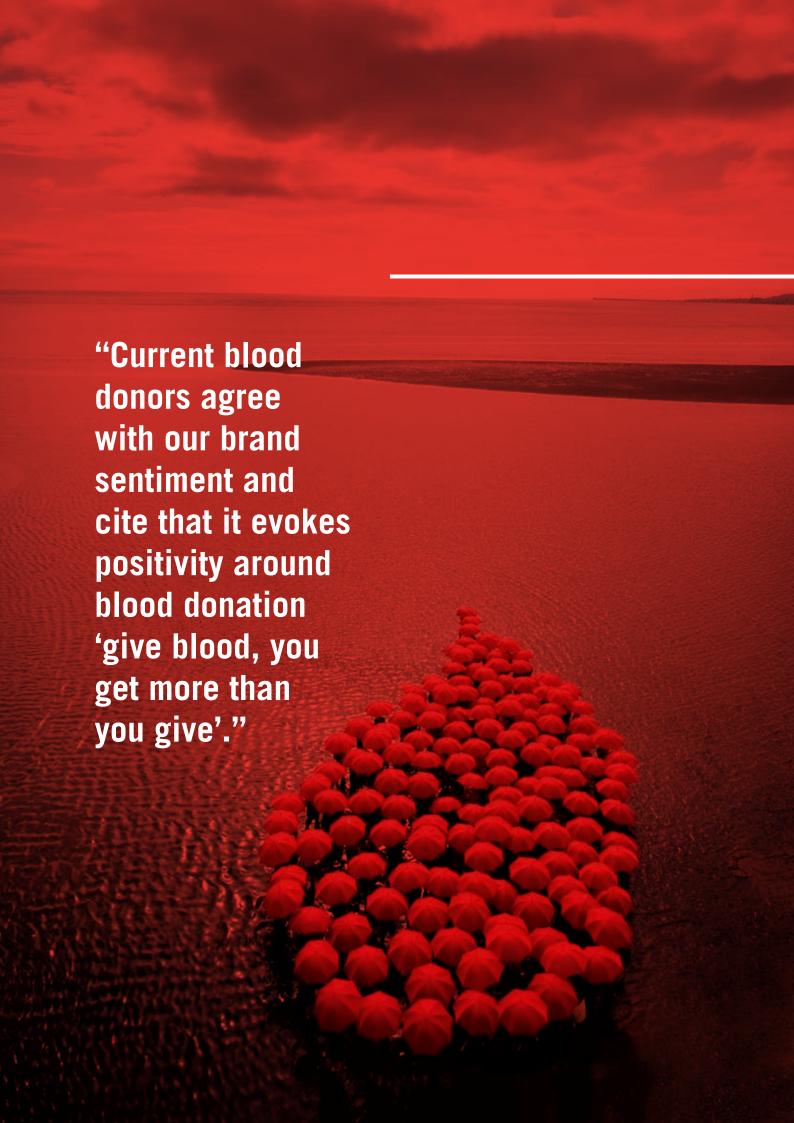




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Foreword

The IBTS primary function is to provide blood and blood components fit for patients. This can only be achieved through the loyal support of voluntary non-remunerated donors who give so generously so that others less well off can benefit.

During 2010 the IBTS carried out qualitative research to find out what donors and non – donors thought of the IBTS and their attitude to donation. This was a very valuable piece of research and the results showed that the IBTS is held in high regard and people see blood donation in a higher order than giving to charity. Perhaps one of the most interesting findings was that people believed that the sense of community or meitheal was returning and generally people wanted to give something back. This was very heartening and is a welcome return to a set of values where the consistency of the blood supply is assured.

Of course one could not reflect on the past year without mentioning the challenging financial times within which the IBTS is operating. This has resulted in the requirement to do more with less resources and to strive for further savings in the drive to returning the public finances to a more sustainable level. The IBTS continues to meet this challenge in a professional and positive manner. The Board recognises this commitment and will support the Executive in making difficult decisions while at the same time ensuring that the quality of the product is assured.

I would like to acknowledge the commitment of my fellow board members, the professional and dedicated manner of all staff across the organisation and congratulate the donors without whom much of modern medicine could not happen.

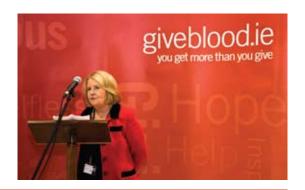
Yours sincerely,

Ms Katharine Bulbulia

Chairperson



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 2010, in accordance with Appendix V of the Revised Code of Practice for the Governance of State Bodies

- I, as Chairperson, acknowledge that the Board is responsible for the Body's system of internal financial control.
- The IBTS system of internal control can provide only reasonable and not absolute assurance against material error, misstatement or loss.
- The Board confirms that there is an ongoing process for identifying, evaluating and managing significant risks faced by the IBTS.
 This process is regularly reviewed by the Board via reports from the Chief Executive.
 - i. Management are responsible for the identification and evaluation of significant risks applicable to their areas of business together with the design and operation of suitable controls. These risks are assessed on a continuing basis and may be associated with a variety of internal or external sources including control breakdowns, disruption in information systems, natural catastrophe and regulatory requirements.
 - ii. Management meets twice monthly on operational issues and risks and how they are

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

- iii. The Chief Executive reports to the Board on behalf of the executive management on significant changes in the work of the IBTS and on the external environment which affects significant risks. Where areas for improvement in the system are identified the Board considers the recommendations made by the Executive Management Team.
- iv. The Director of Finance provides the Finance Committee, which is a sub-committee of the Board with monthly financial information, which includes key performance indicators.
- v. An appropriate control framework is in place with clearly defined matters which are reserved for Board approval only or, as delegated by the Board for appropriate Executive approval. The Board has delegated the day-to-day management of the IBTS and established appropriate limits for expenditure authorisation to the Executive. The Chief Executive is responsible for implementation of internal controls, including internal financial controls.
- vi. The system of internal financial control is monitored in general by the processes outlined above. In addition, the Audit and Compliance

Chairperson's Report

Committee of the Board reviews specific areas of internal control as part of their terms of reference.

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 2010 at its meeting on 8th March 2011.

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 and Children.

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 and Children.

The Board met on 11 occasions during the year.

Attendance by Board members was as follows overleaf.

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.

Members of the Board	Jan	Feb	April	April	May	June	July	Sept	Oct	Nov	Dec
Ms Katharine Bulbulia, Chairperson	1	✓	1	✓	✓	1	1		1	1	1
Mr Mark Moran	1	✓	1	1		1			1	✓	1
Mr David Lowe	1	✓	1	1	1	1	1	1	1	1	1
Mr Dave Keenan	1	1	1	1	1		1	1	1	1	1
Ms Marie Keane	1	1	1	1		1	1	1	1	1	
Dr Mary Cahill**	1	✓	1	1	1	✓		✓	1		
Dr Paul Browne	1	✓	1	1	1			✓	1	✓	
Ms Sinead Ni Mhaille	1		1		1	✓	1	✓	1	✓	1
Ms Ann Horan	1	1	1	1	1	1	1	✓	1	✓	1
Ms Jane O'Brien	1	1	1	1	1	1	1	✓	1	1	1
Mr Sean Wyse	1	1	1	1		1	1	1	1	1	1
Dr Paolo Rebulla*						✓	1	✓	1	✓	1
Dr Hilary O'Leary***											

^{*}Appointed on 3rd June 2010 ** Term ceased on 30th October 2010 ***Appointed on 6th December 2010

Chairperson's Report

	Annual Directors fee	Received 2010	Expenses 2010
	€	€	€
Ms K Bulbulia Chair	20,520	20,520	4,986
Mr D Keenan	11,970	11,970	-
Mr M Moran	11,970	11,970	-
Ms J O'Brien	11,970	11,970	-
Mr S Wyse	11,970	11,970	309
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	771
Ms M Keane	N/A	N/A	94
Dr P Rebulla	11,970	6,983	5,386
Ms A Horan	11,970	12501*	981
Dr H O'Leary	N/A	N/A	-

^{*}Appointed in Dec 2009 - fee $\,$ paid in January 2010 from appt date

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 2010 was €181,340.

