# ANNUAL REPORT 2015







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# Chairperson's Foreword

2015 was a busy year for us, but it was also a year of one bad shock, and many transitions. Our job is to provide a safe, secure, and reliable supply of blood products for patients using the Irish health services. This work includes ensuring the safety of our donors, as well as those who receive our products.

Late in 2015 we discovered that a new device we were using to check the haemoglobin levels in donors was faulty, and that a number of donors had been accepted at haemoglobin levels well below those permitted. We have contacted all our donors, and changed back to our previous method of haemoglobin testing, using a finger prick test.

We have more positive outcomes from 2015.

- Our new computer system is live and working well, after some initial problems. We are offering appointments to donors in our fixed clinics and have piloted appointments with one mobile team, and we will extend this over 2016. If experience elsewhere is a guide, many donors will choose to make appointments.
- All our blood is now being processed in Dublin. After many years of great service, the processing facility in Cork has closed. As our new development on the CUH site progresses, the long, proud tradition of the Munster transfusion centre will continue in a new form, providing essential services both regionally, and nationally.

- We have agreed funding with the Department of Health, and have begun Hepatitis E testing for the Irish blood supply. This will further improve the safety of our products.
- We have begun work on building a new, closer, relationship with those working on clinical applications of cell therapy in Ireland, as we believe the IBTS has skills and capacity to offer in that area.
- We have agreed a way forward to review our current policy on deferral for men who have sex with men. A major conference, chaired by Professor John Bonnar, will be held in Dublin, in April 2016, and this will guide future policy.

We continue to face financial challenges. We hope that our long-standing proposal to link our prices to our internal activity based costing system, will be accepted by the Department of Health and the Minister. We also hope that the long-term problem with our pension fund can be definitely resolved in early 2016, perhaps before this foreword is published. Further steps have been and will continue to be taken to reduce our costs.

As always, I have to thank our staff. Their commitment was well demonstrated in our response to the severe problem with haemoglobin measurement. Every member of staff worked, in many cases well beyond their usual work, to help us resolve the problem, to deal with calls from donors and to bring back into use our previous system. This was a phenomenal amount of work which had to be done to the most exacting standards and it was. Our

executive management team responded very well to some difficult challenges during the year, but kept the blood supply safe and reliable, and the IBTS making progress. Thank you all very much.

Our donors also rallied around. One consequence of moving to the older system is that the number of donors deferred will rise sharply. This is a problem in winter, but will be a bigger problem in Summer 2016. So far, the response to our needs, both from our existing donors, new donors and 'lapsed' donors has been magnificent. My thanks to you all too.

Finally my colleagues on the board, both those who stepped down in 2015 Gerry Kelly, Olwyn Bennett, Cleona Duggan and John Cregan and the new board members deserve all our thanks. The IBTS is a complex organisation with a very specific history, complex functions and strong culture, and my board colleagues all contribute to this.

#### **Professor Anthony Staines**

Chairperson



# Chairperson's Report

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Report of the Chairperson of the Irish Blood Transfusion Service regarding the assessment of internal financial controls of a State body for the year ended 31st December 2015 in accordance with Appendix V of the Revised Code of Practice for the Governance of State Bodies 2009.

- 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.
- 3. The Board confirms that there is an ongoing process for identifying, evaluating and managing significant risks faced by the IBTS. This process is regularly reviewed by the Board via reports from the Chief Executive.
  - i. Management are responsible for the identification and evaluation of significant risks applicable to their areas of business together with the design and operation of suitable controls. These risks are assessed on a continuing basis and may be associated with a variety of internal or external sources including control breakdowns, disruption in information systems, natural catastrophe and regulatory requirements.
  - ii. Management meets twice monthly on operational issues and risks and how they are managed. The Executive Management Team's role in this regard is to review on behalf of the Board the key risks inherent in the affairs of the

IBTS and the system of actions necessary to manage such risks and to present their findings on significant matters via the Chief Executive to the Board.

- iii. The Chief Executive reports to the Board on behalf of the executive management on significant changes in the work of the IBTS and on the external environment which affects significant risks. Where areas for improvement in the system are identified the Board considers the recommendations made by the Executive Management Team.
- iv. The Director of Finance provides the Finance Committee, which is a sub-committee of the Board with monthly financial information, which includes key performance indicators.
- v. An appropriate control framework is in place with clearly defined matters which are reserved for Board approval only or, as delegated by the Board for appropriate Executive approval. The Board has delegated the day-to-day management of the IBTS and established appropriate limits for expenditure authorisation to the Executive. The Chief Executive is responsible for implementation of internal controls, including internal financial controls.
- vi. The board has approved internal auditors to provide independent assurance on the internal controls.
- vii. 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 its 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 2015 at its meeting on the 8th February 2016.

# 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 Revised Code of Practice for the Governance of State Bodies, published by the Department of Finance in 2009.

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 'Revised Code of Practice for the Governance of State Bodies.' 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 has adopted the Revised Code of Practice for the Governance of State Bodies as published by the Department of Finance in June 2009.

#### **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 and had two Special Board meetings, one on 13th April and the other on 28th October.

Attendance by Board members was as follows:

## Chairperson's Report

Board attendance 2015	February	April	June	September	November	December
Prof Anthony Staines	1	✓		✓	✓	✓
Ms Kate Williams	✓	✓	✓	✓		✓
Dr Julie Heslin	✓	✓	✓	✓	✓	✓
Dr Elizabeth Kenny	✓	✓	✓	✓	✓	✓
Dr Jorgen Georgsen		✓	✓	✓	✓	✓
Ms Linda Hickey**		✓		✓	✓	✓
Ms Deirdre Cullivan*				✓	✓	✓
Ms Simon Mills*				✓		
Mr Brian O'Mahony**	✓			✓	✓	✓
Dr Ronan Desmond*						✓
Ms Yvonne Traynor*				✓		✓
Mr John Malone*				✓		✓
Mr John Cregan‡	✓					
Dr Cleona Duggan‡‡	✓	✓				
Ms Olwyn Bennett‡‡	✓	✓				
Mr Gerry Kelly ‡‡	✓	✓				

All members receive appropriate and timely information, to enable the Board to discharge its duties. The Board takes appropriate independent, professional advice as necessary.

