ANNUAL REPORT 2013

Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Contents

“The IBTS has a disarmingly simple mandate – to provide a safe, secure, and reliable supply of blood products for the Irish health service.”

Chairperson's Foreword

The IBTS has a disarmingly simple mandate – to provide a safe, secure, and reliable supply of blood products for the Irish health service. Achieving this mandate requires hard work, focus, dedication and an impressive set of high-end technical skills from our staff. We have one further unique feature which is our dependence on the generosity and commitment of our donors week in week out across the whole country. We have recently established a formal link with the GAA, and over the next year we will visit every county board and as many clubs as possible to make this link real. We will encourage those active in the GAA to donate, or to support others in donating.

This year we have had a new type of event. A speaker at our awards dinner in Cork, Garda Stephen Roe from Cork, organised a four day cycle from Malin Head to Mizen Head in April, as a memorial to his son Alex, who died of leukaemia in 2010. With 12 of his Garda colleagues, he cycled over 660km, and they looked, not for cash donations, but for pledges of blood donations, one for every kilometre cycled. This was a great success, and we thank Stephen, his fellow cyclists, his wife Michelle and his family, and the Garda Síochána who supported this event.

Change continues for us, in most areas of our work. Last year we moved to single site testing as part of a larger programme of structural reform and cost saving. The next step in this programme is the move to single site processing of blood and blood products at the National Blood Centre in Dublin. This will take about 18 months to implement, and will be linked to many other changes, including a much larger stock holding and dispatch operation in Cork.

We have had many years of excellent service from our existing computer system, however it is now coming to the end of its life. We are bringing in a new system, which will further streamline our operations. We will also be able to offer timed appointments to donors in our centres for the first time. The new system is expected to be live from October 2014.

We have opened a new service for patients with haemochromatosis. This is a very common genetic disorder, and Ireland has the highest rate in the world. Patients need to have blood taken regularly. Now, for the first time, patients who are stable, can attend our clinics, and have their blood taken. If the patient wishes to donate, and is otherwise eligible to do so, the blood will be taken for processing, otherwise it will be safely discarded. This service has started in Dublin, but will be rolled out to other centres over the course of 2014.

At the IBTS we are responsible for running our own staff pension fund, and, like many other such funds, it has had difficulties over the last few years. We are hopeful that an agreement will be reached in 2014 to resolve the problems this has caused for our staff.

My final responsibility, and a very pleasant one, is to thank people. My colleagues on our Board have been a tower of strength in challenging times. Minister Reilly, and his colleagues, and the staff at the Department of Health, are always interested in our work, and supportive of our efforts, and we greatly appreciate this. I would also like to thank the staff of the IBTS for their professionalism and commitment to delivering high quality services to our patients and donors. I have the very great pleasure of meeting our donors, and some of our recipients and their families, at our award dinners. It's a privilege to meet them, and to thank them, for their time, their dedication, and the gift they give to patients all over Ireland, every day of the year. They really are everyday heroes.

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 2013, 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.
3. The Board confirms that there is an ongoing process for identifying, evaluating and managing significant risks faced by the IBTS. This process is regularly reviewed by the Board via reports from the Chief Executive.

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

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

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

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

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

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

Chairperson's Report

4. 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 2013 at its meeting on 24th March 2014.

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 Irish Medicines Board on operational and compliance controls and risk management. The Board will continue to review these reports and to work closely with the IMB 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 Chair appointed by the Minister for Health.

The Board met on 8 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	January	February	April	June	September	November	December
Prof Anthony Staines (Chairperson)	✓	✓	✓	✓	✓	✓	✓
Ms Jane O'Brien#	✓	✓	✓	✓	✓		
Dr Lelia Thornton#	✓	✓	✓	✓			
Dr Paolo Rebulla	✓	✓	✓	✓	✓	✓	✓
Dr Paul Browne		✓		✓	✓	✓	
Mr John Cregan	✓	✓	✓	✓	✓	✓	
Dr Conor McGrane***							
Ms Linda Hickey*			✓	✓		✓	✓
Mr Brian O'Mahony	✓	✓		✓		✓	✓
Ms Olwen Bennett*			✓		✓	✓	
Mr Gerry Kelly*			✓	✓	✓	✓	✓
Dr Cleona Duggan**	✓	✓	✓	✓	✓		✓

**Appointed on 17th January 2013
*Appointed on 14th February 2013
*** Resigned on 14th June 2013
# Term of office ended on 31st October 2013

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 2013		
Board members remuneration and expenses were as follows:	**Fees**	**Expenses**
	€	€
Professor Anthony Staines Chairperson	Nil	1,952
Ms Jane O'Brien	10,082	Nil
Dr Paolo Rebulla	11,970	3,526
Dr Conor McGrane	2,762	Nil
Mr Brian O'Mahony	Nil	Nil
Mr John Cregan	Nil	1,872
Dr Paul Browne	Nil	Nil
Dr Hilary O'Leary	Nil	Nil
Dr Lelia Thornton	Nil	124
Ms L Hickey	9,990	Nil
Ms O Bennett	9,990	Nil
Mr G Kelly	9,990	2,921
Dr C Duggan	Nil	677

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.

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 2013 was €154,407.

Medical Advisory Committee

The Medical Advisory Committee is comprised of the medically qualified members of the Board and the medical consulting staff and met 8 times in 2013. 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 five times during the year and is comprised of three members of the Board and two independent external members. It is also attended by the Chief Executive, the Medical & Scientific Director, the Director of Finance, the Operations Director, Director of Quality & Compliance, the Internal Auditor 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. 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 foreseeable future. For this reason, they continue to adopt the going concern basis in preparing financial statements.

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

Chairperson's Report

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.

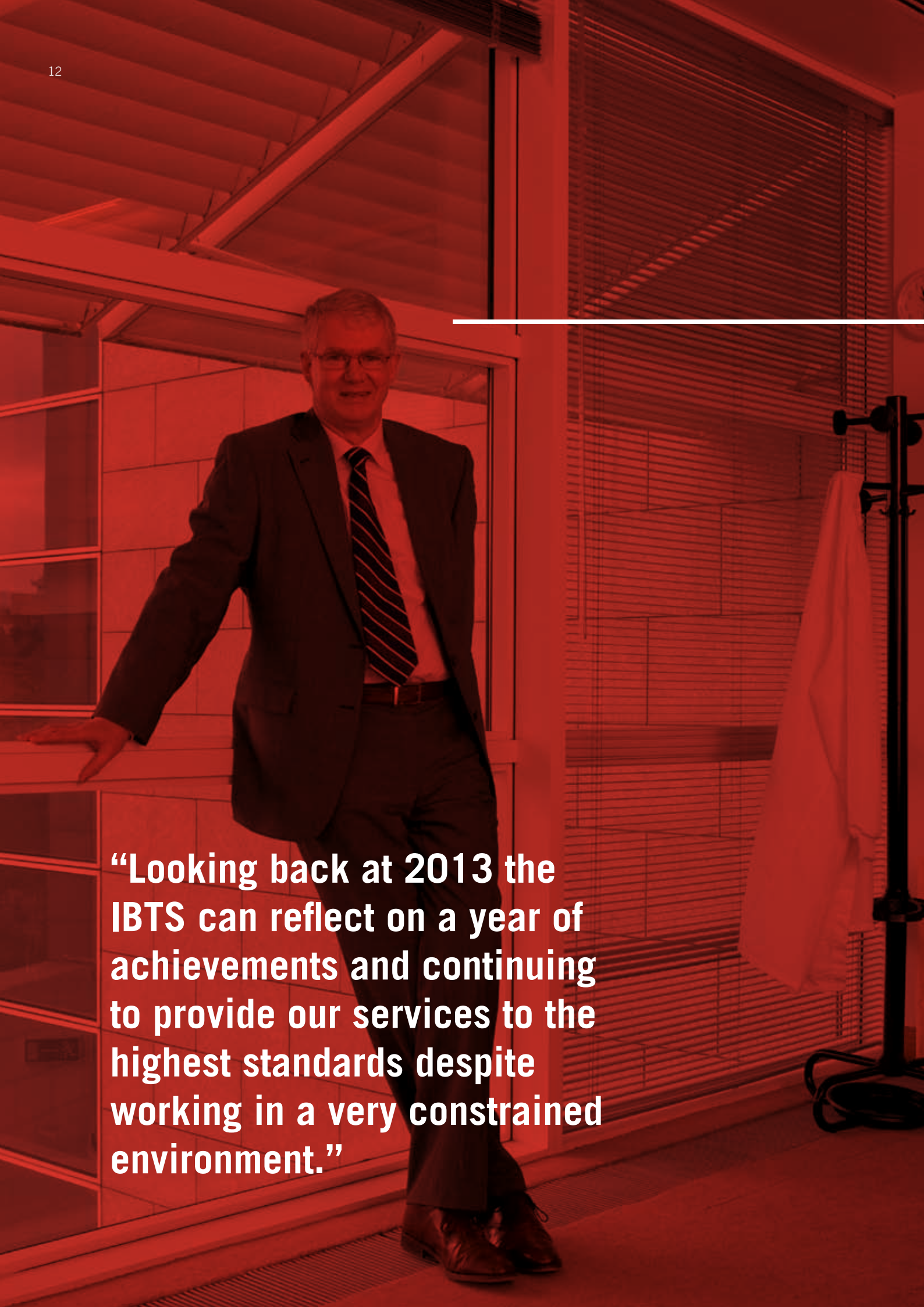
The Board is responsible for keeping proper books of account, which disclose with reasonable accuracy at any time, the financial position of the Irish Blood Transfusion Service and to enable it to ensure that the financial statements comply with the Order. It is also responsible for safeguarding the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

Commercially significant developments

Transport outsourcing

The HSE decided to outsource all cold chain deliveries to hospitals and this included the delivery of blood and blood products. New arrangements for blood and blood product deliveries came into effect in May 2013.

