ANNUAL REPORT 2011

Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

‘delivering services and products to the highest standards to patients and donors.’

Contents

"We can look forward to 2012 with encouragement and the knowledge that IBTS is well placed to continue to deliver services and products to the highest standards to patients and donors."

Chairperson's Foreword

Each year seems to bring new challenges and 2011 was no different for the IBTS. From the very bad weather to the report on prion filters to the wind down of the Recipient Tracing Unit and the continuing demand to produce greater value for money.

The one constant is that our donors are remaining loyal and ensuring that patient requirement was met throughout the health care system. This is an essential prerequisite for any blood transfusion service and is testimony to our advertising campaigns and the professionalism of our staff at the clinics.

In any medical and scientific area it is important to be engaged in research. I am delighted to report that in 2011 the IBTS contracted with a research team led by University Hospital Galway and also including researchers from University College Cork and Trinity College Dublin in the field of stem cells. This is an exciting development and the Board will watch developments with interest over the next few years.

We can look forward to 2012 with encouragement and the knowledge that IBTS is well placed to continue to deliver services and products to the highest standards to patients and donors. I would like to commend all staff in the IBTS for their professionalism and dedication and can confirm that the Board will continue to work with the Executive in dealing with the many issues facing the organisation.

Ms Katharine Bulbulia
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 2011, 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 2011 at its meeting on 13th March 2012.

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 Chairperson appointed by the Minister for Health.

The Board met on 11 occasions for ordinary meetings during the year and once in April for a Special Board meeting. Attendance by Board members was as follows:

Members of the Board	Jan	Feb	Mar	April	April‡	May	June	July	Sept	Oct	Nov	Dec
Ms Katharine Bulbulia, chairperson	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mr Mark Moran*	✓	✓	✓	✓			✓		✓			
Mr David Lowe	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Mr Dave Keenan	✓		✓		✓	✓		✓	✓	✓		✓
Ms Marie Keane	✓			✓	✓	✓			✓		✓	✓
Dr Paul Browne	✓	✓	✓	✓		✓			✓	✓	✓	
Ms Sinead Ni Mhaille	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
Ms Ann Horan	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
Ms Jane O'Brien	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mr Sean Wyse	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Dr Paolo Rebulla*	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓
Dr Hilary O'Leary	✓	✓	✓	✓			✓		✓			✓
Dr Lelia Thornton**											✓	✓

* Term ceased on 20th September 2011
** Appointed on 19th October 2011
‡ In addition to the normal Board meeting in April, the Board also held a special Board meeting.

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

	Annual Directors fee	Received 2011	Expenses 2011
	€	€	€
Ms K Bulbulia Chair	20,520	20,520	4,690
Mr D Keenan	11,970	11,970	-
Mr M Moran*	11,970	8,609	-
Ms J O'Brien	11,970	11,970	-
Mr S Wyse	11,970	11,970	71
Mr D Lowe	11,970	11,970	-
Ms S Ní Mháille	11,970	11,970	-
Dr P Browne	N/A	N/A	-
Dr M Cahill	N/A	N/A	-
Ms M Keane	N/A	N/A	-
Dr P Rebulla	11,970	11,970	5,164
Ms A Horan	11,970	11,970	436
Dr H O'Leary	N/A	N/A	-
Dr L Thornton**	N/A		

* Term ceased 20th September 2011
** Term commenced 19th October 2011

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.

Remuneration 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 complies with guidelines on the payment of director's fees. The Chief Executive's salary in 2011 was €159,569.

Medical Advisory Committee

The Medical Advisory Committee is comprised of the medically qualified members of the Board and the medical consulting staff and meets eleven times a year. 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 5 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 5 times during the year and is comprised of four 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 Management Accountant and the Internal Auditor. The Committee may review any matters relating to the financial 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 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 strategic, clinical, 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 and updated by the ICT Council.

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 control 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:

Chairperson's Report

- 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
- All despatch dockets for issues of products are matched to their relevant invoices 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 substitutes
- 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 independently matched with stores GRN and purchase order
- Payment verification checks of supplier invoices by staff independent of accounts payable staff.

The Board are 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.

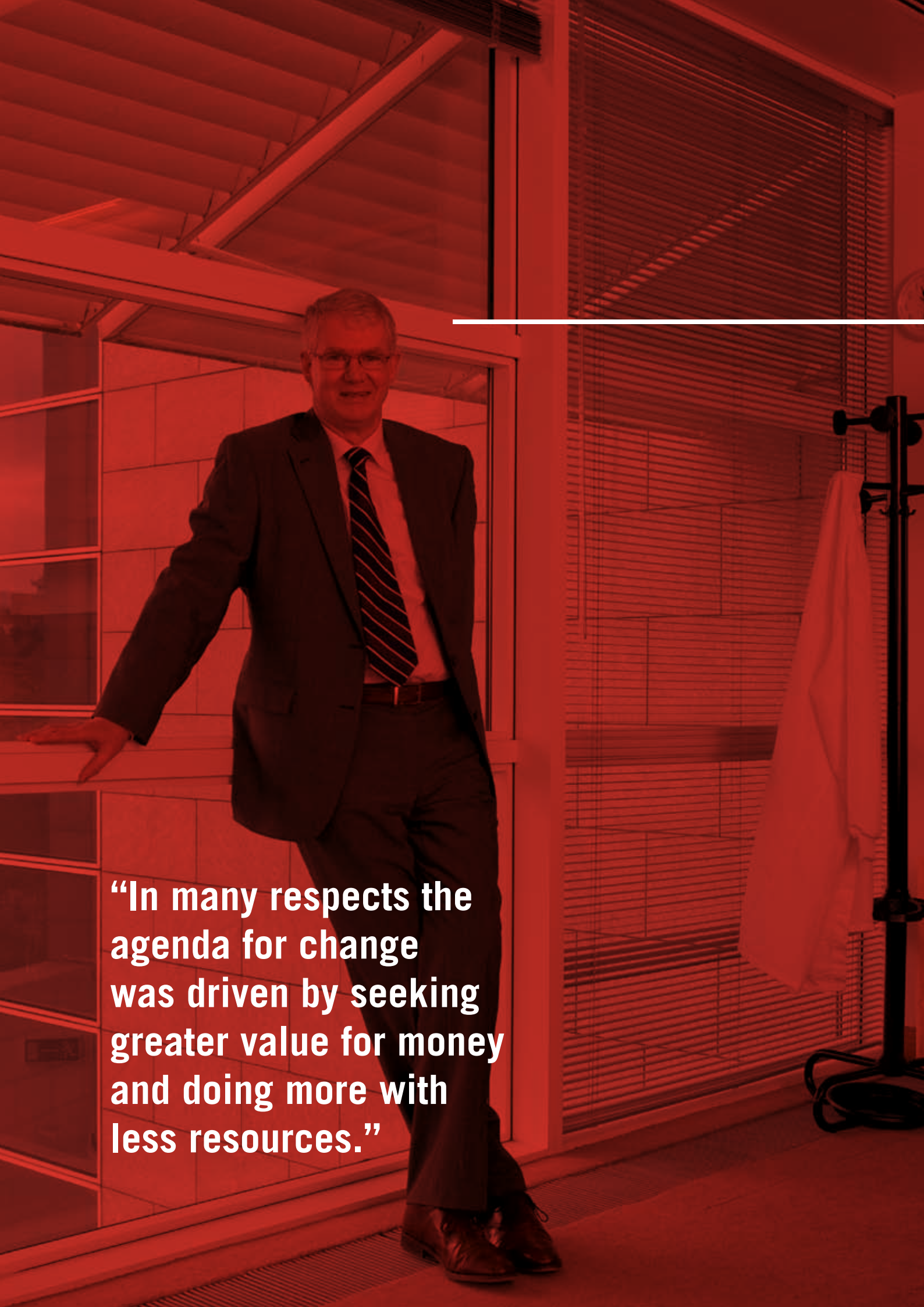
The Board is responsible for keeping proper books of account, which disclose with reasonable accuracy at any time, the financial position of the Irish Blood Transfusion Service and to enable it to ensure that the financial statements comply with the Order. It is also responsible for safeguarding the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

Recombinant Products

The IBTS, under its statutory obligations has been responsible for the sourcing and distribution of blood products. This activity generated income for the IBTS which contributed to the cost of running the service. An alternative contract holder was selected and this was due to come into effect in 2011. The initial loss of income was offset by a reducing grant from the HSE for 2011 and 2012 of €3m and €1.5m respectively.

Ms Katharine Bulbulia
Chairperson



“In many respects the agenda for change was driven by seeking greater value for money and doing more with less resources.”

Chief Executive's Report

At the beginning of 2011 we were faced with supply problems due to the snow and bad weather conditions and the resolve of the organisation and donors was tested. Both came through with flying colours and we quickly replenished stocks due to the resilience, passion and loyalty of our donors.

The New Year brought a change of medical and scientific leadership to the IBTS. Dr Ian Franklin joined us to replace Dr Willy Murphy who was seconded to the HSE for a three year period to lead an Optimal Use Programme. Dr Franklin brought a wealth of experience to this role and has worked assiduously in progressing the medical and scientific agenda. I would like to express my deep appreciation to Dr Murphy for his unstinting commitment to the work of the IBTS and for his medical leadership in many innovations he implemented during his 15 years as Medical and Scientific Director.

In many respects the agenda for change was driven by seeking greater value for money and doing more with less resources. It was also characterised by a change in our funding model where the Department of Health decided that the IBTS should no longer manage the products for haemophilia patients. This was an integral part of our funding model and certainly will require savings to be made to make good the income lost from these products.