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

<sup>\*</sup> Appointed 20/07/2015 \*\*Reappointed 20/07/2015

<sup>‡</sup> Resigned ‡‡ Term expired 31/05/2015

Board Fees and Expenses 2015						
Board members remuneration and expenses were as follows:	Board Fees	Expenses				
	€	€				
Professor Anthony Staines Chairperson	Nil	697				
Deirdre Cullivan	4,834	470				
Mr Brian O'Mahony	Nil	Nil				
Mr John Cregan	Nil	817				
Mr John Malone	4,834					
Ms Linda Hickey	10,359	Nil				
Ms Olwyn Bennett	5,525	Nil				
Mr Gerard Kelly	5,525	1,238				
Simon Mills	4,834					
Dr Elizabeth Kenny	Nil	1,008				
Dr Julie Heslin	Nil	1,149				
Dr Jorgen Georgsen	11,970	4,620				
Yvonne Traynor	4,834					
Ms Kate Williams	11,970	293				
	64,684	10,292				

#### Members of the Board

Professor Anthony Staines (Chairperson) (term expired 31st May 2015 – reappointed 20th July 2015)

Mr Brian O'Mahony (term expired 31st May 2015 – reappointed 20th July 2015)

Mr John Cregan (resigned on 23rd March 2015) Ms Linda Hickey (term expired 31st May 2015 – reappointed 20th July 2015)

Ms Owlyn Bennett (term expired 31st May 2015) Mr Gerry Kelly (term expired 31st May 2015)

Dr Cleona Duggan (term expired 31st May 2015)

Ms Kate Williams

Dr Elizabeth Kenny

Dr Julie Heslin

Dr Jorgen Georgsen

Dr Ronan Desmond (appointed 20th July 2015)
Ms Deirdre Cullivan (appointed 20th July 2015)
Ms Yvonne Traynor (appointed 20th July 2015)
Mr Simon Mills (appointed 20th July 2015)
Mr John Malone (appointed 20th July 2015)

# Guidelines for the appraisal and management of Capital Expenditure Proposals

The Board is committed to complying with the Guidelines for the Appraisal and Management of Capital Expenditure Proposals issued by the Department of Finance in July 1994, (revised Jan 2005) and Circulars 02/09 and 02/11 relating to arrangements for ICT expenditure in the civil and public service.

### Chairperson's Report

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 salary and performance of the Chief Executive. This Committee did not meet in 2015. 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 2015 was €148,964.

#### **Medical Advisory Committee**

The Medical Advisory Committee is comprised of the medically qualified members of the Board and the medical consulting staff and met 9 times in 2015. Its function is to monitor developments relevant to the field of transfusion medicine and related fields, to inform the Board of any such developments and to advise the Board on appropriate action.

#### **Finance Committee**

The Finance Committee met four 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, external audits by the Comptroller and Auditor General, financial and management accounts,

financial KPIs, capital expenditure, working capital and cash flow. It also reviews business planning, costing exercises, procurement, insurance arrangements, contracts, banking, financing arrangements and treasury policy. The Committee reports to the Board on management and financial reports and advises on relevant decision-making. The Finance Committee operates under formal terms of reference which are reviewed by the Board regularly.

#### **Audit & Compliance Committee**

The Audit and Compliance Committee met four 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 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, 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.

#### **Risk Register**

The risk register identifies various types of risks including strategic, reputational, clinical, IT, financial and operational risks to the organisation and the existing controls and further actions necessary to

minimise the impact on the organisation, in the event of the risk occurring. The Risk Register is divided into Organisational, Clinical and IT components. During 2015 the Risk Management Policy and Procedure was approved and a single risk register has been developed. It was also agreed that a set of inherent risks would be set out which would be monitored by the Audit and Compliance Committee and the Board on a regular basis. At present the organisational risk component is reviewed and updated by the Executive Management Team. The clinical risk component is reviewed by the medical consultants and the IT risk component is reviewed by the Chief Executive and the IT Manager.

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 2015 have been prepared under FRS102 for the first time.

#### 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.

#### **Commercially significant developments**

## Consolidation of processing in the National Blood Centre

Prior to October 2015 processing of components was carried out in two sites, the National Blood Centre in Dublin and the IBTS Centre in St Finbarr's Hospital, Cork. The Board decided to consolidate processing in one single site and this was implemented over the October Bank holiday weekend.

#### Introduction of eProgesa

The computer system which underpins all collection, processing, testing and issuing of blood and blood components in the IBTS was upgraded to version eProgesa in September 2015. This was a significant undertaking for the organisation. The implementation also saw the introduction of ISBT128 labelling for all products.

#### **Professor Anthony Staines**

Chairperson





# Chief Executive's Report



The IBTS continued to deliver blood transfusion to the highest standards during 2015 despite the many challenges the organisation faced. We successfully implemented eProgesa and ISBT 128 and at year end there was an agreed solution to our long standing pension issue which required the agreement of staff. We centralised our processing to Dublin in October and this has worked very well. We will have a hot site contingency in our Centre in Cork. In late October we discovered a problem with our Hb measurement technology which had serious consequences for donors and the sustainability of the blood supply. It will require a significant effort to mitigate the impact of the increase in Hb deferrals so that we can maintain a consistent blood supply.

We continue to operate in a very constrained financial environment and there is a requirement for us to effect further cost savings. For the first time in a number of years there was an increase in the use of blood and platelets. However, the usage is 13% and 10% lower than 2009 for red cells and platelets respectively.

The challenge that declining revenue and increasing costs poses for the IBTS is how to remain current with developing technologies and to have sufficient capital to invest in equipment, technology and resources. We had sought to introduce Activity Based Costing as a means of setting our prices in 2016 but this has not been agreed by the Department of Health. This issue needs to be addressed so that an appropriate funding model is agreed that will fund the activities of the IBTS into the future.

We continue to work with key stakeholders in Cork to build a Centre for Transfusion Medicine on the campus of Cork University Hospital. This will change significantly how the IBTS operates in Cork.

We commenced the work of developing a Strategic Plan 2017 – 2019. We met with the Secretary General of the Department of Health and some of his officials on key strategic issues. This work will continue during 2016 with a workshop with the Board, the Executive Management Team, Strategy Group and other key stakeholders in the organisation with a view to publishing a revised strategy in December 2016.

Our Operations Director has decided to leave the IBTS in early 2016. I would like to express my sincere appreciation for his commitment, professionalism and dedication during his term. He made a very significant contribution to the work of the IBTS and made many innovative changes to his area of operations. I wish him and his family well for the future.

I would like to express my sincere appreciation to all staff who work in the IBTS. Without their commitment and professionalism we could not deliver the services that patients need to the highest standard in a timely manner.

#### **Andrew Kelly**

Chief Executive



# Medical and Scientific Director's Report



Research teams in the United Kingdom, the USA, and in Europe are working hard to develop methods to grow red blood cells in stem cell factories for blood transfusions. Others are trying to do the same with platelets – a type of blood cell essential for proper blood clotting. It's a mighty quest, a project of bioengineering unlike any other. It will take years to accomplish, but on their way these projects will solve many problems in large scale bioengineering that will open doors in many other directions in advanced health care. The very fact that several high powered scientific bodies have thrown their hats into this ring points up the essential nature of having adequate supplies of good, safe blood cells, how important that is in today's health care. And how demanding: every day every health care system in the developed and developing world has to safely and securely manage for hundreds or thousands of their healthy citizens give up their time to have a large needle stuck in their arms for no reason other than the good of their fellows. If blood transfusion ever does get superseded by factory-farmed stem cells in some distant future, and that's a very big if, then something extraordinary will have been lost to history. But it is a struggle, balancing patient needs with donors' availability. Donors need to be fit and healthy, and every year new donors must come forward to take the place of those who have done their part, and who for whatever reason are no longer able to donate. Donation is simple and straightforward, but not everyone can easily yield up ten percent of their blood volume on a regular basis. Among those who can there are many reasons why the blood transfusion service won't take their blood for transfusion, at least for the time being. Travel abroad is a major reason why donors are deferred – insect- borne virus diseases acquired when travelling, even within Europe or

the USA, are a concern, since these can be readily transmitted from donor to blood transfusion recipient, even when the donor feels well and healthy. West Nile virus, Chikungunya, and Dengue were present in Continental Europe as well as further afield in 2015, and we kept a wary eye on babesiosis in the North-eastern US and Mers-CoV in the Middle East. More exotic viruses, including Bourbon virus in the Mid-West USA, and Zika virus in South America Virus that was to cause such concern later, were also kept under surveillance. In recent years the task of monitoring potential new and well established transfusion-transmitted infections around the world has become very much easier with the emergence of good working internationally-coordinated surveillance networks. However the difficulties in keeping the blood supply safe remain, and the need for vigilance for, and an adequate response to, emerging threats is constant.

