, led by Mr Andy Kelly, the CE, our Board secretary, Ms Mirenda O'Donovan, and my colleagues on the board all contribute to this. Without their focus, advice, and support, I would find it impossible to carry out my responsibilities.

Prof Anthony Staines Chairperson

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

- I, as Chairperson, acknowledge that the Board is responsible for the Body's system of internal financial control.
- The IBTS system of internal control can provide only reasonable and not absolute assurance against material error, misstatement or loss.
- The Board confirms that there is an ongoing process for identifying, evaluating and managing significant risks faced by the IBTS. This process is regularly reviewed by the Board via reports from the Chief Executive.

i. Management are responsible for the identification and evaluation of significant risks applicable to their areas of business together with the design and operation of suitable controls. These risks are assessed on a continuing basis and may be associated with a variety of internal or external sources including control breakdowns, disruption in information systems, natural catastrophe and regulatory requirements.

ii. Management meets twice monthly on operational issues and risks and how they are managed. The Executive Management Team's role in this regard is to review on behalf of the Board the key risks inherent in the affairs of the IBTS and the system of actions necessary to manage such risks and to present their findings on significant matters via the Chief Executive to the Board.

iii. The Chief Executive reports to the Board on behalf of 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 and Compliance Committee of the Board reviews specific areas of internal control as part of their terms of reference. The Audit and Compliance Committee of the Board have satisfactorily reviewed the effectiveness of the system of internal control on behalf of the Board. The Audit and Compliance Committee carried out a formal review of these systems in respect of 2016 at its meeting on the 8th February 2017.

Additional Reporting Requirements

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

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

A code of business conduct for the Board and an employee code of conduct have been put in place. The Board is committed to review these codes regularly.

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

The IBTS Board reviewed reports on internal controls during the year along with regular reviews of the reports of the Health Products Regulatory Authority on operational and compliance controls and risk management. The Board will continue to review these reports and to work closely with the HPRA to ensure the highest international standards. The IBTS has complied with disposal of assets procedures, as outlined in the 'Code of Practice for the Governance of State Bodies 2016.' The IBTS complies with all relevant obligations as defined under Irish taxation law.

Corporate Governance

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

The Board has a manual for Board members. The Board is currently reviewing its governance and compliance arrangements against the Code of Practice for the Governance of State Bodies as published by the Department of Public Expenditure and Reform in August 2016.

Workings of the Board

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

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

Chairperson's Report

Board attendance 2016	February	April	June	September	November	December
Prof Anthony Staines	√	√	1	√	1	√
Linda Hickey	√		1	√		√
Dr Julie Heslin	√	1	1	√	1	√
Dr Ronan Desmond		1	1	√	1	√
Dr Liz Kenny	√	1	1	√	1	√
Deirdre Cullivan	√	√	1	√	1	√
Kate Williams			1	√	1	√
Simon Mills	√	1				√
John Malone	1	√	\checkmark		1	√
Dr Jorgen Georgsen	√	1	1	√	1	
Dr Yvonne Traynor	√	√	\checkmark		1	√
Brian O'Mahony		√	\checkmark		1	√

All members receive appropriate and timely information, to enable the Board to discharge its duties. The Board takes appropriate independent, professional advice as necessary. The Board undertook an external evaluation of its performance in May and had a one day meeting in March on strategy.

Guidelines for the payment of Board member fees and expenses are observed.

Board Expenses 2016				
Board members expenses were as follows:	Total	Mileage	Subsistence	Other Travel
	€	€	€	€
Anthony Staines	1,166.72	617.32	158.61	390.79
Dr Julie Heslin	963.98	617.31	220.27	126.40
Dr Elizabeth Kenny	2,023.63	189.93	675.70	1,158.00
Dr Jorgen Georgsen	4,473.53	860.14	Nil	3,613.39
Kate Williams	365.30	365.30	Nil	Nil
Deirdre Cullivan	794.75	697.68	82.67	14.40
	9,787.91	3,347.68	1,137.25	5,302.98

Board Fees 2016	
Board members remuneration were as follows:	Total
	€
Linda Hickey	11,970
Kate Williams	11,970
Deirdre Cullivan	11,970
Dr Yvonne Traynor	11,970
Simon Mills	11,970
John Malone	11,970
Dr Jorgen Georgsen	11,970
	83,790

Chairperson's Report

Members of the Board

Professor Anthony Staines (Chairperson) Mr Brian O'Mahony Ms Linda Hickey Ms Kate Williams Dr Elizabeth Kenny Dr Julie Heslin Dr Jorgen Georgsen Dr Ronan Desmond Ms Deirdre Cullivan Dr Yvonne Traynor Mr Simon Mills Mr John Malone

The Public Spending Code

The Board is committed to complying with the provisions of the Public Spending Code and Circulars 02/2016 – arrangements for Digital and ICT-related expenditure in the civil and public service.

The IBTS has also developed its own formal project management methodology, suitable for adaptation, depending on the size of the project in question.

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

Performance and Development Committee

The Board has established a sub-committee to deal specifically with matters regarding the performance and development of the Chief Executive, and the senior management team. The Board complies with Government policy on pay for the Chief Executive and employees. The Board also complies with guidelines on the payment of director's fees. The Chief Executive's salary in 2016 was €148,964. The Performance and Development Committee did not meet in 2016.

Medical Advisory Committee

The Medical Advisory Committee is comprised of the medically qualified members of the Board and the medical consultant staff of the IBTS and met 11 times in 2016. Its function is to monitor developments relevant to the field of transfusion medicine and related fields, to inform the Board of any such developments and to advise the Board on appropriate action.

MAC Attendan	ce 201	6									
Name	Jan	Feb	Mar	Apr	Мау	June	August	Sept	Oct	Nov	Dec
E Kenny	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
J O'Riordan	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Dr Ó Donghaile	Y	Y	Y	Y	Ν	Ν	Y	Y	Y	Y	Y
S NiLoingisgh	Y	Y	Ν	Y	Y	Y	Y	Y	Y	Ν	Y
L Pomeroy	Y	Ν	Y	Y	Y	Y	Y	Ν	Y	Y	Y
E McSweeney	Y	Y	Y	Y	Y	Y	Y	Ν	Ν	Y	Y
J Georgsen	Y (Tel)	Y	Y (Tel)	Y	Y (Tel)	Y	Y (Tel)	Y	N	Y	Ν
B O'Mahony	Y	Ν	Y	Y	Y	Y	Y (Tel)	Ν	Y	Y	Y
J Heslin	Y (Tel)	Y	Y (Tel)	Y	Y (Tel)	Y	Y (Tel)	Y	Y (Tel)	Y	Y
R Desmond	Y	Ν	Y (Tel)	Y	Y	Y	N	Y	Y	Y	Y
N O'Connell	Y	Ν	Y	Y	Y	Y	Ν	Y	Ν	Y	Ν
J Power *	Y										
W Murphy **	Y	Y	Y	Y	Y	Y	Y	Y			
I Hann ***								Y	Y (Tel)	Y (Tel)	Y (Tel)
C DeGascun						Y	Y	Y	Y	Ν	Y
N O Flaherty											Y

* J Power went on extended leave February 2016

- ** W Murphy left IBTS in September 2016
- *** I Hann took over from Dr Murphy in August 2016
- **** C DeGascun appointed as member of MAC June 2016
- ***** N O'Flaherty joined the IBTS in December 2016

Chairperson's Report

Finance Committee

The Finance Committee met five times during the year and is comprised of three members of the Board. It is also attended by the Chief Executive, Medical & Scientific Director, Director of Finance and Management Accountant. The Committee may review any matters relating to the financial affairs of the Board. It reviews the annual capital and operating budgets, financial and management accounts, financial KPIs, capital expenditure, working capital and cash flow. It also reviews business planning, costing exercises, procurement, insurance arrangements, contracts, banking, financing arrangements and treasury policy. The Committee reports to the Board on management and financial reports and advises on relevant decision-making. The Finance Committee operates under formal terms of reference which are reviewed by the Board regularly.