There were major issues dealt with during the course of the year and these were:

- Cessation of the Recipient Tracing Unit and the final report of the Hepatitis C Expert Group,
- Report of the health technology assessment on prion filters by the Health Information Quality Authority,
- Change in the deferral criteria for MSM in England, Scotland and Wales,
- Activity Based Costing exercise to understand the cost drivers in the IBTS,
- Establishment of a hybrid clinic in Cork taking platelets and whole blood by the same staff.

I am sure that the key medical issues will be dealt with by the Medical and Scientific Director in his report.

There were also some issues that had been commenced and would be finalised in 2012 and these were:

- NHO assessment of the SHOT and MHRA systems of reporting,
- Electronic ordering for blood components,
- Pathogen inactivation assessment,
- Participation in the Euroblood pack project led by the NHSBT,
- URS and tender process for a new blood establishment control system, and
- Review of the Quality Function.

However, the one matter that remained unresolved despite significant efforts by the Executive and the Board is the pension issue. This is impacting on staff across the organisation. It must be resolved in 2012 in the interests of staff morale and to bring certainty to the funding arrangements for the pension provision for all staff.

Despite the significant challenges facing the organisation we continue to provide a quality driven service to our patients and donors. This was confirmed through the very positive inspection results of the Competent Authority and is a testimony to the

Chief Executive's Report

professionalism and dedication of staff across the organisation for which I am deeply appreciative.

I wish I could promise that 2012 will be a little less challenging but unfortunately I cannot. If anything the economic environment is getting worse and the drive for further cost savings seems more demanding than ever. It will take a tremendous effort on behalf of all of us but if we work collaboratively we will come through this period with our focus firmly set on providing the highest standard of care to the patient and donor.

Andrew Kelly
Chief Executive


giveblood.ie
you get more than you give
Arnotts

“Happily, I am also able to report that it has not been very exciting in terms of the service, with steady progress regarding blood supply – no shortages impacting on patient care – or safety.”

Medical and Scientific Director's Report

The past year has been a particularly exciting one for me, in my first year as Medical & Scientific Director of the IBTS. Happily, I am also able to report that it has not been very exciting in terms of the service, with steady progress regarding blood supply – no shortages impacting on patient care – or safety. There were considerable fluctuations on a month by month basis in blood usage, some of which may reflect the difficult financial times being felt throughout the country. New initiatives to manage platelet usage may also have played a part – my predecessor, Dr William Murphy, is now working in the HSE as Blood Policy Advisor. For some years now Ireland has one of the lowest usage rates of red cells in the EU developed economies. This is a good thing, and shows that medical staff throughout the country give serious thought to when a transfusion should be given and, just as important, when it is not essential.

Platelet use however, has been relatively high. Safely avoiding transfusion remains an important part of patient care, because as we all know there are adverse effects that can occur in a small minority of transfusions. So the IBTS has been working with the HSE and consultant colleagues throughout Ireland to improve practices in platelet transfusion. In 2012 we expect a newly formed National Transfusion Committee to further drive these initiatives.

In 2011 we had no reports of any transfusion associated virus infections – a key result in the permanent drive to the safest possible blood supply. Cost effectiveness is an important consideration now, however, and it is not possible – if it ever was – to simply introduce every possible new measure. After very detailed consideration and an in depth report, the HIQA recommended that the use of prion filters to reduce the risk of variant CJD by blood transfusion would not be cost-effective. This view was endorsed by the Minister and subsequently IBTS has been in discussion with the Department of Health as to the best way to minimise what is already a very low risk. IBTS itself has assessed a number of other technologies, particularly pathogen inactivation systems, but has concluded that these are not affordable. As yet, no system is available that can destroy remaining viruses or bacteria in all blood treatments, and not in the most commonly used red cell concentrates. We will be continuing to monitor this potentially important area of blood safety on a regular basis.

During 2011 IBTS said goodbye to one of its most senior consultants, Dr Emer Lawlor. Emer had been involved in managing much of the effects of the anti-D / hepatitis C issues, by leading the recipient tracing programme. She also led the Irish Unrelated Bone Marrow Registry and the National HLA Laboratory, as well as heading up the National Haemovigilance Office. Not surprisingly, we have been unable to replace these roles with only one person. We all at IBTS would like to thank Emer for her immense contribution to the service over many years, and to wish her a long and fulfilling retirement.

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

"Of the 16-20 year olds, 80% plan to give blood when they are older."

Operations

Donor Services

Social networking sites have become very useful for creating awareness of our brand and keeping people up to date and informed of our clinics and events through out the year. In December we held a competition via Twitter to win a chance to have your picture taken with the Sam Maguire Cup. The Cup visited the National Blood Centre, on December 22nd and our two lucky Twitter competition winners, Paschal O'Connor and Eileen Collins with Baby Cara got their picture taken with the cup. Staff in the NBC also joined in to welcome Sam to the National Blood Centre, wearing their county colours for the occasion.

Young Scientists Exhibition

As an annual event, the Young Scientist Exhibition proves to be a great way to increase awareness among younger people of the need for giving blood, with approximately 30,000 people attending over the three day exhibition.

A survey of those attending gave some insight into who plans to give blood. For example more males (68%) than females (61%) plan to give blood when they turn 18. Also 73% of respondents who know someone who gives blood plan to give blood versus 39% of respondents who don't know any one who gives blood plan to give blood. Of the 16-20 year olds, 80% plan to give blood when they are older.

Three students from Colaiste Choilim in Ballincollig, Co Cork did a project on the analysis of Blood Flow Patterns using video microscopy. The double headed microscope used by the students was made available by the IBTS. The students were awarded a Highly Commended Display Award.

Defence Forces Gala Concert

The IBTS have sponsored the Defence Forces Gala Concert on an annual basis for a number of years. Again this year, the concert has been a huge success with more than 1,000 people in attendance and special guest Celine Byrne along with the Defence Forces Bands and Pipers made up the great entertainment for the night.

The relationship between the two organisations is strong and continues to grow as we include each other in more functions and activities. The IBTS are proud to support this worthy event on an annual basis and we do enjoy Defence Forces participation, resources and support throughout the year in the form of donation clinics, personnel for crowd installations and photo shoots, PR opportunities at events and contacts for several ad hoc projects.

Ideal Homes Exhibition

The Irish Blood Transfusion Service exhibited at the Ideal Homes Show in the RDS in April 2011. The weekend was a great success, with hundreds of visitors interested in finding out more about blood donation.

We gave away a selection of giveblood merchandise for all those who visited the stand, whether they were current blood donors or those just contemplating taking the first step to saving a life.

IBTS staff was on-hand to answer any queries people had regarding blood donation and dispelled any myths regarding the donation process. We were delighted that so many donors and fans of the Giveblood Facebook page dropped by the stand for a chat over the course of the weekend!

Give Blood Awareness Programme for Students

In 2011, The Irish Blood Transfusion Service launched the Blood Donation Awareness Programme for secondary schools nationwide. The initiative aims to educate students about the process of giving blood and to encourage them to become blood donors when they turn 18.

The pack comprises of a DVD that takes students through the donation process and features a young blood donor, and recipient, who share their personal experiences. There is also a short quiz included in the pack to put student's knowledge to the test!

Former teacher and RTE Nationwide presenter, Mary Kennedy helped launch the initiative with students from Loreto on the Green in February.

Oxegen Promotion

In July 2011, 80,000 music fans descended on Punchestown, Co. Kildare for the Oxegen Music Festival.

The IBTS marketing team were on-hand to bring the message of blood donation to the enthusiastic revellers by handing out Giveblood rain ponchos at the Dublin Bus Oxegen pick-up stop on Parnell Square.

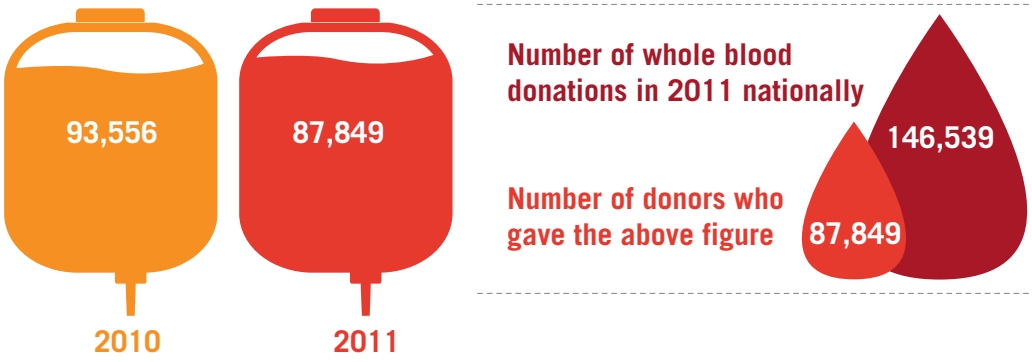
The red ponchos were enclosed in a handy, clip-on ball, which proved very popular with festival goers.

"73% of respondents who know someone who gives blood plan to give blood versus 39% of respondents who don't know any one who gives blood plan to give blood."