Closer to home hepatitis E acquired in Ireland from food required a different approach to deferring people at risk, and funding was obtained to test every donor for the virus for three years starting in January 2016. In this we were the first country to decide on universal donor testing, a measure of Ireland's commitment to providing as safe a blood supply as we can achieve.

Ultimately, blood safety will need effective sterilisation methods for red cells and platelets. We awarded a tender for a technology for pathogen reduction in platelets in 2015; there isn't an available technology for red cell pathogen reduction available as yet, though two manufacturers at least are making progress in developing suitable methods.

## Medical & Scientific Director's Report

During 2015 the IBTS completed the development phases of its Limbal Stem Cell Programme, a major new direction in developing in-house expertise in stem cell therapy. Limbal stem cell transplants restore vision to patients with specific types of diseases of the front of the eye who cannot repair their own corneas after disease or injury. These patients need corneal stem cells to be harvested from tissue donors and cultured in the laboratory for 2 to 3 weeks before transplant. It's a very demanding process in many ways, and achieving this competence puts the IBTS in a pivotal position to support the future development of stem cell therapies in many other areas of medicine in Ireland in the future.

2015 also saw the initiation of blood group genotyping at the IBTS – initially to guide the use of antenatal prophylaxis with anti-D in the prevention of residual cases of Rhesus Haemolytic Disease of the Newborn. This technology – determining the blood types of patients and donors by genetic methods rather than the current standard methods using antibody techniques – will revolutionize much of blood banking in time, leading to better, quicker, and perhaps even cheaper provision of blood transfusions in hospitals.

However, we will still need donors, and those donors will still need the highest achievable levels of care to ensure that the donation is a safe process. Towards the end of 2015, we became aware of an issue with the method we were using to test haemoglobin levels when we took donor blood donations. In 2014, we had introduced a new method for testing the haemoglobin levels in donors - we had replaced the older finger-prick blood test with a new device that measured haemoglobin by analysing xenon light beamed through the tissues of the fingertip. Once the issue was identified, we suspended the use of the new method and reverted to the older finger prick blood test. We have written to every donor who had been tested and accepted for donation using this device, the Haemospect, to apologise for what had happened and to let them know that they should visit their own doctors at the IBTS's expense if they had any concerns. There were approximately 90,000 donors involved.

#### William Murphy, MD, FRCPEdin, FRCPath

Medical & Scientific Director
Consultant Haematologist
UCD Clinical Associate Professor





# **Donor Services**



#### **Garda Cycle to Geneva**

Once again it was time to root out the shorts and Lycra for the annual Garda Blood4Life Cycle. This year the cycle took place over 6 days from June 9th to June 15th. The eighteen strong group left Cork on a cold but otherwise sunny morning with Switzerland in their sights!

The team, many of which are members of An Garda Síochána and all avid cyclists, casually embraced the enormity of this transcontinental spin. This cycle was undertaken by all in an effort to raise awareness about the need for blood donation. Each and every participant had asked members of the public to pledge to give a unit of blood in support of their tremendous efforts.

On the 14th of June, on time and in good spirits, the team rolled into Geneva and arrived at their destination at the World Health Organisation headquarters. What made this arrival extra special was the fact that it was World Blood Donor Day! A fantastic effort from all.

#### **App Update**

Following the launch of the official IBTS app in 2014 we are pleased to see that the new app is proving very popular with our tech savvy donors this year. To date the application has been downloaded over 10,000 times across iOS and Android platforms.

The app which allows donors to find the location of their nearest clinic as well as check essential eligibility criteria is available to download via the homepage on the IBTS website – www.giveblood.ie. It is hoped that extra functionality will be added to

make for a more customised digital experience for our donors. Thanks to all of our regular donors and app users for spreading the word about this new mobile solution.

#### **Emergency Services Partnership launch**

Passers-by were treated to an unusual spectacle at Grand Canal dock on a fresh summer morning in July as members of various emergency service organisations gathered near the Bord Gáis Energy Theatre for a photo-shoot with a difference.

The Gardai, Coast Guard, Defence Forces and Dublin Fire Brigade were on hand at the scene with their equipment and vehicles to show their support for the Irish Blood Transfusion Service in an effort to highlight the importance of giving blood.

"Buddy", a life-sized and super energetic blood drop mascot was the star of the show, posing for photographs with service members and intrigued members of the public who happened to be in the area.

It is hoped that reinforcing our ties with the emergency services will help to ensure a safe and sustainable blood supply in the future.

#### **Door Award Ceremonies**

Donor awards ceremonies took place in Dublin, Carlow, Cork, Tuam and Ardee. A total of 608 donors received recognition for giving over 50 and 100 donations.



#### **Donor Services**

These awards are an important part of the IBTS calendar year as it serves to recognise donors and their continued commitment to giving blood or platelets. It is an opportunity for the IBTS to thank donors for their long-standing loyalty and commitment to saving lives.

At each of these events a patient who has received blood tells their story and brings real meaning to each donor of what their life saving gift means to others.

In Ardee, one hundred and twenty eight 50 time donors received their gold drop and eight 100 time Donors received their porcelain pelicans. In Dublin 115 donors received gold drops and 82 received their porcelain pelican. In Tuam, 89 donors received gold drops and 5 received their porcelain pelican for 100 donations. Cork had 164 donors collect their gold drops and 17 donors who received their porcelain pelicans.

#### **Blood Works**

A great effort was made this year to encourage organisations and businesses of all shapes and sizes to get employees to give blood as part of their corporate social responsibility efforts and activities.

A new information and awareness pack designed to inspire organisations and help them get involved with ease was released over the summer – a time when blood is always in demand.

This reinvigorated corporate awareness programme promotes staff morale and in turn helps organisations fulfil their corporate responsibilities. Continued efforts are underway to deliver this awareness pack to key

decision makers in organisations and businesses that are located in the greater Dublin and Cork areas, with easy access to our fixed clinics in Dublin.

It has never been easier to give blood as part of a team or work group thanks to this initiative.

#### **RCSI MyHealth App**

The new RCSI MyHealth App was developed to provide easy access to credible health information. The IBTS was one of sixteen of Ireland's leading charity organisations supporting this app launch in 2015.

The app offers users the opportunity to discreetly search for information relating to specific health conditions and allows users to take charge of their own health. The information is presented in a clear, focused and organised manner that is easy to understand. It also provides users with information on where to seek advice and support if they are suffering from a health condition.

IBTS have a visible presence on the app and it is hoped that this brand presence will encourage users to consider giving blood regularly.

#### **FAI** and the IBTS

The FAI and SSE Airtricity League joined forces with the Irish Blood Transfusion Service in 2015 to increase awareness of the need for more blood and platelet donors.

SSE Airtricity League players showed their support for the Irish Blood Transfusion Service's platelets awareness campaign by wearing promotional tee-



shirts during match warm-ups and platelet wristbands during competitive games through the year.

