ANNUAL REPORT 2014



"Delivering excellent transfusion healthcare to the people of Ireland."

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DVB 4

"We have a simple, but demanding mandate, to provide a safe, secure, and reliable supply of blood products for patients using the Irish health services."

Chairperson's Foreword

The last year was not the easiest year for the IBTS. We have a simple, but demanding mandate, to provide a safe, secure, and reliable supply of blood products for patients using the Irish health services. Like many other mid-sized organisations, we have had to make very substantial reductions in expenditure, and staff numbers, over the last few years, and this has been hard for our staff. All of them are working harder, being more productive, and more flexible.

I want to place on record that both the Board and I really appreciate everything that our staff, and our executive team, have done over the last few years. Without their dedication, high standards, and support, we could not deliver on our mandate for even a single day. We also have great support from the Minister for Health and the hard working civil servants in his Department. On a personal note I greatly value the support, advice, time, and energy of my colleagues on the Board. Thanks to all!

There have been two big structural changes over the year. The first, our new IT system, is due to go live in June of 2015. The work to permit this began two years ago, and has affected every corner of the IBTS, and every staff member. It is easy for those outside the organisation to underestimate the effort required to do this, but the Board and executive team do not. The second is that the long-delayed plan to build a new blood centre in Cork, to replace our facility in St. Finbarr's Hospital has finally begun. An agreement was reached, towards the end of 2014, between ourselves, UCC, CUH and the HSE, for a new development on the CUH site, and this has recently been approved by the Minister for Health.

More changes are coming. Single site processing, where all our blood processing from donated whole blood, will be done in the National Blood Centre in Dublin, is due to start in September 2015. Our pension fund is being actively reviewed, and there are discussions starting with the Department of Health, and the Department of Public Expenditure and Reform to secure a long-term and stable solution to our current challenges. We have completed a study on Hepatitis-E in the Irish population. Now that a test for this virus is available, we are in discussions with the Department of Health about the best way of responding to these results. Finally, we are reviewing our current policy of lifetime deferral from donation for men who have sex with men. In effect, this is a permanent ban on donations from sexually active gay men. This is the most common arrangement in developed country blood services, but we are committed to a full review of the policy.

I have the privilege of attending our awards ceremonies for those who have donated 50 and 100 times, and meeting our donors and their families. At each ceremony we have a speaker who has been affected by receiving blood, and their stories bring home to me, and to the donors, why the IBTS exists, and the many ways in which we affect the lives of Irish people. We are the second largest voluntary body in Ireland (behind the GAA). Our donors are very special people. Without them, and their regular attendance at donor clinics, in sunshine, rain, storms, and gales, the Irish blood supply would last just under one week. On behalf of my colleagues, and myself, thank you all.

Professor Anthony Staines Chairperson

Our Values

- Excellence in Service
- Honesty
- Respect
- Learning
- Accountability
- Teamwork

Chairperson's Report

Report of the Chairperson of the Irish Blood Transfusion Service regarding the assessment of internal financial controls of a State body for the year ended 31st December 2014, in accordance with Appendix V of the Revised Code of Practice for the Governance of State Bodies

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

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

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

iii. The Chief Executive reports to the Board on behalf of the executive management on significant changes in the work of the IBTS and on the external environment which affects significant risks. Where areas for improvement in the system are identified the Board considers the recommendations made by the Executive Management Team.

iv. The Director of Finance provides the Finance Committee, which is a sub-committee of the Board with monthly financial information, which includes key performance indicators.

v. An appropriate control framework is in place with clearly defined matters which are reserved for Board approval only or, as delegated by the Board for appropriate Executive approval. The Board has delegated the day-to-day management of the IBTS and established appropriate limits for expenditure authorisation to the Executive. The Chief Executive is responsible for implementation of internal controls, including internal financial controls.

vi. The system of internal financial control is monitored in general by the processes outlined above. In addition, the Audit and Compliance Committee of the Board reviews specific areas of internal control as part of their terms of reference.

Chairperson's Report

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 2014 at its meeting on 9th February 2015.

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 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 a one day meeting on Strategy. Attendance by Board members was as follows:

Members of the Board	February	April	June	September	November	December
Professor Anthony Staines	1	~	~	1	1	√
Linda Hickey	1	√	1	√	1	√
Olwyn Bennett	1	√	1		1	√
John Cregan	1		1	√		√
Gerry Kelly	1		1	1	1	√
Dr Paolo Rebulla#	1	√				
Dr Paul Browne##	1			√	1	
Dr Cleona Duggan	1	√	1	√	1	
Brian O'Mahony	1	√				
Dr Jorgen Georgsen**			1	√	1	√
Kate Williams*				√	1	√
Dr Elizabeth Kenny*			1	1	1	√
Dr Julie Heslin*			1	\checkmark		1

#Term finished on 31st May 2014 ##Term finished 10th December 2014 *Appointed 31st May 2014 ** Appointed 1st June 2014

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.

Chairperson's Report

Board Fees and Expenses 2014		
Board members remuneration and expenses were as follows:	Board Fees	Expenses
	€	€
Professor Anthony Staines Chairperson	Nil	1,479
Dr Paolo Rebulla	4,988	837
Mr Brian O'Mahony	Nil	Nil
Mr John Cregan	Nil	1,928
Dr Paul Browne	Nil	Nil
Ms Linda Hickey	11,970	Nil
Ms Olwyn Bennett	11,970	Nil
Mr Gerard Kelly	11,970	1,430
Dr Cleona Duggan	Nil	846
Dr Elizabeth Kenny	Nil	1,055
Dr Julie Heslin	Nil	491
Dr Jorgen Georgsen	6,982	3,089
Ms Kate Williams	9,806	62
	57,686	11,217

Members of the Board

Professor Anthony Staines (Chairperson) Dr Paolo Rebulla (term expired 31st May 2014) Dr Paul Browne (term expired 10th December 2014) Mr Brian O'Mahony Mr John Cregan Ms Linda Hickey Ms Owlyn Bennett Mr Gerry Kelly Dr Cleona Duggan Ms Kate Williams (appointed 21st May 2014) Dr Elizabeth Kenny (appointed 21st May 2014) Dr Julie Heslin (appointed 21st May 2014) Dr Jorgen Georgsen (appointed 1st June 2014)

Public Spending Code

The Board is committed to complying with the Public Spending Code issued by the Department of Public Expenditure and Reform in September 2013 and Circulars 02/09 and 02/11 relating to arrangements for ICT expenditure in the civil and public service.

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

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

Performance and Development Committee

The Board has established a sub-committee to deal specifically with matters regarding the salary and performance of the Chief Executive. 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 2014 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 5 times in 2014. Its function is to monitor developments relevant to the field of transfusion medicine and related fields, to inform the Board of any such developments and to advise the Board on appropriate action.

Finance Committee

The Finance Committee met five times during the year and is comprised of two 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 five times during the year and is comprised of three members of the Board and three independent external members. It is also attended by the Chief Executive, the Medical & Scientific Director, the Director of Finance, the Operations Director, Director of Quality & Compliance, the Internal Auditor, the Risk and Resilience Manager and the Assistant Accountant acts as Secretary to the Committee. The Committee may review any matters relating to the financial, regulatory or compliance affairs of the Board. It reviews the annual financial statements, reports of the Internal Auditor, quality reports, 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 Risk Registers. During 2014 the Risk Management Policy and Procedure was approved and work commenced on developing a single risk register. 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.