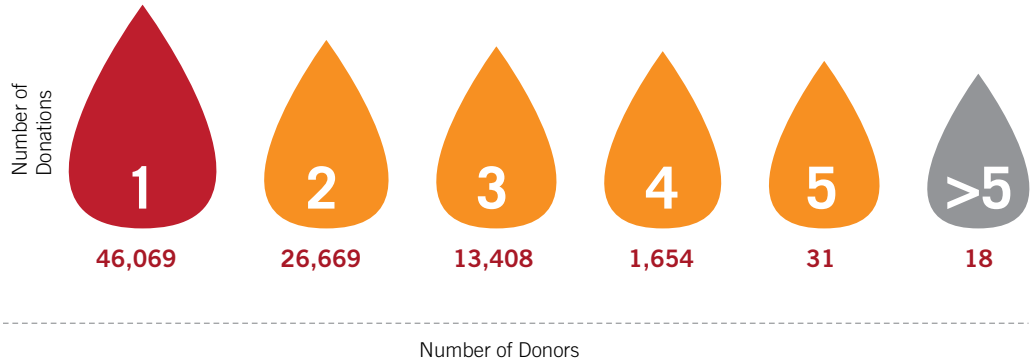

giveblood.ie

Donor Statistics

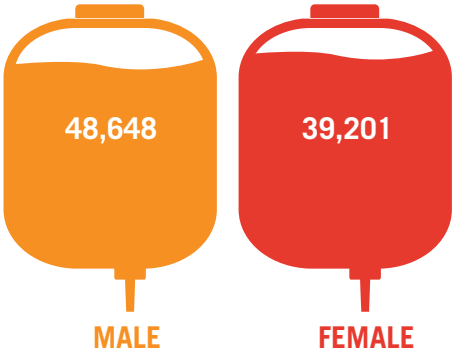
Donors 2010 vs 2011



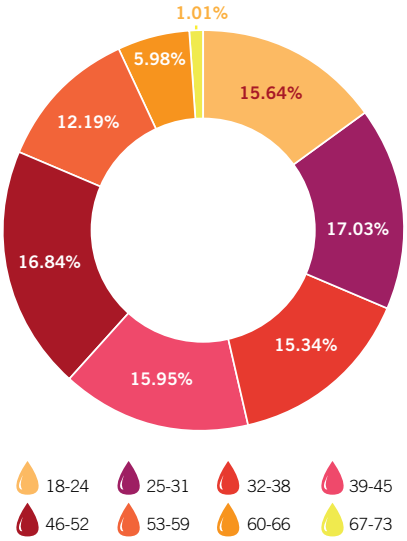
Whole Blood Donations by Donors



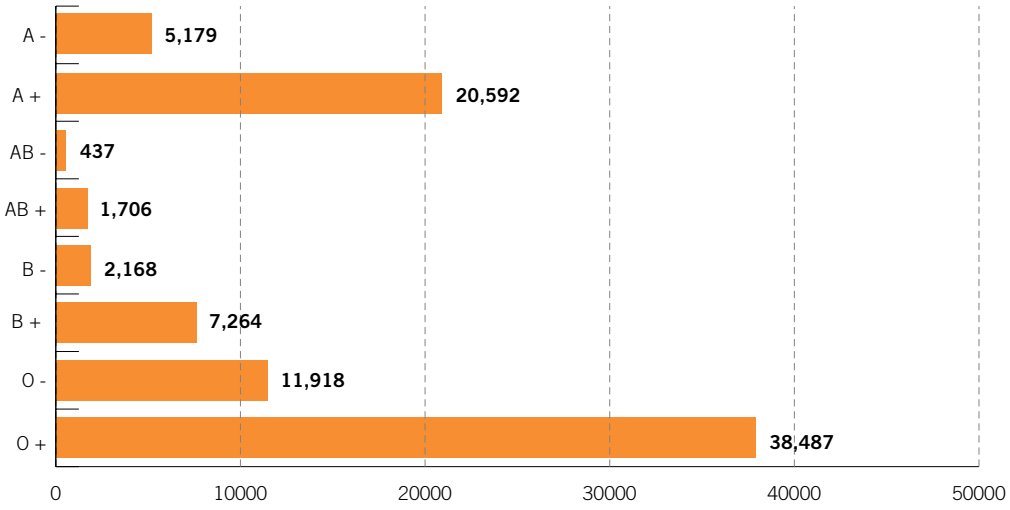
Whole Blood Donors by Gender



Whole Blood Donors by Age



Whole Blood Donors by Bloodgroup



Hospital Services

The scope of this function within the IBTS covers the management, storage, packaging and distribution of blood components and manufactured therapeutic products. It provides the day to day link between the hospital blood banks and the Hospital Services department located in both the NBC and MRTC. The departments in both centres are responsible for the safe and secure distribution of all products released for treating patients. It also covers the transport function for the collection of donations at clinics throughout the country as required and provides a scheduled blood delivery service to hospitals throughout the country on a daily basis. The processing department is responsible for the processing, labelling and release of all components from whole blood and apheresis donations. It also provides Medical Scientist cover in the hospital services area.

The hospital services area works closely with the processing area on a day to day basis in each centre. Medical Scientists support order intake in the Issue laboratory for specialist orders for patients e.g phenotyped red cell requests, specialist neonatal products, irradiated products. Hospital Services operates on a 24/7 basis manned by staff from both Supplies officers and Medical Scientists.

An electronic ordering system was developed by the Components and IBTS IT staff during the start of 2011. A prototype was tested in three hospitals during the Summer of 2011. The revised web based system was introduced between the IBTS and all hospitals in 2011 (which is expected to be installed in every hospital by February 2012). This electronic ordering system replaces the manual order receipt in both the Despatch and Issue laboratory areas and has further strengthened the relationship between Processing and Hospitals Services departments. It provides an improved and more efficient link to the hospitals. It enables the effective use of resources and greatly reduces the verbal communication and opportunity for error between all parties concerned. It provides an improvement in the quality of service and is a more efficient service both internally at the IBTS and externally to the hospitals.

Blood, Blood Components & Blood Products Issued

Product	2011	2010
Red Cells & Whole Blood	135,963	137,933
Platelets - Therapeutic Doses	24,735	24,394
Frozen Plasma	266	249
Octaplas	22,890	23,075
Cryoprecipitate	74	68
Factor VIIA (xIU)*	400	122,050
Factor VIII Recombinant (x IU)	36,300,000	34,361,750
Von Willebrand Factor (x IU)	790,600	623,500
Factor IX Recombinant (xIU)	11,935,750	9,848,250
Prothromplex (x IU)	787,200	643,800
Factor XIII	7,000	6,000
Plasma For IVD Use (Litres)	38,422	30,000

* Factor VIIA is no longer supplied by the IBTS from 13th January 2011

Testing

Nucleic Acid Testing (NAT) Laboratory

The Nucleic Acid Testing (NAT) laboratory

The Nucleic Acid Testing (NAT) laboratory is located at the NBC and provides national 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 HIV-1/HCV/HBV assay (January to November 2011). The Procleix Ultrio 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 Tigris instrument is a fully automated closed system for NAT testing of individual donations with the Procleix Ultrio and subsequently, Ultrio plus assay. The NAT laboratory successfully completed the validation and implementation of the Ultrio Plus assay in November 2011 to replace the Ultrio assay and to improve the detection of HBV DNA in blood donations. ID-NAT testing of IBTS donations using the Ultrio plus assay has provided the blood supply with an additional margin of safety.

An archive sample is retained on all donations. Every donation collected in 2011 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-1, HCV, HBV), Bracket Controls and Internal Control (IC). The IC is used to control sample processing, amplification and detection steps and used to ensure all manufacturer testing processes are operating correctly. Tigris Bracket Controls are used following testing of every 100 samples in each worklist. Calibrator results must meet assay specifications.

Interlaboratory comparisons using EDCNet software and participation in numerous External Quality Assurance Schemes (EQAS) in 2011 allow us to perform peer review with other Novartis and non-Novartis users of NAT assays 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. The Tigris Testing system robustness was excellent in 2011 with minimal impact on the processing of blood and blood products. The laboratory is currently preparing for ISO 15189 accreditation.

Virology

The virology laboratories receive a clotted serum sample from each donor taken at the time of donation which is identified with a unique bar code identifier. The sample is tested for the presence of specific viral markers that may be transmitted by transfusion. Approximately 160,000 donations were tested in 2011.

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

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. Screening for Syphilis and Cytomegalovirus (CMV) takes place on the DiaSorin ETImax processor.

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. A serum sample (Archive sample) is also stored frozen from each donation. When all tests are complete and if satisfactory results are obtained, the unit is cleared and labelled for issue provided also negative for Nucleic Acid testing.

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 quality of the testing system is ensured 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 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 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).

NHIRL

National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL)

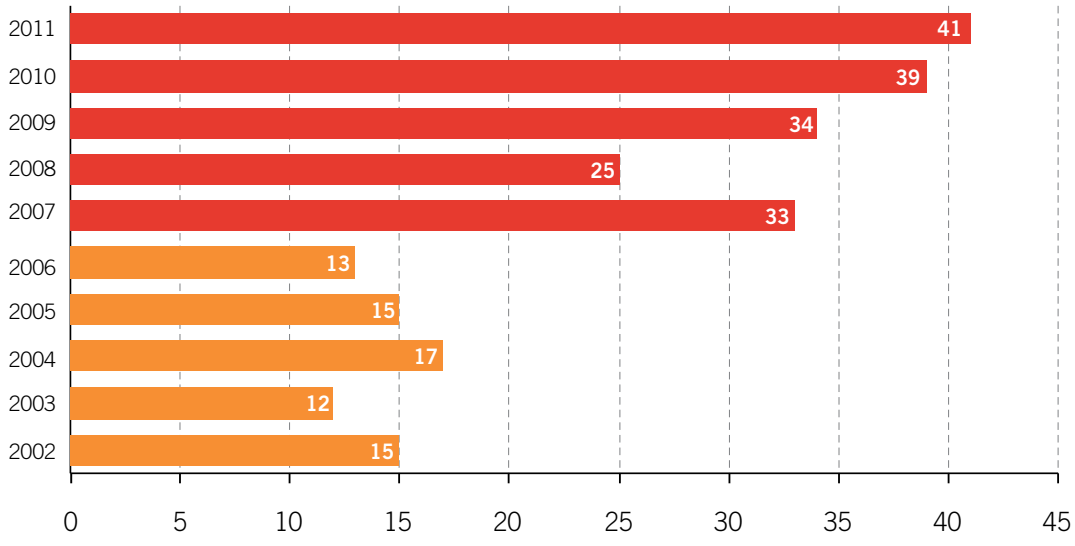
The National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL) provides a comprehensive range of clinical testing services designed to support the allogeneic haematopoietic stem cell transplantation (HSCT) programmes at St. James's Hospital and Our Lady's Children's Hospital, Crumlin.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

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

The laboratory has an extensive quality assurance programme including participation in both internal and external proficiency testing programmes for HLA typing, human platelet antigen (HPA) genotyping and HLA/HPA antibody investigations. The NHIRL has been accredited by the European Federation for Immunogenetics (EFI) since 2001.