Professor Anthony Staines
Chairperson



“Looking back at 2013 the IBTS can reflect on a year of achievements and continuing to provide our services to the highest standards despite working in a very constrained environment.”

Chief Executive's Report

Looking back at 2013 the IBTS can reflect on a year of achievements and continuing to provide our services to the highest standards despite working in a very constrained environment. We maintained a safe and consistent blood supply which is our core function. We faced many challenges that stretched our resources but through the professionalism and resilience of all staff we met these challenges successfully.

We published our Strategic Plan 2013 - 2016 in June and a presentation was made in all Centres on the main elements of the Plan. We used the Balanced Scorecard methodology for the first time in developing this Plan. We will review progress each quarter to ensure that we are maintaining our focus on the targets that we have set ourselves.

We had to revert to the levels of Haemoglobin (Hb) in the Directive from 30th September 2013. This was a significant challenge but through the work of a multi-disciplinary team we introduced a series of measures that allowed us to implement the higher levels of Hb and maintain supply. This work will continue so that when we come into the Summer of 2014 we can ensure that there will be no drop off in supply.

We continued our commitment to Haemochromatosis patients by opening our second clinic in D'Olier Street in August. While progress has been slow this service is much needed and in time will deliver a proportion of blood to the national supply. Plans are well advanced to open a clinic in our Cork Centre in January 2014.

Technology drives so much of our business activities. In late 2012 we commenced the project to replace our blood bank control system and to implement eTraceline, eRiskline and Tissue, Cord, Stem (TCS) in the IBTS. This project continued during 2013 with the focus on implementing eTraceline. This is well advanced at year end and will go live in Qtr 1 2014. In addition, work has been ongoing on the other modules and it is intended that the complete suite of systems will be live by end 2014. This requires significant IT resources and will also require major commitment from users to ensure that we meet our deadlines.

The Board in November made the decision to centralise processing to Dublin. This has significant impact on the staff in Cork and they must be dealt with in an appropriate manner over the coming months. The project itself will be a major piece of work and will require detailed planning and working with contingency partners. It is expected that this project will be completed by September 2015. In preparation for this we have been reviewing our risk management policy and risk registers. We also appointed a Risk and Resilience Manager to take responsibility for this area including Business Continuity.

The use of blood and platelets has continued to decline which has serious impact on our income. While the IBTS has always encouraged appropriate use of our products the continued decline has occurred much more quickly than we expected especially in red cells. However, we know from our European colleagues that this is a trend that is happening throughout Europe. It is unclear what the

Chief Executive's Report

exact reasons are but undoubtedly some of them are less wastage, improved surgical techniques, reviewing at hospital level of transfusion practice and less elective surgery taking place due to the cutbacks in health spending. This trend looks like it will continue over the next few years and this poses a major challenge to IBTS to reduce costs even further. While there may be some scope for further reduction in costs this will not be sufficient to meet the reduction in income.

The IBTS relies heavily on our interactions and networking with our European colleagues. In 2013 the IBTS hosted the European Blood Alliance board meeting in Dublin and the BEST meeting. It is very important that we continue our active involvement in these forums to enable us to be aware of the challenges that are emerging and how other blood services are dealing with them. We are especially grateful to NHSBT for facilitating our medical and scientific staff participation on a number of key committees. The British Government has an Advisory Body on Blood and Tissue called SaBTO. This is the Body that recommended the change in the deferral arrangements for MSM. Late last year the IBTS were given observer status on this Advisory Body and this was a significant step for us. The Medical and Scientific Director is the IBTS representative.

The one big issue that remains unresolved is the funding of the pension scheme. We had the High Court case in 2013 and the judgment has clarified matters. This issue is a source of great frustration and concern for staff. We need to find a resolution to the funding question in 2014. This will require a concerted effort on behalf of all of us to make this happen. The resolution of this issue must be the priority of the Board, management, staff, trustees, the unions and Department of Health in 2014. Let this be the last time this issue is mentioned in my report.

There is much work still to be accomplished by the implementation of the recommendations in the Administration Review, the remainder of the Quality Review recommendations, develop a succession plan because there are key posts that will become vacant in the next five years and planning the replacements must commence now, updating our administration/ office technology while at the same time continuing to meet patients and donor needs.

I would like to especially thank Dr Ian Franklin who has been the Medical and Scientific Director for the past three years. He brought a wealth of experience and knowledge to the role. He immersed himself in Irish culture, language and games. We wish him well in his retirement to pursue his many interests. I would like to welcome Dr Willy Murphy back and look forward to working with him over the coming years to meet the many challenges that we will encounter.

I would like to express sincere appreciation to all staff who continue to deliver services to patients and donors to the highest standards. I realise that this gets more difficult each year given the constraints we are operating under. However, I know from my visits to all the Centres and discussions with staff that you approach your work in a very professional manner and are determined to work to the highest standards of quality and care.

Andrew Kelly
Chief Executive

“2013 was marked by a further reduction in the usage of red cells by hospitals in Ireland. This has important implications for IBTS in terms of finance, but what does this mean in terms of medical care?”

Medical and Scientific Director's Report

2013 was marked by a further reduction in the usage of red cells by hospitals in Ireland. This has important implications for IBTS in terms of finance, but what does this mean in terms of medical care? It has been known for almost 20 years that there are significant differences in the use of red cell transfusions by developed Western health systems. No one knows what the optimal level of use should be, and it will depend upon issues such as the age of the population and general health indices. But custom and practice, or the habits of doctors, seem likely to be just as important. Within Europe some countries such as Germany and Denmark have transfused over 50 red cell units per 1000 people each year, as does the USA. Others, such as Ireland and France, are around 30 per thousand. Canada and Australia are also at the low end. The overall health indices for France suggest good healthcare there, so a level of 30 per thousand should be safe. Also, clinical trials where less transfusion was compared to more has tended to suggest that less is better.

A survey in the north, by the Northern Irish Blood Transfusion Service, suggested that even at a transfusion level of about 30 per thousand, a substantial number of transfusions were undertaken outside current guidelines. So transfusing even less than 30 per thousand red cells per year might be safe and achievable. Given the age of the population of Ireland, it seems unlikely that there will be any trend soon to needing more blood. However, it is possible that the economic situation of the past 6 years is biting into healthcare activity and reducing transfusion demand as a secondary effect. That would not be consistent with optimum medical care. Due to other clinical trials that reported recently, we now know much more about how to transfuse platelets – dose, frequency and scheduling are all better understood than even 5 years ago. In the main, these results suggest that slightly fewer platelets may be needed going forward if the evidence does drive practice.

What are the next big issues that IBTS will need to consider? Technology that treats platelets to reduce the risk of infection – known as pathogen inactivation – has been licensed for some years now. A detailed investigation into cost-effectiveness in the UK will be followed carefully by IBTS, and some important decisions made. Plasma used in Ireland is already subjected to pathogen inactivation, but as ever these systems are not perfect and it is possible that new and additional tests will need to be considered in 2014. For some years now, there has been interest in whether fresher blood might be better for transfusion, or perhaps more precisely, is older blood inferior? Trials looking at 'age of blood' at time of transfusion will likely report in 2014, and the results will be awaited eagerly by IBTS, doctors and, of course, patients.

After three years as Medical & Scientific Director for IBTS, I am leaving to pursue other interests in retirement. I wish my successor, Dr Willy Murphy, who returns from secondment, all my best wishes. He will certainly have some interesting and important challenges to face with his medical and other senior colleagues in IBTS.

Dr Ian Franklin
MBChB, PhD, FRCP [Lond; Glas; Edin], FRCPath.
Medical & Scientific Director
MCRN 401650

“the GAA community is key in helping us in our continued mission of maintaining a safe and sustainable blood supply, whilst building a community spirit around blood donation.”

Operations

Donor Services

Awards Ceremonies

Donor awards ceremonies took place in Carlow, Dublin, Cork and Ardee in 2013. A total of 853 donors received recognition for giving 50 times and 122 donors received recognition for giving 100 times. These awards serve as a thank you to the donors for what is described as a lifetime 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.

Branding

A new TV advertisement was developed and shot on location in the National Blood Centre along with the help of numerous members of staff. The ad has been well received in the media and has gained significant coverage through out the months of air time. It has proved a popular ad and given insight to the public on what their altruistic donation gives to those who need it most.

Prior to going live on TV there was an internal launch of the ad whereby we recognised the input of the numerous volunteers who partook in the filming.

The ad itself created a great atmosphere within the organisation as key members of staff found themselves on TV for the first time.

Research

A trial direct mail piece was undertaken in 2013 to further engage with lapsed donors – those who have not given for two or more years. Three different types of letters were sent to select groups throughout Dublin, Cork and Ardee. These letters each contained different messages to encourage donors to return to clinic. They ranged from a hard ask to a soft approach and one contained a survey as to why people had not returned. The results were surprising with the hard ask letter encouraging 601 donors to return to clinic.

Of those who were surveyed roughly 38% stated that they had emigrated to another country. This would warrant future research in itself to determine what age demographic is leaving and how to encourage those who are still living in Ireland to become regular donors.