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

Audit & Compliance Committee

The Audit and Compliance Committee met five times during the year and is comprised of 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.

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:

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

Chairperson's Report

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

Statement of Board Members' Responsibilities

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

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

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

Commercially significant developments

Supply of Plasma

Since 2001, the IBTS has not used the plasma collected as part of the whole blood donation as one of the measures taken to mitigate the risk of transmission of vCJD. In 2009, discussions commenced with a commercial company who are involved in manufacturing control materials for blood analysers and who were interested in purchasing this plasma. The IBTS commenced supplying plasma to this company in March 2010. This generates income in the region of €1m a year for the IBTS.

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. In 2010, this funding model was altered and the IBTS no longer held the contract for one particular product. It was agreed that an alternative contract holder be selected and this will come into effect in 2011. This reduced IBTS funding in 2010 by approx €2.0m with further reductions to be effected in subsequent years. The initial loss of income will be offset by a reducing grant from the HSE for 2011 and 2012 of €3m and €1.5m respectively.

Price reduction

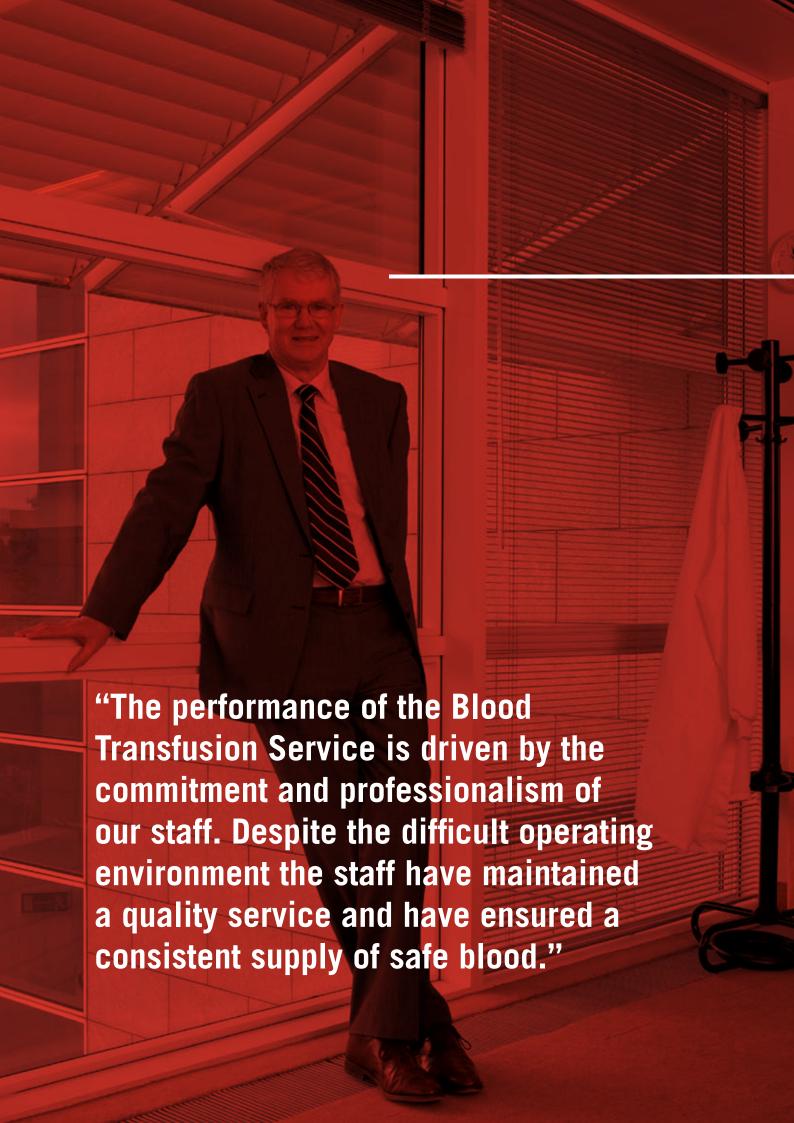
The IBTS reduced the price of a unit of red cells in 2010 by 9% and the price of testing services to hospitals was reduced by 5% while the margin on blood products was reduced from 20% to 15%

Laboratory agreement in Cork

The introduction of a laboratory agreement in the Cork Centre in January 2010 resulted in an extended working day and a reduction in overtime hours.

Ms Katharine Bulbulia

Chairperson



Chief Executive's Report



In Ireland in 2010 it was impossible to escape the coverage of our deep economic difficulties and the impact these had on the availability of funding to deliver public services. The agenda was driven by the absolute need to make cost savings and to deliver the same level of service with less resources in terms of finance and people. The IBTS like all other State Agencies had to adopt this policy while ensuring the quality of the product and the services we provided was not compromised.

There were two really significant developments during 2010. The first was the reduction of 7% in the use of platelets after 10 years of year on year growth and the second was the decision that IBTS would no longer be the contract holder for recombinant products which forms a core element of our funding model.

The year was characterised by the need to review all areas of activity and to manage the change required to realise cost savings in collaboration with staff and their representatives. This was challenging for all but the discussions were entered into with a willingness to find solutions mindful of the need to make the IBTS more cost effective.

There were a number of significant milestones achieved during the course of the year. The most significant change process continued in the collection teams with the implementation of the final elements of the Donation Process Review. This has resulted in a national framework for all collection teams and has streamlined the operation of the clinic. This has improved the experience for the donor. There are a number of other change programmes underway which will deliver improved services over the next few years.

The IBTS received a bequest to carry out research in ocular medicine. The IBTS and DCU partnered to develop Limbal Stem Cells fit for transplantation. This is a major departure for the IBTS and is very exciting project.

The IBTS has over the past few years undertaken collaborative research projects with a number of universities and also used some of the money set aside to carry out research to improve current practice. During 2010 the Board decided that the focus of the research and development programme should be on cell therapies.

Consequently the IBTS sought expressions of interest from universities where there were medical schools to undertake this research. It is expected that the International Peer Review Group will evaluate the proposals in 2011 and award the contract.

The performance of the Blood Transfusion Service is driven by the commitment and professionalism of our staff. Despite the difficult operating environment the staff have maintained a quality service and have ensured a consistent supply of safe blood. I would like to commend them for their efforts and for the manner in which they approach this vital service to patients and donors.

Andrew Kelly

Chief Executive



Medical and Scientific Director's Report



It is a truism in medical practice that where more than one treatment is available for a disease, none of them is completely effective. Watching economists generate heat rather than light in their prescriptions for our economic woes, a dispassionate observer might conclude that it is fairly obvious that none of them can be certain either of the future, or of the effect of their proposed actions on that future. Science, after all, even if economics is a science, does not predict the future: the best it can do is to provide a better set of questions to guide us through the fog¹. Instead, we are obliged to live with uncertainty, and to manage the uncertainty of the future with a greater or lesser degree of caution and a balancing of unavoidable risk.

Blood transfusion requires a high degree of managing the future: during the last thirty years tsunamis of disaster have swept over transfusion on several occasions, coming from a clear blue sea to carry away thousands of lives – HIV, Hepatitis C and Hepatitis B. Variant CJD, the human form of mad cow disease could well have followed in their wake; if it has not then it has been by luck rather than judgement or evasive action – by 1996, when we first became aware that the human disease even existed, it was too late to stop the first wave of transfusion transmissions. That that wave was very small was due to the fact that the number of food-derived cases of vCJD was nearly one thousand times fewer than was considered plausible around that time².

It follows that infectious risk from blood transfusion is more like the risk of civil disaster than the risk of a medical complication of treatment, at least from a public point of view. Measures to reduce that risk should be considered more as measures to reduce civil risk, similar to those for risk associated with aviation, road traffic, or environmental hazards, rather than as a problem simply associated with medical care of individual patients. Does anyone imagine that the National Car Test should be waived in these times because of difficulty in paying, or that we should scrap the requirement for seat belts in commercial vehicles to bring down the cost of motoring for businesses or that a certain airline should be able to hire out seat belts on aeroplanes at a premium to those prepared to pay a little extra for the additional safety? Methods to mitigate grave risks in civil society are managed differently to the way improvements in medical care are introduced, or the way access to such improvements is managed in the community. Yet in blood transfusion safety improvements are costed as if they were medicines, and not the disaster-prevention or disaster-mitigating steps that they are.