The IBTS have also sponsored domestic league matches in an effort to drive awareness of the need for blood donation. Through the season FAI match officials and referee's wore a heavily branded and highly visible "Give Blood" arm band at all league matches.

#### "Roll up your sleeves" advertising campaign

In late 2015 Ireland's blood supply was under huge pressure due to donation restrictions implemented for certain female donors.

The IBTS and their partner creative agency developed a clever communications campaign that encouraged people to make a special effort to give blood, despite the clinical issues that the oragnisation were experiencing. This was a targeted communication that was built to specifically appeal to donors of a certain demographic.

Soon after the campaign launched, donation levels returned to near normal levels meaning that the IBTS did not have to take immediate further action. This campaign was released on both digital and traditional communication platforms. The IBTS employed a heavy digital media bias for the duration of this campaign.

#### Flesh and Blood Initiative

Launched in April 2015, the "Flesh and Blood" campaign saw priests and pastors from a variety of denominations urge their congregations to embrace the spirit of Easter and donate blood as part of the Christian tradition of giving.

The IBTS is delighted to have the support of the churches to bring real awareness of the constant need for blood donations and enable us to reach in to communities to help maintain supply to all our hospitals.

The Flesh and Blood campaign began in the UK to increase the number of blood and organ donors and is now being promoted in Ireland. As part of the campaign launch, Saint Patrick's Cathedral was wrapped in a red gift ribbon to highlight and encourage organ and blood donation as a gift.



# Components and Hospital Services

2015 was a very busy year for all of the staff in the Components and Hospital Services department. Three of the organisations major strategic objectives listed below were implemented.

- The introduction of eProgesa, the IBTS mainframe computer system
- The introduction of ISBT128 full face labelling of blood components.
- Transition to single site processing in the National Blood Centre.

These had a major impact on all of the operations within the department. From the start of the year staff members were involved in the preparation of validation plans, execution of testing, staff training and successful implementation.

#### Computer System eProgesa

On 6th September 2015 the main computer system was upgraded from Progesa to eProgesa which is the mainframe computer system in use for processing and issue of all blood components. This change had a major impact on the laboratory.

#### **ISBT 128 Product Codes**

ICCBBA (International Council for Commonality in Blood Banking Automation) is a non – governmental organisation that manages the development and also licences ISBT 128. This is a global standard for the identification, labelling and information transfer of human blood, cells, and tissue and organ products across international borders and disparate health care systems. (ICCBBA 2014).The underlying structure of the code is based on concepts of class,

modifiers and attributes. (ISBT 128 Standard 2104). The data structure of the product codes was changed from Codabar to ISBT-128. This was implemented at the same time as the new computer system. The product names were updated at the same time as the new coding. The project required close cooperation between Components, IT, and the hospital laboratories.

The IBTS Product Master Files were updated to include the new product names and codes. This update afforded an opportunity to perform a general review of the product master files and to update them accordingly.

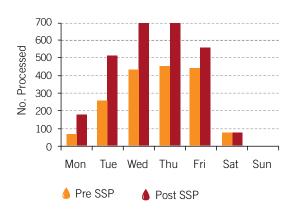
The Introduction of ISBT 128 labelling impacted on every hospital. This was a big challenge for the hospitals as each hospital had to validate and test their own laboratory information system for the new labelling standard. At the time of go live some but not all of our hospitals were in a position to change to the new label. For those not in a position to transition to the new labels, Codabar barcodes were also made available by the IBTS on new transition label. The LIMS (mainly Apex users) in these hospitals needed a patch applied to them to support the new system, and this is being validated at present. Currently 15 hospitals have transitioned to full ISBT 128 labelling and 31 hospitals are using the Codabar label.

#### Single Site Processing

The processing of whole blood donations in the Cork Centre ceased on 23rd October 2015. Following that date all whole blood processing was consolidated in the NBC site. This had a major impact on the

day-to-day operations of the Components Laboratory. The shift in processing load is shown in the following chart:

#### Whole Blood Processed in NBC



From 23/10/2016 the Components Laboratory in the Cork Centre is responsible for processing plateletapheresis collected at the fixed centre clinic in Cork as well as secondary processing of blood and blood products.

A stock holding unit was established to supply Munster hospitals. The stock levels are reviewed daily and algorithms were developed to ensure supply is transferred between the two centres.

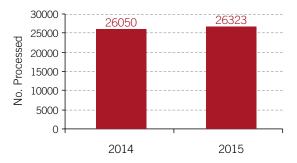
The Components Laboratory Cork is also a dedicated contingency laboratory for the NBC Components laboratory and has been equipped to cater for an unforeseen event. The policy is to endeavour to hold 30% of the National stock of blood in the Cork Centre as a contingency measure in the event of an issue with the NBC.

In addition to the strategic objectives, Hospital Services supported the introduction of the new platelet transport system from 5th October for non-scheduled delivery of platelets to all hospitals. This was carried out in conjunction with First Direct Medical contracted to the HSE. This new platelet transport method replaced the use of the IBTS transport system which has been in existence for a number of years.

The Components Laboratory and Hospital Services departments are responsible for processing, labelling, banking and issuing of the whole blood and plateletapheresis donations collected nationally. Pooled platelets are also prepared in the National Blood Centre.

The Components Laboratory in the NBC is also responsible for selection for issue of non-standard whole blood and red cell products and all platelet products. A total of 26,323 product orders were received electronically in the NBC in 2015. This was a 1.05% increase on the number processed in 2014.

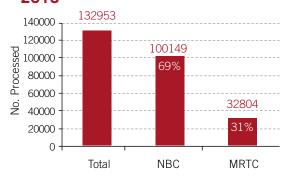
#### **Electronic Orders Processed in NBC**



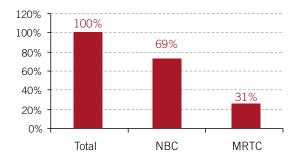
# Components and Hospital Services

A total of 132,953 whole blood donations were processed nationally in 2015. Of this total, 69% were processed in the National Blood Centre and 31% were processed in Cork.

# Whole Blood Donations Processed - 2015



# Breakdown of Whole Blood Processed by Centre - 2015



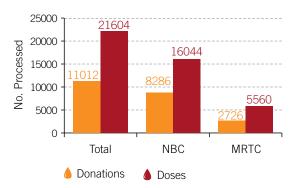
Plateletapheresis production consisted of 11,012 donations collected and processed in the two centres, with 69% being processed in the National Blood Centre and 31% being processed in the Cork Centre. The 10,279 plateletapheresis donations yielded a total of 21,604 issuable doses. This is a dose per donation rate of 1.96, increasing to 2.06

when technically unusable donations (508 donations) are excluded.

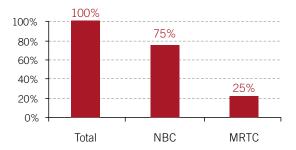
Of the 21,604 issuable plateletapheresis doses prepared, 11,186 (51.8%) were suitable for neonatal use, and 10,418 (48.2%) were suitable for adult use only.

A total of 5,556 pooled platelets were prepared in the National Blood Centre.