Partnerships

GAA

On June 16th 2012 it was agreed at the Coiste Bainistí/Ard Chomhairle meeting that a partnership between the GAA and the Irish Blood Transfusion Service would be established. After the initial agreement members of staff from the IBTS travelled to each provincial board and then county board to initiate talks with clubs joining the partnership. This took up most of the latter half of 2012 and 2013.

The aim is that the initiative will lead to 15,000 donations annually through the GAA. With similar attributes like community spirit, pro-social commitment and volunteerism the GAA community is key in helping us in our continued mission of maintaining a safe and sustainable blood supply, whilst building a community spirit around blood donation.

The partnership was officially launched in the National Blood Centre by the Chief Executive and President of the GAA, in addition key high profile GAA players were in attendance along with numerous national media. There was extensive media coverage through the following days and weeks.

Gardai cycle from Malin to Mizen

A group of Gardai from Cork took part in a gruelling cycle from Malin Head in Co Donegal to Mizen Head in Co Cork. The Malin to Mizen Cycle was done to raise awareness about the importance of giving blood. This was the initiative of Garda Stephen Roe, who learned the value of blood donation when his son Alex was diagnosed with Leukaemia. Sadly Alex lost his battle with the disease but his father said they owed 5 happy years of life with Alex to the numerous blood transfusions he received. Most of the 13 Gardai taking part are members of the Garda Traffic Corps. They see people fighting for their lives after major trauma on an all too regular basis. Many of them are involved in transporting patients and urgent blood supplies to hospitals. The cycle took place from 27th to 30th April, 2013.

Media

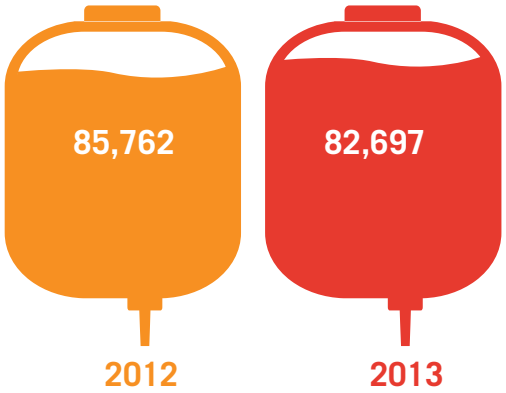
RTE Nationwide ran a full length programme about blood donation on 16th September where they interviewed both IBTS staff and blood donors around the country. The programme also covered the link between the GAA and the IBTS.

The episode covered the process of giving blood with both Mary Kennedy and Mary Fanning interviewing donors across the country. Fellow IBTS staff member Barry Doyle and his wife Molly were interviewed in our D'Olier Street clinic along with their son Tom who received blood.

“The Malin to Mizen Cycle was done to raise awareness about the importance of giving blood.”

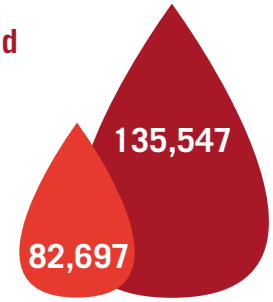
Donor Statistics

Donors 2012 vs. 2013

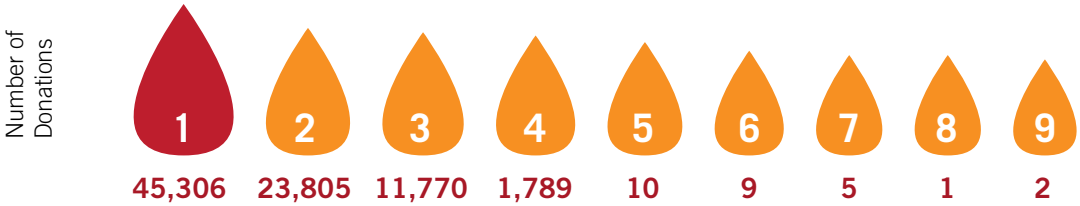


Number of whole blood donations in 2013

Number of donors who donated the above figure

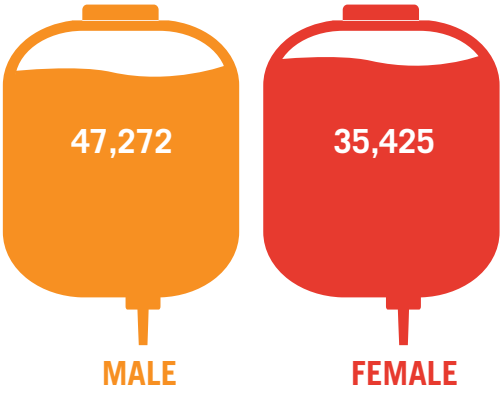


Whole Blood Donations by Donors

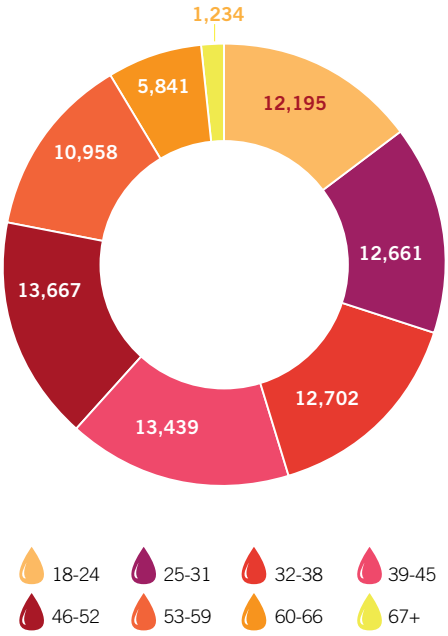


Number of Donors (Note: donors who gave 4+ times are on the HH panel)

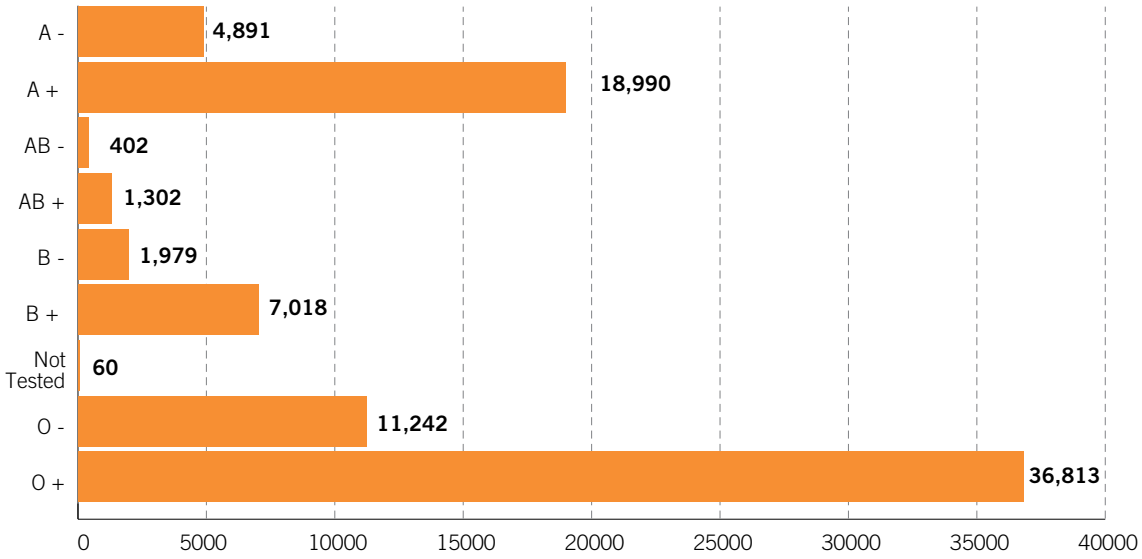
Whole Blood Donors by Gender



Whole Blood Donors by Age



Whole Blood Donors by Bloodgroup



Hospital Services

The Hospital Services Department in both NBC and MRTC are responsible for the distribution of all blood products and manufactured products nationally by the use of the Electronic Ordering System.

In 2013 the Hospital Services department managed the transition to LG-Octaplas on both O and A Octaplas working closely with the supplier Octapharama and the hospitals during this time.

In 2013 the delivery of blood and blood products transitioned from the IBTS transport function to a medical courier company called First Direct under contract to the HSE. This delivery service in temperature controlled vehicles went live on the 27th May 2013. The Hospital Services department played a key role in ensuring that a system was in place to support the successful transition of this 24/7 service.

Blood, Blood Components & Blood Products Issued		
Product	2013	2012
Red Cells & Whole Blood	126,560	133,199
Platelets - Therapeutic Doses	22,509	24,127
Frozen Plasma	198	277
Octaplas	18,896	20,961
Cryoprecipitate	167	160
Riastap	5,100	4,675
Factor VIII Recombinant (x IU) *	-	13,349,000
Von Willebrand Factor (x IU) *	-	304,200
Factor IX Recombinant (xIU) *	-	3,684,250
Prothromplex (x IU) *	-	291,600
Factor XIII *	-	5,500
Plasma For IVD Use (Litres)	15,382	31,798

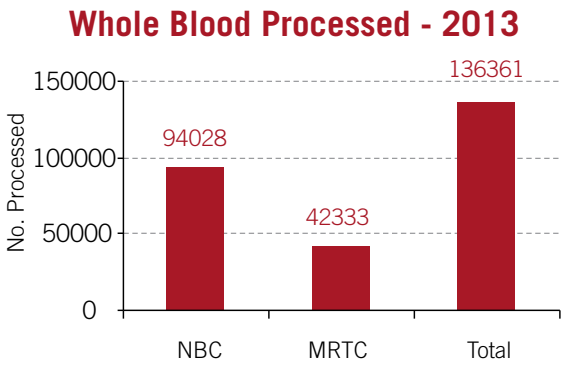
* The figures for 2012 for factor concentrates for the treatment of blood clotting disorders reflect issues from January to April as the responsibilty was transferred to St James's Hospital from April 30th 2012.