Chairperson's Report

At present the organisational risk register is reviewed and updated by the Executive Management Team. The Clinical Risk Register is reviewed by the medical consultants and the IT Risk Register 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 directors 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. While the Board understands that the IBTS is in a strong financial position for 2015, the continuing increase in contributions which, under the Trust Deed fall to be paid by the employer, will inevitably make the continuation of the current superannuation arrangements unsustainable. This would result in serious implications for the staff of the IBTS. It could also seriously impact the organisation's capacity to deliver a safe and sustainable blood service, to the appropriate standards of quality and efficacy.

Internal Control

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

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

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

- A comprehensive system of financial reporting
- Annual Budget prepared and presented to both the Finance Committee and the Board
- Monthly monitoring of performance against budgets by Finance Committee and Board
- Sign off by budget holders on individual budgets
- Budget reviews with budget holders
- Clearly defined finance structure
- Appropriate segregation of duties
- Clear authorisation limits for capital and recurring expenditure approved by the Finance Committee
- Key financial processes are fully documented in written procedures
- Regular stock takes and reconciliations carried out by staff independent of stores staff
- Financial system possesses verification checks and password controls
- Issues of products are reconciled to ensure all of the Board's activities are fully billed
- Regular monitoring of credit control function
- Purchase orders signed by Purchasing Officer or authorised substitute
- Stock items are requisitioned by means of automatic ordering
- All non stock invoices signed and coded by budget managers or their authorised signatories
- All stock invoices are independently matched with stores GRN and purchase order
- Payment verification checks of supplier invoices by staff independent of accounts payable staff

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

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.

Professor Anthony Staines Chairperson

"The IBTS continued to deliver blood transfusion to the highest standards during 2014 despite the many challenges the organisation faced."

Chief Executive's Report



The IBTS continued to deliver blood transfusion to the highest standards during 2014 despite the many challenges the organisation faced. While there were many achievements during the year the single biggest change was in how we measured haemoglobin at our donation clinics.

The IBTS has had high deferrals for Hb and for the previous number of years we did not operate the Hb levels applicable in the EU Blood Directive. This was in agreement with our Competent Authority. The introduction of the haemospect changed that and not only did the IBTS comply with the Directive we reduced our deferral for Hb by 5%. For the first time we did not have to run special campaigns over the Summer months appealing for donations. This innovative approach was spearheaded by the Medical and Scientific Director, Dr William Murphy, and he and the people who worked closely with him in implementing this technology must be congratulated.

The IBTS is upgrading our blood bank control system and two elements of the system went live during 2014. These were eTraceline a patient module and eRiskline a work flow module. The main element eProgesa was still a work in progress and is expected to go live in quarter 1 2015. The IBTS depends on volunteers and local communities to fulfil its mission of providing a safe and sustainable blood supply. In January 2014 we launched a partnership with the Gaelic Athletic Association (GAA) the organisation that organises our national games to promote blood donation. This is a very exciting development and should deliver additional donations across the country. In addition we opened our second haemochromotosis clinic in Cork and this provides the opportunity for people with HH to donate blood.

The biggest challenge facing the IBTS is declining revenue and increasing costs from our pension arrangements. The pension issues have impacts far in excess of the provision of pension arrangements. It threatens to seriously hinder the capacity of the IBTS to continue to deliver a blood transfusion service to the highest standards of quality and efficacy.

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

Andrew Kelly Chief Executive

"Safety, efficacy and supply remain the main concerns of Blood Transfusion Services worldwide."

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Medical and Scientific Director's Report



Safety, efficacy and supply remain the main concerns of Blood Transfusion Services worldwide. Safety is compromised by internal quality concerns and by emerging infections in the general population who provide the essential blood donations – the approximately 140,000 incredibly generous donations from ordinary people that the country needs to support care for patients having surgery, being treated for cancer, or bleeding because of accidents or obstetric complications.

Quality assurance and control have come a very long way in blood transfusion, and what was once a series of add-on tests in the process of blood collection, storage and distribution is now a very major part of the fabric of the IBTS. It's a time-consuming, meticulous, expensive business integrated and embedded in everything that happens in the hundreds of separate processes and components of a blood transfusion service.

Emerging infections have caused very serious problems and recurrent disasters in the world of blood transfusion. vCJD caused a great deal of distress and cost a great deal of effort in the 1990s and 2000s.

It is now receding as a threat from blood transfusion, though a few cases with very long incubation periods may still emerge in the future from dietary infection prior to 2000. As a result we remain cautious in our approach to moving away from the measures we put in place to reduce the risk of spreading the disease by blood transfusion. These include the much unloved ban on blood donation in Ireland from people who lived in the UK (including Northern Ireland) for a year or more between 1980 and 1996, and the very costly discarding of plasma separated from donated blood. Mosquito-borne diseases are extending their ranges northwards with climate change – malaria returned briefly to Greece, and West Nile Virus, dengue and chikungunya have appeared or reappeared in Europe in recent years. But as happened with vCJD, HIV and hepatitis B & C, patients receiving blood transfusions are much more at risk from diseases that have long incubation periods than they are from acute infections like dengue or even Ebola.

Hepatitis E poses a threat at present – this is a food borne disease that has reappeared recently in Ireland and in other parts of Northern Europe. It is a very mild infection in healthy people, causing at worst a mild transient illness, and often no symptoms of infection at all. In a small percentage of hospital patients however, infection can cause persistent hepatitis leading to serious liver disease. Studies at the IBTS in 2014 have revealed that the hepatitis E virus is present in about 1 in 5000 healthy donors. At the end of the year we requested additional support from the Department of Health to fund screening of blood donors for this virus in the future.

The controversial ban on donating blood for men who have had sex with men continues to rankle and cause public debate. During 2014 the IBTS presented the Minister of Health with a review of the history and rationale behind the introduction of the ban in the 1980s in the face of the poorly-understood threat of blood-borne AIDS at the time, along with the options and implications of removing the ban or changing its duration.

Medical & Scientific Director's Report

Every option, including maintaining the status quo in the face of public opposition, carries a degree of uncertainty, and the possibility of some increased risk of window period transmissions of HIV to patients receiving blood transfusions. (A window period transmission is where a person gives a blood donation very soon after contracting HIV – up to a week or less – where no test can detect the low levels of virus in the blood donation.) While the increase in risk from changing the ban is probably very low, it is all carried by patients getting transfusions, and any decision to accept the risk on their behalf will require a process of public engagement as well as a scientific analysis of uncertainty. This process of review and engagement continues into 2015.

Less controversially, during 2014 the IBTS was the first national blood service worldwide to introduce non-invasive haemoglobin checking for blood donors. This is a new method of testing the level of haemoglobin in blood to make sure the donor is fit to donate. Instead of taking a blood sample from the tip of the finger, white xenon light is shone through the tissue of the finger pulp, and the haemoglobin level in the donor is calculated from the absorption pattern of the red spectrum. Once we got over some initial delay problems at the clinics the system proved to be quicker, cheaper and better that the old one, and nobody minded not having a needle stuck in their fingers any more. We continue to be occupied with several other developments in the field including foetal Rhesus D genotyping from maternal blood samples to guide antenatal treatment, and methods for treating platelet concentrates to reduce further the risk of transmitting infection by transfusions. Outside of Ireland, clinical trials began in 2014 to see if similar methods can be applied to red cells for transfusion as well, raising the prospect that before much longer concerns about emerging or window period infections may become very much less acute.