Of course that is not to say that proposed measures for blood safety should not be effective, or at least likely to be effective, and affordable, and safe to use. Obviously too they should be subjected to a competent and objective assessment, remembering that time is important – the risk of silently spreading a new infection by blood is ever-present.

As the decline of the Irish economy continues, the problem of affordability of safety measures for the blood supply becomes more intense. From the

¹ Robert May. Risk and uncertainty. Nature 2001 Jun 21;411(6840):891

² Ghani AC, Ferguson NM, Donnelly CA, Anderson RM. Predicted vCJD mortality in Great Britain. Nature. 2000 Aug 10;406(6796):583-4.

Medical and Scientific Director's Report

late 1990s the Irish Blood Transfusion Service has been an early adopter of emerging technologies for improving blood safety. Universal leucodepletion – a technique of filtering all units of blood to remove the white cells; nucleic acid testing – the most sensitive testing available to detect early infectious donations with HIV, hepatitis B and hepatitis C; extensive haemovigilance; bacterial testing of platelets, and other techniques and technologies – all were introduced well in advance of most countries in the developed world. While the cost of producing blood rose in parallel, this was always considered a price worth paying for risk attenuation and mitigation so obtained.

Now however, the money to pay for safety improvements in blood transfusion is obtained only in competition with other demands for the taxpayers' euro, and measures to prioritise the allocation of funds are required. While that is unavoidable, the costing model that considers blood transfusion risk as a disease to be treated, rather than a disaster-susceptible phenomenon to be managed, needs reappraisal. To be fair, all countries seem to grapple with this problem, and few if any have reached an explicit solution.

During 2010, the IBTS participated in a health-technology assessment conducted by the Health Information and Quality Authority into a new prion filter. This is a disposable device designed for use with every unit of blood collected that may, or may not, reduce the residual risk of transmission of vCJD through blood transfusion from donors who are silently carrying the disease. That risk is likely to be very small, though no one can say it is zero. There

is a considerable degree of uncertainty. The filter is expensive, and would add considerably to the costs of blood transfusion. That money has to come from somewhere else in the health care system as things now stand, and someone has to decide whether to extract that money or not. There is no universally right answer – no other country has deployed this device, but apart from the UK, no other country has our level of risk, unquantified though that level may be.

The process of engaging HIQA in a transfusionrelated health technology was a first for Ireland. Such a process is regularly used elsewhere, where Governments make decisions about blood safety at ministerial level rather than leaving it to the transfusion services themselves. The final report of the HIQA health technology assessment was not yet available by year end, and a ministerial decision will be awaited in 2011. However the exercise itself was a philosophical watershed in Irish health care - the power to determine the introduction of new technologies and to pass the costs onto consumers went from being in the almost exclusive gift of the IBTS to a more complex interagency process. This is as it should be, and more closely mirrors the process in other states. However it is essential that in this process the IBTS retains the capacity to respond to emerging threats and emerging technological advancements that has served blood safety in this country well in the recent past, notwithstanding the inevitable associated costs. Something has been lost, and needs to be retrieved, while the needs of all patients, not just transfusion recipients, are comprehensively addressed.

While the infectious protein that is the agent of vCJD causes a lot of concern in the world of blood transfusion, viruses continue to exact their share of attention. There was a new addition in 2010 to the zoo of viruses that require consideration and often action. XMRV -xenotropic murine leukaemia virus related- virus - was reported as being associated with, and possibly causing, the debilitating condition of chronic fatigue syndrome, or ME as it's more commonly known here. It was considered possible that the virus, and possibly the disease, could be transmitted by transfusion from carriers. There was no direct evidence of this, and by year end the spectre was fading, but it served as a reminder that as yet uncharacterised viruses circulate among us, and there are many chronic diseases that are not currently explained, and that may in some way be caused or sparked off by a virus, that in turn could be spread by transfusion.

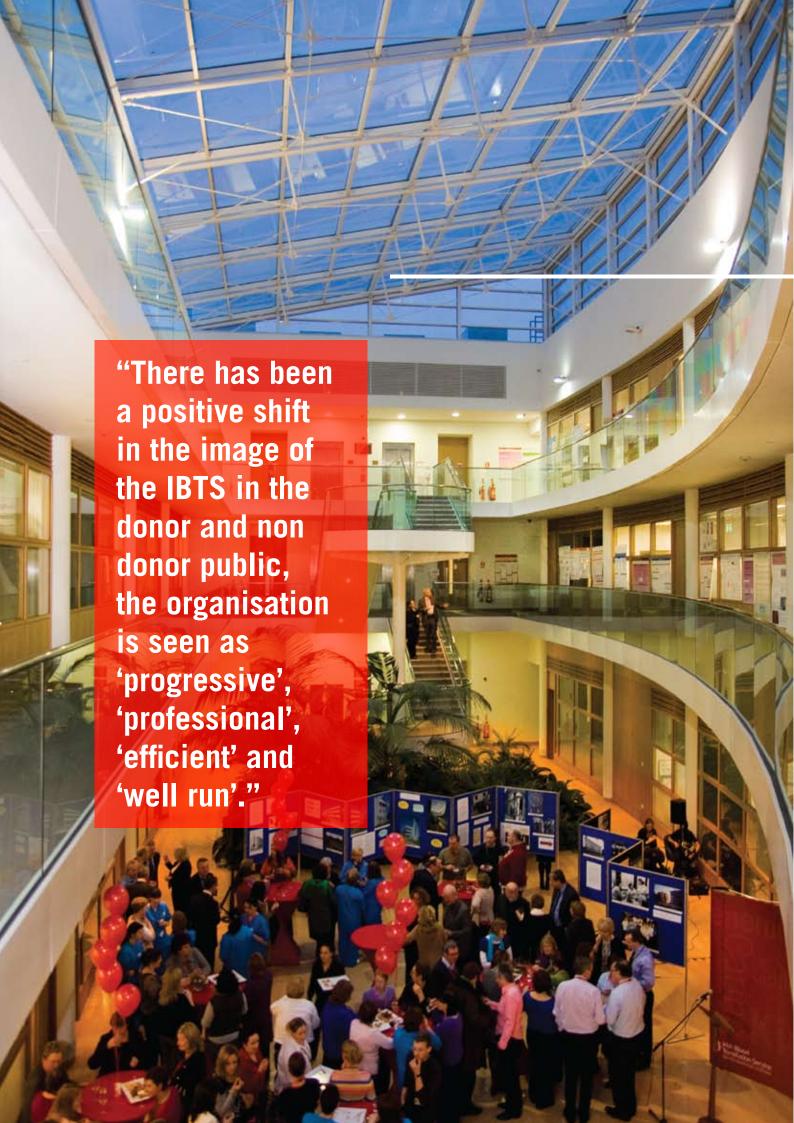
Apart from XMRV, and the set of major viruses we test every donation for³, the viruses that required further consideration or action during the year were Dengue, West Nile, Rift Valley Fever, and St Louis encephalitis. An outbreak of Q fever, a non-virus infection, in the Netherlands, also gave rise to concern.

Not all problems associated with transfusion are infections, and issues of supply and costs are a constant challenge. In addition, non-infectious complications of transfusion exist. Most of these are captured and addressed through the haemovigilance system, but from time to time new issues emerge. Questions around the efficacy and indeed the

safety of blood that has been stored for longer than 2 or 3 weeks continue to be the subject of intense investigation worldwide; while it is by no means clear that prolonged storage is a clinical problem, definitive studies to address the question are underway in the UK, the US and elsewhere, and will be watched closely in the IBTS. It has become apparent in recent years that healthy donors with normal blood counts may have very low iron stores unbeknownst to themselves and to the blood transfusion services - measures to investigate this were introduced in the IBTS on a pilot basis in 2010, and will be developed further in the future. Lastly, on the opposite side of the iron question, the involvement of the IBTS with the clinical management of haemochromatosis in Ireland continued successfully in 2010 – several hundred people with haemochromatosis regularly attend IBTS clinics for their treatment and regular care. Plans to enlarge this commitment in the future are under very active consideration.