### **Plateletapheresis Processed**



### **Platelets Processed by Centre**



The manufactured products distributed nationally are as per the table below:

Riastap 1g	6469
Octaplex 500	22
LG Octaplas O	10470
LG Octaplas A	5690
LG Octaplas B	1842
Uniplas	1225
Rhophylac	1

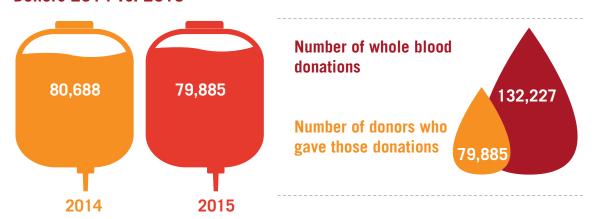
#### **Transport**

The IBTS driver clerk's functions include transport of all whole blood donations from every clinic to the National Blood Centre each night. This year 132,953 whole blood donations were collected from across the country. Driver clerks are the first point of contact for all donors at donor registration. They are responsible for transport of staff and equipment to the donation clinics. In 2015 the refrigerated vans and the mobile team buses replaced.

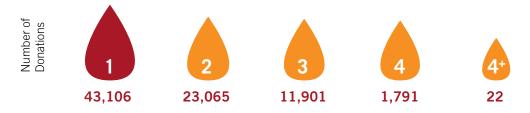
Blood, Blood Components & Blood Products Issued					
Product	2015	2014			
Red Cells & Whole Blood	125,325	124,233			
Platelets - Therapeutic Doses	22,666	22,412			
Frozen Plasma	19	55			
Octaplas	19,147	20,392			
Cryoprecipitate	139	111			
Riastap	6,456	5,490			
Plasma For IVD Use (Litres)	7,907	9,998			

# **Donor Statistics**

#### Donors 2014 vs. 2015

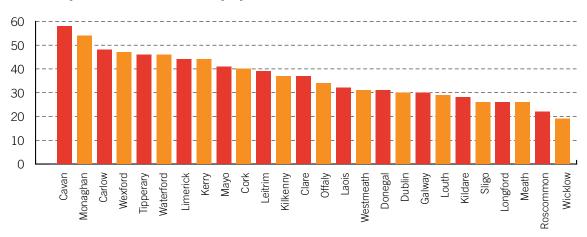


## Whole Blood Donations by Donors 2015

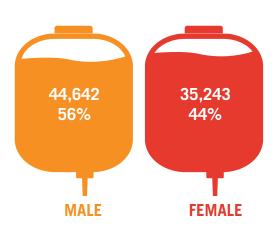


Number of Donors (Note: donors who gave 4+ times are on the HH panel)

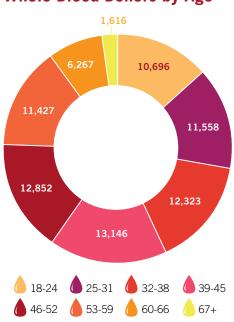
### **Donors per thousand of the population**



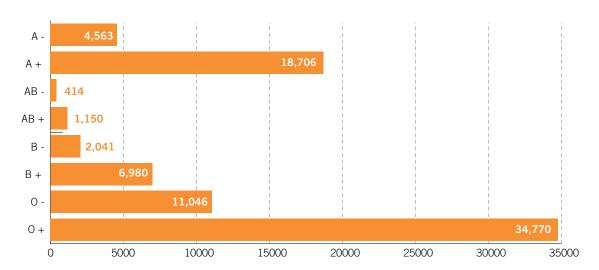
## Whole Blood Donors by Gender



## Whole Blood Donors by Age



## Whole Blood Donors by Bloodgroup





## 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 very low levels of viral RNA/DNA that may not be detectable through current approved serological assays during the very early stages of an infection, 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. The Procleix HEV assay has been CE marked and this evaluation has proved to be a suitable assay for screening blood donation samples for HEV RNA. Funding has been approved by the Department of Health for the introduction of universal HEV RNA testing of IBTS donations for an initial period of 3 years. The implementation of this project occurred on Monday 4th January 2016.

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 2015 with no discrepancies to report. Interlaboratory comparisons using EDCNet software (National Reference & Serology Laboratory, NRL, Australia, www.nrlqa.net) allow us to perform peer review with other Panther/Ultrio Elite and WNV users worldwide. The NAT laboratory is committed to continuous improvement of the NAT process, as demonstrated by implementing corrective and preventative actions resulting from Quality Incident Reports and Internal Audit reports.

# 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 Anaemi.
- Investigation of Haemolytic Disease of the Fetus
   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 2015 a total of 2374 samples were referred to the Diagnostics laboratory. This represented an 8.9% increase on 2014. There was an increase in sample numbers in every category, most notably anti-c quantitation (58.4%), complex compatibility testing (11.3%) and antibody identification (11%).

## Comparison of 2014 and 2015 sample numbers

As in previous years, there was a continued high level of serologically difficult or rare samples received. In 2015 the following difficult or rare allo-antibodies were identified through the NBC: Anti-Ch/Rg (3), anti-H (2), anti-Inb (1), anti-Lub (1), anti-U (1), CR1-related (5), Rh-related (1), HTLA-type (11), anti-Yka (1).

	Total No. Samples tested		Antibody ID	Quantitation anti-D	Quantitation anti-c	Total Compatibility Test	Complex Compatibility Test
2014	2180	175	1956	610	154	419	355
2015	2374	184	2171	643	244	441	395
Increase	8.9%	5%	11%	5.40%	58.4%	5.20%	11.30%
(%)							

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 has developed 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. This has resulted in the number of referrals from the Diagnostics laboratory NBC to the International Blood Group Reference Laboratory (IBGRL) decreasing substantially over the last decade to the current 3 samples for antibody confirmation in 2015.

#### Importation of Rare Blood/Products

In 2015 a total of 24 red cell units were imported from outside Ireland for named patients.

### Red Cell Units Imported from Outside Ireland

Antibody	Case Details	Units	Source
Anti-U	Planned Delivery	2	NHSBT Tooting (1)
			American Red Cross Philadelphia (1)
Anti-H	Planned Delivery	2	NHSBT Liverpool (1)
			NHSBT Tooting (1)
Anti-c	Medical case	20	NHSBT Liverpool (13)
(r'r' phenotype)			Sanquin Amsterdam (7)

#### **eProgesa**

The Diagnostics laboratory successfully participated in the implementation of the new BECs system eProgesa.

## Participation in External Quality Assurance Schemes

The Diagnostics laboratory participated in 3 different quality assurance schemes. Four exercises in IEQAS and AQQAS and 10 exercises in NEQAS, all were satisfactory.

# Diagnostics Cork Centre

### **Diagnostics Cork Centre**

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

The services provided by the Diagnostics laboratory include;

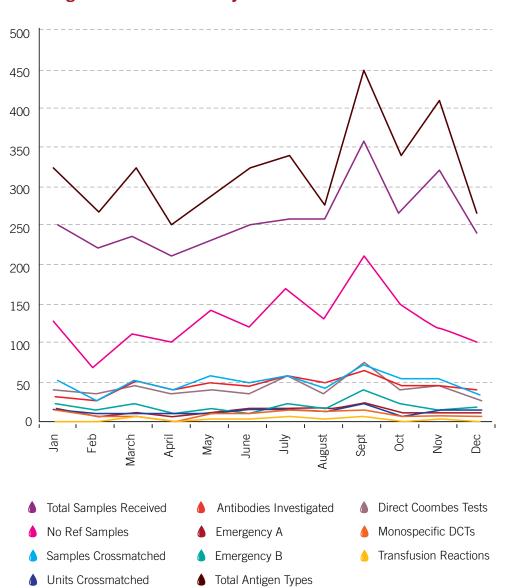
- As hospital Blood Bank for several city hospitals: MRTC undertakes blood grouping, antibody screening, provides cross-matched red cells and other components for individual patients. Provides laboratory and clinical advice for these patients. Investigates possible transfusion reactions, participates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

cases may take several hours to investigate fully and may require donation screening where matching red cells are not available on the shelf. Six 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 MRTC 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 NEQAS and IEQAS
   meetings.