William Murphy MD, FRCPEdin, FRCPath

Consultant Haematologist Medical & Scientific Director MRN 021564 GRADE

"We continue to be occupied with several other developments in the field including foetal Rhesus D genotyping from maternal blood samples to guide antenatal treatment, and methods for treating platelet concentrates to reduce further the risk of transmitting infection by transfusions."

GARDE

CARACLER

"The Hospital Services Department in both NBC/ MRTC continued to play a key role in the continuous improvement of the delivery of blood and blood products transitioned from the IBTS transport function"

Operations

Hospital Services

The Hospital Services Department in both NBC and MRTC are responsible for the distribution of all blood products and manufactured products nationally. Distribution is performed in both sites. The following table shows the number of blood products distributed in 2014 nationally.

Product Description	Distributed
Whole blood	5
Red cells	125972
Platelets (apheresis)	18450
Platelets (pooled)	4134
Cryoprecipitate (pooled)	0
Cryoprecipitate (single) neonate use	111
Fresh frozen plasma	55
Other: Pooled Leucocytes (source	
of granulocytes)	46

The manufactured products distributed nationally are as per below table:

Product Description	Distributed
Riastap 1g	5500
Octaplex 500	0
LG Octaplas O	11293
LG Octaplas A	5363
Octaplas B	636
LG-octaplas B	2218
Uniplas	942

In 2014 the Hospital Services department managed the transition to LG-Octaplas B - working closely with the supplier Octapharama and the hospitals during this time.

The Hospital Services Department in both NBC/ MRTC continued to play a key role in the continuous improvement of the delivery of blood and blood products transitioned from the IBTS transport function to the company under contract to the HSE which went live 27th May 2013.

In addition, the Hospital Services Department in both NBC/MRTC supported the implementation of eTraceline which went live St Patrick's weekend 2014.

Blood, Blood Components & Blood Products Issued				
Product	2014	2013		
Red Cells & Whole Blood	124,233	126,560		
Platelets - Therapeutic Doses	22,412	22,509		
Frozen Plasma	55	198		
Octaplas	20,392	18,896		
Cryoprecipitate	111	167		
Riastap	5,490	5,100		
Plasma For IVD Use (Litres)	9,998	15,382		

Components

The Components Laboratory is responsible for processing, labelling, and banking the whole blood and plateletapheresis donations collected nationally. Processing is performed in two sites – the National Blood Centre (NBC) in Dublin and the Munster Regional Transfusion Centre (MRTC) in Cork. Pooled platelets are also prepared in the National Blood Centre.

The Components Laboratory in the NBC is also responsible for the issue of non-standard whole blood and red cell products and all platelet products. A total of 26,050 product orders were received electronically in 2014. These were managed by close cooperation between the Components Laboratory and Hospital Services personnel.

A total of 134,036 whole blood donations were processed nationally in 2014. Of this total, 69% were processed in the National Blood Centre and 31% were processed in the Munster Regional Transfusion Centre.

Whole Blood Donations Processed

- 2014

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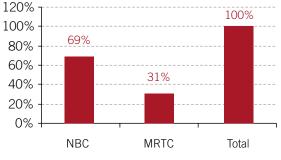
MRTC

Total

NBC

Processed by Centre - 2014

Breakdown of Whole Blood

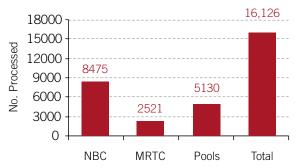


Platelet production consisted of 10,996 apheresis donations and 5,130 pooled platelets prepared. The apheresis donations were collected and processed in the two centres, with 77% being processed in the National Blood Centre and 23% being processed in the Munster Regional Transfusion Centre. The 10,996 plateletapheresis donations yielded a total of 21,815 issuable doses. This is a dose per donation rate of 1.98, increasing to 2.08 when technically unusable donations (515 donations) are excluded.

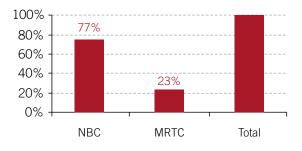
Of the 21,815 issuable plateletapheresis doses prepared, 11,005 (50.4%) were suitable for neonatal use, and 10,810 (49.6%) were suitable for adult use only.

The pooled platelets were prepared in the National Blood Centre only.

Platelatapheresis Donations and Pooled Platelets Processed



Pooled Platelets Processed by Centre



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

Primary Product	Number prepared
Whole Blood and Red Cells	
Whole blood for neonatal use	2,008
Red Cell Concentrate	117,852
Red Cell Concentrate for	
neonatal use	9,982
Red Cells, Clotted	4
Plasma Products	
Fresh Frozen Plasma, Filtered	110
Fresh Frozen Plasma for neonatal	
use	228
Fresh Frozen Plasma for	
Cryoprecipitate Production	181
Fresh Frozen Plasma for	
Cryoprecipitate for neonatal use	228
Serum for Tears	4
Buffy Coats	
Leucocytes, Buffy Coat for pooled	
platelet production	33,135
Leucocytes, Buffy Coat	3690

Secondary Product	Number prepared
Red Cells	
Red Cell Washed	94
Red Cells for IUT	64
Red Cells, Plasma Reduced	585
Red Cells Split for Neonatal Use	1,125
Plasma Products	
Pooled Cryoprecipitate	19
Cryoprecipitate for neonatal use	142
Platelets	
Platelets, Washed	20
Platelets, Paediatric Dose	12
Platelets, Hyperconcentrated	1
Granulocytes	
Leucocytes, Pooled	24
Leucocytes, Pooled, Red Cell	
Reduced	22

The Medical Scientist and Laboratory Assistant rosters were updated in November and October respectively. The change was introduced to better align the staffing to the work flow in the laboratory.

Donor Services



Awards Ceremonies

Donor awards ceremonies took place in Dublin, Limerick, Ardee, Carlow and Cork. A total of 704 donors received recognition for giving over 50 and 100 donations. These awards are an important part of the IBTS calendar year as it serves to recognise donors and their continued commitment to giving blood or platelets. It is an opportunity for the IBTS to thank donors for their long-standing loyalty and commitment to saving lives. At each of these events a patient who has received blood tells their story and brings real meaning to each donor of what their life saving gift means to others.

Cork – 194 Limerick - 167 Dublin – 186 Carlow – 103 Tuam – 54

Science Gallery

In October 2014, the IBTS sponsored the latest exhibition in The Science Gallery – "Blood, Not for the faint hearted". The exhibition showcased all things blood and the IBTS held a blood grouping typing station for the duration of the exhibition and it also served as a platform to showcase our newly developed app. The exhibition ran from October 2014 to January 2015 and gave extensive coverage for the IBTS in a very different environment and to diverse audiences.

iPhone and Android App launch

2014 saw the launch of our brand new iPhone and Android app. This is the first time that the IBTS introduced an app across both platforms, something donors have been asking about since we released an iPhone version a number of years ago. The Android app currently stands at over 5,000 downloads. This was achieved without any advertising budget behind it; we boosted posts via Facebook and Twitter in order to engage with our key audience. The iPhone app is currently at almost 6,500 downloads.