In 2011 samples from 204 Irish patients for potential haematopoietic stem cell transplants and their relatives were HLA typed by the NHIRL. For those patients without a suitable family donor, an unrelated donor may be identified from the registry of volunteer donors. The NHIRL provides an immunogenetics

Number of Irish Patients receiving a HSCT from an Unrelated Donor 2002-2011



support service for the Irish Unrelated Bone Marrow and Platelet Registry (IUBMR) and in 2011 the laboratory HLA typed 778 new volunteer donors to add to the registry.

In the last 10 years the IUBMR has facilitated 244 unrelated donor transplants for Irish patients, 70% (n=172) of these transplants have been performed in the last five years and 33% (n=80) in the last two years.

The NHIRL also provides a routine disease association HLA typing service. This service represented over 50% of the investigations performed in 2011. The majority of samples are referred for determining the presence or absence of HLA-B27 which is associated with Ankylosing Spondylitis; a painful, progressive rheumatic disease mainly affecting the spine and sacroiliac joints.

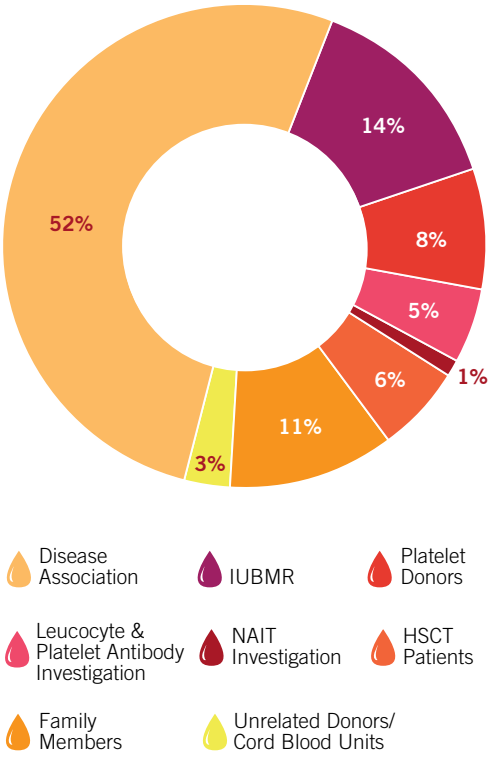
In addition, a platelet immunology service for the serological investigation of neonatal alloimmune thrombocytopenia (NAIT), post transfusion purpura (PTP), platelet refractoriness, alloimmune thrombocytopenias and adverse transfusion reactions is provided. Notably, the number of investigations for NAIT increased by nearly 30% in 2011 when compared to 2010.

A total of 448 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 overall number of samples received for investigation rose from 6061 in 2010 to 6189 in 2011.

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 2011 in collaboration with Trinity College Dublin.

- Innate immune genes synergize to predict increased risk of chronic disease in hepatitis C virus infection. M Dring, M Morrison, B McSharry, K Guinan, R Hagan, Irish HCV Research Consortium, C O'Farrelly, C Gardiner. PNAS 2011; 108 (14): 5736-5741.

NHIRL Investigation Distribution



Automated Donor Grouping

Automated Donor Grouping is continually striving to introduce the most up to date testing techniques and expand the number of red cell antigens that can be routinely typed. In 2010 / 2011 two new blood typing analysers were installed in the Donor Grouping Laboratory and after extensive validation were commissioned for routine use. Consolidation of testing, which was first established in 2010, continued throughout the year at the National Blood Centre and the smooth transition between regional and national testing is a reflection of the commitment of staff in both centres. This ensured the continuing high standards of service in both centres.

To make the most efficient use of this new technology all blood grouping samples from the blood donor clinics are transported to the NBC overnight and tested the following day. This has facilitated the early release of some products and the standardisation of testing methods throughout the country. Donors from the Munster region are now being extensively Rh phenotyped and further antigen tested. Over 90% of the active donors in Ireland now have a full Rh history, enabling the timely issue of rare units for patients with known or multiple immune antibodies.

In 2011 over 159,000 donations were tested and all red cell units require certain mandatory tests before they may be released for issue. These include ABO & RhD types and a screen for irregular antibodies. During 2011 there were over 10,500 new donors bled, which represent 6% of the total donations. Over 47% of donors receive a full Rh phenotype (C, c, E and e type) every time they donate and 20% of these will go for further antigen screening or typing. These donations are then available for issue to patients who are known to have produced multiple red cell antibodies. Over the last year red cell units have been made available for several cases, where the frequency of that particular cell type in the donor population would be less than 1 in 1000. In real terms this means that if every donation was typed, only 3 donations per week would be suitable for such cases. However, with selective typing and good stock management, in most cases units can be provided out of current stock for emergency issue.

In order to maintain a high level of confidence in the quality of testing, the laboratory regularly participates in the United Kingdom National External Quality Assessment Scheme, in both serology and screening for Haemoglobin S (HbS sickle screening).
Over the 8 years the laboratory has been participating in the scheme a 100% compliance in the results submitted has been achieved. This year also saw the participation in an international quality assessment scheme controlled by the European Directorate for the Quality of Medicines & Health Care. This compares the results from over 100 international testing facilities.

The participation in these schemes ensures the laboratory is up to date and compliant with current national and international testing standards.

Diagnostics

National Blood Centre

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 difficult cases and for hospitals without Blood Transfusion Laboratories
- Investigation of antibody problems
- 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 Newborn (HDN)
- Prevention of HDN 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 total, 2350 samples were referred in 2011 (a 17% increase from 2010).

2011 was a significant year as more complex antibodies were detected by the laboratory reflecting the changing demographic of the population.

The Emergency Reference Red Cell Immunohaematology On-Call Service, for patients with a clinically urgent requirement for antibody Investigation/Compatibility testing continues to operate well. There were over 117 cases where a Scientist was required to provide service in 2011 (a 65% increase from 2010)

Anti-c Quantitation testing was introduced to the laboratory in February 2011. This testing is operating satisfactorily with 192 samples from 47 patients processed during the year. In total 819 samples were quantitated in 2011 (a 41% increase from 2010).

“In total, 2350 samples were referred in 2011 (a 17% increase from 2010).”

Cork Centre

The diagnostics laboratory at the Cork Centre provides crossmatching services for a number of city hospitals and acts as a reference laboratory for hospitals within the Munster region.

The services provided by the diagnostics laboratory include;

- Acts as hospital Blood Bank for several city hospitals
- Provision of phenotyped blood (not available on the shelf)
- Investigation of antibody problems
- Investigation of Haemolytic Transfusion Reactions
- ABO/Rh typing, including typing problems
- Investigation of positive Direct Antiglobulin Tests
- Investigation of Autoimmune Haemolytic Anaemia
- Investigation of Haemolytic Disease of the Newborn (HDN)
- Provision of suitable blood at delivery for at risk pregnancies
- Scientific advice to hospital colleagues
- Extended phenotyping for transfusion dependent patients
- Filling hospital orders for Phenotyped Blood
- Filling hospital orders for Irradiated Blood
- Filling hospital orders for Platelets

In total, 2907 samples were tested in 2011 a slight decrease from 2010, 254 samples were referred in 2011 (a 33% increase from 2010).

The Emergency Reference Red Cell Immunohaematology On-Site Service, for patients with a clinically urgent requirement for antibody Investigation / Compatibility testing continues to operate well.

“In total, 2907 samples were tested in 2011 a slight decrease from 2010, 254 samples were referred in 2011 (a 33% increase from 2010).”

Other Services

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 tissue bank was inspected by the IMB in September 2011 in accordance with the tissue and cells directive of 2004 and no deficiencies were recorded.

The bank is responsible for distributing human tissue used in ophthalmic surgery nationally. Products supplied include corneas, sclera, amnion and pericardium. These products are all imported from the US. 2011 saw an increase of 14% in demand for corneas. 43% of corneas imported were pre cut (DSAEK) corneas, a rise of 6% on 2010. The IBTS also provides autologous serum eye drops for patients with severe dry eye on receipt of a request from an ophthalmologist.

During 2011 the Limbal stem cell project successfully transferred its operations from a GLP setting in to the GMP clean rooms located in the tissue bank suite. During 2012 the IBTS will seek authorisation from the IMB to produce limbal stem cells for clinical use under the Advanced Therapy Medicinal Products Directive.

The IBTS continues to process, cyropreserve and distribute human cardiovascular tissue on behalf of the Mater Misercordiae University Hospital. During 2011 there was 70% increase in heart valve donations to the bank, bringing the donation level back to 2007/2008 levels. This is in line with the increase also observed in organ donation.