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 issue 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 26,086 product orders were received electronically in 2013. These were managed by close cooperation between the Components Laboratory and Hospital Services personnel.

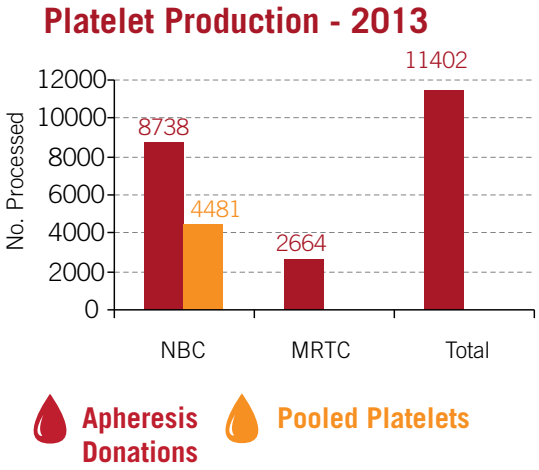
A total of 136,361 whole blood donations were processed nationally in 2013. Of this total, 69% were processed in the National Blood Centre and 31% were processed in the Munster Regional Transfusion Centre.



Platelet production consisted of 11,402 apheresis donations and 4,481 pooled platelets prepared. The apheresis donations were collected and processed in the two centres, with 76.6% being processed in the National Blood Centre and 23.4% being processed in the Munster Regional Transfusion Centre. Each apheresis donation yielded 2.1 platelet doses. This gave a total platelet production of 28,425 doses.

Of the 22,986 plateletapheresis doses prepared, 11,162 (48.6%) were suitable for neonatal use, and 11,824 (51.4%) were suitable for adult use only.

Pooled platelets were prepared in the National Blood Centre only.



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	1,876
Red Cell Concentrate	120,761
Red Cell Concentrate for neonatal use	9,571
Red Cells, Clotted	3
Plasma Products	
Fresh Frozen Plasma, Filtered	985
Fresh Frozen Plasma for neonatal use	230
Fresh Frozen Plasma for Cryoprecipitate Production	343
Fresh Frozen Plasma for Cryoprecipitate for neonatal use	192
Serum for Tears	3
Fresh Frozen Plasma for IVD use	128,582
Buffy Coats	
Leucocytes, Buffy Coat for pooled platelet production	30,343
Leucocytes, Buffy Coat	3,896

Secondary Product	Number prepared
Red Cells	
Red Cell Washed	40
Red Cells for IUT	54
Red Cells, Plasma Reduced	646
Red Cells Split for Neonatal Use	1,080
Plasma Products	
Pooled Cryoprecipitate	55
Cryoprecipitate for neonatal use	185
Platelets	
Platelets, Washed	12
Platelets, 50ml neonatal aliquots	24
Granulocytes	
Leucocytes, Pooled	29
Leucocytes, Pooled, Red Cell Reduced	15

Testing

Virology

The function of the Virology laboratory at the NBC, Irish Blood Transfusion Service is the screening of blood donations for transfusion transmissible diseases.

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 149,000 samples were tested in 2013.

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. When all tests are complete and if satisfactory results are obtained, the unit is cleared and labelled for issue provided it's also negative on Nucleic Acid Testing (NAT).

These tests are performed using the latest 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 blood donation screening. 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 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 Acrometrix 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

NHIRL

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/ Public Health England. The confirmed positive rates and reactive rates for testing kits and confirmatory results 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 VQC-Acrometrix in association with National Serology Reference Laboratory Australia (NRL, Australia) and one by the European Directorate for the Quality of Medicines & HealthCare (EDQM), Strasbourg.

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 2013.

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.

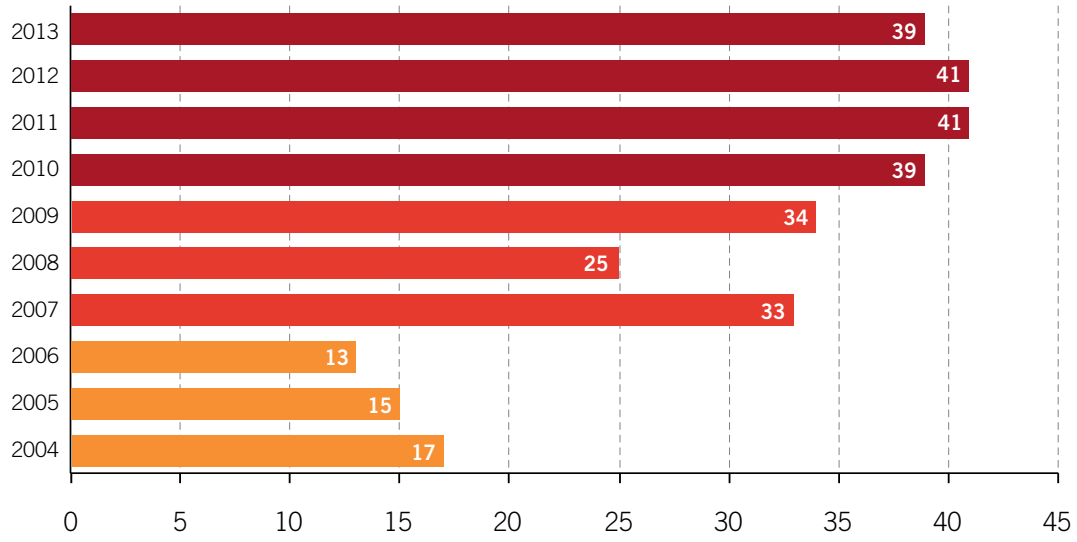
The laboratory determines the Human Leucocyte Antigen (HLA) type of all patients and donors (related or unrelated) prior to transplantation to aid donor selection. The laboratory uses exclusively molecular methods based on the Polymerase Chain Reaction (PCR) to define the genes that encode the HLA molecules. 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 2013 samples from 192 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 2013 the laboratory HLA typed 867 new volunteer donors to add to the registry.

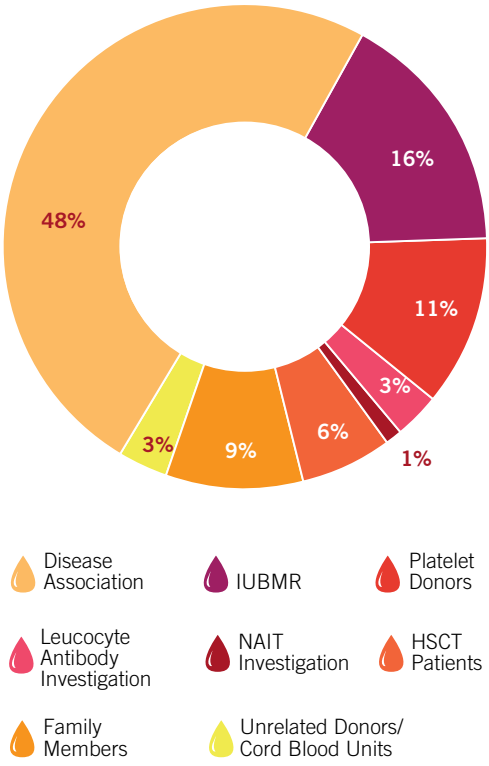
Number of Irish Patients receiving a HSCT from an Unrelated Donor 2004-2013



In the last 10 years the IUBMR has facilitated 297 unrelated donor transplants for Irish patients, 85% (n=252) of these transplants have been performed in the last seven years and 65% (n=160) in the last four years.

The NHIRL also provides a routine disease association HLA typing service. This service represented 48% of the investigations performed in 2013. 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 2012.

A total of 593 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 poster was presented in 2013 in collaboration with St. James's Hospital, Dublin at the 20th Conference on Retroviruses and Opportunistic Infections (CROI 2013) March 3-6, 2013 Atlanta.

- Human leukocyte antigen subtype associations with immunological recovery and drug toxicities in HIV infected adults. O'Halloran JA, Crowley J, Fagan M, Hickey C, Stokes S, Tuite H, , Kinsella A, Hagan R, Bergin C.

Diagnostics/ Crossmatch Dublin

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;

- 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.

In 2013 a total of 2,325 samples were referred to the Diagnostics Laboratory. This represented a 4.9% increase in antibody investigations, a 15% increase in anti-D quantitation (overall quantitation increase of 9.4% - compared to 2012).

The most notable increase was seen with referrals for RhD investigation; an increase of 104% when compared to 2012. This was a direct 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 2013 the following difficult or rare allo-antibodies were identified through the NBC:

Anti-Chido/Rodgers (11), CR1-related (7), System-Specific (4), Anti-U (3)
Anti-Lea+b (3), Anti-k (2), Anti-Csa (1), Anti-JMH (1), Anti-H (1), Anti-Yta (1)
Anti-Jsb (1), Anti-D from RhD+ (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.