Star donors

Throughout the years we have had some high profile donors come through our doors, however in 2014 we had a Star visitor to our D'Olier Street Clinic cause quite a stir!



GAA Partnership

The GAA partnership was officially launched on January 14th 2014 with a press conference that took place in The National Blood Centre. The partnership was officially launched by Uachtaran Cumann Luthchleas Gael Liam O'Neill and IBTS Chief Executive Andy Kelly. Also in attendance were intercounty GAA stars Tony Kelly, Eoghan O'Gara, Anna Geary and Laura McEnaney. The partnership aims to raise awareness of the 70,000 people who require blood transfusions annually in Ireland.



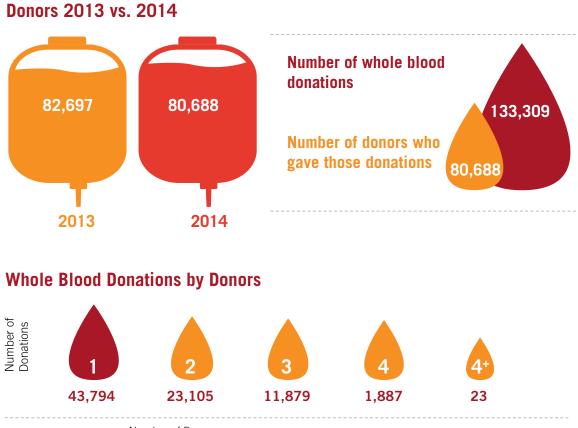
Garda Blood 4 Life Cycle

The Garda Blood 4 Life Cycle took place again this year from May 12th to May 16th with 18 cyclists visiting 26 counties in 5 days. The aim of the cycle was to raise awareness of the need for blood throughout Ireland.

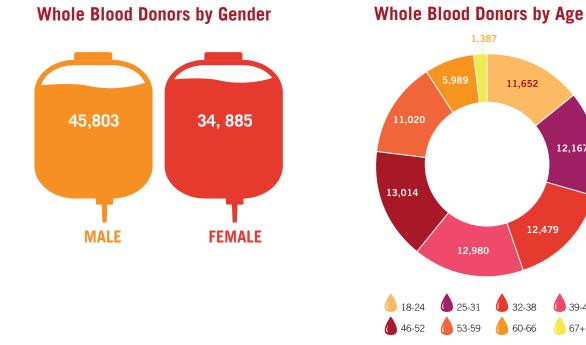
Day one saw the cyclists travel 195km through Cork, Kerry, Limerick, Clare, Tipperary and Laois. They also got to meet a few famous faces along the way!! They were met by the Deputy Mayor of Limerick Cllr Joe Leddin and Aileen Browne, Area Manager the Irish Blood Transfusion Service at Limerick City Hall. While garda Stephen Roe was pictured with All Ireland winner, Tony Kelly.

In the days that followed the cyclists bravely battled all types of weather conditions to continue there 1000km total cycle to finish up at Cork City Hall where they were met by numerous family and friends and Lord Mayor of Cork, Councillor Mary Shields.

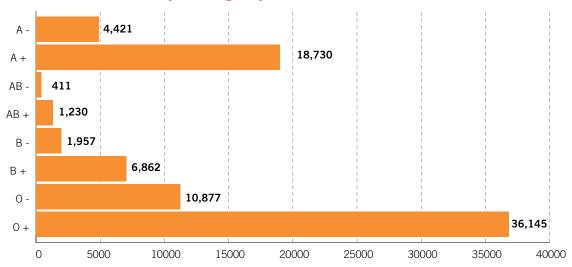
Donor Statistics



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



Whole Blood Donors by Bloodgroup



12,167

39-45

67+

l

Irish Blood Transfusion Service

Testing

Virology



Virology Laboratory

The function of the Virology laboratory at the NBC is the mass screening of blood donations for transfusion transmissible disease. The Virology laboratory receives a clotted serum sample from each donor taken at the time of donation which is identified with a unique bar code identifier and all samples from the blood donor clinics are transported to the NBC overnight and tested the following day. The sample is tested for the presence of specific viral markers that may be transmitted by transfusion. Approximately 144,055 donation samples and 2,281 first time nondonor samples were tested in 2014.

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 U.K.', 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.

NHIRL

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 SNBTS External Contingency testing plan in 2014.

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.

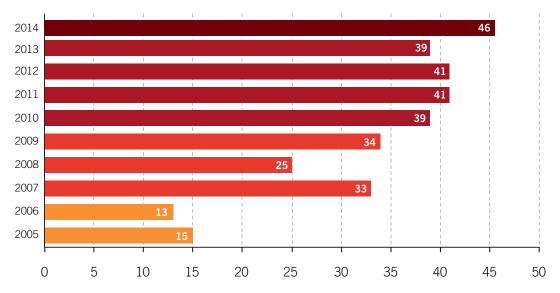
The laboratory determines the human leucocyte antigen (HLA) type of all patients and donors (related or unrelated) prior to transplantation to aid donor selection. The laboratory uses exclusively molecular methods based on the polymerase chain reaction (PCR) to define the genes that encode the HLA molecules. 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 2014 samples from 209 Irish patients for potential haematopoietic stem cell transplants and their relatives were HLA typed by the NHIRL. For those patients without a suitable family donor, an unrelated donor may be identified from the registry of volunteer donors.

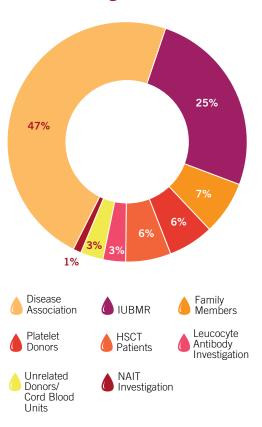
The NHIRL provides an immunogenetics support service for the Irish Unrelated Bone Marrow Registry (IUBMR) and in 2014 the laboratory HLA typed 1512 new volunteer donors to add to the registry.

Number of Irish Patients receiving a HSCT from an Unrelated Donor 2005-2014



In the last 10 years the IUBMR has facilitated 327 unrelated donor transplants for Irish patients, 63% (n=207) of these transplants have been performed in the last five years.

The NHIRL also provides a routine disease association HLA typing service. This service represented 47% of the investigations performed in 2014. 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.



NHIRL Investigation Distribution

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 2013.

A total of 377 platelet donors were HLA-A, -B typed and included on the panel of platelet donors in order to support the provision of an optimal platelet product to the hospitals.

The laboratory continues to be actively involved in research projects with Irish hospitals and universities to elucidate the role of HLA and killer cell Ig-like receptors (KIR) genes in various diseases. The following paper was published in 2014 in Clinical and Experimental Dermatology in collaboration with St. Vincent's University Hospital, Dublin.