Audit & Compliance Committee

The Audit and Compliance Committee met five times during the year and is comprised of three members of the Board and three independent external members. It is also attended by the Chief Executive, the Medical & Scientific Director, the Director of Finance, the Operations Director, Director of Quality & Compliance, the Internal Auditor, Risk and Resilience Manager and the assistant accountant acts as secretary to the committee. The Committee may review any matters relating to the financial, regulatory or compliance affairs of the Board. It reviews the annual financial statements, reports of the Internal Auditor, quality reports internal and from the HPRA, the accounting policies, compliance with accounting standards and the accounting implications of major transactions. The external auditors meet the Committee to review the results of the annual audit of the Board's statutory financial statements. The Audit & Compliance Committee operates under formal terms of reference, which are reviewed by the Board regularly.

Finance Committee Attendance	February	Мау	July	September	November
Ms Linda Hickey Chairperson	√	√	1	√	\checkmark
Ms Deirdre Cullivan	√	1	1	1	1
Ms Kate Williams	1	1	1	1	1

Audit & Compliance Committee Attendance	February	April	June	September	December
Dr Yvonne Traynor Chairperson	\checkmark	\checkmark	\checkmark	√	\checkmark
Mr John Malone	√	√	\checkmark		√
Mr Simon Mills		1	1	1	

Risk Register

The risk register identifies various types of risks including strategic, reputational, clinical, IT, financial and operational risks to the organisation and the existing controls and further actions necessary to minimise the impact on the organisation, in the event of the risk occurring. The IBTS has appointed a Risk and Resilience Manager with responsibility for overseeing the risk register and contingency arrangements. During 2016 work on a single risk register was completed. A set of inherent risks have also been identified which are monitored by the Audit and Compliance Committee and the Board on a regular basis. At present the risk register is reviewed and updated by the Executive Management Team.

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

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.

Internal Control

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

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

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

- A comprehensive system of financial reporting
- Annual Budget prepared and presented to both the Finance Committee and the Board
- Monthly monitoring of performance against budgets by Finance Committee and Board
- Sign off by budget holders on individual budgets
- Budget reviews with budget holders
- Clearly defined finance structure
- Appropriate segregation of duties
- Clear authorisation limits for capital and recurring expenditure approved by the Finance Committee
- Key financial processes are fully documented in written procedures
- Regular stock takes and reconciliations carried out by staff independent of stores staff
- Financial system possesses verification checks and password controls
- Issues of products are reconciled to ensure all of the Board's activities are fully billed

Chairperson's Report

- Regular monitoring of credit control function
- Purchase orders signed by Purchasing Officer or authorised substitute
- Stock items are requisitioned by means of automatic ordering
- All non stock invoices signed and coded by budget managers or their authorised signatories
- All stock invoices are independently matched with stores GRN and purchase order
- Payment verification checks of supplier invoices by staff independent of accounts payable staff

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

The Financial Statements for the year ended 31st December 2016 have been prepared under FRS102.

Statement of Board Members' Responsibilities

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

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

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

Procurement

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

Protected Disclosures

The IBTS has procedures in place for the making of protected disclosures. There were no protected disclosures in 2016.

Commercially significant developments

Hepatitis E Testing

The IBTS commenced testing for Hepatitis E Virus in January 2016. This testing has been grant funded by the Department of Health for 3 years.

Print Management

The IBTS introduced an organisation wide print management system in 2016.

Fleet replacement

The replacement of all IBTS mobile units commenced in 2016.

Haemospect Device

The IBTS introduced a new device to measure Haemoglobin (Hb) levels in donors in July 2014. This device was in use in clinics until October 2015, when it was replaced, due to concerns about its performance. The devices used previously were reintroduced. There is currently litigation ongoing in relation to this matter.

Professor Anthony Staines

Chairperson

"The IBTS continues to supply blood, platelets, tissue and blood products to patients in Ireland within very high standards of quality."

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 struggle to maintain a consistent supply to hospitals.

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 recruited more than 20, 000 new donors in 2016 which was a 40% increase on 2015 but despite this we struggled for much of the year to maintain an adequate supply. We had some very successful promotion campaigns particularly the re-introduction on *Blood for Life Week*, the international campaign *Missing Type* and a much more visible presence on digital platforms. We also engaged a new Creative Company which we hope will bring renewed interest in blood donation and at year end the planning for this campaign was well advanced.

We surveyed our staff at the end of 2015 to find out how they viewed the organisation from the point of view of working environment, communication and opportunities to develop. The results were communicated to staff during 2016 and by the end of the year an action plan was being developed in conjunction with staff representatives to deal with the key issues that came out of the survey. We have also prioritised it as a specific objective in the Strategic Plan 2017 – 2020. The current Strategic Plan finished at the end of 2016 and during the year the development of the successor plan was done through a series of workshops with the Board, EMT and a number of Groups representing staff across the organisation. These sessions provided valuable input for the Plan 2017 – 2020 and this Plan was set to be approved by the Board early in 2017. The contents will then be communicated throughout the organisation and 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 sessions will not be lost.

One of the issues that occupied a lot of time was the proposal to change the donation criteria for MSM. This was a topic which was debated widely in the IBTS and with the Department of Health. The IBTS organised a conference in April 2016 at which speakers from many of the Blood Transfusion Services who had changed the criteria presented their data showing the before and after scenarios. This data was invaluable in allowing the IBTS propose a change to one year for MSM donating. There were other changes relating to STIs. This recommendation was accepted by the Minister for Health and an implementation date of January 2017 was set. Most of this work was led by Dr Willy Murphy, Medical and Scientific Director, and we are indebted to him for leading us through this sensitive issue. We also had a MSM donor who sought and was given leave to take Judicial Review proceedings against the IBTS on the lifetime ban for MSM donating. Due to the change the IBTS was proposing the case was settled.

Chief Executive's Report

Risk management is 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 and Compliance Committee and the Board. We also carried out a desk top exercise on the BCP to find out if it worked. The exercise was very worthwhile and we discovered a number of issues that needed to be addressed and were addressed by year end.