Dr William Murphy

Medical & Scientific Director MD, FRCPEdin, FRCPath



Operations



Qualitative Research

The IBTS undertook qualitative research amongst donors, lapsed donors and non donors to gain insight into people's attitude towards IBTS, blood donation and to measure this in the context of cultural changes since our last piece of qualitative research six years ago.

The research demonstrated a shift in values where people are keen to get back to basics with regards to their communities, friends and families, which is a favourable environment for blood donation campaigns.

Current blood donors agree with our brand sentiment and cite that it evokes positivity around blood donation 'give blood, you get more than you give'. Donors were also asked if blood donation was akin to supporting a charity and this proposition was firmly rejected as donors clearly felt that giving blood is of a much higher order than giving to charity.

There has been a positive shift in the image of the IBTS in the donor and non donor public, the organisation is seen as 'progressive', 'professional', 'efficient' and 'well run'.

Communications most favoured by participants included radio advertising, thank you text messages, www.giveblood.ie and the IBTS facebook page. IBTS merchandise rated very highly among regular donors, where such pencils, pens, key rings and other items are recognised as a token of appreciation and novel, useful gifts.

Research among non donors showed that the main reasons for not giving blood included an acute lack of awareness of the need for blood, where you could donate, the process of blood donation and a preference to only consider blood donation in the context of a group and not something to be braved alone. This research, carried out by Behaviour and Attitudes, won in the Public Policy/Social Research category of the Marketing Society 2010 Research Excellence Awards.

World Blood Donor Day

World Blood Donor Day was marked with a human blood drop, assembled on Sandymount Strand, with no less than 150 volunteers who stepped out to mark Ireland's contribution to the world wide campaign. We assembled staff, donors, facebook fans, Defence Forces personnel and volunteers to raise awareness of the day itself and the constant need for blood in Ireland.

ADfx Awards

The IBTS advertising agency, Cawley Nea\TBWA was honoured with an Advertising Effectiveness Award for our 'crisis to consistency' TV ad campaign at the IAPI ADfx awards in October 2010. As the blood supply reached a consistent level and there was an increase in donation frequency the campaign was recognised for its success in the Public Service, Social Welfare and Education category.





Donor awards ceremonies

In 2010 award ceremonies were held in Dublin, Cork, Limerick, Ardee, Carlow and Claremorris. A total of 856 blood and platelet donors were honoured for either 50 or 100 donations to date. Each and every ceremony was well attended and comprised of presentations, a celebration meal and recipients of blood and platelets who shared their story with the people who helped saved their lives.

Ezine

Bloodlines, our new electronic newsletter was launched in 2010. It is circulated to 90,000 donors on a quarterly basis. We include donor and recipient stories, science features, events nationwide, donor facts and statistics, development updates, campaign information and more.

Initial reaction to the Ezine shows a 97% satisfaction rate with the Ezine, where donors cited it as 'a great idea', 'informative' and 'an enjoyable read'.

10 year celebration

November marked the 10 year anniversary of the National Blood Centre relocating to James's street. To mark the occasion staff past and present were invited to view an exhibition of photographs from the IBTS archives and a scientific poster exhibition. IBTS Chairperson Katherine Bulbulia opened the exhibition and a guest speaker and blood recipient told her moving story of how blood donations saved her life and that of her newborn daughter.

"Initial reaction to the Ezine shows a 97% satisfaction rate with the Ezine, where donors cited it as 'a great idea', 'informative' and 'an enjoyable read'."



Lifeblood24

In response to the constant need for O negative blood, we developed and rolled out a campaign to capture a 'rapid response' group of O negative donors. This now comprises of almost 1000 donors, who have pledged to give blood within 24 hours of a call or text message. These donors are affiliated to one of our 3 fixed centres nationwide and have been successfully called to action twice since the initiative has been set up.

National Apheresis Programme

The apheresis programme at the NBC and IBTS Cork Centre allows donors to give a particular blood component, platelets on a monthly basis. The technology extracts whole blood, separates the platelets from the red cells and plasma and allows these to be returned to the donor. Platelets can be collected as single, double or triple donations.

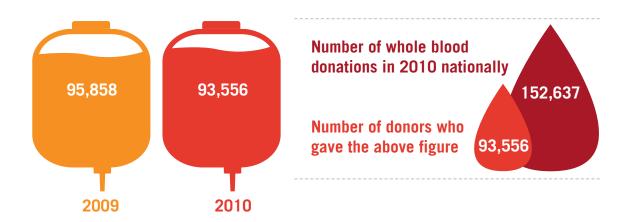
During the year 997 donors joined the national apheresis donor panel. 11,224 platelets donations were given, amounting to 22,258 individual doses collected. This was an increase of 12.5% of donors giving platelets and an increase of 11% on the total doses collected.

The introduction of the appointment scheduler in BOSS has proved to be very successful, while an education programme on blood groups is ongoing.

"There was an increase of 12.5% of donors giving platelets and an increase of 11% on the total doses collected."

Donor Statistics

Donors 2009 vs 2010

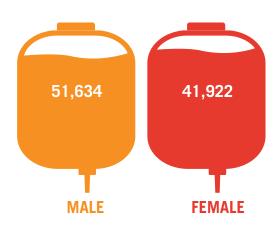


Whole Blood Donations by Donors

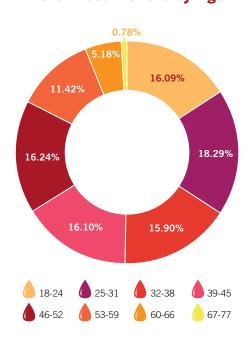


Number of Donors

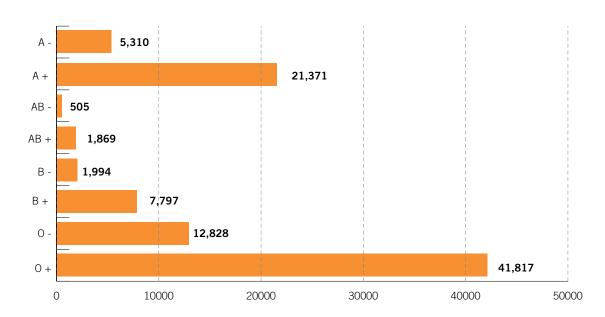
Whole Blood Donors by Gender



Whole Blood Donors by Age



Whole Blood Donors by Bloodgroup



Hospital Services

The scope of the Hospital Services function within the IBTS covers the management, storage, packaging and distribution of blood, 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.

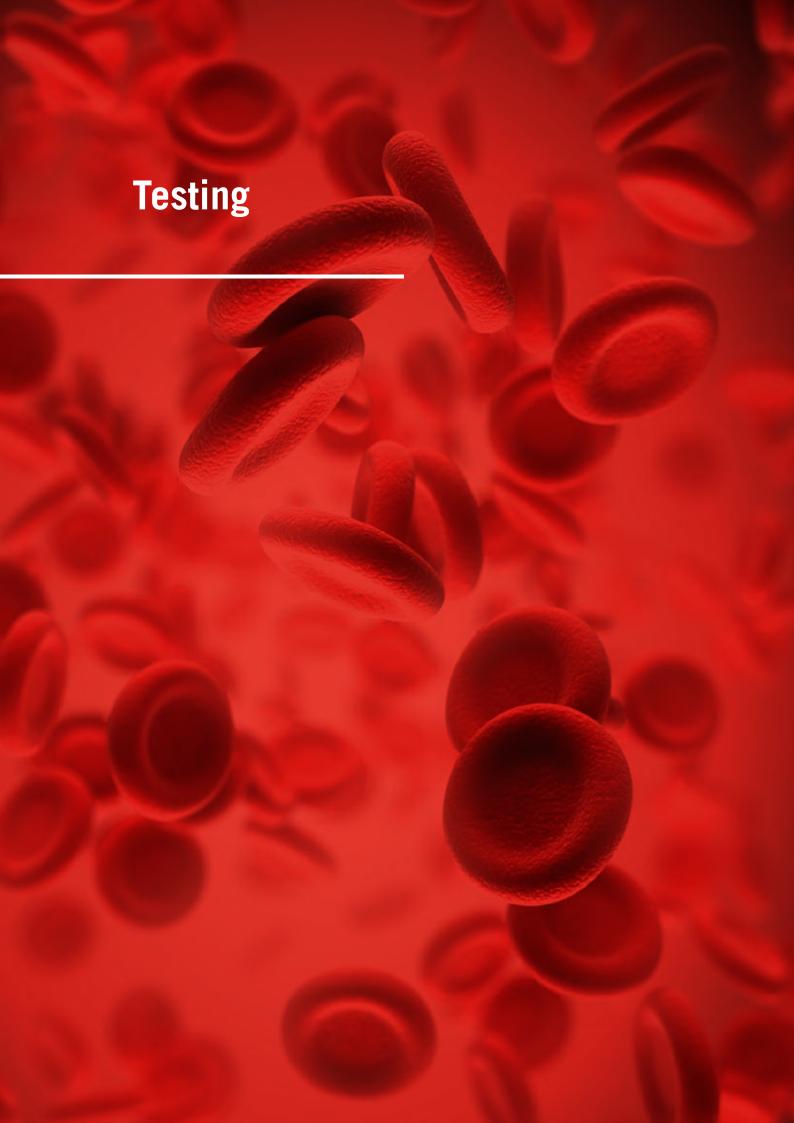
The departments in both centres are responsible for the safe and secure distribution of all products released for treating patients and work closely with Components on a day to day basis in each centre.