 Genetic markers of treatment response to tumour necrosis factor- inhibitors in the treatment of psoriasis. Ryan C, Kelleher J, Fagan MF, Rogers S, Collins P, Barker JN, Allen M, Hagan R, Renfro L, Kirby B. Clin Exp Dermatol 2014 Jun;39(4):519-24.

Diagnostics/ Crossmatch Dublin

Diagnostics Dublin

The diagnostics laboratory at the NBC provides Red Cell Immunohaematology and Antenatal services for hospitals nationwide.

The services provided by the Diagnostics Laboratory include;

- Provision of phenotyped blood (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 typing problems.
- Investigation of positive Direct Antiglobulin Tests (patients and donors)
- Investigation of Autoimmune Haemolytic Anaemia
- Investigation of Haemolytic Disease of the Fetus & Newborn (HDFN)
- Prevention of HDFN by routine Antenatal Screening for 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

Laboratory Activity

In 2014 a total of 2,211 samples were referred to the Diagnostics Laboratory. This represented a 3.8 % decrease in antibody investigations, a 2.7 % decrease in anti-D quantitation and (overall quantitation decrease of 5.9 % - compared to 2013). There has been a further increase in referrals for RhD investigation; an increase of 12 % when compared to 2013. This is an on-going result of changes in the guidelines for pre-compatibility testing issued by the British Committee for Standards in Haematology [Transfusion Medicine 2013;23:3-35].

As in previous years there is a continued high level of serologically difficult or rare samples received. In 2014 the following difficult or rare allo-antibodies were identified through the NBC:

Anti-Chido/Rodgers (9), CR1-related (7), Anti-U (2), Anti-Ge2(1) Anti-Csa (1), Anti-JMH (1),

The majority 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 dramatically over the last decade to the current 2 samples for antibody confirmation.

ETraceline

The Diagnostics Department successfully implemented the new BECS system on 15/03/2014. It is called eTraceline and it is the patient module of eProgesa. The introduction brought an improvement in the style of reports issued to our Hospital Blood Banks.

Importation Of Rare Blood/Products

In 2014 a total of 14 red cell units and 4 platelets were imported from outside Ireland.

Units Imported from Outside Ireland				
Anti-IgA	Medical	1	NHSBT	
	case		Liverpool	
Anti-U	Medical	4	NHSBT	
	case		Liverpool	
Anti-U	Planned	2	NHSBT	
	Delivery		Liverpool	
HLA	Medical	4	NHSBT	HLA
antibodies	case		Liverpool	matched
				platelets
Anti-c	Medical	7	NHSBT	
r'r'	case		Liverpool	
phenotype				

Anti-U

The IBTS handled two cases, one for a planned delivery and one haematological case with rare anti-U.

Anti-c

This case involved a patient with cardiac complications. The sample was investigated, an anti-c was detected and the patient typed as r'r', which is a rare type. Seven units were imported on three occasions from the National Frozen Bank at NHSBT Liverpool.

NEQAS

The Diagnostics department participated in 4 different quality assurance schemes. Four exercises in IEQAS and AQQAS, 10 exercises in NEQAS and one exercise in Molecular Workshop Blood Group Genotyping, all were satisfactory.

Diagnostics/ Crossmatch Cork



Diagnostics Cork

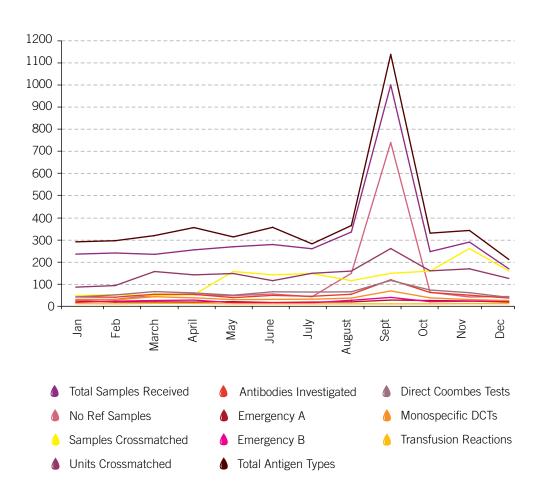
The diagnostics laboratory at MRTC provides both routine and reference immunohaematology and laboratory services. The former to South Infirmary University Hospital (SIVUH), St. Finbarrs', Mater Private Cork and Marymount University Hospital & Hospice, and reference immunohaematology & laboratory Services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

- As hospital Blood Bank for a small number of 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 dependant patients, positive direct antiglobulin tests, auto-immune haemolytic anaemia, haemolytic disease of the fetus/newborn, and complex antibodies providing extended matched (phenotyped) and crossmatched red cells for these patients. Individual samples in these cases may take several hours to investigate fully and may require donation screening where matching red cells are not available on the shelf. Eleven 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 having oversight of the Platelet continuous monitoring 'BacT' system,

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.

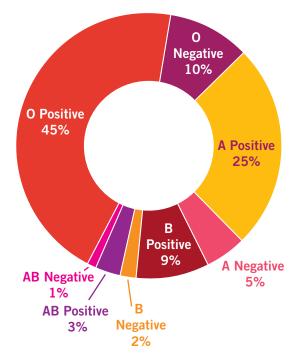


MRTC Diagnostics Laboratory Activities

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 2014 over 146,000 donations were tested and of these 11213 (7.6 %) 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 2014

Apart from performing the mandatory serological tests (ABO, RhD and antibody screening) the laboratory routinely screens and types donors in order to find the rarer phenotypes or combinations of types, which may be requested in an emergency. The laboratory performed over 101,000 Rh phenotypes and 53,000 other antigen types in 2014. These typed units provided typed blood for routine hospital orders, Intrauterine Transfusions and emergency requests for more complex antigen negative units.

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, screening O RhD Negative units over the past 2 years has still failed to identify a suitable donor, the typing is now being expanded to cover A RhD Negative.

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 250 donors have been identified and placed on a specially selected panel. Any requests for k negative blood can now usually be dealt with "off the shelf", or specific donors of the appropriate ABO group and 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 (but Rh C positive donors) were targeted for screening first and 10 further examples of these very rare types have been found and confirmed. Screening in 2015 will progress to include Rh E positive donors.

The Automated Grouping Department partakes in two external quality assessment schemes, which involves the submission of 15 separate exercises per year. 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 2014 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 machines 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 2014 all 4 shipments were handled without incident and the results received promptly. It is planned to directly integrate the results into the 'live' data base with the implementation of the e Progesa system in 2015.

Nucleic Acid Testing (NAT) Laboratory

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 pre-seroconversion window period.

The NAT laboratory performs Individual Donation (ID)-NAT using the Panther platform in conjunction with the Ultrio Elite HIV-1/2 / HCV / HBV assay. The Panther instrument is a fully automated closed system for NAT testing of individual donations with the Procleix Ultrio Elite assay. The Procleix Ultrio Elite assay is a multiplex Transcription Mediated Amplification (TMA) assay for the detection of Human Immunodeficiency Virus type 1and 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 Ultrio Elite assay on the Panther system was introduced into routine NAT screening of IBTS donors on 16th December 2013 as a replacement for the Ultrio Plus assay on the Tigris system.