Of significance is the fact that all of these specificities were identified internally, 2 samples were only referred externally for confirmation of antibody status. Both of these antibodies are rare: anti-Jsb and anti-H.

Anti-Jsb is an antibody to the high frequency antigen Jsb. The Jsb-phenotype is rare and almost exclusively found in individuals of African origin. The IBTS identified the anti-Jsb and arranged importation of Jsb- units in less than 24 hours.

Anti-H is an antibody to the high frequency antigen H. The H- phenotype (Bombay phenotype; Oh) is very rare and is the result of a silencing of the FUT1 gene (FUT1*N). In Europe the frequency of H- individuals is approximately 1 in 1,000,000.

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.

Importation of rare blood

In 2013 a total of 8 units were imported from outside Ireland.

Table 3.2.1. Units Imported from Outside Ireland

Antibody	Case Details	Units	Source
Anti-U	Planned Delivery	2	NHSBT Liverpool
		2	ARC, New Jersey
Anti-U	Planned Delivery	2	NHSBT Liverpool
Anti-Jsb	Medical case	2	NHSBT Liverpool

Anti-U

The IBTS handled two cases of planned delivery involving two separate women with rare anti-U.

Anti-Jsb

This case involved a patient with haematemesis. The sample was investigated and reported on the same day and anti-Jsb was identified. Two units were imported from the National Frozen Bank at NHSBT Liverpool within 24 hours of sample receipt at the IBTS. Units were held on-standby and finally transfused.

Diagnostics/ Crossmatch Cork

The diagnostics laboratory at MRTC provides both routine and reference immunohaematology & laboratory Services. The former to South Infirmary University Hospital (SIVUH), St. Finbarrs', Mater Private Cork (Service transfer from the former Shanakiel Hospital early 2013) and Marymount University Hospital & Hospice, and reference immunohaematology & laboratory Services to the Munster Region. Medical Scientists and despatch officers are on-site 24/7 supported by Specialist Medical Staff and Consultant Haematologist.

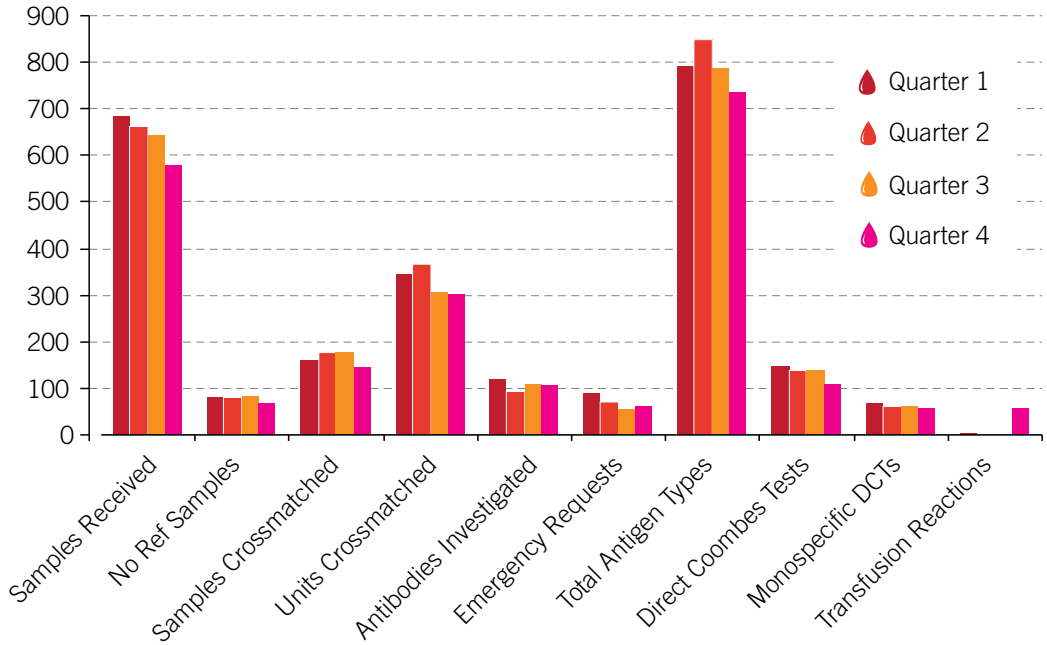
Re-configuration of Clinical Services continued in the Region in 2013, impacting in particular on SIVUH and Waterford Regional Hospital was aligned with UCC associated hospitals. A review of Routine Immunhaemotology Service in the region was also undertaken.

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 anomalous red cell typing, extended typing for transfusion dependant patients, positive direct antiglobulin tests, auto-immune haemolytic anaemia, haemolytic disease of the fetus/newborn, and complex

MRTC Diagnostics Laboratory Activities

By Quarter 2013



Automated Donor Grouping

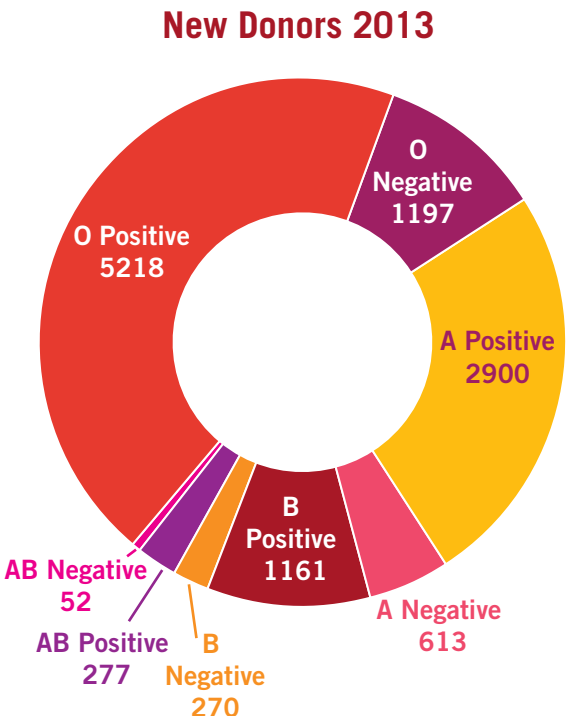
antibodies providing extended matched (phenotyped) and crossmatched red cells for these patients. Individual samples in these cases may take several hours to investigate fully and may require donation screening where matching red cells are not available on the shelf. Seven patient samples required further 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 meetings.

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 2013 over 148,000 donations were tested and of these 11,688 (7.8 %) were new donors. From the results obtained from testing new donors it is possible to estimate the frequencies of blood types in Ireland.



Apart from performing the mandatory serological tests (ABO, RhD and antibody screening) the laboratory routinely screens and types donors in order the find the rarer phenotypes or combinations of types, which may be requested in an emergency. The laboratory performed over 125,000 other antigen types in 2013 and 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, but screening O Negative units over the past 18 months has still failed to identify one.

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 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 5 further examples of these very rare types have been found and confirmed. Screening in 2014 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 has 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 2013 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 2013 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.

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 Tigris platform in conjunction with the Ultrio Plus HIV-1/HCV/HBV assay. The Tigris instrument is a fully automated closed system for NAT testing of individual donations with the Procleix Ultrio Plus assay. The Procleix Ultrio Plus assay is a multiplex Transcription Mediated Amplification (TMA) assay for the detection of Human Immunodeficiency Virus type 1 (HIV-1) RNA, Hepatitis C virus (HCV) RNA and Hepatitis B virus (HBV) DNA in human plasma. The Ultrio Elite assay was introduced by Novartis Vaccines and Diagnostics as a third generation triplex assay to specifically include sensitivity for HIV type 2 RNA detection on the next generation 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 2nd September 2013. The Procleix West Nile Virus (WNV) assay reliably detects low level WNV RNA in blood donations using the Tigris 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 September 1st to December 13th 2013.

An archive sample is retained on all donations. Every donation collected in 2013 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 Novartis Procleix assays include Calibrators (Negative, HIV, HCV, HBV), Bracket Controls (Negative, HIV-1, HCV, HBV- Tigris only) 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. Tigris Bracket Controls are used following testing of every 100 samples in each worklist. Calibrator results must meet assay specifications. Following implementation of the Panther system, bracket controls are no longer required for assay performance.

Interlaboratory comparisons using EDCNet software (National Reference & Serology Laboratory, NRL, Australia, www.nrlqa.net) and participation in External Quality Assurance Schemes (EQAS) in 2013 allow us to perform peer review with other Tigris/Ultrio Plus 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. Cornea imports were down 9% on imports for 2012 but imports of all other ocular products was consistent with 2012 figures.

In the last quarter of 2013, an application was submitted to the Irish Medicines Board, under the Advanced Therapy Medicinal Products directive to allow us to offer cultured limbal stem cells to patients with limbal stem cell deficiency. It is envisaged that this treatment will be available to Irish patients in 2014.

In 2013 the Mater Misericordiae University Hospital received their tissue establishment licence under the Tissue and Cells Directive 2004/23/EC. The IBTS is a third party contractor to the MMUH for the processing, cyropreservation and distribution of human cardiovascular tissue. Activity levels for 2013 were on par with those of 2012.

The Directed/Sibling Cord blood bank collects and cryopreserves cord blood on request from the oncology/haematology team in OLCHC and Newcastle.

“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.”

Therapeutic Apheresis Service

MRTC provides Therapeutic Apheresis treatments to patients in Cork hospitals, Cork University, Mercy University and Bon Secours. This is a front line public 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 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.