There were a number of changes to key personnel in 2016. The Medical and Scientific Director and Operations Director resigned and in January 2017 the Consultant responsible for testing will retire. These contributed very significantly to the work of the IBTS and brought many innovations, change to how we conducted our business and had a broad network of international peers which were invaluable to the IBTS. I thank them most sincerely for their commitment, dedication and professionalism during their time with IBTS and wish them well for the future. 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 who we serve.

Andrew Kelly

Chief Executive

Medical and Scientific Director's Report

"2016 has been a very busy year for the IBTS as it made its first foray in to regenerative medicine."

Medical and Scientific Director's Report

New challenges in transfusion can appear from unexpected places. A new monoclonal antibody, Daratumumab, was licensed in Europe in 2016 for the treatment of multiple myeloma (a blood cancer). This drug appears to be an advance in myeloma treatment, which is encouraging news for those patients afflicted by this condition. However, it interferes with pre-transfusion testing for patients, potentially masking the presence of a red cell antibody which could cause a serious transfusion reaction.

The IBTS offers a referral red cell

immunohaematology service for patients with complicated transfusion needs and identified the need to investigate approaches to continue to safely deliver transfusion for support for patients receiving this drug. A number of methods had been described by researchers internationally to counteract the interference. The IBTS Diagnostics Laboratory in Dublin put their technical skills to work and evaluated a number of methods prior to the drug becoming available to patients in Ireland. This resulted in both IBTS centres in Cork and Dublin being able to provide a cross-matching service for patients as it became available on compassionate use grounds.

The IBTS continues work on introducing and developing a blood group genetics capability. A collaborative study with both the National Maternity Hospital and the Rotunda hospital was begun in 2016 and is ongoing with the aim of introducing noninvasive fetal RHD typing as a service. Other planned uses include blood group genetic testing for patients (e.g. weak D genotyping, RHD/RHCE genotyping for Haemoglobinopathy patients) and donors to allow high throughput identification of rarer blood groups.

2016 has been a very busy year for the IBTS as it made its first foray in to regenerative medicine. Regenerative Medicine is an exciting emerging discipline, which aims to develop novel treatments, to repair and regenerate damaged and diseased tissues. These therapeutics typically utilise stem cells. There has been a lot of progress globally in stem cell research and bespoke regenerative medicine and the development of this discipline has been a natural fit within the Irish Blood Transfusion Service. There are a lot of synergies between blood and tissue and world wide a lot of tissue banks are housed within the national blood service. The IBTS has the largest tissue bank in Ireland located at its headquarters in Dublin and the range of tissue services provided by the IBTS continues to grow year on year.

In early 2016, the tissue bank was inspected by the HPRA and granted a GMP license to allow it to produce limbal stem cells. This treatment was not available in Ireland up to this point so this is an important juncture in the development of services to Irish patients and one which the IBTS is very proud to be associated with. During 2016 the IBTS produced 2 limbal stem cell grafts which were successfully used to restore sight in 2 patients. This achievement is the result of years of research and development largely funded by the IBTS and a bequest left to the Eye bank by a generous benefactor. Research in regenerative medicine is bringing tremendous advances in science, technology, health and medicine and to be able to translate this research into treatments for Irish patients is very satisfying. Many other stem cell treatments are being investigated and research shows promise in the clinical trials being carried out. These advances hold promise for further development of innovative treatments for injuries and illnesses.

Regenerative medicine continues to develop at a rapid pace and the IBTS is now well placed to provide additional products and services to Irish clinicians and patients. The IBTS was also delighted to start a collaboration with the burns unit in SJH and help in the provision of human skin for the treatment of severe burns.

Professor Ian Hann MD FRCP FRCPath FRCPCH FRCPEd FRCPGIas FRCPI

Acting Medical and Scientific Director MCRN: 400427

Irish Blood Transfusion Service

Operations

'The SSE Airtricity League teams got in on the act also, with the captains of each football team posing for a prematch kick off photograph with the Giveblood sponsored referees, all holding a Blood 4 life week cup."

Donor Services



Blood 4 Life week

IBTS ran Blood 4 Life week in June 2016 to raise awareness of the need for more blood donations, particularly from young people. The week included a week long promotion with 2FM Nicky Byrne and Jenny Greene show including the roadcaster at our D'Olier Street clinic on World Blood Donor day.

The SSE Airtricity League teams got in on the act also, with the captains of each football team posing for a prematch kick off photograph with the Giveblood sponsored referees, all holding a Blood 4 life week cup. This included the Dundalk/Cork match live on RTE.

#MissingType campaign

IBTS were delighted to participate in the international #missingtype campaign with blood centres throughout the world. 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, Failte Ireland, Dublin Tourism, Paddy Power, Irish Mirror, Irish Rail and lots of other companies, we trended number 1 on social media. The digital campaign was a great success in bringing our message to younger people in particular and was accompanied by other non-digital promotions. It also gave donors a chance to let others know they gave blood (an idea we want to continue in 2017) by posting selfies with a selfie blood group board at canteens on our clinics.

As part of the campaign, we aimed to increase the number of first time donors attending our clinics to 20,000 throughout 2016. This was achieved by December and reflected an increase of 40% compared to 2015.

Advertising campaigns

With challenging circumstances all year due to the higher deferral rate on clinic, we ran a number of themed advertising campaigns at different times of the year to increase attendance. We advertised on national and local radio in addition to digital advertising on popular websites and apps. Campaigns included 'Christmas has left us drained' and 'Be a good egg for Easter'. During these campaigns we also ran a number of additional





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Donor Services

used to reply to many donor comments and queries daily. This contact with donors has enabled us to share experiences of donors and patients with a wider group of people and to inspire and further promote the message and benefits of giving blood.

Partnerships

We were very fortunate to link up with Platelets donor Paul Byrne of the Defence Forces who with the help of Airtricity ran the Dublin Marathon in memory of his father Martin, a recipient of platelets and blood during his illness. Paul also attended the IBTS Give Platelets sponsored Remembrance Run for those who have passed away, with Athletics Ireland in November.

Our very significant partnership continued with Vodafone who cover the cost of the nearly 2 million texts we send annually.

Donor Awards Ceremonies

President Michael Higgins attended the donor awards ceremony for 100 times donors in June. Ceremonies were also held on nine other occasions throughout the country.

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1

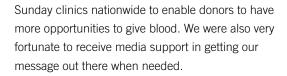
3

2

1

10

it	Donor Awards 2016								
1		50s	100s	Ceremo					
;	Carlow	190	12						
	Limerick	169	12						
	Ardee	78	7						
	Dublin Mobile	398	79						
	Cork	218	43						
s.	Tuam	81	4						
	Total	1134	157						



IBTS and 1916 – Donation. Once. Again.

It's great to have a donor like Brendan Plunkett who made his 100th donation at our D'Olier street clinic before the weekend of the Rising celebrations, and not far from where the surrender of the 1916 leaders had taken place at Brendan's grandparents home in Moore street.

Reactivating Neonatal O negative donors – 206,460 people can't save her life. You can.