The decision was taken by the IBTS to implement selective testing of blood donors for West Nile Virus (WNV) RNA in the NAT laboratory from the 9th June 2014. 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 9th June 2014 to 5th January 2015. An archive sample is retained on all donations. Every donation collected in 2014 was tested within the laboratory and there was no requirement to invoke the External Contingency testing plan which the IBTS has with the Scottish National Blood Transfusion Service (SNBTS).

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). IC is added to each test sample via the addition of working Target Capture Reagent (wTCR). 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.

Interlaboratory comparisons using EDCNet software (National Reference & Serology Laboratory, NRL, Australia, www.nrlqa.net) and participation in External Quality Assurance Schemes (EQAS) in 2014 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.

Other Services

Tissue Bank

Tissue Bank

The Tissue bank at the NBC is comprised of the National Eye Bank, The Heart Valve bank and the Directed / Sibling Umbilical Cord Blood Bank and is licensed 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 responsible for distributing human tissue used in ophthalmic surgery nationally. Products supplied include corneas, both for DSAEK and PK procedures, sclera, amnion, pericardium and fascia lata. These products are all imported from the US. 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, but it is envisaged that this secondary processing will transfer to the Tissue Establishment in University Hospital Galway in 2015.

In house validation and proficiency runs for cultured limbal stem cell grafts continued during 2014 and an inspection by the HPRA, under the Advanced Therapy Medicinal Products directive is planned for January 2015. It is envisaged that this treatment will be available to Irish patients in the summer of 2015.

The IBTS is a third party contractor to the MMUH for the processing, cyropreservation and distribution of human cardiovascular tissue. 2014 saw a decrease in donations to the bank but an increase in valves distributed for clinical use. The Directed/Sibling Cord blood bank collects and cryopreserves cord blood on request from the oncology/haematology team in OLCHC and Newcastle. The number of cords processed has continued to decline year on year.

During 2014 the IBTS imported human cadaver skin for the burns unit in St. James hospital and are in negotiations re the establishment of a national skin bank.

In the last quarter of 2014, the tissue bank went to tender for the replacement of the liquid nitrogen vats which will be commissioned in 2015. The introduction of a new computer system for tissue (Mak - TCS) commenced as part of the upgrade of the computer system used by the IBTS. This will be operational on a phased basis during 2015.

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

Therapeutic Apheresis Service

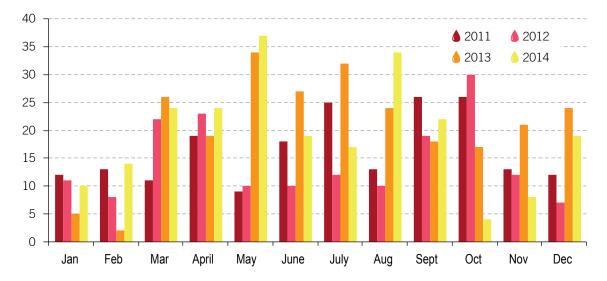
Therapeutic Apheresis

MRTC provides Therapeutic Apheresis treatments to patients in Cork hospitals, Cork University, Mercy University and Bon Secours. This is a front line service. These treatments are provided on request from the patient's hospital based Consultant. The service is demand led, with resultant variability in activity levels. All treatments are performed in the acute hospital setting. Apheresis procedures are performed on patients with rare and often life/organ threatening disorders from a wide range of specialities including Haematology, Renal, Neurology and Hepatology. The emergent and urgent cases are often very unwell on high dependence wards and undergoing other treatment modalities or intensive investigations.

The MRTC Consultant Haematologist leads the service and a medical evaluation of each patient is performed by the Haematologist / Specialist medical staff. The Apheresis Team is led by a Specialist Medical Officer who undertakes procedures together with a specialist nurse, with cell separator technology. The majority of therapeutic apheresis procedures worldwide are Plasma Exchange but other treatments include Leucodepletion and Red Blood Cell Exchange. MRTC TAS practice is guided by the American Society for Apheresis (ASFA- 2013) Guidelines and indications for treatment.

MRTC commenced this Service in 1985 after the first technology was purchased by the Irish Cancer Society. This Haemonetics 30 supported the Service over many years to an upgrade to Haemonetics 50 and MCS + in turn. In early 2013 the Spectra Optia Apheresis System was introduced. This platform allows for a number of applications and the continuous flow system reduces the procedure time but requires dual venous access. In August 2014 the leukopheresis software was enabled.

The trend and variability in Service demand over recent years are shown below.

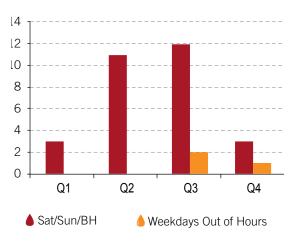


Trend by Service Demand by Patients and Procedures

Weekend / Out of Hours Service Provision -

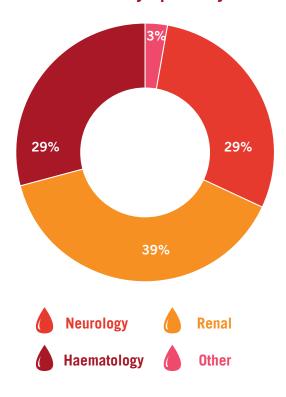
Patients may present for emergency care out of hours when their diagnosis is life or organ threatening or their programme of treatment may extend through a weekend period. During 2014, 31 (13%) procedures were provided out of hours including two bank holidays. The trend in this demand through the year on the service is represented by quarter below.

Weekend / Out of hours Service Provision by Quarter



Service Profile by Clinical Specialty, Patient and Procedures.

The demand on the Service from Clinical Specialties is represented here.



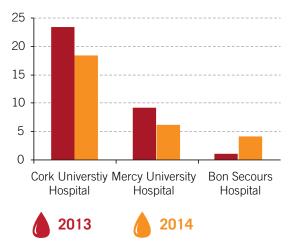
Patients by Speciality

Therapeutic Apheresis Service

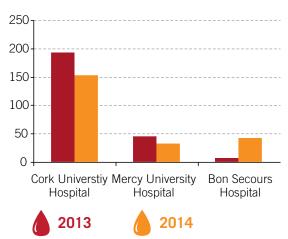
Service Provision by Hospital (Patient and Procedures)

The demand on the Service from Hospitals in Cork for 2013 and 2014 is detailed here.

Service Provision to Patients by Hospital 2013 - 2014

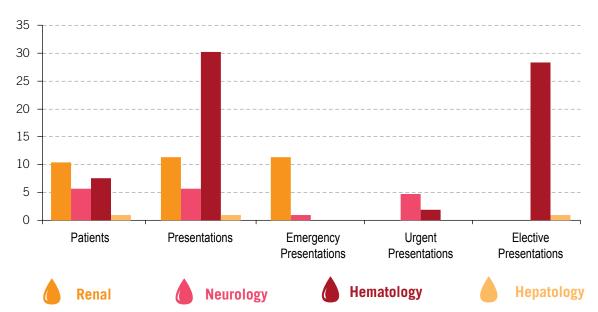


Procedures by Hospital 2013-2014



Service Provision by Degree of Urgency

Therapeutic Apheresis may in some conditions form part of the urgent clinical response to patients presenting to the Health Service, where early apheresis may impact on the threat to life or organ. Patient presentations in 2014 are categorised in relation to the degree of urgency in providing the Service by clinical specialty.