The Directed/Sibling Cord blood bank collects and cryopreserves cord blood on request from the oncology/haematology team in OLCHC. Collections of umbilical cord blood for 2011 were down 45% on the number collected in 2010. The cord blood is stored in the National Blood Centre for the intended recipients use only. In 2011, five cord blood units were collected and stored. A total of 119 units have been collected to date of which two have been transplanted.

The directed cord blood programme operates under the IBTS tissue establishment license under SI 158 of 2006 (License number TE-012).

“During 2011 there was 70% increase in heart valve donations.”

Therapeutic Apheresis Service

The Therapeutic Apheresis Service is based in the National Blood Centre and the Cork Centre and provides Therapeutic Apheresis treatments to patients in the main Dublin and Cork hospitals. These treatments are provided on request from the patient's primary medical care team. The service is demand led, characterised by peaks and troughs and all treatments are performed in the acute hospital setting. Apheresis procedures are performed on patients with rare and often life threatening Haematology, Renal, Neurology or Hepatology disorders.

An IBTS Consultant Haematologist leads the service in each Centre and a medical evaluation of each patient is performed by IBTS specialist medical staff. Specialist IBTS medical staff are available for consultation for all procedures and are required to attend for first procedures in acutely ill patients and also complex procedures. Providing the patient is fit and the treatment is deemed appropriate, treatments are managed and administered by specially trained therapeutic apheresis nurses. The majority of therapeutic apheresis procedures are Plasma Exchange but other treatments include, Red Blood Cell Exchange/Depletion, Leucodepletion and Platelet Depletion.

Apheresis Procedures

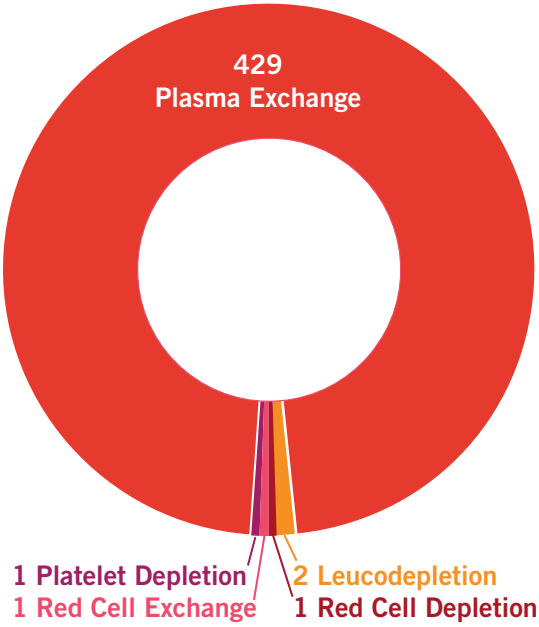
The total number of procedures performed

- 2011 = 434

Type of Procedures

The majority of procedures performed were plasma exchange 98%.

Type of Procedures

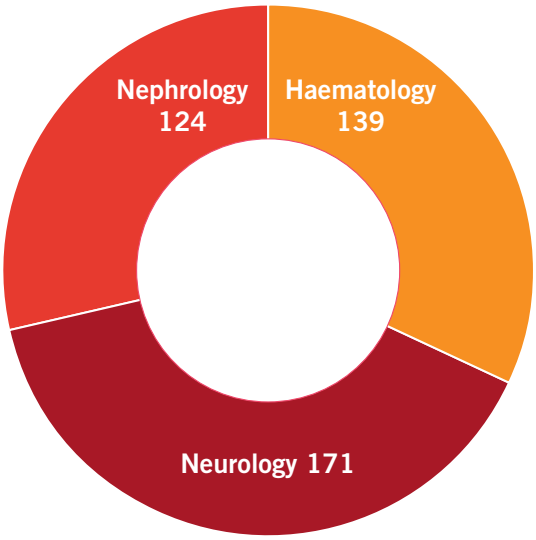


Procedures - in order of Priority

- **Emergent:** treatment is required for threatening disorders during day or night hours.
- **Urgent:** treatment is required for disorders that warrant treatment on week-ends and public holidays.
- **Elective:** non-urgent planned procedures performed during core hours.
- **Maintenance:** non-urgent planned procedures performed for out-patents during core hours.

Therapeutic Apheresis Service

Procedure by Specialty



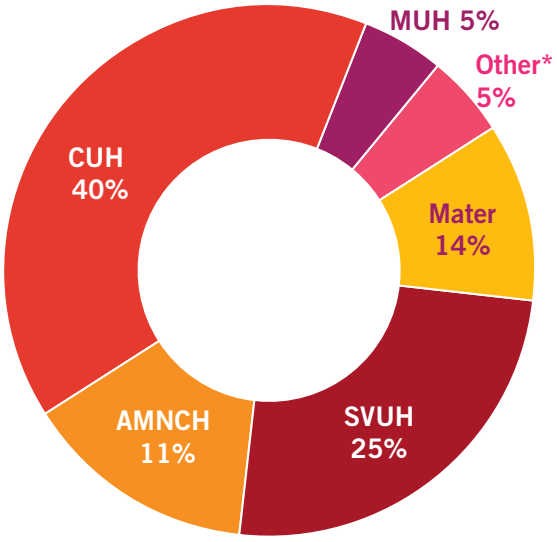
American Society for Apheresis (ASFA) - Categories

Treatments are classified according ASFA Indicator Categories 2010M(Evidence-based categories which include analysis bases on the quality of evidence as well as the strength of the recommendation derived from the evidence).

- Category 1 - Standard acceptable therapy, primary or adjunct to other treatments.
- Category 2 - A supportive therapy, available evidence supports efficacy,
- Category 3 - Insufficient data to determine effectiveness of apheresis.
- Category 4 - Evidence shows therapeutic apheresis ineffective

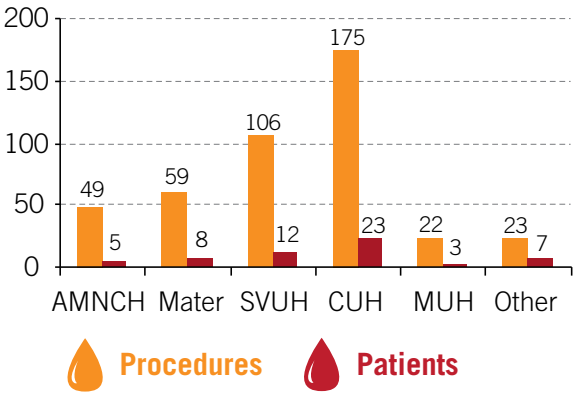
Due to staff shortages at the National Blood Centre, the out of hours and on call service ceased in November.

Procedures by hospital



*this includes the Mater Private, Beaumont and SJH

Number of Procedures / Patients



National Haemovigilance Office (NHO)

National Haemovigilance Office

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 eleven years of its existence, (2000-2010), a total of 2983 serious adverse transfusion reactions and events have been reported. During 2011, Dr Anne Fortune, Consultant Haematologist was Acting Director of the NHO until June 2011. Dr Ian Franklin, Medical and Scientific Director of the IBTS, became the Director of the NHO 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. These reports came from facilities, hospital blood banks and blood establishments and included near miss events where patients were not transfused. One hundred and sixty one mandatory SAE were reported, which was 61% of all AE. In addition, 102 non mandatory SAEs, primarily relating to errors in clinical areas, were reported under professional responsibility, which was 39% of all SAE .

Serious Adverse Reactions (SARs) – mandatory and non mandatory

In 2011, 130 SARs were accepted by the NHO, mainly in Acute Allergic, Anaphylactic Transfusion and Febrile Non-Haemolytic Transfusion Reactions categories. One hundred and twenty eight SAR met the criteria of a mandatory report under Directive 2002/98/EC, two SAR involving SD plasma were non mandatory SAR.

Annual Notification of Serious Adverse Reactions and Events (ANSARE)

In compliance with Commission Directive 2005/61/EC Annex II D and III C for hospitals transfusing blood, all hospitals transfusing blood together with all blood establishments (BE) must complete and return an ANSARE form to the NHO. Two hundred and eighty nine mandatory reports were accepted by the NHO in 2011, with a review of a small number of individual cases and compilation of ANSARE report ongoing at time of writing.

NHO Annual Conference

The NHO Annual Conference was held in the Radisson Blu Royal Hotel, Dublin on Friday 11 November, 2011 with more than 200 delegates with multidisciplinary backgrounds in attendance. The conference is regarded as a valuable opportunity to network and refocus on the clinical aspects of Haemovigilance by sharing individual views and experiences.

In his opening address the Minister for Health, Dr. James Reilly, highlighted the importance of continuous improvement in the areas of patient quality of care and safety noting that these goals were achievable when supported by robust error identification, citing haemovigilance as an example.

National Haemovigilance Office (NHO)

He acknowledged that haemovigilance demonstrated effective cross-organisational effort and teamwork and thus influenced other areas of concern such as the importance of positive patient identification, improved management and practice in warfarin reversal and awareness of serious transfusion reactions such as transfusion associated circulatory overload, (TACO) and transfusion related acute lung injury (TRALI).

Irish Medicines Board (IMB)

The Competent Authority for implementation of all aspects of the EU Blood Directive is the IMB and 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 and transfusion education for nursing and medical laboratory science students by working closely with hospital based HVO. In addition, efforts are being made to expand transfusion specific education and training for medical staff.

Haemovigilance Education Initiatives at DCU

The partnership between the National Haemovigilance Office (NHO) at the Irish Blood Transfusion Service (IBTS) and Dublin City University (DCU) enabled the provision of degree level stand-alone professional development since 2004 and post-graduate modules in blood transfusion and haemovigilance since 2008.