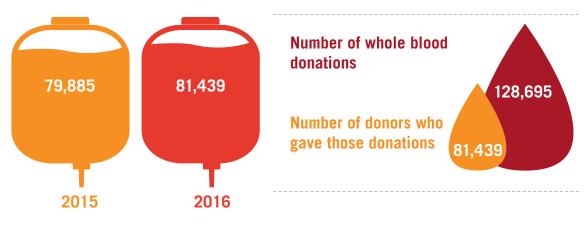
We ran a special direct marketing campaign to reactivate O negative donors whose blood is particularly suitable for transfusions for very young children. These children can only use blood no older than 5 days so, as O negative neonatal compatibility is quite rare but obviously very valuable, we needed to recruit more of these donors to help us supply hospitals with a weekly neonatal supply.

Reactivating donors who have not given in recent times – Do you want to save lives again? IBTS started an email reactivation campaign to recruit back to the donor panel, donors who had not given in the last 2 years. This was very successful in filling the gap of deferred donors who were unable to give.

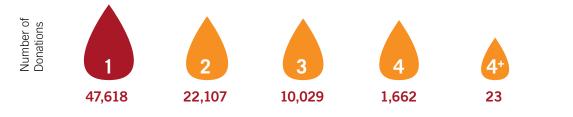
Focus on digital marketing and social media Throughout the year, IBTS increased its focus on digital communication with donors particularly via Facebook and Twitter during promotional campaigns. Our Facebook page now has 90k plus fans and is

Donor Statistics

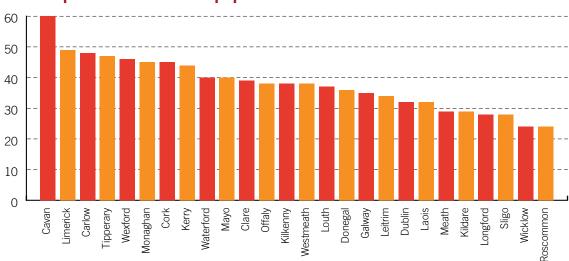




Whole Blood Donations by Donors 2016



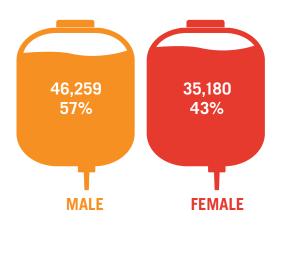
Number of Donors (Note: donors who gave 4+ times are on the HH panel)



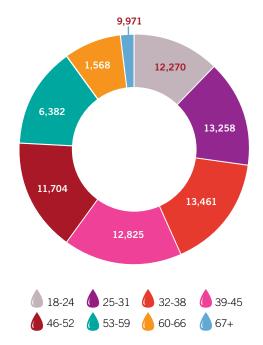
Donors per thousand of the population

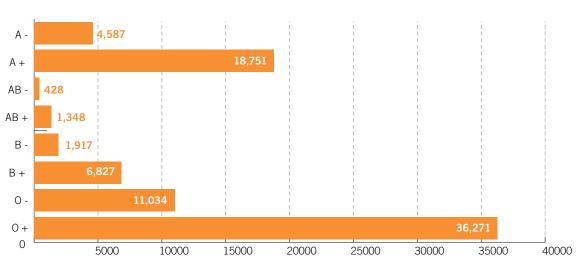
Donor Statistics

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 in the National Blood Centre (NBC) in Dublin, as well as the Components Laboratory and Hospital Services in the Cork Centre.

The NBC Components Laboratory is responsible for processing, labelling, and banking the whole blood collected nationally and plateletapheresis donations collected in the NBC, 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 Components Laboratory in the Cork Centre is responsible for processing, labelling, and banking the plateletapheresis donations collected in the MRTC and also manages the stock holding units based in the Centre. The Hospital Services Department in the NBC and 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 selects and issues all routine red cell products while the Components Laboratory Medical Scientists are responsible for selecting and issuing all platelet products and all non-routine whole blood and red cell products. Cork Hospital Services is responsible for selecting and issuing all routine red cell products while the Cork Crossmatch Laboratory is responsible for selecting and issuing all platelet products and non-standard whole blood and red cell products.

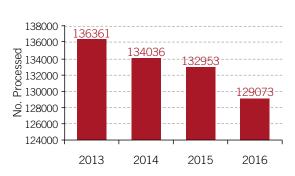
A total of 33,414 product orders were received electronically in 2016. Of these 27,257 were received in the NBC and 6157 were received in Cork. All orders received were managed by close cooperation between the Components Laboratory and Hospital Services personnel in the NBC and between the Components, Hospital Services, and Crossmatch personnel in the Cork Centre.

A revised roster pattern was implemented in the Hospital Services Department in NBC on 16th April 2016. This was the final phase of the Components/ HSD restructuring project. The new roster required participation of all 6 Supplies Officers in both day and night/weekend cover in the area. All 6 staff now rotate through all work patterns. Prior to this change the night/weekend cover was provided by 2 staff permanently assigned to that role and the remaining staff were rostered to cover the days on Mondays to Fridays.

Processing and Hospital Services

Components Laboratory

A total of 129,073 whole blood donations were processed in the NBC in 2016. This represents a 2.92% reduction on the number processed in 2015.

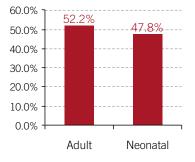


Whole Blood Donations Processed

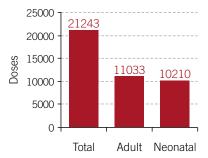
Platelet production consisted of 10,763 apheresis donations collected nationally and 5,639 pooled platelets prepared in the NBC. The apheresis donations were collected and processed in the two centres, with 75% being processed in the NBC and 25% being processed in Cork.

The 10,763 plateletapheresis donations yielded a total of 21,243 issuable doses. This is 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, 52.2% were suitable for adult use only and 47.8% were suitable for adult and neonatal use.

Apheresis Donations by Phlebotomy Type



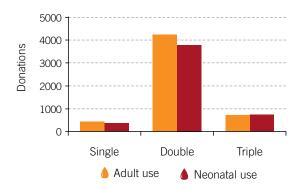
Platelet apheresis Doses by Phlebotomy Type



Processing and Hospital Services

Of the 21,243 issuable plateletapheresis doses prepared, 10,210 (48.1%) were suitable for neonatal use, and 11,033 (51.9%) were suitable for adult use only.

Apheresis Donations by Donation Type



Processing and Hospital Services

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 for neonatal use	1,666	2
Red Cell Concentrate	113,894	116,936
Red Cell Concentrate for neonatal use	10,399	7,842
Red Cells, Clotted	2	N/A
Plasma Products		
Fresh Frozen Plasma, Filtered	12	0
Fresh Frozen Plasma for neonatal use	175	0
Fresh Frozen Plasma for Cryoprecipitate Production	0	N/A
Fresh Frozen Plasma for Cryoprecipitate for neonatal use	360	N/A
Serum for Tears	2	2
Fresh Frozen Plasma for IVD use	123,886	N/A
Buffy Coats		
Leucocytes, Buffy Coat for pooled platelet production	30,117	N/A
Leucocytes, Buffy Coat	3,347	N/A

Secondary Product	Number prepared	Distributed
Red Cells		
Red Cell Resuspended	941	874
Red Cell Washed	50	39
Red Cells Thawed/Washed	0	0
Red Cells for IUT	28	28
Red Cells, Plasma Reduced	593	450
Red Cells Split for Neonatal Use	952	834
Red Cell, Irradiated	15,751	15,337
Plasma Products		
Cryodepleted Plasma	167	0
Cryoprecipitate for neonatal use	167	113
Platelet Products		
Platelets, Washed	87	86
Platelets, Paediatric Dose	11	12
Platelets, Hyperconcentrated	0	0
Platelets, Extended Life	8,634	N/A
Pooled platelets	5,639	4,775
Apheresis platelets	21,243	17,777
Buffy Coats		
Leucocytes, Pooled	0	0
Leucocytes, Pooled, Red Cell Reduced	0	0

Please note that produced will not match distributed due to incoming stock available from 2015 and issued in 2016.