Summary of Patients and Presenations by degree of urgency

Service Provision by American Society for Apheresis (ASFA) Guidelines recommendations for treatment.

The ASFA practice guidelines are evidence based on both quality of supporting evidence as well as the strength of the recommendation derived from that evidence. Revised Guidelines were published in 2013. $\label{eq:category 1} \mbox{ Category 1} - \mbox{ First-line therapy, primary standalone or in conjunction with other treatments}$

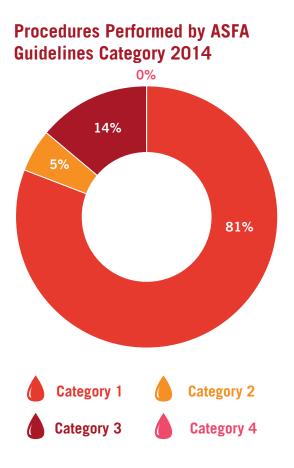
Category 2 – Second-line therapy, standalone or in conjunction with other treatments.

Category 3 – Optimum role of Apheresis not

established - Decision individualised.

Category 4 – Evidence shows Therapeutic Apheresis ineffective.

Therapeutic Apheresis Service



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 and in the fourteen years of its existence, (2000-2014), a total of 4577 serious adverse transfusion reactions and events have been reported at the time of this report. The NHO liaises with and supports the Haemovigilance Officers (HVO) based in hospitals 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 200 mandatory SAEs were reported, which was 70% of all SAEs. In addition, 85 non mandatory SAEs, primarily relating to errors in clinical areas, were reported under professional responsibility, which was 30 % of all SAEs.

Serious Adverse Reactions (SARs) - mandatory and non mandatory

There continues to be a considerable increase in the overall number of accepted SARs. At the time of this report 385 reactions have been accepted in 2014, an increase of 131 SAR reports from previous year. This trend can be accounted for the fact that the NHO now accept reports of Delayed Serological Transfusion Reactions. The number of mandatory SAR (72) is unchanged from 2013.

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 forty-two mandatory reports were accepted by the NHO in 2013, with the compilation of 2014 ANSARE report ongoing 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.

Therapeutic Apheresis Service

Irish Unrelated Bone Marrow Registry (IUBMR)

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 2015.

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 2014 work continued on adapting the programme content to facilitate access on 'Smartmedia' devices. At the time of writing work is almost complete on a module in Good Manufacturing Practice for Blood Establishments, and a module on Acute Transfusion Reactions. 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. At the time of writing there were over 22,000 users registered, 55% were nurses, 25 % medical staff and the remaining 20% were medical scientists, phlebotomists, porters and students.

Hemopoietic progenitor cell transplantation is a life saving therapy for certain patients with leukaemias, bone marrow failure syndromes and for particular inherited metabolic disorders. For the many patients who do not have the preferred option of a fully matched sibling, an unrelated donor from one of the 25 million volunteer donors worldwide provides a suitable alternative.

To meet the need for hemopoietic 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 Irish Medicines Board 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 2014 eighty six (86) patients were referred to the IUBMR for unrelated searches.

Forty six (46) Irish patients received stem cells from an unrelated donor in 2014. The majority were from international donors (38)

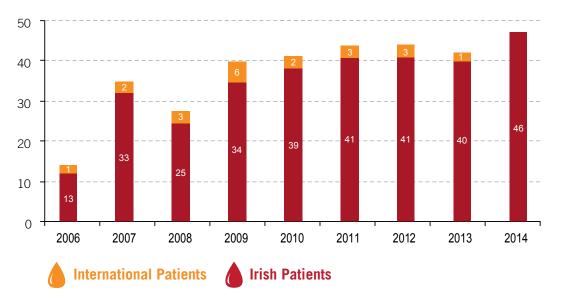
International Activities

Preliminary searches were received on behalf of three hundred and thirteen (313) international patients of which eighty four (84) donors were activated for additional typing requests.

Irish Donors

Bone marrow volunteers are recruited by the bone marrow recruitment nurse at blood donation clinics two days a week. In 2014 the number of newly recruited donors was 1,512.

There were eight (8) donations from Irish donors of which four (4) were peripheral blood stem cell collections and four (4) were bone marrow.



IUBMR Transplants Facilitated From Irish And International Donors For Irish And International Patients 2006 - 2015

Quality & Compliance

"Continued focus on cost containment and cost reduction was a central focus for 2014, but ensuring that Quality Standards and the highest level of safety in service delivery is also maintained is the central goal of the Quality function."

150

HUUT

450 ml

Quality & Compliance

The implementation of the recommendations from the Quality Review continued in 2014. The appointment of a Haemovigilance Officer with responsibilities for Blood, Tissue and ATMP product vigilance was a welcome addition to the Quality Team and will enable delivery of the Quality Review recommendations.

During 2014, the Health Products Regulatory Authority (HPRA, formerly known as the IMB) carried out 6 Blood Establishment regulatory inspections covering the main NBC centre, the Cork processing centre and clinics nationally. There were no major non-compliances raised during these inspections and 33 other observations.

In addition the HPRA carried out a special inspection of the activities of the National Haemovigilance Office (NHO), there were 3 Major Non-compliances raised during the inspection which were replied to by the IBTS.

A 10 year review of the IBTS Compliance rates was performed which highlighted that 88 inspections have been carried out by the IMB/HPRA between 2004-2014 with zero Critical non-compliances, an average of 0.23 Major non-compliances per inspection and 4.69 Other non-compliances noted.

The IBTS target is an average of <1 major per annum for regulatory inspections. The QA internal audit programme covered a total of 46 individual department audits during the year. There were 4 vendor audits carried out in 2014 of critical vendors, including distribution service supplier to the HSE. The reporting of Quality metrics to the EMT and IBTS Board was done quarterly, covering close out rates for IRs, review of recalls, complaint rates, Vigilance data, Laboratory EQAS data.

The Internal Incident Reporting System during 2014 benefited from regular review of close out rates at the weekly Quality Management Review which resulted in a year end close out rate of 86.5%, exceeding the target of 80%.

Donor Service Complaints were captured, investigated and closed out within the set targets and achieved a close out rate of 98% by year end.

The IBTS also has a very active Complaint Handling System whereby hospitals lodge details of service/ product complaints, which are subsequently investigated by the IBTS. Close out by year end was 91.5%, meeting target.

Post marketing surveillance through the recording of Serious Adverse Events (SAE) and Serious Adverse Reactions (SAR) is also operated by the IBTS. There were 105 SAEs and 107 SARs reported to the National Haemovigilance Office by the IBTS in 2014. The development of BE systems by the IBTS HVO has resulted in earlier detection of potential SAEs and faster investigation and disposition of cases.

Further detail on this data is contained in the Annual Report submitted by the IBTS to the HPRA in 2014.

In addition a Donor Vigilance system captures events relating to donors (clinics), there were a total of 640 events reported in 2014. A composite annual report is sent to the HPRA on Donor Vigilance.

Human Resources

"The Human Resources Department continued to focus on improving internal human resource strategies to ensure staff are enabled to meet the needs of our donors and patients"

Human Resources

The Human Resources Department continued to focus on improving internal human resource strategies to ensure staff are enabled to meet the needs of our donors and patients throughout the year, and achieve related strategic goals and efficiencies as outlined in the Balance Score Card.