This redevelopment of degree level professional development haemovigilance modules along with the continued availability of post –graduate modules either as a stand alone option or as part of a graduate diploma in nursing / health care practice, is evidence of the NHO's commitment to provision of ongoing support and education on safe transfusion practice. This also demonstrates the commitment of the IBTS to work with academic institutions to grow a research base (Irish Blood Transfusion Service Strategic Plan 2010-2).

e-Learning

The IBTS continued to license and provide the 'Learnbloodtransfusion' e-learning programme to hospitals. This programme was developed by the Scottish National Blood Transfusion Service (SNBTS) with the NHO and IBTS contributing to editorial content. There are eight e-learning blood transfusion modules. Recently, modules on indications for Anti-D Immunoglobulin, Cell Salvage, Good Manufacturing Practice and Safe Paediatric Transfusion Practice have been added. Seventy four hospitals engaged in blood transfusion practice in Ireland actively use the programme, with medical and nursing undergraduates in several universities undertaking the modules as a mandatory course requirement. At the end of 2011, of the 9,000 users registered on the programme, 58% were nurses, 23% medical staff and the remaining 19% were medical scientists, phlebotomists, porters and students.

Irish Unrelated Bone Marrow Registry (IUBMR)

Allogeneic stem cell transplantation remains the only curative therapy for some leukaemias, bone marrow failure syndromes and for some inherited metabolic disorders. For the many patients who do not have the preferred option of a matched sibling donor, a matched stem cell transplant from one of the 19 million volunteer donors worldwide provides a suitable alternative.

To meet the need for unrelated stem cell donors for both Irish and International patients, the Irish Unrelated Bone Marrow Registry (IUBMR) was set up in 1989 and the panel currently consists of 20,293 donors. Since 2001 all donors going 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 and had a successful audit carried out by members of the IMB in September, 2011.

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. The IUBMR achieved accreditation status with the WMDA in 2007, the 8th Registry in the World to be accredited. Currently there are twenty (20) registries accredited worldwide.

Retention of Accreditation is stringent with a yearly review and an on site inspection every four years.

The IUBMR will have the first on site visit by WMDA accrediting members early in 2012.

Irish Patients

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 Childrens Hospital Crumlin (OLCH). In 2011 fifty five (55) patients were referred to the IUBMR for unrelated searches.

Forty one (41) Irish patients received stem cells from an unrelated donor in 2011. Thirty four (34) stem cell donations were sourced from Europe including Ireland (8) and seven (7) from outside the EU.

The majority of the patients received a PBSC graft (22), Bone marrow (17) cords (2). Fifteen(15) of the patients who received PBSC had a reduced intensity conditioning(RIC) transplant.

The most common indication for the patients transplanted in 2011 were AML/MDS (16)39%, Lymphomas (9)22%, Anaemias (8) 19%, ALL (4) 10%, CML(2)5%, Other (2)5%.

In contrast to the patients transplanted in 2010, ALL was thirteen (13) 33% Lymphomas two (2) 5% and Anaemias four (4)10%

Irish Unrelated Bone Marrow Registry (IUBMR)

Irish Donors

Bone marrow volunteers are recruited by the bone marrow recruitment nurse at blood donation clinics 2 days a week. This year 633 donors were recruited to the panel. However, 914 donors were deleted from the panel, 377 because the upper age limit was reached and the majority of the remainder were closed after a panel review in preparation for the new database.

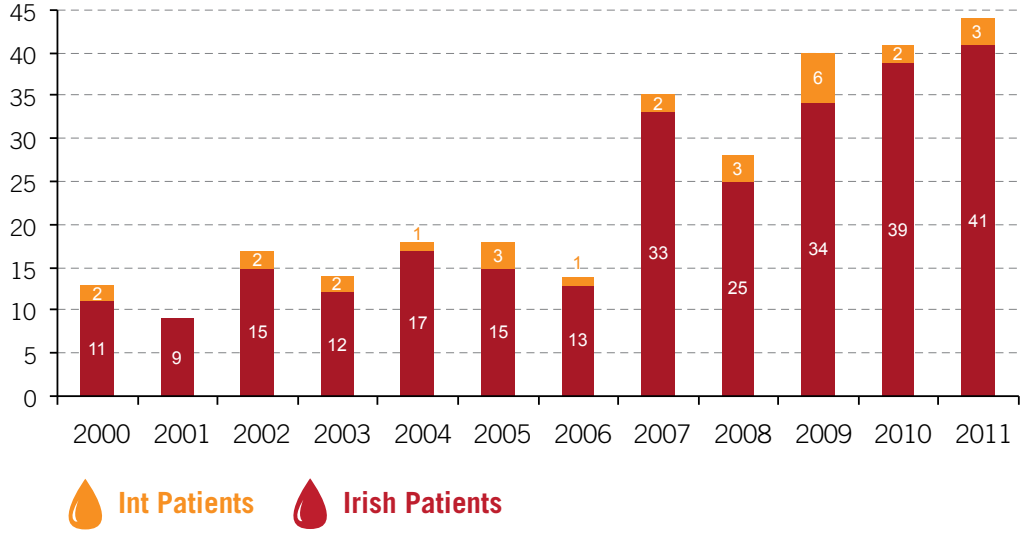
Of the 20,393 donors on the panel the majority are in the 36-45 age range and similar to registries worldwide there are more female (54%) than male donors.

When an Irish donor is identified as a potential match for a patient they are counselled and medically reviewed by the bone marrow registry nurse. Samples are taken to perform a higher level of typing and infectious disease markers (IDMs)

If the donor is a suitable match for the potential recipient, the donor commences the workup process which is co-ordinated with St. James's Hospital which is the adult collection centre.

The donor will be seen by the Medical Director/ designate of the IUBMR, an independent medical physician and the consultant who will be performing the collection procedure to assess donor suitability for the procedure. In 2011, eleven donors donated, 8 donated PBSC and 3 donated bone marrow.

IUBMR Transplants Facilitated From Irish And International Donors 2000 - 2011



Donor Database

Currently the records of all IUBMR donors are held in the SOLAR database. In 2011 the implementation began of the new database Prometheus. This has already been implemented in many other bone marrow registries worldwide.

The Prometheus database will be linked to the European Marrow Donor Information System(EMDIS) of which many registries worldwide have signed up to. EMDIS is a messaging service which acts like a virtual international registry and is an online method of accessing international registries and reduces the need for fax/email. It will also help to automate the registry workflow.

International Activities

Preliminary searches were received on behalf of 286 international patients of which 70 were activated for additional typing requests. Three donors went on to donate PBSCs for international patients. Two donations to Europe and one outside the EU.

Irish Unrelated Bone Marrow Registry
Irish Unrelated Donors Stem Cell Donations 2000 - 2011

Recipient Tracing Unit

Recipient Tracing Unit

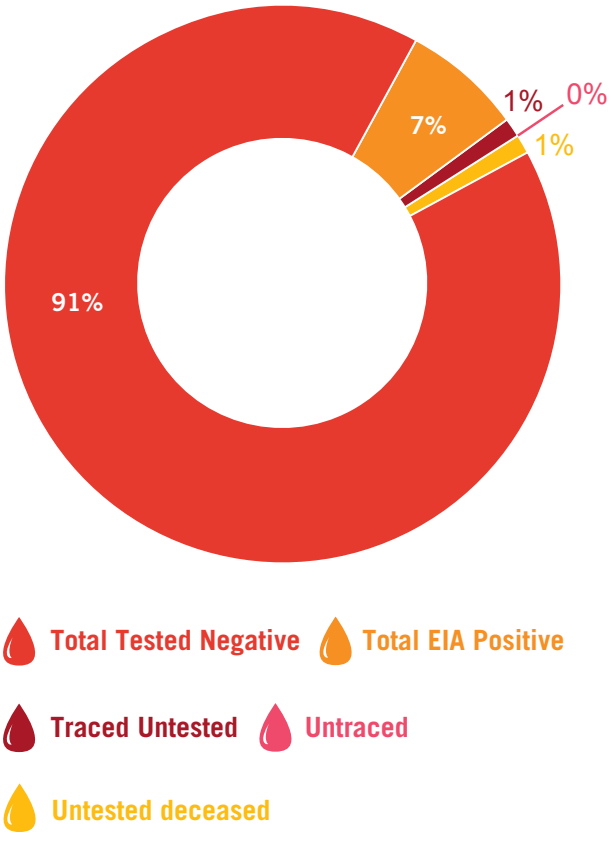
In 2011 the Recipient Tracing Unit (RTU) successfully completed the task of tracing and offering testing to known recipients of infectious or potentially infectious Anti-D in the two risk periods 1977-1978 and 1991-1994, as the final part of the Anti-D/HCV National Screening Programme. This was a huge undertaking involving not just the RTU but the cooperation and support of the laboratory, medical, nursing and support departments of the IBTS and also many outside agencies.

Major challenges were encountered in tracing and retracing individuals due to a number of factors e.g. absence of IBTS despatch records, missing or inadequate hospital maternity records, lack of critical identifying information, name changes, confidential pregnancies and increased immigration patterns during the time periods in question. However these were overcome by establishing links with a wide and varied network of external organisations both in Ireland and abroad who assisted the RTU in successfully tracing individuals. As a result of a very successful Tracing Programme developed between the IBTS and a number of key agencies in Ireland and abroad, the RTU have traced recipients in five continents. As a result of extensive tracing, the RTU has successfully traced 99% of all those identified to the programme.