They distribute both routine stock orders and non routine stock orders. Hospital Services operates on

a 24/7 basis. 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 introduction of changes in work practices in late 2008 provided an opportunity to streamline processing of blood donations. Since then all processing, labelling and bag label verification of products and release for issue to Hospital Services is now performed by dedicated Components Staff. The laboratory now has defined areas to perform primary processing, secondary processing and issue of non routine stock orders.

Blood, Blood Components & Blood Products Issued				
Product	2010	2009		
Red Cells & Whole Blood	137,933	142,459		
Platelets - Therapeutic Doses	24,394	26,256		
Frozen Plasma	249	447		
Octaplas	23,075	23,401		
Cryo Depleted Plasma	-	39		
Cryoprecipitate	68	1,316		
Factor VIIA (xIU)	122,050	286,950		
Factor VIII Recombinant (x IU)	34,361,750	30,979,500		
Von Willebrand Factor (x IU)	623,500	1,057,500		
Factor IX Recombinant (xIU)	9,848,250	8,912,250		
Prothromplex (x IU)	643,800	481,200		
Factor XIII	6,000	6,000		
Plasma For IVD Use (Litres)	30,000	-		



Nucleic Acid Testing (NAT)

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. The Tigris instrument is a fully automated closed system for NAT testing of individual donations with the Procleix Ultrio assay. The Procleix Ultrio assay is a multiplex 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 instrument provides inventory management, and has a wide range of built-in process controls to help ensure cGMP compliance. The inclusion of HBV DNA detection in the assay provides the blood supply with an additional margin of safety. The Ultrio assay has demonstrated its ability to detect low viral load donations during the pre-seroconversion window of infection by detecting the first NAT HBV yield case in 2009.

An archive sample is retained on all donations. Every donation collected in 2010 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). IC is added to each test sample via the addition of working Target Capture Reagent (wTCR). The IC is used to control sample processing, amplification and detection steps and used to ensure all manufacturer testing processes are operating correctly. Tigris Bracket Controls are used following testing of every 100 samples in each work list. Calibrator results must meet assay specifications.

Inter-laboratory comparisons using EDCNet software and participation in External Quality Assurance Schemes (EQAS) in 2010 allow the IBTS 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 has improved considerably in 2010 with minimal impact on the processing of blood and blood products by the Components laboratories at the NBC and MRTC. 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 at the time of donation. The sample is tested for the presence of specific viral markers that may be transmitted by transfusion. Over 160,000 donations were tested in 2010.

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. The Abbott Prism underwent a major software upgrade and selected hardware refresh programme in 2010. 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 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 UK', and a multimarker control from Acrometrix as 'go/no go' controls on all testing runs. This ensures that equipment is functioning to the highest standard. 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 Blood Service/Health Protection Agency. The confirmed positive rates and reactive rates for testing kits and confirmatory results using various lot numbers of reagents with the National Blood Authority 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) study on serological testing for Hepatitis B Surface Antigen.

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. These tests improve not only the safety of red cell products, but also increase the efficiency of providing red cells of rare or complex phenotypes in response to specific requests from hospitals.

In 2010 over 165,000 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 the year there were over 13,500 new donors, which represent 8% of the total donations.

Over 38% of donors receive a full Rh phenotype (C, c, E and e type) every time they give blood 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.

In 2009 Olympus Diagnostics Division was purchased by Beckman Coulter, who will now supply the PK7300 blood typing machine. In early 2010 a new PK7300 was installed and began its extensive validation procedures. The PK7300 has a higher throughput rate and the operating system shows many changes to improve the quality control within the testing procedures. This will mean once again that the donor grouping laboratory in the National Blood Centre will be using the most up to date automation to provide a high quality, cost effective testing system for typing blood donations in Ireland.

The donor grouping laboratory has seen major changes in 2010 apart from the introduction of the new blood grouping technology. To make most efficient use of this new technology, all blood group testing in Ireland was consolidated at the National Blood Centre in Dublin in July. 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.

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.

Screening for the presence of high titre anti-A and anti-B haemagglutinins is performed on all donations in the IBTS using a saline agglutination method on the PK 7200. This is regarded as a risk reduction measure to reduce the risk of haemolysis associated with the administration of non ABO identical plasma replete products to patients. However this test does not identify all potentially haemolytic antibodies as highlighted by successive Serious Hazards of Transfusion (SHOT) and National Haemovigilance Office (NHO) reports.

The Special Advisory Group for Immunohaematology Committee (SAC-IH) which has IBTS representation in an observer capacity is reviewing this issue

for the next edition of the Red Book (Guidelines for the UK Blood Transfusion Services). The UK Blood Transfusion services have been reviewing their procedures and in particular the feasibility of screening donations for immune (IgG) type antibodies as an alternative to saline or mainly IgM reacting antibodies technique. The IBTS donor grouping laboratory completed a short evaluation of this technique using column agglutination cards and ascertained that a significant increase in donations would be labelled for ABO matched use only.

During 2008/2009 the donor grouping laboratory evaluated the latest technique in antigen typing. This PCR technique involved the extraction of DNA and using it to establish the genotype of many various blood group antigens using a Bioarray method. As a direct result of this project it was established that some individuals show a difference between their serological typing result and their true genotype. Since this technique was released there have been further advances in the use of DNA techniques to type for various blood group antigens. It is planned to evaluate these new techniques in 2010 – 2011. These tests are changing rapidly and are at present relatively expensive, but some are at the stage of becoming fully automated techniques, which would make them far more cost effective and easier to implement on a more routine basis. This again will keep the Irish Blood Transfusion Service at the forefront of blood typing innovation.

"Automated donor grouping is continually striving to introduce the most up to date testing techniques"

NHIRL

National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL)

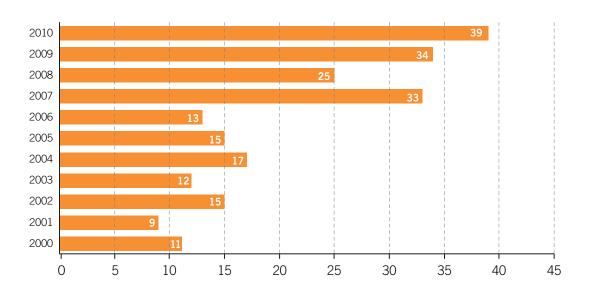
The National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL) provides a comprehensive range of clinical testing services designed to support the allogeneic haematopoietic stem cell transplantation (HSCT) programmes at St. James's Hospital and Our Lady's Children's Hospital, Crumlin. 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 and maintained this status following an inspection in September 2010.