The following represents an overview of the organisational structure of the Human Resources function in 2014:

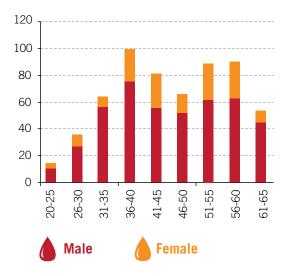
Remuneration	Employee &	Staffing &	Organisational	Health
& Benefits	Industrial Relations	Workforce Planning	Development	& Safety
Payroll	Policies & Procedures	Recruitment	Learning & Development	Safety Compliance
Sick Leave	Labour Relations	Performance	Performance	Occupational
Administration		Management	Development	Health
HR Administration	Dispute	Equality	Assisted	Safety
	Resolution	& Diversity	Education	Statements
Pension	HR Projects	Succession Planning	Change Management	
VHI & EAP			Internal Communications/ Intranet	

Human Resources

Staff Structure

Human resources strategies are developed in line with the structure of staffing:

Staff Profile by age group and gender



Human Resources Projects

2014 saw a significant role for human resource management in support of change management programmes, workforce management, planning and resourcing and on-going training and development.

Change Management Projects

Single Site Processing

2014 Voluntary Redundancy programme implemented

Redeployment process commenced internally, with external redeployments to CUH ongoing Restructuring and reorganising of impacted services from the Cork Centre to the National Blood Centre

Amalgamation of Hospital Services /
Components Laboratory

Consultation Process concluded with Labour Court outcome awaited

Medical Administration Review
Phase 1 review completed and report
presented to Executive Management Team

HR Management, Planning and Resourcing Projects

- Softco project Phase 1: Implementation of soft-copy HR file system incorporating historical files
- Ongoing implementation of the Haddington Road Agreement: Top of scale increment date freeze
- Pension: A protracted process of consultation was ongoing throughout 2014 involving Unions, IBTS Management and the Department of Health and Department of Public Expenditure and Reform. The services of the Labour Relations Commission was utilised to assist with this ongoing impasse. Further consultation with the Commission is planned

HR - Audit Review: An audit of payroll processes was undertaken during Quarter 2 of 2014. Key recommendations for implementation in 2014 include exploring opportunities to further automate some processes. An internal audit appraisal of the Performance Management and Development System (PMDS) was undertaken in Quarter 2 and 3 of 2014, with the key finding recommending that in 2015 the system be re-designed to be more accessible to the enduser.

Corporate Training and Development

Organisational Training, Development and Education

A review of organisational-wide training, development and education was completed in Quarter 4 of 2014 with the objectives of appraising and assessing current practices in terms of :

- Effectiveness, value for money and resource efficiency
- Best practice comparison
- Fitness for purpose
- Currency and future-proofing

The next stage of the review includes appointing a Corporate Training and Development Manager and then assessing the key findings and implementing an action plan to address the agreed recommendations. In addition to standard procedural and on-the-job training, the main focus for corporate training and development programmes in 2014 were:

- Corporate Orientation Programme, Induction Training
- EH&S training for managers and staff
- Manager skills training

Human Resources

Corporate Training & Development Programmes	Total Attendees
Corporate Orientation Programme	44
Data Protection / FOI	14
HR Policies & Procedures	12
EH&S Training Programmes, including	
1. Manual Handling	163
2. Donor - Manual Handling	38
3. Fire Safety	49
4. Occupational First Aid	14
5. Chemical Risk / Gas Handling	29
6. Emergency Response & Evacuation Training Clinic & Building	32
7. Personal Security	12
8. Laboratory Safety	43
9. Safety Statement	36
10. Radiation Safety Training	7
11. Environmental Health & Safety	14
Management Development	
Communications Skills, Team Building, Conflict resolution, Managing People, Customer	
Service & Client Centered Communications, Interviewer Skills	

IBTS Assisted Education Scheme

Financial assistance was granted for further education in a variety of disciplines including Nursing, Laboratory Science, Quality Management and Management Development

12 new applications in 2014

Environmental, Health and Safety

Environmental, Health and Safety has strategic importance within the organisation. To assist with legislative compliance and continue to promote an awareness of environmental, health and safety within the organisation, environmental health, safety and welfare programmes continue to be reviewed and developed. The Environmental, Health & Safety primary focus for 2014 was on:

- IBTS chemical safety programme
- Biological agents safety programme
- A major review of the fire safety programme was undertaken within the National Blood Centre (NBC), which included audit of alarms system, fire fighting equipment, signage and fire exists routes in preparation for the NBC becoming the single processing site in Ireland
- Revision and update of NBC and MRTC Safety Statements
- Further revisions and updates of national IBTS Emergency Response Plan (Mobile Clinics) and relevant training
- Provision of EHS guidance and support in the roll out of weigher/mixer equipment for collections teams across the country.

Finance

Summary Ac	counts for the	year ended 31	1st December 2014
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	2014 €'000	2013 €'000
Income		
Recurring income	64,004	65.269
Non-recurring income	878	1,204
Total income	64,882	66,473
Expenditure		
Total expenditure	66,620	67,928
Surplus / (Deficit) for year	(1738)	(1,455)
Actuarial gain / (loss) on pension scheme	(48,088)	8,245
Transfer to Capital Reserves	(130)	(241)
Transfer to Research Reserve	(1,106)	(36)
Accumulated Deficit at 1st January	(8,888)	(15,401)
Accumulated Deficit at 31st December	(59,950)	(8,888)

Income

The Board's total income for 2014 of €64.88 million (2013 €66.47 million) is analysed into recurring and non-recurring income. Recurring income consists of revenue generated from sales of products and services provided to hospitals of €64.00 million (2013 €65.27 million). Non-recurring income of €0.88 million (2013 €1.20 million) includes interest on bank deposits and proceeds from the sale of fixed assets. The drop in income represents reduced volumes and the reduction in interest rates on deposits.

Expenditure

Expenditure for 2014 amounted to €66.62 million (2013 €67.93 million). The reduction in expenditure mainly arises from the continuation of the IBTS cost reduction programme implemented by the Board in 2009.

The Board accounts for pensions in accordance with financial reporting standard 17 'Retirement Benefits' (FRS 17).

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 2014 was €8.40 million.

In 2006 the Board set up a research reserve. In 2014 €1,106,361 was added to the reserve. (In 2013 €36,000 was added to the reserve).

Capital Expenditure

The Board invested €3.07 million in capital projects and equipment during 2014 (€3.01 million 2013).

The main investments during the year included expenditure on a new Blood Establishment Computer Systems (BECS), Fleet replacement, replacement of weigher mixer equipment, non-invasive Hb measurement equipment and IP telephone system.

There was 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 2014, under the terms of applicable legislation, invoices to the value of €126,449.56 were late, by an average of 15.66 days. These invoices constituted 0.67% by number and 0.33% 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 €4,917.81

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

Cork Centre

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

Dublin Blood Donor Clinic

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

Stillorgan Blood Donation Clinic

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

Ardee Centre

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

Carlow Centre

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





National Blood Centre

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