Anti D/HCV National Tracing and Screening Programme

A total of 14,724 (98%) recipients were tested out of the 15,080 recipients identified who received potentially infectious batches of Anti-D from both risk periods. Of those tested, 1,089 (7%) tested Elisa Positive of which 503 (3.4%) tested PCR positive indicating continuing HCV infection. The remaining 13,577 (91%) tested HCV negative. A further 1% have been offered testing, but have not chosen to be tested, 1% were found to be deceased and less than 1% remain untraced. The majority of the PCR positive individuals identified, 91% were from the 1977-79 cohort, with only 9% from the 1991-94 cohort.

The Anti-D/HCV National Screening ProgrammeSummary of Final Results for both risk periods 1977-79 & 1991-94



Reassurance Programme

The Reassurance Programme was established to ensure that all those individuals who had received an infectious or potentially infectious batch of Anti-D and had previously tested HCV negative were offered a HCV retest and informed of the batch that they received. Of the 9,884 individuals tested under the REP programme, two (0.1%) tested HCV EIA and PCR positive on retest. Both of these positive individuals had been exposed in 1993 and had been tested in 1994 less than a year after exposure i.e. within the 'seroconversion' window period. The remaining 9,882 (99%) individuals retested negative for HCV.

Donor Reinstatement Programme

As many of these HCV negative individuals were also blood donors, a special testing protocol was introduced to ensure that they would be able to continue to donate and help maintain the Rh negative blood supply. As a result of this programme a total of 5,109 donors have been reinstated to the donor panel and of these 3,347 have donated again.

Conclusion of Programmes

The Final Report on the Programme was presented to the Expert Group on Hepatitis C and the Department of Health and Children in June 2011 which was accepted by the Minister for Health in August 2011.

The RTU has therefore ceased active tracing, but will continue to provide a confidential helpline (1800 222 111), to anyone who did not avail of testing but wishes to be tested in the future or requires follow up on any aspect of the programme. It will also continue to have the remit to manage donor reinstatements, targeted lookbacks and legal queries.

"As a result of extensive tracing, the RTU has successfully traced 99% of all those identified to the programme."

Quality & Compliance

“The focus during 2011 was on maintaining the highest standards in Quality and Compliance throughout the IBTS while ensuring cost reduction/ cost effectiveness in all areas. ”

Quality & Compliance

The focus during 2011 was on maintaining the highest standards in Quality and Compliance throughout the IBTS while ensuring cost reduction/ cost effectiveness in all areas. Some innovative solutions were implemented through the goodwill of staff to ensure continuity of testing activities. Regular quarterly reporting of the Quality Compliance Metrics at the Executive level, as well as to the Audit and Compliance Committee of the IBTS Board ensured appropriate focus on maintaining standards. A review of the Quality function commenced in October 2011.

As part of the regulatory review, the IBTS was inspected twice during 2011 as a licensed Blood Establishment. The Tissue Bank activities were also inspected by the Competent Authority for Tissue & Cells, the Irish Medicines Board in September 2011. Of note was that there were no citations recorded during the inspection. Additionally there was a Good Distribution Practice inspection of the NBC for the wholesale licensing activity.

There were a total of 19 non-conformances raised throughout all these inspections, 18 of which were graded as other and 1 major non-conformance. The major non-conformance related to the management of donors outside the lower Haemoglobin limits.

Subsequent to this a major project was undertaken by the IBTS to introduce a venous haemoglobin test at clinics to ensue that donors are only bled at/above the minimum haemoglobin level. It is envisaged that this test will be introduced nationally by end March 2012.

As part of the Quality Management System an internal audit programme is completed. There were 46 compliance audits conducted internally during 2011, and additionally there were 8 vendor audits conducted.

These audits and responses are managed in the electronic document management system SmartAudit. The system incorporates comprehensive reporting of compliance and non-compliances and associated corrective and preventative actions.

Compliance in the IBTS is not only measured through audit (external/internal) but also through the capture and reporting of incidents. By the end of 2011, a close out rate of 82.5% was achieved nationally for incident reports (IRs), meeting the target of 80% closure. As in other years, the majority of IRs are raised against manual activities. The introduction of SmartCAPA was postponed during 2011, to coincide with changes in the quality function architecture. It is planned that a redesign of the CAPA system will take place during 2012.

Close out rates for other measures are also reported regularly. The close out rate for change orders (SOP changes) nationally was at 95% at year end against a target of 80%. The close out rate for change controls (process changes) nationally was 77% at year end, as against a target of 60%.

The project for nationalising SOP's ongoing since May 2009, achieved a total of 900 national SOP's by end 2011. The target set was 915. While there was a shortfall in not meeting target through the consolidation and streamlining of SOP's there is an overall reduction of 13% in total SOP numbers since the project began.

Quality & Compliance

A major drive to retrain all IBTS staff on Good Manufacturing Practice (GMP) for Blood Services was initiated in 2011. For the first time through the collaboration of training and quality functions a unique, customised programme was developed and delivered to almost 80% of staff nationally by December 2011. The remainder will be complete early in 2012.

As an essential part of the service, the IBTS has complaint handling systems in place for product and service complaints. During 2011, the Donor Service Department took ownership of the Service Complaints System. 98.2% complaints were closed on time, a vast improvement on prior years.

The Product Complaint System has a target of 90% closure, but by year end the close out rate stood nationally at 76%. While some complaints require complex investigation, this is an area requiring improvement. However, the overall number of complaints continue to decrease with a total of 901 recorded nationally in 2011, an 8% reduction on 2010 figures.

A major contribution was the introduction of an online electronic ordering system for hospitals, resulting in an improved level of the quality of the service to our customers.

The reduction in false positive results for the Bacterial Screening programme continues through 2011 resulting in a further reduction in product recalls. During 2011, 212 product recalls were initiated, representing a 21% decrease on the 2010 figure of 269. There has been a continuing trend downwards in product recalls since 2009.

As part of the regulatory obligations, the IBTS operates vigilance systems, covering Donor Vigilance, Haemovigilance and Tissue Vigilance.

During 2011, there were 405 Donor Vigilance cases, all of which were investigated and the donor appropriately managed. Tracking and trending of this data is performed and benchmarked against other Blood Services in Europe.

Haemovigilance reports within the Blood Establishment are derived from internal IRs, as potential Serious Adverse Events (SAEs), and through product complaints as potential SAEs and Serious Adverse Reactions (SARs).

These reports are compiled by the Quality function and reported quarterly to the National Haemovigilance Office (NHO) and annually to the Competent Authority, the Irish Medicines Board (IMB), through the end of year report.

There were 34 SARs confirmed and 44 SAEs confirmed with the NHO for 2011.

As part of the external validation of the testing laboratory activities, all IBTS Test Laboratories (covering Grouping, Diagnostics, HLA, Virology, NAT and QC) participate in External Quality Assurance schemes (EQAS). All tested samples scored in accordance with expected external results.

Finally, some of the initiatives started/implemented during 2011 which contributed improvements in the IBTS systems:

- introduction of the online Electronic Ordering System for hospitals. It is planned that this will be completed nationwide Q1 2012.
- the design and validation of an electronic paperless environmental monitoring system by the Environmental Monitoring Department will ensure more accurate/timely delivery of results and enable more extensive tracking, trending and reports to be completed. The system should be fully operational by Q2 2012.
- the introduction of the Procleix Ultrio Assay on the NAT Tigris Technology during 2011 further enhanced safety testing of donors' blood.
- the design and development of a comprehensive requirements specification for a future Electronic Blood and Tissue Computer System was completed in 2011.

Involvement in the development of the Europack Blood Bag Specification and contribution to European Blood Alliance (EBA) Blood Bag tender process cultivated better exchange of experience and knowledge by Blood Services throughout Europe. The IBTS is a full participant in these ventures and will benefit positively in the long term from this participation.

"The design and development of a comprehensive requirements specification for a future Electronic Blood and Tissue Computer System was completed in 2011."

Energy Usage

“The main energy users at IBTS are at our processing and testing facilities: of the total energy consumed by the organisation, the National Blood Centre accounts for 80% of the total.”

Energy Usage

Overview of Energy Usage

The main energy users at IBTS are at our processing and testing facilities: of the total energy consumed by the organisation, the National Blood Centre accounts for 80% of the total, the Munster Regional Transfusion Centre for 12%, our fleet of 19 vehicles for 5% and the six regional centres for the remaining 3%.

Nearly two thirds of the energy consumption at the NBC and MRTC is used in the production and testing laboratories; for example the power used in the production and testing processes, cold storage of blood products and associated reagents, and utilities such as air conditioning for production purposes.

Lighting, office equipment, and office air conditioning account for the remaining energy consumed at these facilities.

In 2011, IBTS consumed 11,040 MWh of energy which is a 6% reduction on the energy used in 2010.

The breakdown of the figures for 2011 consisted of

- 5,424 MWh of electricity;
- 5,617 MWh of fossil fuels, including 5,013 MWh of natural gas and 603 MWh of transport fuels.

Background to making energy savings

The construction of the National Blood Centre was completed in 1999, and it incorporates many modern energy saving devices such as variable speed drives on pumps and fans. The organisation continually optimises the operation of such devices to maximise the energy savings available.

The organisation operates within a Quality System in which there is tight control of conditions within our cold rooms and appliances, and tight control of environmental parameters such as temperatures within laboratories. The relatively cool summer weather in 2011 reduced the energy required for air conditioning of our laboratories.

Changes we may wish to make to utilities to save energy need to be scoped and evaluated in advance to establish that the impact on the organisation's products and Quality System is acceptable to the organisation.