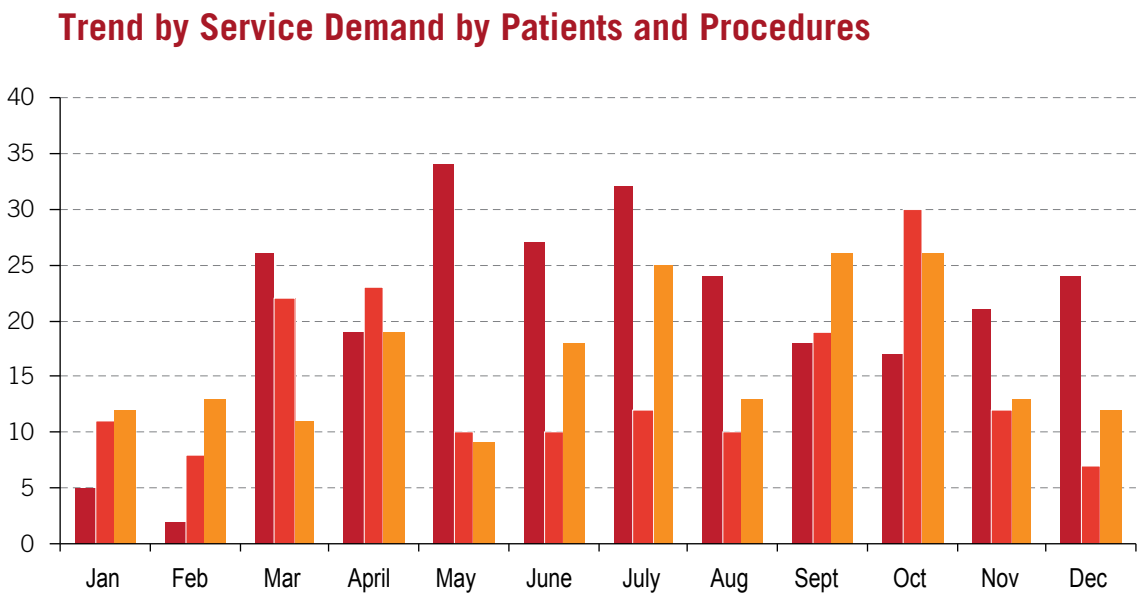
The MRTC Consultant Haematologist leads the service and a medical evaluation of each patient is performed by the Haematologist / Specialist medical staff. The Apheresis Team is led by a Specialist Medical Officer who undertakes procedures together with a specialist nurse, with cell separator technology. The majority of therapeutic apheresis procedures are Plasma Exchange but other treatments include Leucodepletion. The 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.

Service Demand trends

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

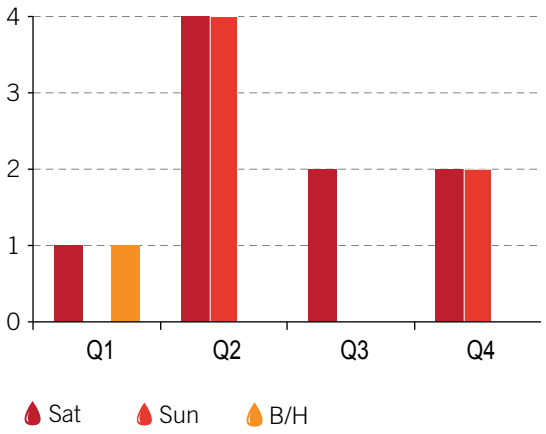
Service demand 2011 - 2013, by month.



Weekend / Out of Hours Service Provision

Patients may present for emergency care out of hours or their programme of treatment may extend through a weekend period. This demand on the Service is represented below.

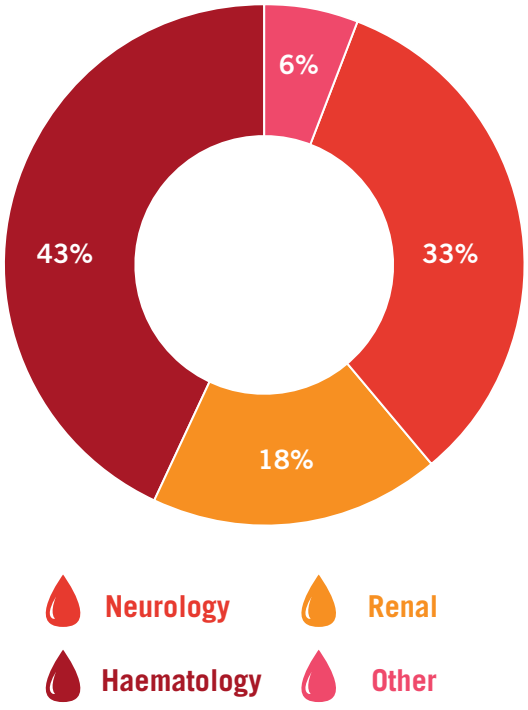
Weekend / Out of hours Service Provision by Quarter 2013



Service Profile by Disease Specialty, Patient and Procedures

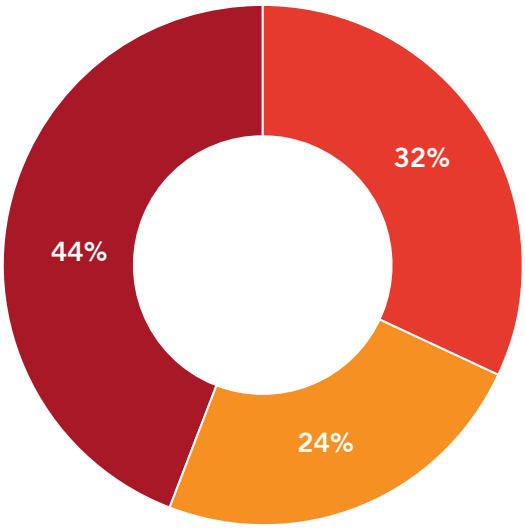
The demand on the Service from Clinical Specialties is represented below.

Patients by Speciality 2013



Therapeutic Apheresis Service

Procedure by Speciality 2013

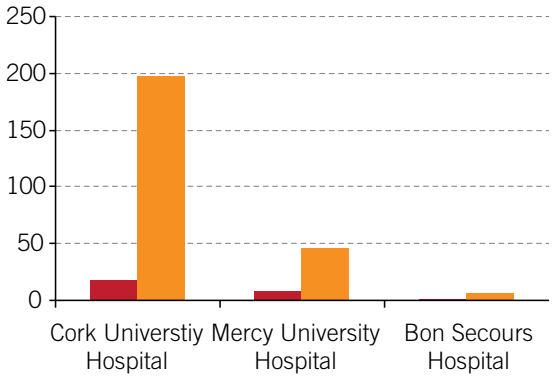


Neurology
Renal
Haematology

Service Provision by Hospital, Patient and Procedures

The demand on the Service from Hospitals in Cork is detailed below.

Service Provision by Hospital, Patient and Procedures - 2013

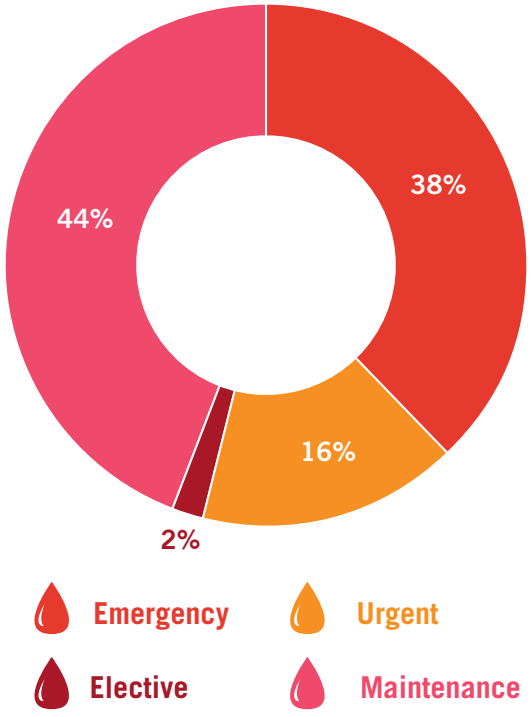


Patients
Procedures

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 outcome of the presenting illness. The procedures undertaken in 2013 are categorised in relation to the degree of urgency in providing the Service.

Procedures by Degree of Urgency - 2013



Service Provision by ASFA Guideline indications for treatment

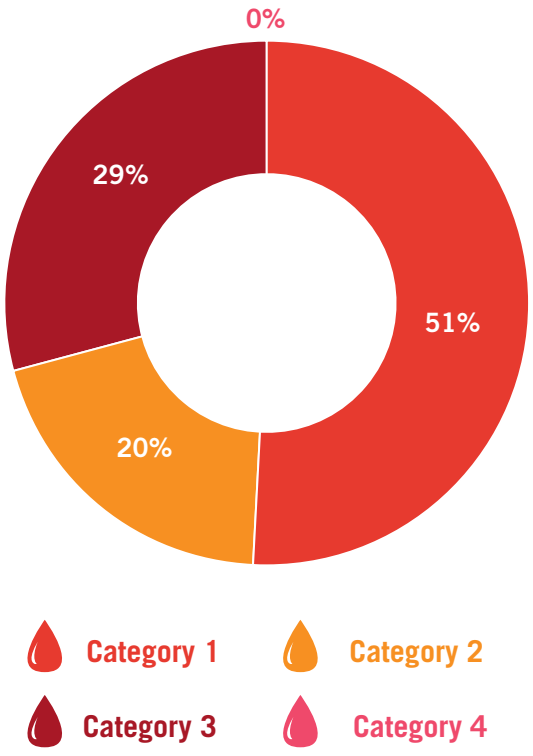
The ASFA practice guidelines are evidence based on both quality of supporting evidence as well as the strength of the recommendation derived from that evidence. Revised Guidelines were published in 2013.