Total samples received 2015: 3075 (2014:3655)

## **Diagnostics MRTC Activity 2015**



# Virology Laboratory

The function of the Virology laboratory 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 143,135 donation samples and 2,069 first time tested non donor samples were tested in 2015.

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
- antibody to Human Immunodeficiency Virus
   1/2
- 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.

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 UK', and a

multimarker control from the National Serology Reference Laboratory Australia (NRL, Australia) "Acrometrix Q Connect Yellow" 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).

All IBTS virology testing in Ireland was consolidated at the National Blood Centre in Dublin in June 2012 and the IBTS has an external contingency testing plan with the Scottish National Blood Transfusion Service (SNBTS) in the event of a critical failure whereby the Virology laboratory is unable to provide

some/all of the current mandatory Virology results. This plan is tested four times each year by sending a small number of samples to the SNBTS for Virology testing. There was no requirement to invoke the SNBT's external contingency testing plan in 2015.

"Approximately
143,135
donation
samples and
2,069 first time
tested non donor
samples were
tested in 2015."

# 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.

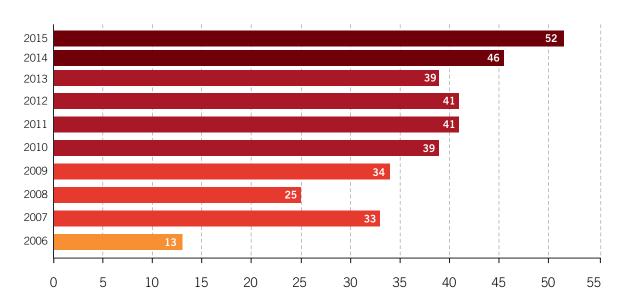
The laboratory determines the human leucocyte antigen (HLA) type of all patients and donors (related or unrelated) prior to transplantation to aid donor

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 2015 samples from 227 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

# Number of Irish Patients receiving a HSCT from an Unrelated Donor 2006-2015



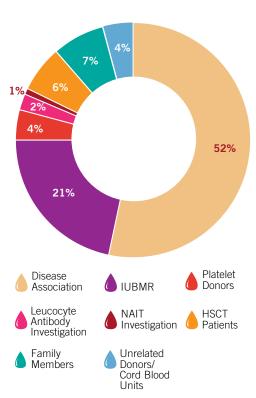
donor may be identified from the registry of volunteer donors. The NHIRL provides an immunogenetics support service for the Irish Unrelated Bone Marrow Registry (IUBMR) and in 2015 the laboratory HLA typed 1337 new volunteer donors to add to the registry.

In the last 10 years the IUBMR has facilitated 364 unrelated donor transplants for Irish patients. In 2015 (n=52) four times as many unrelated donor transplants were performed by St. James's hospital and Our Lady's Children's hospital, Crumlin, than in 2006 (n=13). Thirty-six sibling donor transplant were also performed between the two transplant centres, giving a total of 86 haematopoietic stem cell transplants in 2015.

The NHIRL also provides a routine disease association HLA typing service. This service represented 52% of the investigations performed in 2015. 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 2014.

## **NHIRL Investigation Distribution**



A total of 266 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.

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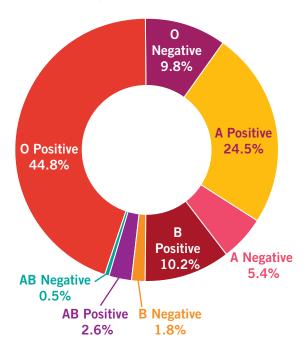
# Automated Donor Grouping

## **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 2015 over 145,000 donations were tested and of these 10,673 (7.3 %) were new donors. From the results obtained from testing new donors it is possible to estimate the frequencies of blood types in Ireland.

**Blood Groups in New Donors 2015** 



Apart from performing the mandatory serological tests (ABO, RhD and antibody screening) the laboratory routinely screens and types donors in order the find the rarer phenotypes or combinations of types, which may be requested in an emergency. The laboratory performed over 141,000 other antigen types in 2015 and provided typed blood for routine hospital orders, intrauterine transfusions and emergency requests for more complex antigen negative units.

The laboratory is continually screening units for patients with multiple antibodies or for units suitable for intrauterine transfusion and on average there are at least 10 such cases dealt with on a daily basis.

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. In 2015 the first donor with this rare antigen type was identified in an O Rh D Negative donor.

The second project is now nearly complete, which is to build up a panel of k (cellano) negative donors (frequency 1:1000). To date over 200 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 12 donors with rare weak RhD types identified.

The Automated Grouping laboratory 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 scored 100% accuracy in the UK National External Quality Assessment Scheme (UK NEQAS) since the laboratory's first registration in 2008.

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. In 2015 the Donor Grouping laboratory scored 100% accuracy for all tests performed and was in the top 5% of laboratories surveyed.

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 2015 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.



# Tissue Bank

#### Tissue Bank

The Tissue bank at the NBC is a licensed tissue establishment (TE-12) under the Tissue and Cells Directive 2004/23/EC which sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. The bank is inspected every 2 years by the Health Products Regulatory Authority. The tissue bank manages all ocular tissue, heart valves and some musculoskeletal tissue on a national basis.

Products supplied include corneas, both for DSAEK 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.

In 2015 the Tissue bank applied for a licence to produce limbal stem cells under the Advanced Therapy Medicinal Products directive. Full market authorisation was not sought, but to provide the service under the hospital exempt clause. The first clinical case is planned for April 2016.

The IBTS is a third party contractor to the MMUH for the processing, cyropreservation and distribution of human cardiovascular tissue. 2015 saw an increase in donations to the bank and this is attributed to the new Organ Donation Transplant office which opened in April 2015.

In October 2015, 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 were suspended indefinitely due to lack of resources.

The installation of new liquid nitrogen vats for the storage of tissue has commenced and is expected to be completed in 2016. Following the introduction of a new computer system (eProgesa) for blood, the tissue module (Mak - TCS) will be installed on a phased basis during 2016.

"The bank is responsible for distributing human tissue used in ophthalmic surgery nationally."