Actions undertaken in 2011

In 2011 IBTS undertook a range of initiatives to improve our energy performance, including:

- Lighting control upgrade in the main production laboratory which saved an estimated 61 MWh per annum.
- IBTS participated in Energy MAP programme organised by Sustainable Energy Ireland, demonstrating our commitment to the National Energy Efficiency Action Plan and the targets set for the Public Sector Efficiency Programme.

Actions planned for 2012

In 2012 IBTS intends to further improve our energy performance by undertaking the following initiatives:

- Changes to air conditioning operating mode in the main production laboratory which could save up to 80 MWh per annum.
- Installation of new air compressor and associated controls which will better match the reduced compressed air requirement of our facility at night time. This will result in an estimated 25 MWh of annual electricity savings.
- Further participation in the Energy MAP programme.

Human Resources

“The objective of Human Resources is to ensure that IBTS employees are enabled to meet the needs of donors and patients.”

Human Resources

The objective of Human Resources is to ensure that IBTS employees are enabled to meet the needs of donors and patients.

Projects in 2011 focused on achieving greater efficiency through improved practices and the successful conclusion of a number of change programmes under the Croke Park Agreement.

Performance Measurement

The Performance measurement system is EMT led, linking performance throughout the organisation. It has been designed and developed involving employees of various grades and disciplines. The defined targets will enable the measurement of performance consistently.

Change Management Project

We continue to promote and foster a culture of continuous change that enables the delivery of a quality driven service. The restructuring of the fixed clinic in the Cork Centre has introduced the first hybrid platelet apheresis/whole blood clinic, with an aggregated hours rostering model.

Corporate Training & Development

The main areas for Corporate Training & Development focus in 2011 were:

- HR Policy & Procedures
- EH&S training for managers & staff

The IBTS Training and Development function in 2011 has seen the following activities taking place which represent mandatory training requirements and continuous improvement development;

Training and Development Projects

- Succession and Skills Contingency Planning. This project has developed a Succession Plan for critical business roles within the IBTS. This will ensure corporate memory is maintained through planning for the replacement of key roles by appropriate skills training.
- Internal Communications – Staff Newsletter was re launched and there was an intranet editorial and format update completed.

Human Resources

Corporate Training & Development Programmes	Total Attendees
Corporate Orientation Programme	20
HR Policies & Procedures, including	
• Review of HR Staff Policies & Procedures	350
• Employee Assistance Programme	75
• Finance & Budgeting	25
• Training for CoreHR systems	11
EH&S Training Programmes, including	207
• Manual Handling (various tailored modules)	110
• Fire Safety	40
• Fire Warden	36
• Ergonomics / Postural Awareness (clinic)	23
• Chemical Risk Assessment	30
• Driver Safety	68
• Emergency Evacuation planning	19
• Health & Safety Committee / Rep	24
• Laboratory Safety	170
• Occupations Blood Exposure (developed into SOP)	69
• Functional Risk Assessment	21
• Safety Statement	11
• Radiation Safety	5
• Contractor Safety	11
Skills Development Customer Service / Client Centred Communications, MS Office, Minitab with Statistics, Process validation, Professional Administration, Project Management, Performance Management & Supervisory Skills	53
IBTS Assisted Education Scheme Financial assistance was granted for further education in a variety of disciplines including Operations, Business or Healthcare Management, Bio-Medical Science, Nursing and Medicine. Most Educational Assistance is for academically awarded programmes.	17 New 11 ongoing

Library Services

The Library continues to drive and support the learning, research and information needs of IBTS staff.

Training was provided on sourcing both quality medical and management information, with group and individual library and information skills sessions being maintained throughout 2011. New library guides were produced on advanced searching and referencing skills.

In response to developing the Library's alerting and current awareness service, new subject specific email lists were set up for stem cell research and Xenotropic murine leukemia virus-related virus (XMRV). The Library now maintains over 50 subject specific lists which staff can sign up to and receive updates in their areas of interest.

Library staff continued to develop enhancements to the Intranet so that information can be more easily uploaded and produced, producing guides to encourage staff to upload material to the Intranet themselves.

Additions were made to the digital photographic archive of images outlining the history of the organisation from the 1940s to the present day. Images were shared with staff through the Intranet and the staff newsletter I-ByTeS.

The Library continued its role in the organisation's internal communications as the Research Officer/ Librarian co-edits the IBTS staff newsletter I-ByTeS.

The Research Officer/Librarian also presented at various conferences within the library and research fraternity to foster relationships and promote the organisation. A number of library groups visited the library including UCD and DBS students studying Library and Information Science. The Library also hosted two "Academic Writing for Librarians" workshops in 2011.

Environmental, Health and Safety

Environmental, Health & Safety plays an important role in ensuring legislative compliance and that comprehensive environmental health, safety and welfare programmes continue to be developed and adopted.

Environmental Health & Safety Consultation and Communication

- Regional Health and Safety Committees
  Regional Health and Safety Committees were reformed with common Terms of Reference in the IBTS Centres in Carlow, Tuam, Ardee and NBC (D'Olier St. & Stillorgan) and training was provided for each regional committee.

- National Waste Management Committee
  The National Waste Management Committee was re-established with revised Terms of Reference.

IBTS Health and Safety Risk Assessment Process

A review of the health and safety risk assessment process took place throughout the organisation in 2011. The aim is to ensure a standardized formal approach to risk assessment is adopted in all areas.

As a result of this review process the following was introduced;

- Specific Chemical Risk Assessment templates and a new training programme on chemical awareness and risk assessment training.
- Specific Manual Handling risk assessment templates were introduced for tasks/activities which involve a substantial element of manual handling and manual handling training was tailored accordingly.

IBTS Contractor Management Programme

A Contractor Management Programme was agreed and implemented within the organisation. As part this programme health and safety induction training was made mandatory for all contractors undertaking work within the IBTS. Contractor Health and Safety Induction Training is provided by means of an e-learning programme tailored specifically for the IBTS.

Work Transport Programme included:

- Certificate of Professional Competence (CPC) Training
- Decision Driver Training
- Vehicle Risk Assessments

Occupational Health

- **Selection of New Occupational Health Provider** The IBTS retains the services of an external Occupational Health Provider to fulfil the organizations occupational health requirements in accordance with Safety, Health and Welfare at Work Act 2005 and the Safety, Health and Welfare at Work (General Application) Regulations 2007. Following a tender process a new Occupational Health Provider was selected and contract provisions were put in place.

- **Hepatitis B Vaccination Management** Programme conclusion of project by IBTS Occupational Health Providers to amalgamate Hepatitis B Vaccination status records for all IBTS staff onto one database. A scheduled employee Hepatitis B vaccination follow- up programme was also commenced.

- **Office Ergonomics Programme** One hundred and seventy nine staff completed the online ergonomic training programme in 2011 and one hundred and sixty ergonomic workstations assessments in both office and laboratory environments were completed.

In line with the Safety, Health and Welfare at Work (General Application) Regulations 2007, Chapter 5 of Part 2, the IBTS Office Ergonomics Programme was revised and further developed.

The following was undertaken as part of this programme:

- Revision and further development of the IBTS Display Screen Equipment Policy
- Development and roll out of an online ergonomic training programme
- Development and roll out of on online self assessment questionnaire

Finance

Summary Accounts for the year ended 31st december 2011

	2011 €'000	2010 €'000
Income		
Recurring income	103,923	109,906
Non-recurring income	4,314	854
Total income	**108,237**	**110,760**
Expenditure		
Total expenditure	**102,044**	**106,814**
Surplus for year	6,193	3,946
Actuarial loss on pension scheme	(12,217)	(523)
Transfer to Capital Reserves	(681)	-
Transfer from Research Reserve	159	296
Accumulated surplus/(deficit) at 1st January	1,510	(2,209)
Accumulated surplus / (deficit) at 31st December	**(5,036)**	**1,510**

Income

The Board's total income for 2011 of €108.23 million (2010 €110.76 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 €103.92 million (2010 €109.90 million). Non-recurring income of €4.31 million (2010 €0.85 million) includes HSE Grant income, interest on bank deposits and proceeds from the sale of fixed assets. The drop in income represents reduced volumes and the elimination of mark-up on resold blood products.

Expenditure

Expenditure for 2011 amounted to €102.04 million (2010€106.81 million). The reduction in expenditure mainly arises from the continuation of the IBTS cost reduction programme implemented by the Board in 2009.

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 2011 was €7.68 million.

In 2006 the Board set up a research reserve. In 2011 €159,000 was expended from the reserve. (In 2010 €296,000 was expended from the reserve).
The Board accounts for pensions in accordance with financial reporting standard 17 'Retirement Benefits' (FRS 17).

Finance

Capital Expenditure

The Board invested €1.46 million in capital projects and equipment during 2011 (€1.7 million 2010). The main investments during the year included replacement freezers, facility enhancements, national grouping solution equipment and an automated multichannel screening transfusion instrument upgrade.

There was recurring expenditure for the replacement of ICT infrastructure, medical and other plant and equipment. In addition, expenditure was incurred on the firewall upgrade, environmental monitoring system and document management software.

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 31st December 2011, under the terms of applicable legislation, invoices to the value of €2,233,303 were late, by an average of 23.22 days. These invoices constituted 0.94% by number and 2.96% 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 €4,561.53. 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:info@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

Irish Blood Transfusion Service

Seirbhís Fuilaistriúcháin na hÉireann

National Blood Centre
James's Street, Dublin 8.

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

www.facebook.com/giveblood
www.twitter.com/giveblood.ie
www.giveblood.ie
Donor Infoline 1850 731 137

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