The manufactured products distributed nationally in 2016 are as follows:

Product	Distributed
Riastap 1g	6437
Octaplex 500	16
LG Octaplas O	10,050
LG Octaplas A	5,124
LG Octaplas B	1,945
LG Octaplas AB	320
Uniplas	450
Rhophylac	9

Irish Blood Transfusion Service

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 or the preseroconversion window period.

The NAT laboratory performs Individual Donation (ID)-NAT using the Panther platform in conjunction with the Ultrio Elite 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 Ultrio Elite assay was introduced as a third generation triplex assay to specifically include sensitivity for HIV type 2 RNA detection on the Panther system.

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 2nd June 2015 to 3rd January 2016.

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 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. Interlaboratory comparisons using EDCNet software (National Reference & Serology Laboratory, NRL, Australia, www.nrlga.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, as demonstrated by implementing Corrective and Preventative actions resulting from Quality Incident Reports and Internal Audit reports.

Virology Laboratory

The function of the Virology laboratory at the NBC is the mass screening of 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 139,368 donation samples and 2,458 first time tested non donor samples were tested in 2016.

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) in order to have a supply of Cytomegalovirus 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-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. The IBTS introduced the more sensitive Abbott Prism HIV Ag/ Ab assay in place of the Abbott Prism HIV O Plus antibody only assay in 2016.

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 SNBTS External Contingency testing plan in 2016.

NHIRL

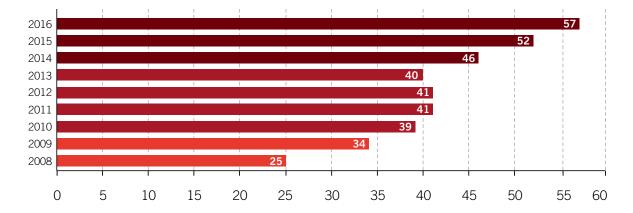
National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL)

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 2016 samples from 199 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



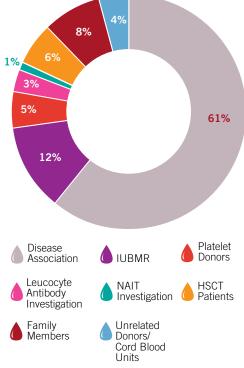
Number of Irish Patients receiving a HSCT from an Unrelated Donor 2008-2016

support service for the Irish Unrelated Bone Marrow Registry (IUBMR) and in 2016 the laboratory HLA typed 694 new volunteer donors to add to the registry.

In the last 9 years the IUBMR has facilitated 375 unrelated donor transplants for Irish patients. In 2016 a total of 57 unrelated donor transplants were performed. Forty-six by St. James's Hospital and eleven by Our Lady's Children's Hospital, Crumlin. Forty sibling donor transplants were also performed between the two transplant centres, giving a total of 97 haematopoietic stem cell transplants in 2016.

The NHIRL also provides a routine disease association HLA typing service. This service represented 59% of the investigations performed in 2016. 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 2015.

NHIRL Investigation Distribution



A total of 290 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.

Diagnostics Laboratory NBC

Diagnostics Laboratory NBC

The Diagnostics Laboratory at the NBC provides Red Cell Immunohaematology and Antenatal services for hospitals nationwide.

The services provided by the Diagnostics Laboratory include;

- Phenotyping of red cells (when phenotyped units not available on the shelf)
- Provision of crossmatched blood for patients with complex antibodies and for hospitals without Blood Transfusion Laboratories
- Investigation of red cell antibodies
- 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 Foetus & Newborn (HDFN).
- Antenatal Screening for red cell antibodies to identify at risk pregnancies. (Includes the

quantitation of Anti-D, anti-c and titration of clinically significant antibodies).

- Provision of suitable blood at delivery for at risk pregnancies.
- Scientific advice to hospital colleagues.
- Extended phenotyping for transfusion dependant patients and for patients with complex red cell antibodies.
- Importation of rare blood for named patients

Laboratory Activity

In 2016 a total of 2444 samples were referred to the Diagnostics Laboratory, a 3% increase on 2015 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-c quantitation. The number of these patients decreased from 50 in 2015 to 39 in 2016. From October to December 2016, 36 samples were referred to IBGRL for RhD classification by molecular methods, in addition to serological work-up by the IBTS. These samples were from females of child bearing potential and molecular testing of RhD is considered more specific than serological methods with regards to distinguishing between different weak D sub-types. This testing will better inform

		RhD Type Workup	Antibody ID	Quantitation anti-D	Quantitation anti-c		Complex Compatibility Test
2015	2374	184	2171	643	244	441	395
2016	2444	199	2243	752	188	490	445
Increase	3%	8%	3.3%	17%	-29.7%	11%	12.6%
(%)							

Comparison of 2015 and 2016 Sample numbers

their requirements with regards to the potential administration of prophylactic anti-D.

273 samples were received for antibody quantitation where the patient has been given prophylactic anti-D. These samples are now been referred following the publication of the 2014 BCSH guidelines on the use of anti-D immunoglobulin for the prevention of haemolytic disease of the foetus and newborn where it states that 'regardless of any prior administration of anti-D lg, any anti-D detected at 28 weeks should be quantified and the results made available'.

As in previous years, there was a continued high level of serologically difficult or rare samples received. In 2016 the following difficult or rare allo-antibodies were identified through the NBC:

Antibody	Patients	Referrals
Anti-Chido/Rogers	8	14
Anti-f	1	12
Anti-Kpb	2	2
Anti-H	1	1
Anti-Vw	1	1
Anti-Wra	5	6
Cr1-related	4	4
Anti-Ge2	1	1
Other HTLA-type	7	13
Rh-related	1	1
Anti-JMH	1	6
System specific	16	21
Daratumumab Interference	19	68
Total	67	150

Many of these patients were antenatal. In conjunction with identification of the antibody, the risk of HDFN and possible blood requirements for mother and baby had to be 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.

In 2016 the laboratory evaluated a number of methods to mitigate against the interference caused by the drug Daratumumab. This drug was first used in 2016 to treat patients with Multiple Myeloma, however, it interferes with key pre-transfusion serological tests. The use of DTT treated reagent red cells was proven to be the most suitable method following evaluation and this method was validated by tube and card IAT methods. Sixty eight samples from 19 patients were tested using this method in 2016.

Importation of Rare Blood/Products

No blood components were imported in 2016.