# Therapeutic Apheresis

## Therapeutic Apheresis

The Therapeutic Apheresis Service (TAS) in the Cork Centre provides therapeutic apheresis for patients in the Munster region. The hospitals the 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 from Terumo. All procedures performed in 2015 were Therapeutic Plasma Exchange (TPE). However the OPTIA machines have been up-graded to enable Red Blood Cell Exchange (RBCX) and White Blood Cell Depletion (WBCD). Specialised training

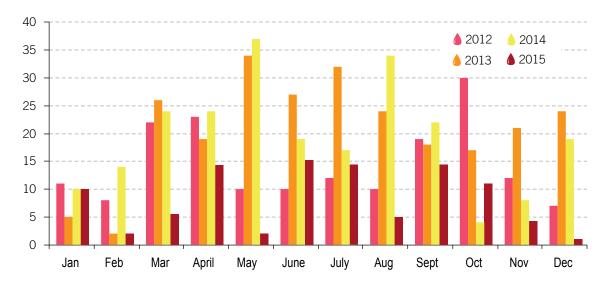
is provided by Terumo to enable IBTS TAS nurses to deliver RBCX and WBCD.

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-2013) '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. 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 2012 - 2015 By Month



In 2015 the TAS performed 98 procedures for 17 patients in three hospitals in Cork. As displayed in the following tables and figures, the demand for TAS is varied and unpredictable. Variations are displayed vis- à –vis previous years demands, months, weekends and out of hours.

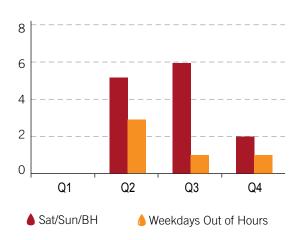
#### Service demand trend

The trends and variability in service demand over recent years are shown on previous page.

#### Weekend, bank holiday and out of hours 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 98 procedures carried out in 2015, 13% were performed at the weekend and 4% were performed out of regular working hours during the week. The trend in demand for weekend, bank holiday and out of hours service is displayed below by year quarter.

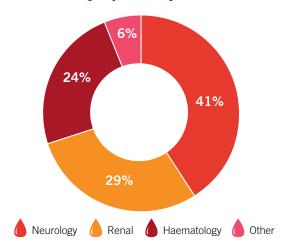
## Weekend, Bank Holiday, Out of hours Service Provision 2015



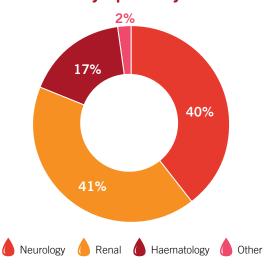
#### Clinical speciality by patient and procedure

The majority of patients (41%) presented with neurological conditions, followed by renal (29%) and haematology (24%). Six 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 2015



## **Procedure by Speciality 2015**



# NHO

# National Haemovigilance Office (NHO)

Haemovigilance operates to collect and assess information on unexpected or undesirable effects resulting from blood transfusion, and to prevent their occurrence or recurrence. Haemovigilance in Ireland is co-ordinated by the National Haemovigilance Office (NHO) based at the IBTS. Since its inception in 1999 a total of 5426 serious adverse transfusion reactions and events have been reported. The NHO liaises with and supports the Haemovigilance Officers (HVO) based in hospitals and blood establishments throughout Ireland and the Medical Consultants with haemovigilance responsibilities. In addition, the NHO maintains links with colleagues internationally through the International Haemovigilance Network, and the UK Transfusion Network.

# Serious Adverse Events (SAEs) – mandatory and non mandatory

The NHO reviewed and accepted mandatory SAEs relating to the quality and safety of blood under the EU Blood Directive 2002/98/EC in addition to non-mandatory SAEs related to the clinical aspect of blood transfusion. These reports came from blood establishments, hospital blood banks and facilities. At the time of this report 163 mandatory SAEs were accepted, which was 68% of all SAEs. In addition, 76 non mandatory SAEs, primarily relating to errors in clinical areas were also accepted under professional responsibility which were 32% of all SAEs accepted in 2015.

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

At the time of this report 333 reactions have been accepted in 2015, a decrease of 52 reports from the previous year. The number of mandatory SAR (66) accepted to date is also a slight decrease on 2014 figures.

# 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. Two-hundred and sixty five mandatory reports were accepted by the NHO in 2014, with the compilation of 2015 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. In keeping with its remit to support hospital based staff, the NHO continued the provision of one day Regional Workshops and this initiative is to continue during 2016.

# **IUBMR**

#### e-Learning

The IBTS continued to licence and provide the 'Learnbloodtransfusion' e-learning programme to hospitals via LearnProNHS. This programme was developed by the Scottish National Blood Transfusion Service with the NHO and IBTS contributing to editorial content. In 2015 work continued on adapting the programme content to facilitate access on 'Smartmedia' devices. Modules in Good Manufacturing Practice for Blood Establishments and on Acute Transfusion Reactions were completed and launched in 2015. The majority of Irish hospitals and a number of third level institutions are registered on the programme. This includes hospital staff and health care undergraduates in several universities undertaking the modules as a mandatory course requirement.

#### **IUBMR**

Haemopoietic progenitor cell transplantation is a lifesaving therapy for certain patients with leukaemia, bone marrow failure syndromes and for particular inherited metabolic disorders. For the many patients who do not have the preferred option of a fully matched sibling, an unrelated donor from one of the 27 million volunteer donors worldwide provides 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).

The registry is licensed by the HPRA under the EU Tissue Directive 2004/23/EC.

#### **International Accreditation**

Since 1991, the IUBMR has been affiliated to the World Marrow Donor Association (WMDA), an organisation which sets operational standards for bone marrow registries worldwide. In 2012 the IUBMR was awarded full registry accreditation.

#### **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's Hospital (SJH) and Our Lady's Children's Hospital Crumlin (OLCH). In 2015 eighty five (85) patients were referred to the IUBMR for unrelated searches.

## **IUBMR**

Fifty eight (58) Irish patients received stem cells from an unrelated donor in 2015. The majority were from international donors (52).

#### **International Activities**

Preliminary searches were received on behalf of two hundred and fifteen (215) international patients of whom forty nine (49) donors were activated for additional testing requests.

#### **Irish Donors**

Bone marrow volunteers are recruited by the bone marrow recruitment nurse at blood donation clinics two days a week. In 2015 the number of newly recruited donors was 1121. There are now in excess of 21000 donors listed on the Irish registry.

There were seven (7) donations from Irish donors of which three were peripheral blood stem cell collections and four by bone marrow harvest.





## Quality & Compliance

During 2015 focus was on the implementation of e-Progesa/ISBT128 and the single site processing project. This also included a comprehensive update of all Product Master Files due to product code renaming conventions as a result of ISBT 128 introduction. During the year the withdrawal of Hemospect and reintroduction of Hemacue technologies as a result of field failures of the Hemospect technology became a large task for the IBTS.

In addition to the routine Health Products Regulatory Authority (HPRA) a special inspection was conducted in November 2015 to provide oversight of this process. There were 11 inspections in total for 2015, two covering Tissue (2 yearly cycle), one covering the Hemospect withdrawal, four covering clinics, one for cATMP Authorisation, one in the Cork Centre, one in NBC (inspection performed in 2016 February to cover 2015 programme) and one unscheduled inspection covering packaging and distribution of platelets. There were four major non-compliances and 26 others raised by the HPRA during the inspections.

During 2015 the IBTS ceased to operate as a hospital blood bank for three institutions in Dublin, these are now part of the larger hospital system.

The QA Internal Audit programmes covered a total of 46 inspections during the year, across the Blood Establishment, Tissue Establishment, GDP and ATMP activities. Separate and distinct licenses are maintained for each of these activities.

As a result of such high levels of project activities a total of 1120 Change Controls and Change Orders were raised during 2015, representing a 28% increase in change turnover for the year. The total for 2014 was 807.