Category 1 – 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

The procedures undertaken in 2013 are categorised by ASFA Guideline below.

Therapeutic Apheresis procedures by ASFA Guideline

Service Provision by ASFA Guideline Category - 2013



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 thirteen years of its existence, (2000-2013), a total of 3,853 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 Better Blood Transfusion Network. This year marked the retirement of Dr Ian Franklin, Medical and Scientific Director of the IBTS and Director of the NHO. Dr Sorcha Ni Loingsigh was appointed as Acting Director thereafter.

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. One hundred and sixty seven mandatory SAEs were reported, which was 67% of all SAEs. In addition, 81 non mandatory SAEs, primarily relating to errors in clinical areas, were reported under professional responsibility, which was 33 % of all SAEs.

Serious Adverse Reactions (SARs) - mandatory and non mandatory

There was a considerable increase in the overall number of accepted SARs from 137 in the previous year to 256 in 2013. This trend can be accounted for the fact that the NHO began accepting reports of Delayed Serological Transfusion Reactions. In contrast there was a notable decrease in the number of mandatory SAR to 76/256 from the 131 reports accepted in 2012. This is attributed to changes in mandatory reporting requirements to the European Commission.

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-three mandatory reports were accepted by the NHO in 2012, with the compilation of 2013 ANSARE report ongoing at time of writing.

NHO Annual Conference

The NHO Annual Conference was held in the Hilton Hotel, Dublin on Tuesday 12th November with just over 220 delegates from various disciplinary backgrounds in attendance. The theme of the conference which was opened by Mr.Andrew Kelly, Chief Executive of the IBTS was ‘Supporting Appropriate Transfusion Practice’. There were three

keynote speakers: Dr.Lise Estcourt, Consultant Haematologist spoke on recent research findings of studies involving platelets, Professor Ian Roberts, Professor of Epidemiology and Public Heath on the use of Tranexamic Acid in major bleeding and lessons from the CRASH-2 Trial, and Dr. Deirdre Madden, Senior Law Lecturer spoke on informed patient consent for transfusion. The NHO staff presented the findings and major recommendations of analysis of reports accepted during 2012, and a number of hospital staff presented poster presentations.

Irish Medicines Board (IMB)

The Competent Authority for implementation of all aspects of the EU Blood Directive is the IMB 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 began a series of one day Regional Workshops, and this initiative is to continue during 2014.
Haemovigilance Education Initiatives at DCU
Due to recent economic changes in Ireland and following a survey conducted in 2011, the format of the post-graduate modules facilitated by the NHO in conjunction with Dublin City University was revised. A single 10 credit module was provided in April and October to 24 students from various disciplines working in transfusion practice.

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 2013 a video on safe sampling for transfusion was added and work began on adapting the programme content to facilitate access on 'Smartmedia' devices. Ninety-four Irish sites 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 just over 20,000 users registered, 55% were nurses, 24 % medical staff and the remaining 21% were medical scientists, phlebotomists, porters and students.

Irish Unrelated Bone Marrow Registry (IUBMR)

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 23 million volunteer donors worldwide provides a suitable alternative.

The Irish Unrelated Bone Marrow Registry (IUBMR) was set up in 1989 to meet the need for hemopoietic progenitor cell donors for both Irish and International patients. 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

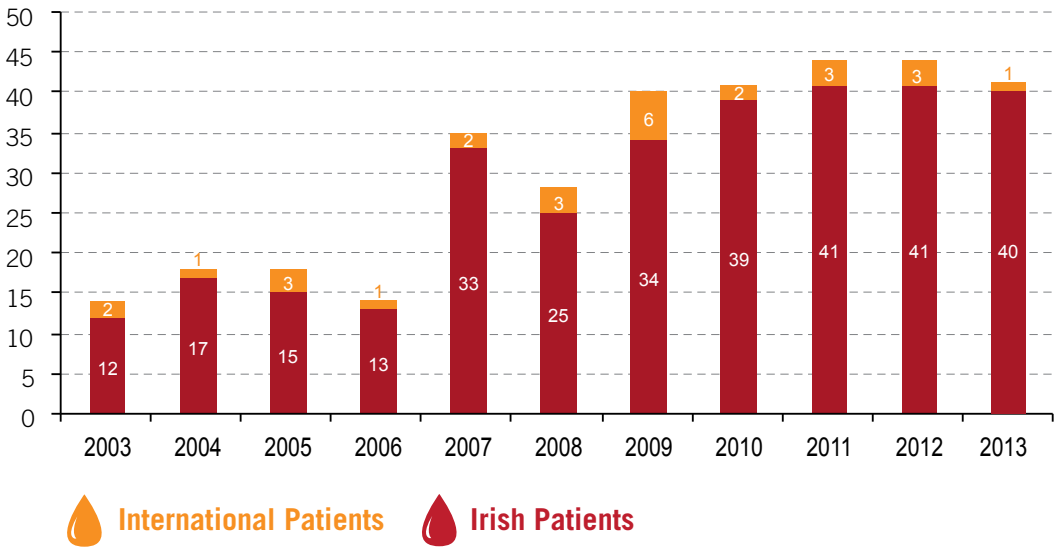
Since 1991, the IUBMR has been affiliated to the World Marrow Donor Association (WMDA), an organisation which sets operational standards for bone marrow registries worldwide. In 2012 the IUBMR was awarded full registry accreditation.

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 2013 fifty eight (58) patients were referred to the IUBMR for unrelated searches.

Forty (40) Irish patients received stem cells from an unrelated donor in 2013. The majority were from

IUBMR Transplants Facilitated From Irish And International Donors For Irish And International Patients 2003 - 2013



international donors (28) and in a marked increase from previous years, twelve (12) patients received transplants using stem cells collected from Irish donors.

International Activities

Preliminary searches were received on behalf of three hundred and sixteen (316) international patients of which fifty five (55) 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 2013 the number of newly recruited donors was 770. There were thirteen (13) donations from Irish donors of which ten (10) were peripheral blood stem cell collections and three (3) were bone marrow.

Quality & Compliance

“Continued focus on cost containment and cost reduction was a central focus for 2013, 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.”

Quality & Compliance

The implementation of the recommendations from the Quality Review continued. The permanent appointment to the post of Quality Assurance Manager in November 2013 has stabilized the Quality Assurance Unit and will enable delivery in 2014 of the Quality Review Recommendations.

Continued focus on cost containment and cost reduction was a central focus for 2013, 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.

The IMB carried out the annual Blood Establishment regulatory audits but also in addition two Tissue inspections were carried out. A total of nine inspections were performed by the IMB, one to assess compliance with GDP requirements (Cork), two covering the Tissue and Bone Marrow/Cord Blood activities in the NBC and six inspections under the Blood Establishment registration covering the main NBC centre, the Cork processing centre and associated clinics. There were no major non-compliances raised during these inspections and 31 other observations.

The target is an average of < 1 major per annum was met for the year.

The QA internal audit programme was discharged by using some external expertise for 2013, a total of 45 individual department audits were carried out during the year.

A programme of audits was also completed of hospital activities where the IBTS acts as the hospital blood bank. These covered the six sites in Dublin and three sites in Cork.

There were three vendor audits carried out in 2013 of critical suppliers. One was performed in conjunction with the UK NHSBT as a result of the award of tender for Blood Bags.

The reporting of Quality metrics to the EMT and IBTS Board was done quarterly in the new format. Targets will be set for 2014 arising from 2013 performance.

The Internal Incident Reporting System during 2013 benefited from clear focus and regular review of close out rates. The introduction of the weekly Quality Management Review maintained focus which resulted in a year end close out rate of 92%.

Donor Service Complaints were captured, investigated and closed out within the set targets and achieved a close out rate of 99% by year end.