Number of Irish Patients receiving a HSCT from an Unrelated Donor 2000-2010



In 2010 samples from 215 Irish patients for potential haematopoietic stem cell transplants and their relatives were HLA typed by the NHIRL. For those patients without a suitable family donor, an unrelated donor may be identified from the registry of volunteer donors. The NHIRL provides an immunogenetics support service for the Irish Unrelated Bone Marrow and Platelet Registry (IUBMR) and in 2010 the laboratory HLA typed 933 new volunteer donors to add to the registry.

In the last 11 years the IUBMR has facilitated 223 unrelated donor transplants for Irish patients, one third (n=73) of these transplants have been performed in the last two years, with 39 being facilitated in 2010 alone.

The NHIRL also provides a routine disease association HLA typing service. This service represented over 50% of the investigations performed in 2010. 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.

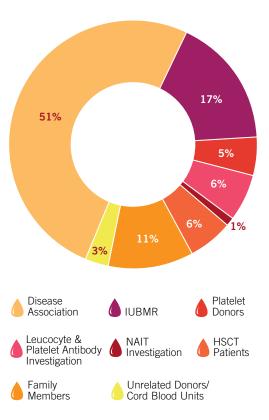
In addition, a platelet immunology service for the serological investigation of neonatal alloimmune thrombocytopenia (NAIT), post transfusion purpura (PTP), platelet refractoriness, alloimmune thrombocytopenias and adverse transfusion reactions is provided.

A total of 265 new 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 introduction of the Luminex instrumentation in September 2010 has made a significant contribution to the screening and identification of HLA Class I antibodies and on the selection of HLA matched platelets for patients with alloimmune platelet refractoriness.

Overall the NHIRL saw a moderate rise in the number of specimens received for investigation from 6039 in 2009 to 6061 in 2010.

NHIRL Investigation Distribution



Diagnostics

Diagnostics NBC

The diagnostics laboratory at the NBC provides red cell immunohaematology and antenatal services for hospitals nationwide.

The services provided by the Diagnostics Laboratory include;

- Provision of phenotyped blood (not available on the shelf)
- Provision of crossmatched blood for 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 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 dependent patients.

In total, over 2000 samples were referred in 2010.

The Emergency Reference Red Cell Immunohaematology On-Call Service, for patients with a clinically urgent requirement for antibody investigation/compatibility testing is in place. There were over 70 cases where a scientist was required to provide service in 2010 (a decrease of 14% from 2009).

2010 failed to see ISO 15189 implementation, despite a satisfactory INAB pre-Inspection. A number of issues require resolution before the laboratory can proceed. These relate specifically to where the IBTS acts as a blood bank for a number of hospitals. Further discussions are planned with the accrediting body. The validation and introduction of anti-c Quantitation Testing will be completed in early 2011.

Molecular test development continued in 2010 however as no capital expenditure was allocated for patient testing for 2011 this project is currently on hold. 2011 will see introduction of Donor RhD molecular typing.

The Diagnostics User Satisfaction Survey was conducted in 2010. The overall satisfaction with the laboratory was 78%. Further surveys will be circulated in 2011 to monitor customer satisfaction.

Diagnostics Laboratory Cork

Clinical and laboratory immunohaematology services are provided by the diagnostics laboratory at the Cork Centre which include: routine serology services for Cork city hospitals, reference service for hospitals in the Munster region on a 24 hour seven day basis, secondary processing out of hours, component modification and special preparations for paediatric patients. The diagnostics laboratory also investigates suspected transfusion reactions in all hospitals for which we provide compatibility services.

The diagnostics laboratory has responsibility for the management of platelet inventory and supply and to ensure that platelet components are negative by bacterial testing at time of issue to patients. Hospital requests for special red cell requirements, including paediatric requirements, specific antigen negative red cells, cytomegalovirus negative and irradiated red cells are also managed by the diagnostic laboratory on a 24 hour seven day basis throughout the year, for all routine and emergency requests.

During 2010 activity was as follows:

- 3,152 samples were referred to the laboratory; compatibility testing was undertaken for 1,616 samples and 3,464 corresponding red cell preparations were issued.
- 410 antibody investigations were carried out, of which 256 were reference samples received from hospitals with blood banks.
- 84 patients had rhesus phenotype determined and a further 3,302 antigen typing tests were performed.
- 877 direct antiglobulin tests were undertaken, of which 303 required a Mono-Specific DCT.
- 5 suspected transfusion reactions were investigated.

Of the samples received 377 were managed as emergencies within the working day (i.e. outside routine batches) and in addition 449 were processed as out of hours emergency by evening/night duty staff.

1002 red cell components not clinically applied at St. Mary's Orthopaedic Hospital, Mercy University Hospital and South Infirmary Victoria University Hospital were transferred to Cork University Hospital Blood Bank. 993 (99%) of these were subsequently transfused at CUH.

A blood bank was established in the Mercy University Hospital in 2010 to carry out activities relating to Crossmatching of blood components for the patients in that hospital. This service was previously provided for by the IBTS at MRTC.

100% traceability compliance was achieved with the bag and tag traceability system. The traceability manual is available on the IBTS website. (www. giveblood.ie/clinical_services/hospital_services/ traceability)

"The Diagnostics User Satisfaction Survey was conducted in 2010. The overall satisfaction with the laboratory was 78%."



Tissue Bank

The Tissue bank at the NBC is comprised of the National Eye Bank, the Heart Valve Bank and the Directed Cord Blood Bank and is licensed under the EU Quality and Safety of Human Tissues and cells regulations 2006.

The eye 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. 2010 saw a continued increased demand for pre cut (DSAEK) corneas for endothelial keratoplasty. DSAEK corneas now account for 37% of all corneas issued. There was a 100% increase in demand for pericardium during 2010 while other tissue remained static with 2009 figures.

The IBTS also provides autologous serum eye drops for patients upon request from an ophthalmologist. The IBTS in association with the ophthalmic director of the eye bank, Mr. William Power, RVEEH and Professor Martyn Clynes and Dr. Finbarr O'Sullivan DCU successfully transferred the culturing of limbal stem cells from DCU to a GLP setting in the IBTS. During 2011 this work will transfer to a GMP setting and then seek authorisation from the IMB to produce limbal stem cells for clinical use under the Advanced Therapy Medicinal Products directive. This project has been made possible by a bequest from Ms Edith Bingham.

The IBTS continues to process, cyropreserve and distribute human cardiovascular tissue on behalf of the Mater Misercordiae University Hospital. The cardiothoracic director of the heart valve bank, Prof. A. E. Wood retired during 2010 and was replaced by Mr. Lars Nolke, MMUH / OLCHC. 2010 saw close to a 40% reduction in heart valve donations to the bank. This is in line with the reduction also observed in organ donation.

Therapeutic Apheresis Service

The Therapeutic Apheresis Service is run from the National Blood Centre and the Cork Centre, providing Therapeutic Apheresis treatments to patients.

Treatments are provided on request from the patient's primary medical care team. It is a demand led service characterised by peaks and troughs, with all treatments performed in an acute hospital setting.

An IBTS Consultant Haematologist leads the service and a medical evaluation of the patient is performed by IBTS specialist medical staff. If the treatment is deemed appropriate and the patient is fit, the treatments are managed and administered by specially trained therapeutic apheresis nurses. Apheresis procedures are performed on patients with rare and often life threatening Haematology, Renal, Neurology or Hepatology disorders.

The majority of procedures are plasma exchanges but other treatments provided include, red blood cell exchange/depletion, leucodepletion and platelet depletion.

Case load

The total number of procedures performed

• 2010 = 395

This compares to previous years;

- 2009 –Total procedures = 473
- 2008 Total procedures = 504
- 2007 Total procedures = 428

Type of Procedures

The majority of procedures this year were Plasma Exchange, 99% (n=391), while the others were White Cell Depletion (n=1), Red Cell Depletion (n=2) and Red Cell Exchange (n=1).

The procedures are mostly nurse led with medical support by the hospital medical team. 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.

Procedures are categorised 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.