Participation in External Quality Assurance Schemes

The Diagnostics department participated in 3different quality assurance schemes.4 exercises in IEQAS and AQQAS and 10 exercises in NEQAS, all were acceptable.

Diagnostics/Crossmatch Laboratory 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 & laboratory Services to the Munster region. Medical Scientists and Hospital Services officers are on-site 24/7 supported by Specialist Medical Staff and a Consultant Haematologist.

The services provided by the Diagnostics laboratory include;

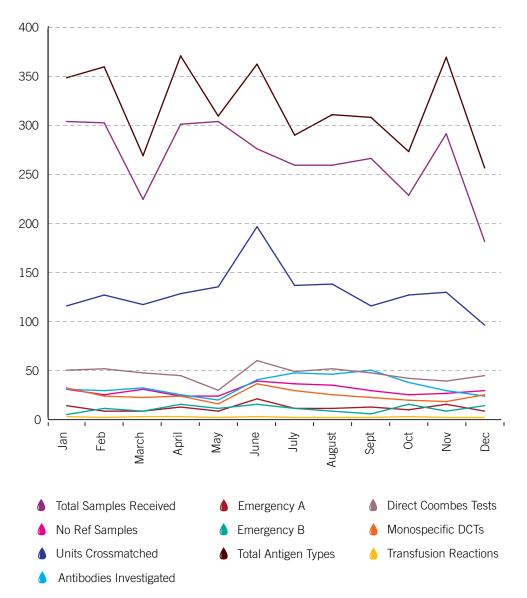
- As hospital Blood Bank for several city hospitals: the Cork Centre undertakes blood grouping, antibody screening, provides crossmatched red cells and other components for individual patients. Provides laboratory and clinical advice for these patients. Investigates possible transfusion reactions, participates in Patient Blood Management and transfusion practice planning and review through the hospital transfusion committees and audit, and manages component traceability.
- As a reference laboratory Diagnostics Cork 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 foetus/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. Twenty eight 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 Diagnostics Cork investigates ante-natal patients with red cell antibodies and tracks their care through the pregnancy to plan availability of matched blood for mother and baby at delivery.
- The Diagnostics' laboratory staff manage special component stock for the region. This includes all platelet components and all orders received by the electronic order system (EOS) for antigen typed red cells, irradiated blood components and blood components for babies.
- As the scientists on duty out of hours the diagnostics' laboratory contributes to the service by undertaking secondary processing of blood components, 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 2016: 3201 (2015:3075)

Diagnostics Cork activity 2016



Automated Donor Grouping

Automated Donor Grouping

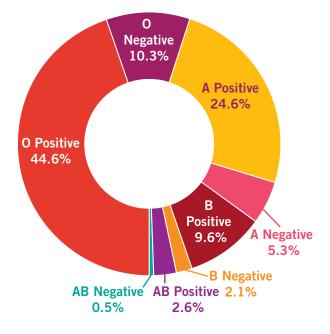
Automated Donor Grouping is continually striving to introduce the most up to date and sensitive testing techniques available. This is achieved by individual research or by way of projects performed as part of further study. These changes not only improve the safety of blood products, but also increase 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. 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.

In 2016 over 140,000 donations were tested and of these 15,117 (10.7 %) 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 100,000 Rh phenotypes (C,c,E,e) and over 34,000 other antigen types in 2016 and provided typed blood for routine hospital orders, intrauterine transfusions and emergency requests for more complex antigen negative units.





The laboratory in 2016 saw an increase in demand for typed and screened units for patients with sickle cell disease and 8090 units were screened for the HbS trait.

There are three on-going projects to identify donors with rare antigen types. The first is a national screening project to find Kpb negative donors. This is required as there have been requests in the past for this rare blood type, which necessitated the importation of suitable units. The frequency of such Kpb negative units should be 1:5000 and the project to screen Rh D Negative units has now been running for three years. Up to date only one donor of this rare type has been identified. The second project is now nearly complete, which is to build up a panel of k (cellano) negative donors (frequency 1:1000). To date 310 donors have been identified and placed on a specially selected panel. 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.

The third project initiated in 2013 involved the use of 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 14 donors with rare weak RhD types identified.

The Automated Grouping Department partakes 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.

The 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 2016.

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 2016 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

"A lot of resources have been utilized in 2016 with the configuration and validation of a computer system for the tissue bank."

Tissue Bank

Tissue Bank

2016 was a very exciting year for the tissue bank. In January 2016, the tissue bank received a manufacturing authorisation from the HPRA to produce Limbal Stem cells. These grafts are used to treat patients with Limbal stem cell deficiency. This treatment was not available for Irish patients before this and to date 2 patients have received this treatment with more planned for 2017.

The Tissue bank at the NBC operates primarily 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. The tissue bank manages all ocular tissue, heart valves, 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 2015. 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.

The activities of the Directed/Sibling Cord blood bank which collects and cryopreserves cord blood on request from the oncology/haematology team in OLCHC and Newcastle stopped activity in October 2015.

A lot of resources have been utilized in 2016 with the configuration and validation of a computer system for the tissue bank. This is specific for Tissue, cells and stem cells. It is envisaged that the new system will be ready for use by summer 2017.

Tissue Bank Activity	
Corneas	163
Sclera	28
Amnion	25
Pericardium	18
Fascia lata	2
ASEs	1
Skin	75 (39,140 cm)
Cord blood	0
Limbal	2
Heart valves	41

IUBMR

Irish Unrelated Bone Marrow Registry

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

To meet the need for haemopoietic 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 Immunology Reference Laboratory (NHIRL)

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 registry was awarded full registry accreditation and following scheduled inspection was reaccredited in 2016.

National Activities

The registry searches for suitable donors on the Irish Panel and Bone Marrow Donors Worldwide (BMDW) on behalf of the Irish Transplant Centres at St James Hospital (SJH) and Our Lady's Children's Hospital, Crumlin (OLCHC). In 2016 seventy nine (79) patients were referred to the IUBMR for unrelated searches. Fifty six (56) Irish patients received stem cells from an unrelated donor in 2016. The majority were from international donors (48).

International Activities

Preliminary searches were received on behalf of three hundred and nine (309) international patients of whom sixty five (65) donors were activated for additional testing requests.

Irish Donors

Bone marrow volunteers are recruited to the panel through the whole blood and platelet donation clinics. In 2016 the number of newly recruited donors was 789, there is over 21,000 donors listed on the Irish registry.

There were ten (10) donations from Irish donors, seven (7) for Irish patients and three (3) for International patients. Of these ten (10) donations, three (3) were bone marrow harvests and seven (7) peripheral blood stem cell collections.

Staff Training

The World Marrow Donor Association (WMDA) in collaboration with the EBMT developed training programmes to standardise the level of expertise of staff performing searches and providing recommendations on graft selection for hematopoietic stem cell transplantation. In 2016 two staff members successfully completed the basic course and are currently completing the advanced level. A third member of staff commenced the basic level course.