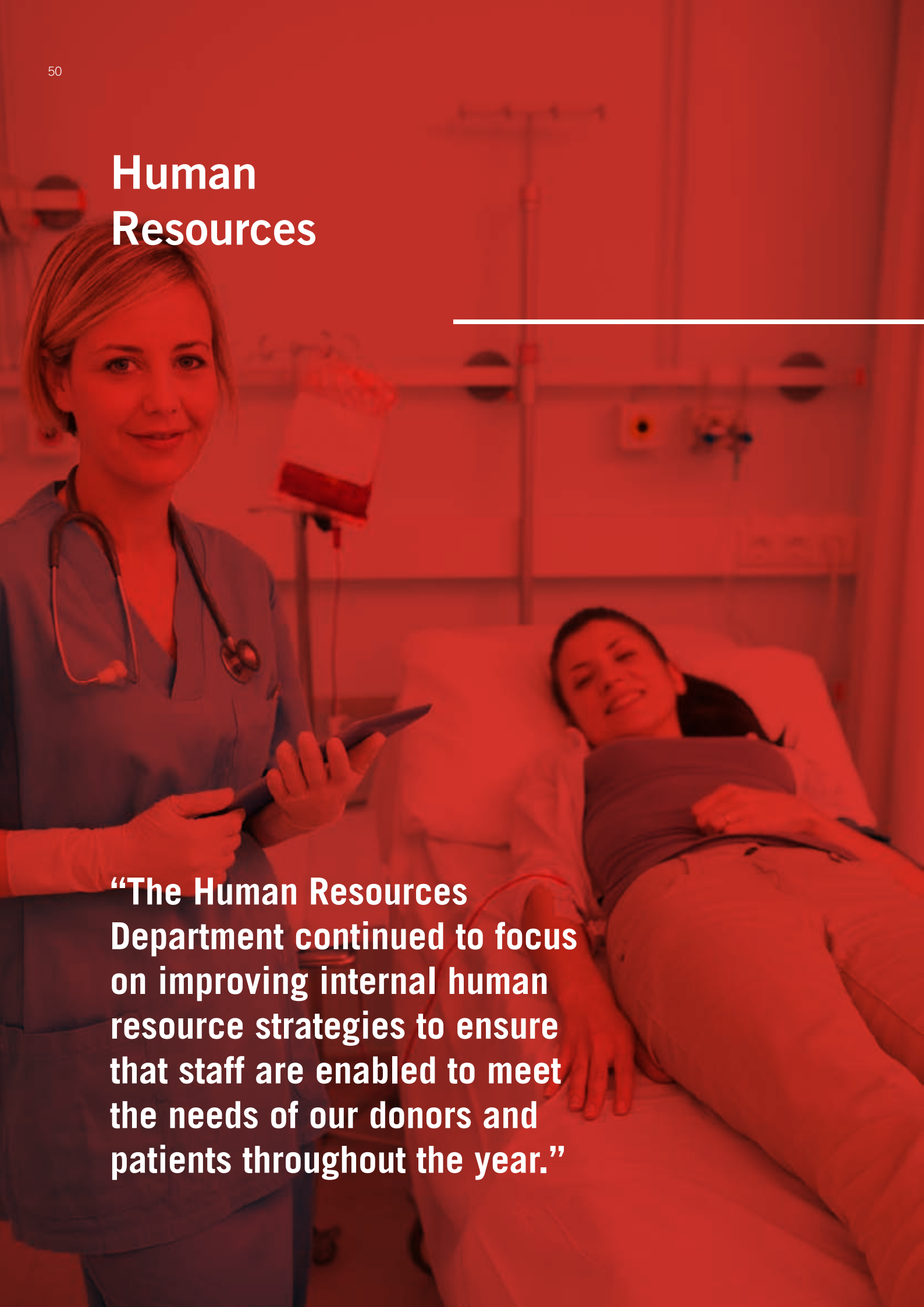
The IBTS also has a very active Complaint Handling System whereby hospitals lodge details of service/ product complaints, which are subsequently investigated by the IBTS. Close out by year end was 90%, meeting target.

Post marketing surveillance through the recording of Serious Adverse Events (SAE) and Serious Adverse Reactions (SAR) is also operated by the IBTS. There were 85 SAEs and 63 SARs reported to the National Haemovigilance Office by the IBTS in 2013.

Details of this data are contained in the Annual Report submitted by the IBTS to the IMB in February 2014.

In addition a Donor Vigilance system captures events relating to donors (clinics), there were 414 reported in 2013.

Human Resources



“The Human Resources Department continued to focus on improving internal human resource strategies to ensure that staff are enabled to meet the needs of our donors and patients throughout the year.”

Human Resources

The Human Resources Department continued to focus on improving internal human resource strategies to ensure that staff are enabled to meet the needs of our donors and patients throughout the year, and achieve related strategic goals as outlined in the Balance Score Card. 2013 saw significant change management projects in the organisation and within the Human resources department a re-structuring process commenced as a result of reducing resources due to natural attrition.

Change Management Projects

The objective of IBTS change management remains to enhance the development of service delivery to our patients and donors. We are committed to the wider health service reform agenda within the current Public Service Agreement and internal strategic performance management. This is an ongoing priority for human resource management.

The status of a number of projects is as follows:

- **Single Site Processing**
  A strategic decision was made in November 2013 by the IBTS Board, recommended by the Executive Management Team (EMT) to move to Single Site Processing and to explore alternative delivery of the IBTS Diagnostic Services.
- **Review of Transport Services**
  The IBTS entered a comprehensive consultation process with our transport division, to progress required efficiencies, specifically regarding changes to an accumulated hour's rostering system and the transfer of delivery services to the HSE.
- **Therapeutic Apheresis**
  Agreement was reached to relocate this service to St James Hospital, with the redeployment/ secondment of 2 IBTS staff to St James and 1 internal redeployment.
- **National Rota for Medical Consultants**
  Open consultation with IBTS Medical Consultants to merge the two regional rosters into a national roster was ongoing at year end to result in greater resource availability on a national level for the IBTS.
- **Haddington Road Agreement**
  The implementation of the Public Service Stability Agreement 2013-2016, referred to as the Haddington Road Agreement resulted in significant workplace change and efficiencies within the IBTS, of note:
  - Salary Cuts
  - Increased Hours
  - Increment Deferrals
  - Reduction in Annual Leave / Related Salary Deduction
  - Engagement with Department of Health on redeployment within the HSE

Corporate Training and Development

The main areas for Corporate Training and Development focus in 2013 were:

- EH&S training for managers and staff
- Manager Skills Training

Human Resources

Corporate Training & Development Programmes	Total Attendees
Corporate Orientation Programme	58
EH&S Training Programmes, including	
1. Manual Handling	135
2. Donor - Manual Handling	127
3. Fire Safety	119
4. Fire Warden	17
5. Occupational Blood Exposure	120
6. Chemical Risk Assessment	15
7. Emergency Response & Evacuation Training Clinic & Building	98
8. Health & Safety Rep	16
9. Laboratory Safety	40
10. Accident & Incident Reporting	13
11. PMDS	114
12. Radiation Safety Training	58
13. Environmental Health & Safety	28
Management Development	
Communications Skills, Conflict resolution, Managing People, Customer Service & Client Centered Communications	69

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

- 14 new applications in 2013

Projects Ongoing

- Performance Measurement & Development Programme (PMDS)
- Succession Planning
- Staff Newsletter, Intranet Maintenance & Internal Communications

Environmental, Health and Safety

Environmental, Health & Safety has strategic importance within the organisation and comprehensive environmental health, safety and welfare programmes continue to be developed and adopted. Such programmes assist with legislative compliance and continue to promote an awareness of environmental, health and safety within the organisation.

The Environmental, Health & Safety focus in 2013 was the revision of key framework and guideline policies, as follows:

- Revision and update of national IBTS Parent Safety Statement, with relevant training
- Revision and update of national IBTS Emergency Response Plan (Mobile Clinics) and relevant training
- Revision and update of national IBTS Radiation Safety Manual and relevant training.

Finance

Summary Accounts for the year ended 31st December 2013		
	2013 €'000	**2012 €'000**
Income		
Recurring income	65.269	78,542
Non-recurring income	1,204	3,208
Total income	**66,473**	**81,750**
Expenditure		
Total expenditure	**67,928**	**79,212**
Surplus / (Deficit) for year	(1,455)	2,538
Actuarial gain / (loss) on pension scheme	8,245	(12,504)
Transfer to Capital Reserves	(241)	(343)
Transfer to Research Reserve	(36)	(56)
Accumulated Deficit at 1st January	(15,401)	(5,036)
Accumulated Deficit at 31st December	**(8,888)**	**(15,401)**

Income

The Board's total income for 2013 of €66.47million (2012 €81.75 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 €65.27 million (2012 €78.54 million). Non-recurring income of €1.20 million (2012 €3.20 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 HSE Grant Income.

Expenditure

Expenditure for 2013 amounted to €67.93million (2012 €79.21 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. During

2009 €2 million was transferred to the fund. The balance in the fund for the year ended 31st December 2013 was €8.27 million.

In 2006 the Board set up a research reserve. In 2013 €36,000 was added to the reserve. (In 2012 €56,000 was added to the reserve).

Capital Expenditure

The Board invested €3.01 million in capital projects and equipment during 2013 (€1.95 million 2012).

The main investments during the year included the commencement of expenditure on a new Blood Establishment Computer Systems (BECS), replacement of therapeutic apheresis equipment and upgrade of eFinancials.

There was recurring expenditure for the replacement of ICT infrastructure including the Storage Array, laboratory and other plant and equipment. In addition, expenditure was incurred for fire engineering upgrade to clinics and centres.

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 2013, under the terms of applicable legislation, invoices to the value of €1,054,567 were late, by an average of 17.96 days. These invoices constituted 1.47% by number and 2.75% by value of all payments to suppliers for goods and services during the year. Total interest paid in respect of all late payments amounted to €3,781.71 The Board continuously reviews its administrative procedures in order to assist in minimising the time taken for invoice query and resolution.

Contact details

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Solicitors

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Dublin 2

Bankers

Allied Irish Bank
Dame Street
Dublin 2

Irish Blood Transfusion Service

National Blood Centre
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t: 01/4322800
f: 01/4322930
e:contactus@ibts.ie
www.giveblood.ie Donor infoline 1850731137

Cork Centre
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Douglas Road
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f: 021/4313014

Dublin Blood Donor Clinic
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t: 01/4745000

Stillorgan Blood Donation Clinic
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Stillorgan, Co Dublin
t: 1850 808 808

Ardee Centre
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f: 041/ 6859996

Carlow Centre
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Carlow
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f: 059/9132163


give platelets
give pla
100
MODEL SE

Irish Blood Transfusion Service
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Donor Infoline 1850 731 137

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