Quality metrics to the Executive Management Team (EMT) were reported quarterly, with close out rates not achieving target of 80%.

By year end the Quality Management System requirement to report incidences impacting on product/process quality missed the target of 80% closeout, achieving 78% closure. The total number of IRs raised during 2015 was 1401, a reduction of 23% on the 2014 figure of 1717.

The impact of large projects such as BECS and SSP were the reasons for non-closure by departments. The Product Complaint Handling System processed 944 complaints from hospitals during 2015, achieving a close out rate of 82% Of these, 39.5% (373) were due to post donation information from donors, 13.3% (126) were from hospitals notifying the IBTS of potential Adverse Reactions in patients, 9% (83) were due to in house aggregates in product and 3.5%(33) were due to customer complaints regarding labelling of product.

As a result of Product Complaints 327 recalls were executed in 2015, 77% (252) due to post donation information.

Analysis is performed of complaints and IRs to indicate Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs), there were 235

SAEs investigated in 2015, with 74 reported and accepted by the National Haemovigilance Office (NHO) as meeting the criteria. There were 135 SARs investigated with 50 reported and accepted by the NHO.

A donor vigilance system is in place which captures events relating to donors/clinics, there were a total of 525 for 2015, a 22% decrease on 2014 figures of 640. A composite report at year end is sent to the HPRA.

A system for capturing donor/clinic service complaints recorded a total of 176 items in 2015, all were closed out within target, this reflects favourably on 2014 figures when 197 complaints were recorded.



# **Human Resources**

#### **Pension Issue Resolution**

The process of consultation to address the IBTS Pension issue, with the Department of Health and the Department of Public Expenditure and Reform was on-going throughout 2015 involving IBTS management and cross-union discussions.

The services of the Workplace Relations Commission were utilised to assist. Focused consultation with the WRC with all parties was on-going throughout the year, culminating in an agreed recommendation. This recommendation also required a vote of union members in December 2015. The recommendation was accepted by the employees.

#### **Single-Site Processing**

The successful implementation of this project brings significant cost efficiencies and aligns the organisation with current trends of consolidation seen in other European Blood Services. Delivering on the strategic objective of the project to manage human resource efficiencies was achieved through managing natural and voluntary attrition and also through negotiating internal redeployments and external redeployments into the HSE – South.

This was managed in line with the provisions of the current Public Service Agreements. Co-operation amongst the staff groups, management and the HSE-South contributed to the successful conclusion.

#### **Learning and Development**

A comprehensive external review of learning and development was completed, evaluating the effectiveness and efficiency of learning and development within the IBTS.

Three key questions were addressed;

- What is the current approach to the identification, design, delivery and evaluation of learning and development programmes across the IBTS?
- 2. How are resources allocated to its provision, structure and what costs are involved?
- **3.** What is the role of technology systems in managing/monitoring this process?

The report made several recommendations, aligned with the IBTS Strategic Plan 2013 to 2016. The recommendations were prioritised and a phased introduction began in late 2015. Learning and development continues to play a key role in creating and sustaining a high performance culture, based on both donor and staff needs.

#### **People Capability Working Group**

An organisation-wide group was established to design and deliver new learning and development strategies. The group brings a holistic approach driven by quality assurance. Chaired by HR Director and reporting into the Chief Executive, this reflects the IBTS sustained commitment to a people development strategy. The group also provided a framework for continuous improvement. This involves the development of agreed metrics to evaluate the effectiveness of the new strategy.

#### Environmental Health and Safety (EHS) Fire Safety and Emergency Response Programme

As the organisation moved to single site processing the IBTS focused on the Fire Safety and Emergency Response programme. Key aspects of the

programme included;

- Implementation of a Fire Safety Policy and Strategy for the organisation
- A major review of the Internal Emergency Response Plans for the National Blood Centre and all IBTS Regional Centres
- Revision of the Fire Plan for the National Blood Centre
- Policy for the Prevention and Control of arson
- Implementation of revised Fire Safety and Emergency Response Training Programmes

**Chemical Safety Programme** 

In conjunction with the second phase of the transition arrangements of the Classification, Labelling and Packaging (CLP) Regulation, EHS continued to review and develop the Chemical Safety Programme.

This includes

- An occupational health chemical review within NBC laboratories in liaison with IBTS occupational health providers
- Revision of the organisations Chemicals Policy and Chemical Spills Procedure

#### **Library Services**

Training was provided on advanced search skills and PubMed search skills with group and individual library skills sessions being held throughout 2015. Many of the Library "How to" guides on the Intranet were updated as self-learning aids. In addition, Lunchtime learning sessions were organised by the Library as well as celebrating Library Ireland Week 2015 with an online quiz.

A number of groups visited the Library including UCD students studying for a postgraduate in Library and Information Science. The Research Officer/Librarian also delivered guest lectures in the SILS Library School in UCD. A case study based on the IBTS Library was used as for a SILS Capstone project on role management of a specialist library.

# **Finance**

#### Summary Accounts for the year ended 31st December 2015

	2015 €'000	2014 €'000
Income		
Recurring income	65,429	64,004
Non-recurring income	260	878
Total income	65,689	64,882
Expenditure		
Total expenditure	71,607	68,034
Surplus / (Deficit) for year	(5,918)	(3,152)
Actuarial gain / (loss) on pension scheme	24,163	(47,155)
Transfer to Capital Reserves	(88)	(130)
Transfer to Research Reserve	(53)	(1,106)
Accumulated Deficit at 1st January	(61,079)	(9,536)
Accumulated Deficit at 31st December	(42,975)	(61,079)

Note: Some figures for the comparative year have been restated under FRS102

#### Income

The Board's total income for 2015 of €65.69 million (2014 €64.88 million) is analysed into recurring and non-recurring income. Recurring income consists of revenue generated from sales of products and services provided to hospitals of €65.43 million (2014 €64.00 million). Non-recurring income of €0.26 million (2014 €0.88 million) includes interest on bank deposits. The increase in recurring income represents increased volumes in 2015 while the reduction in non-recurring income is due to reduced interest rates on deposits.

#### **Expenditure**

Expenditure for 2015 amounted to  $\in$ 71.61 million (2014  $\in$ 68.03 million).

The increase in expenditure mainly arises from increased employer pension costs.

The Board accounts for pensions in accordance with FRS102.

#### Reserves

The Board has a Capital reserve for the development of new facilities in Cork. The balance in the fund for the year ended 31st December 2015 was €8.50 million.

In 2006 the Board set up a research reserve. In 2015 the balance of research funds was  $\in$ 1.310 million. (2014  $\in$ 1.257 million).

#### **Capital Expenditure**

The Board invested €2.7 million in capital projects and equipment during 2015 (€3.07 million 2014).

The main investments during the year included expenditure on a new Blood Establishment Computer Systems (BECS), fleet upgrade and software licences.

There was also recurring expenditure for the replacement of ICT infrastructure, laboratory 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 2015, under the terms of applicable legislation, invoices to the value of €268,869.95 were late, by an average of 26.7 days. These invoices constituted 0.64% by number and 0.63% 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 €5,852.30.

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

# Contact details

## **Auditors**

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**

James's Street, Dublin 8

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

www.facebook.com/giveblood.ie www.giveblood.ie