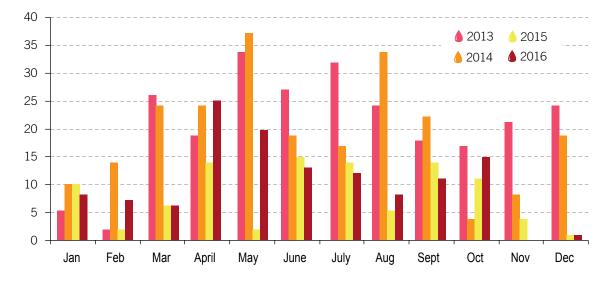
Therapeutic Apheresis

Therapeutic Apheresis

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

The TAS is led by a Consultant in Transfusion Medicine, supported by Specialist Medical Officers and two nurses trained in therapeutic procedures. The procedures are carried out at the patient's bedside using mobile apheresis equipment, in particular the OPTIA Spectra. All procedures performed in 2016 were Therapeutic Plasma Exchange (TPE). However the OPTIA machines have been up-graded to enable Red Cell Exchange (RBCX) and White Blood Cell Depletion (WBCD). The TAS plan an individualised apheresis protocol for each patient in conjunction with the requesting clinical hospital team in charge of the patient. TAS practice is guided by the American Society for Apheresis (ASFA- 2016) 'Guidelines and Indications for Treatment' and takes into account other guidelines including those from the British Society for Haematology.

The TAS conforms to GMP SOP documentation and adverse events reporting, which are regularly being analysed. TAS takes notice and follows hospital procedures in relation to care for patients which are incorporated into the IBTS Therapeutic SOPs. The service intends to participate on international data gathering as this is an important aspect of monitoring service demands and trends. TAS staff attend national and international meetings, and comply with Continuing Professional Development (CPD) as required.



Service demand 2013 - 2016 By Month

Therapeutic Apheresis

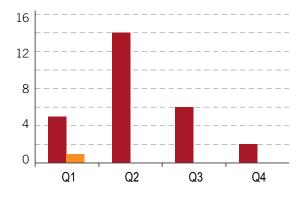
Service Demand 2013 – 2016 By Month

In 2016 the TAS performed 126 procedures, for 23 patients, in two hospitals in Cork. As displayed in the following tables and figures, the demand for TAS is varied and unpredictable. Variations are displayed vis-a-vis previous years' demands, months, weekends and out of hours.

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 126 procedures carried out in 2016, 21% were performed at the weekend and 1% was performed out of regular working hours during the week. The trend in demand for weekend, bank holiday and out of hour's service is displayed below by year quarter

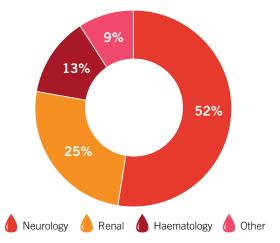
Weekend, Bank Holiday, Out of hours Service Provision 2016



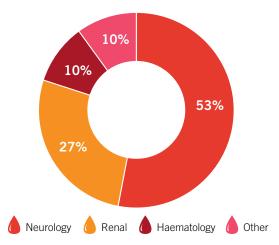
Clinical speciality by patient and procedure

The majority of patients (53%) presented with neurological conditions, followed by renal (25%) and haematology (13%). Nine per cent of patients presented under other specialities. The table below displays the percentage of patients by speciality and the last one displays the percentage of procedures by speciality.

Patients by Speciality 2016



Procedure by Speciality 2016



NHO

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 in 1999 with a total of 5847 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 2016, 154 mandatory SAEs were accepted (69% of all SAEs). In addition, 69 non-mandatory SAEs, (31% of all SAEs) primarily relating to errors in clinical areas, were also accepted.

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

At the time of this report, 154 reactions have been accepted in 2016, a decrease of 179 reports from the previous year. This is primarily due to the fact that from January 2016 the NHO no longer accepted reports of Delayed Serological Transfusion Reactions. Mandatory SAR (60) accepted to date is also a slight decrease on those accepted in 2015 (66).

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. 231 mandatory reports were accepted by the NHO in 2015, with the compilation of 2016 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 undergraduates and specialists registrars also continued during the year. 50

NHO

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. Seventeen HVOs attended this event.

NHO Conference 2016

Over 250 delegates from medical, nursing and scientific backgrounds gathered in the Croke Park Conference Centre on 15th November for the NHO Conference 2016. Delegates attended from almost every hospital in the Republic of Ireland together with representatives from Northern Ireland and other parts of the United Kingdom. Based on the theme 'Transfusion Safety through Quality' speakers were drawn from many disciplines involved in both blood transfusion and patient safety. Where permitted, presentations have been made available on www.giveblood.ie.

A poster competition run at this event attracted 21 entries. The winning submission, Implementation of pre-assessment anaemia pathway reduces transfusion rates and improves outcomes for patients was compiled by a team from Our Lady's Hospital, Navan. Judges commented on the high standard of entries this year.

A number of industry exhibitors maintained stands throughout the day.

e-Learning

The IBTS provides 'Learnbloodtransfusion' e-learning programme under licence to hospitals via LearnProNHS. This programme was developed by the Scottish National Blood Transfusion Service with the NHO and IBTS contributing to editorial content. The majority of Irish hospitals and a number of third level institutions are registered on the programme. This includes hospital staff and health care undergraduates in several universities undertaking the modules as a mandatory course requirement.

"The NHO supports the ongoing development of hospital inservice training programmes by working closely with hospital based HVOs." "The IBTS maintains a number of licenses under the Blood Directive, Tissue Directive, GDP requirements and a Manufacturing Authorisation of Limbal Stem Cells (hospital exemption cATMPs)."

450 ml

Quality & Compliance

Quality and Compliance

During 2016 a number of changes in personnel within the Quality Unit occurred including the appointment of a new National Quality Assurance Manager and Biovigilance Officer. The Medical and Scientific Director retired after a number of decades service to the organisation. Despite these changes, the programme for change within the Quality Management System proceeded as before with major projects like the introduction of Hepatitis E Testing, replacing the donor Haemoglobin Screening Technology, development of the Foetal Genotyping Laboratory, the first product release from the Limbal Stem Cell programme, evaluation of a Pathogen Reduction Technology and the introduction of deferrals relating to travel to Zika virus areas.

The Annual HPRA programme of inspections covered 6 inspections during 2016 covering 3 clinics and 3 site visits. Two major non compliances were raised relating to Quality System issues. Five reports received and one outstanding for the National Blood Centre inspection in November 2016.

The IBTS maintains a number of licenses under the Blood Directive, Tissue Directive, GDP requirements and a Manufacturing Authorisation of Limbal Stem Cells (hospital exemption cATMPs). Annually these licenses are updated and annual reports are filed on activity levels for the year.

As always changes in the Quality Management System are captured through the Change Control System. There were 590 Change Controls raised during 2016 and 653 Change Orders. This represents a slight increase of the activity over 2015. Internal changes to the Quality Management System now requires more detailed information, on risk assessment and validation / Change Controls plans in advance of approval of changes. This should speed up the approval process and ensure better planning in design of changes.

Metrics were reported to the EMT during 2016 with close out rates targets not being met. During 2017 the metrics reported and the ownership of reporting will be reviewed to make them more relevant. The target of achieving 80% close out for Incident reports (IRs) and Complaints were only achieved for 2016 figures in Quarter 1 2017. The total number of IRs raised during 2016 was 1475, a slight increase over the number reported for 2015 at 1401. A number of updates for operational reasons were introduced to the Blood Establishment Computer System (BECS) during the year.