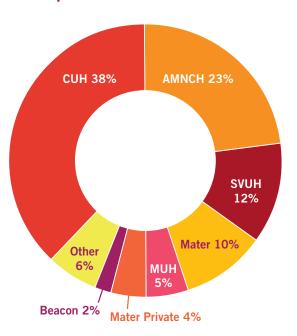
Out of Hours procedures

The working week is nominally 9am-5pm, Monday to Friday. An 'on call' rota system exists, currently applicable from 9am to 9pm at weekends and public holidays only. However, therapeutic staff have facilitated and responded to emergency demands outside these hours: 11% of all procedures in 2010 were provided outside normal working hours with a total of 23 procedures performed at weekends. These cases are classified as Emergency or Urgent.

Procedures by hospital

Hospital	No. of Procedures		
AMNCH	91		
SVUH	49		
Mater	42		
Mater Pvt	18		
Beacon	10		
SJH	2		
SVPH	2		
Connolly	1		
Rotunda	1		
CUH	152		
MUH	22		
Bons Secours	5		
Total	395		

The service provided procedures to 12 hospitals in 2010



National Haemovigilance Office (NHO)

Haemovigilance is internationally recognised as essential to the development of safe clinical transfusion practice. In Ireland, Haemovigilance is co-ordinated by the National Haemovigilance Office (NHO) based at the IBTS. In the ten years of its operation (2000-2009), a total of 2127 serious adverse transfusion reactions/events have been reported to the NHO.

Serious Adverse Events (SAEs) and Incorrect Blood Component Transfused (IBCT)

SAEs relating to the quality and safety of blood which are mandatory under the EU Blood Directive 2002/98/EC are collected by the NHO. Non mandatory SAEs, termed Incorrect Blood Component Transfused (IBCT), relating to errors in clinical areas, are also reportable under professional responsibility. The total IBCT SAEs reported to the NHO in 2009 was 157 representing 59% of all incidents (157 of 267) of which 46 (29%) were classified 'mandatory' SAEs.

Serious Adverse Reactions (SARs)

In 2009, 110 SARs were accepted by the NHO, mainly in Acute Allergic, Anaphylactic Transfusion and Febrile Non-Haemolytic Transfusion Reactions categories.

Four cases of Suspected Transfusion Transmitted Infection (STTI) (three viral and one bacterial) were reported. Transfusion transmitted infection was excluded, or considered unlikely in all cases.

Annual notification of Serious Adverse Reactions and Events (ANSARE)

Compliance with Commission Directive 2005/61/ EC Annex II D and III C for hospitals transfusing blood requires all hospitals transfusing blood and all blood establishments (BE) to complete and return an ANSARE form. Seventy-five reporting establishments submitted reports for 2009. Of the 267 reports accepted by the NHO, 154 (58%) were reported on ANSARE.

No of Reporting Establishments	Reported in 2009 on ANSARE	
17 (23%)	One or more SAR	
6 (8%)	One or more SAE	
16 (21%)	Both SAR and SAE	
36 (48%)	No SAR or SAE	

The ANSARE does not collect non-mandatory clinical IBCT incidents, which accounted for 41% of the total number of reports accepted by the NHO in 2009. Therefore, these results underestimate the overall reporting rate to the NHO from participating establishments.

NHO Annual Conference (2010)

"Haemovigilance, a Culture of Quality and Safety in Transfusion"

The NHO Annual Conference was held in the Gresham Hotel, Dublin, in November, 2010, with 200 delegates attending, drawn from medical, nursing and scientific backgrounds.

The programme covered a range of areas relating to Haemovigilance such as improving practice by learning lessons from reported reactions and errors, problems and issues for the transfused patient, the appropriate use of blood and blood products and issues that can arise for hospitals.

Dr. Emer Lawlor, marked her retirement as Director of the NHO by presenting reflections on ten years of NHO, highlighting the contribution of the programme to patient safety during the decade as Haemovigilance developed in Ireland. The NHO team provided a summary of the recommendations and findings of reports received in 2009. Other Haemovigilance Officers (HVO) presented aspects of their work, with a number of posters on display during the Conference.

A workshop for doctors in training was also held in the National Blood Centre the following day to cover specific transfusion related issues.

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 HVOs. In addition, efforts are being made to expand transfusion specific education and training for medical staff.

Open Days

The NHO arranges 'Open Days' for all newly appointed HVO to explain the operations of the NHO, especially reactions and event reporting. One open day was held in 2010 with 22 people attending.

Haemovigilance Education Initiatives at DCU

The partnership between the NHO and Dublin City University (DCU) continued during 2010. Two degree level stand alone modules were delivered in February and March 2010. Students from both clinical and donation practice areas completed these modules.

In September 2010, three students commenced a post graduate diploma in nursing, during which they will complete four core modules and two optional haemovigilance modules, before completing research in their chosen subject area. The NHO co-ordinates and delivers the haemovigilance modules and provides ongoing academic and practice supervision of the core modules.

The availability of degree programmes afford a unique opportunity to progress to post graduate study in Haemovigilance at DCU and delivers a recognised pathway for transfusion practitioners to develop their roles to advanced specialist level.

Irish Unrelated Bone Marrow Registry (IUBMR)

E-Learning

The National implementation of the e-learning programme developed and co-ordinated by the 'Learnbloodtransfusion' Editorial Group and the Scottish National Blood Transfusion Service continued throughout 2010. The programme is now mandatory in some tertiary institutions and reporting establishments. New modules on Anti D Immunogloblin, Paediatrics, and Good Manufacturing Practice were launched, and the programme now comprises a total of 8 modules. The IBTS continues to support the development of the curriculum while the NHO participates in the editorial review of the programme content.

The IUBMR was set up in 1989 to meet the need for unrelated stem cell donors for Irish and international patients. The panel currently consists of 20,362 donors of whom 836 were recruited in 2010. Since 2001 all donors accepted on the unrelated panel are typed exclusively by DNA methods by the National Histocompatibility Immunology Reference Laboratory (NHIRL).

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 14 million volunteers of the 57 volunteer donors stem registries throughout the world provides a suitable alternative and the numbers of matched unrelated transplants has increased markedly in the last few years both in Ireland and Worldwide.

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). The Registry works closely with the EFI accredited NHIR laboratory in the IBTS to ensure optimal patient and donor selection.

Also, in conjunction with SJH, the IUBMR coordinates donations from Irish donors for Irish and international patients. The registry is licensed by the Irish Medicines Board under the EU Tissue Directive 2004/23/EC.

The IUBMR has been affiliated to the World Marrow Donor Association (WMDA), an organisation which sets operational standards for bone marrow registries worldwide since 1991. The IUBMR achieved accreditation status with the WMDA in 2007.

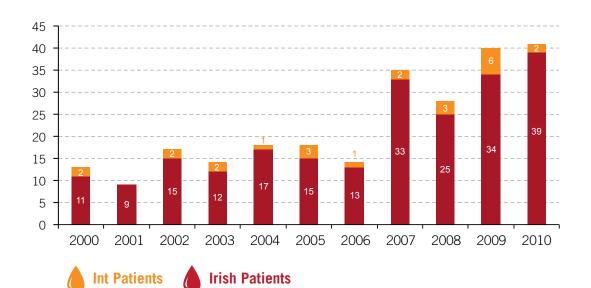
In June 2010, the IUBMR hosted the prestigious Biannual WMDA Conference in Trinity College with the largest attendance to date (250) since the Inaugural Conference in 1998. The working group meetings before the conference also surpassed previous attendance figures.

The topics discussed at the 2 day event included the use of cord blood in the unrelated transplant setting, HLA and population genetics, new developments in the use of haematopoietic stem cells (HSCT) and late effects in donors.

Umbilical cord blood transplants are an alternative for some patients who do not have a suitable volunteer donor but due to the small size of the cord product, cords are usually only suitable for children. Recently it has been shown that transplantation of two cords provides enough stem cells for adults. In October in conjunction with SJH the IUBMR facilitated the 1st double cord transplant in Ireland for a patient with AML who did not have a matched or suitably mismatched donor available.

In 2010 sixty (60) patients were referred to the IUBMR for unrelated searches from the Irish Transplant Centres at St. James's Hospital and Our Lady's Childrens' Hospital. The number of searches for unrelated transplants for Irish patients has continued to increase exponentially due to the changing indications for matched unrelated transplants and extension of the upper age limit for patients.