Quarterly contingency testing was performed with the Scottish Blood Transfusion Service. The processing contingency site was also tested a number of times during 2016 with a view to identifying issues that would need to be addressed in advance of a real contingency.

The Complaint Handling System processed 932 complaints from hospitals covering problems with the issuing of unusable / incorrect product to the slowness with distributing product to hospitals. A similar number of complaints were processed in 2015. A close out rate of 84% was achieved by early 2017 for the year 2016.

Quality & Compliance

A total of 329 recalls were investigated during 2016 with the majority due to post donation information from donors.

Ongoing analysis of both complaints and IRs is done throughout the year to ensure that Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs) are captured and analysed.

There were 83 SAEs accepted by the NHO from the IBTS as a Blood Establishment during 2016 and a total of 47 SARs were reported and accepted by the National Haemovigilance office. These figures compare favourably with those reported for 2015.

Annual Report 2016

Human Resources

Human Resources

Human Resources

The Human Resources department continued to focus on internal human resource strategies. This focus enabled the staff to meet the needs of our donors and patients throughout the year. The internal human resource strategies include remuneration and benefits, employee and industrial relations, staffing and workforce planning, organisational development, environmental health and safety and library services.

Organisational development was the key theme for 2016. This led to the creation of a multidiscipline Learning and Development Working Group who were responsible for the development of a comprehensive 3 year Learning and Development Strategy. The Learning and Development Strategy is designed to support the immediate and longer term business objectives of the IBTS, through innovative learning and development for all.

Our vision is 'Working, Learning and Growing together' which has at its core, the idea that positive change resulting from a culture of learning, working and growing together and through opportunities for innovative life-long learning, thereby enabling the whole organisation to become a great place to work. In addition to the above three high level goals were identified as the foundation upon which to deliver this strategy. They are:

- Expertise
- Growth
- Delivery

These goals will facilitate the realisation of the organisation's mission statement and objectives through the development of our employees. They will ensure that the focus is on having the necessary expertise to achieve the excellence in service to which the IBTS aspires, both now and into the future. Achievement of these goals will promote the nurturing and growth of this expertise. In addition, the development of new and better ways to deliver our services, through on-going continuous improvement, will assist in attaining the IBTS primary objective of excellent transfusion services for the people of Ireland

A comprehensive implementation plan has been developed for the next three years, which sets out the journey required to successfully deliver this ambitious strategy.



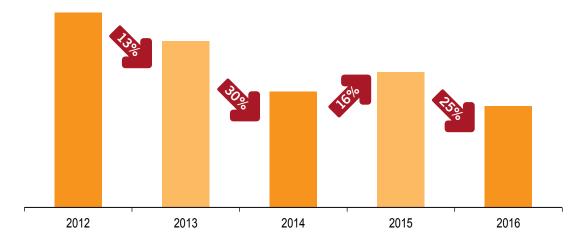
Environmental, Health and Safety (EHS)

The downward trend in staff accidents and incidents continued in 2016

Occupational Health Programme

The IBTS continued to work with Occupational Health in the area of monitoring and surveillance with more than 100 current employees completing and submitting assessment questionnaires.

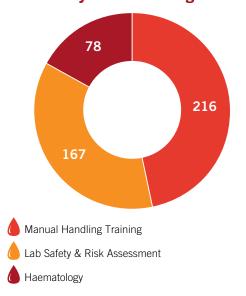
Number of Accidents - Annual Comparison 2012-2016



Biosafety programme

EHS in conjunction with a working group comprised of representatives from various departments came together to produce a Biosafety Manual for the organisation. The Biosafety Manual provides an overview of biosafety principles to manage the risk of exposure to biological agents and materials in addition to the legal requirements of the safety, Health & Welfare at Work (Biological Agents) Regulations 2013 and associated Health and Safety legislation.

Mandatory Staff Training 2016



Finance

Summary Accounts for the year ended 31st December 2016

	2016 €'000	2015 €'000
Income		
Sales and Tests	64,825	65,429
Other Income	11,175	525
Total income	76,000	65,954
Expenditure		
Total expenditure	69,436	71,872
Surplus / (Deficit) for year	6,564	(5,918)
Actuarial gain / (loss) on pension scheme	(23,639)	24,163
Transfer to Capital Reserves	(70)	(88)
Transfer to Research Reserve	(449)	(53)
Accumulated Deficit at 1st January	(42,975)	(61,079)
Accumulated Deficit at 31st December	(60,569)	(42,975)

Income

The Board's total income for 2016 of €76 million (2015 €65.95 million) is analysed into income from sales and tests and other income. Income from sales and tests consists of revenue generated from sales of products and services provided to hospitals of €64.83 million (2015 €65.43 million). Other income of €11.18 million (2015 €0.53 million) includes both grants from the Department of Health and interest on bank deposits. The decrease in income from sales and tests represents decreased volumes in 2016 while the increase in other income is due to a grant received of €840K for Hepatitis E virus testing of donations and also a once off grant of €10m in relation to the IBTS Pension Scheme.

Expenditure

Expenditure for 2016 amounted to €69.44 million (2015 €71.87 million). The decrease in expenditure mainly arises from reduced employer pension costs. The Board accounts for pensions in accordance with financial reporting standard 102.

Reserves

The Board has a Capital reserve for the development of new facilities in Cork. The balance in the fund at the year ended 31st December 2016 was €8.60 million.

In 2006 the Board set up a research reserve. In 2016 the balance of research funds was €1.76 million. (2015 €1.31 million).

Capital Expenditure

The Board invested €1.4 million in capital projects and equipment during 2016 (€2.7 million 2015).

The main investments during the year included expenditure on the IBTS motor fleet and there was also investment in ICT infrastructure, laboratory fridges, freezers and other plant and equipment.

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 2016, under the terms of applicable legislation, invoices to the value of €269,235.37 were late, by an average of 18.27 days. These invoices constituted 1.7% by number and 0.54% by value of all payments to suppliers for goods and services during the year. Total interest and fines paid in respect of all late payments amounted to €12,114.09

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

Solicitors

Arthur Cox Earlsfort Centre Earlsfort Terrace Dublin 2

Bankers

Allied Irish Bank Dame Street Dublin 2

Irish Blood Transfusion Service

National Blood Centre

James's Street, Dublin 8 t: 01/4322800 f: 01/4322930 e:contactus@ibts.ie

www.giveblood.ie Donor infoline 1850731137 www.facebook.com/giveblood www.twitter.com/giveblood.ie

Cork Centre

St Finbarr's Hospita Douglas Road Cork t: 021/4807400 f: 021/4313014

Dublin Blood Donor Clinic

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

Stillorgan Blood Donation Clinic

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

Ardee Centre

John Street Ardee Co Louth t:041/6859994 f:041/ 6859996

Carlow Centre

Kernanstown Industrial Estate Hackettstown Road Carlow t: 059/9132125 f: 059/9132163





National Blood Centre

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