IUBMR Transplants Facilitated From Irish And International Donors 2000 - 2010



Irish Unrelated Bone Marrow Registry (IUBMR)

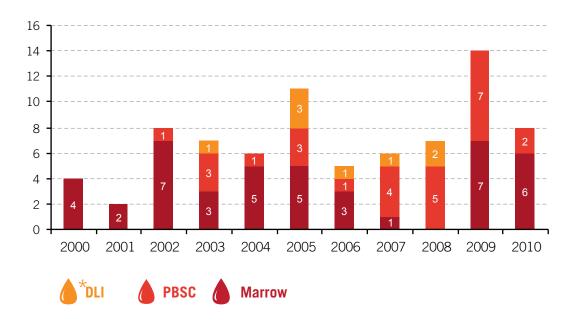
From 1995 – 2005 the average number of transplants facilitated for Irish patients was 13. In 2006 the number of patients referred to the IUBMR was 41 and 13 subsequently proceeded to transplant. In 2010, 60 patients were referred of whom 39 proceeded to transplant. Twenty eight (28) stem cell donations were sourced from Europe including Ireland (6) and eleven (11) from outside the EU.

Bone marrow was the preferred product for most patients (22). Thirteen, (13) patients received peripheral blood stem cells (PBSC) and four (4) of the patients received unrelated cord blood units (CBU) as a source of stem cells.

Preliminary searches were received on behalf of 347 international patients of which 124 were activated for additional typing requests. Two (2) donors went on to donate for international patients.

* Donor lymphocyte infusions (DLI) are white cell infusions from the same stem cells donor which are sometimes given post transplant to prevent relapse or fight infection.

Irish Unrelated Bone Marrow Registry Irish Unrelated Donors Stem Cell Donations 2000-2010



Directed Cord Blood Programme

The IUBMR also co-ordinates the collection and storage of cord blood for directed stem cell transplantation. The cord unit is only harvested from the mother of a child with a haematological or other disorder where a stem cell transplant is likely to be indicated in the future and where a request is submitted by the affected childs Haematologist/ Oncologist.

On receiving a request for a cord blood collection, the CNMII of the IUBMR travels to the appropriate maternity hospital and trains both medical and nursing staff in the collection procedure.

The cord blood is stored in the National Blood Centre for the intended recipient's use only. In 2010, 9 cord blood units were collected. A total of 114 units have been stored 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.



Quality & Compliance

Close monitoring of the quality compliance metrics was focused on by both the Executive Management Team and the Audit and Compliance Committee of the IBTS.

In keeping with maintenance of the Blood Establishment Licensing requirements, the IMB carried out a total of 10 inspections on IBTS centres during 2010. These included a full licensing inspection of both the National Blood Centre and the MRTC and 7 inspections of both fixed clinic and mobile activities. The inspection of MRTC also combined an inspection under GDP licensing requirements.

A total of 18 non-compliances arose, with one classed as a major non-compliance. This related to customer service/despatch activities and is being addressed through a number of initiatives including electronic ordering by hospitals (to be rolled out nationally during 2011), reorganization of work flow activities and reinforced vigilance of despatch activities.

A full site audit of HLA activities was also carried out in September 2010, by EFI (European Federation of Immunogenetics) to monitor continuous compliance with standards. The outcome of the audit was favourable.

While the IBTS is subject to external audit on a continuous basis, there is also an active programme of internal audit according to GMP requirements. A total of 56 internal audits were conducted throughout the IBTS in 2010 covering all activities from collections through processing, testing and despatch.

A programme of auditing significant suppliers to IBTS was also in place, as well as auditing those hospitals where the IBTS acts as Blood Bank. Nine such audits were carried out in 2010.

As part of the Quality Management System, an IBTS wide process of capturing incident reports (IR) is active. Closure rate of IRs exceeded 85% during 2010. The majority of IRs were raised against manual activities conducted throughout the IBTS. Reporting of IRs is actively encouraged and is continually reinforced through training. The electronic capture of IRs through SMART CAPA was developed during 2010 with the future system design put in place. SMART CAPA will be launched for use IBTS wide during 2011.

Other metrics continuously monitored on a quarterly basis include close out rates of Change Orders and Change Controls, both of which exceeded the target of >80% close out by year end.

The drive to nationalise practice continued in 2010, with the target of achieving 815 national SOPs by year end met. This represents a significant movement from a base of 318 national SOPs when the initiative commenced. There has also been an overall reduction of 10% in the total number of SOPs within IBTS.

Quality & Compliance

Continuous improvement initiatives which drove efficiencies and change in 2010 ranged from

- separating NAT testing from component labelling operations thus facilitate longer run times required by Tigris (new technology)
- changes in work practices implemented in February 2010 in MRTC which facilitated covering 7.00am–7.00pm of laboratory and production operations
- introduction of dual barcode labelling (codabar and ISBT 128) for customers in June 2010, thus facilitating the hospital requirements for archiving unit id numbers
- implementation of the national grouping solution in July 2010, whereby all donor grouping activities are now carried out on Olympus technology at the NBC
- supply of plasma for IVD use since March 2010 has ensured a productive use for this material and consequently reduced waste stream volumes.

Donor service and product complaint systems are in place in the IBTS, with a national system for capturing donor service complaints.

There were 242 Donor Service Complaints recorded in 2010, approximately 21% related to clinic management, 15% to the donation process and 12% to deferral queries. It is envisaged that Donor Services will maintain this database with oversight by the QA function from mid 2011. A close out rate of 85.5% was achieved by year end, a decrease on 2009 close out rates.

There was an overall decrease in the number of product complaints recorded during 2010, with a total of 986 complaints received in 2010 as against 1182 complaints received in 2009. This represents almost a 20% decrease in complaints. A major contributing factor was the introduction of new loading patterns for the Bact Alert bottles used in the bacterial screening of platelet products. A decrease in false positive results was the outcome which translated into the reduction of complaints.

Consequently there was also a large decrease in the number of product recalls instigated during 2010, with a total of 269 recalls for 2010, as against 363 product recalls for 2009. This is the lowest level of recalls recorded since 2005. This is due to the reduction in recalls generated by false positive reactions due to limitation of the Bact Alert systems.

Associated with donor service and product complaints, the IBTS operates a Donor Vigilance, Haemovigilance and Tissue Vigilance system.

On January 1 2010, a National Donor Vigilance System was put in place. There were 414 donor vigilance events recorded, investigated and followed up by the Donor Consultant. Annually these figures are shared with other European Blood Services to look at trending and effect improvements.

Haemovigilance is operated within the Blood Establishment through measurement of major IRs as potential Serious Adverse Events (SAEs) within the QMS, and product complaints as potential SARs or Serious Adverse Reactions. These are compiled and through quarterly meetings with the National

Haemovigilance Office (NHO), they are designated as reportable or not.

The end of year report to the Competent Authority, the Irish Medicines Board (IMB), details the BEs, SAEs and SARs for that year.

There was a decrease in the SARs reported by the MRTC for 2010, this reflects the movement of the Mercy Hospital to establishing its own hospital blood bank on May 1 2010. Previously the MRTC acted as the hospital blood bank for the Mercy Hospital.

The number of SAEs from MRTC, for 2010 increased slightly to 44, 31 of which were manual grouping discrepant results. This revealed itself with the move to donor grouping testing being performed nationally on Olympus technology.

The NBC had a large increase in SARs reported for 2010 to 45, and a decrease in the number of SAEs reported to 46. It is planned that during 2011, Haemovigilance within the BE will be more fully resourced, in line with the decision to separate the mandatory reporting activities of the NHO.

The implementation of that part of the QMS covering training and training records, SmartTrain made good progress during 2010, with Phase I complete. Phase II cross functional records will be rolled out during 2011. Finally, as part of the participation in external quality assurance schemes the laboratories in the IBTS participated in 197 exercises in 2010. All tested samples scored in accordance with expected external results.

Energy Usage

In accordance with the provisions of Statutory Instrument 542 of 2009, the IBTS has undertaken a number of initiatives to reduce energy consumption. **Under this Statutory** Instrument, "from 1 January 2011, a public body shall include in its annual reports published after that date, a statement describing the actions it is taking, or has taken, to improve its energy efficiency and an assessment of the energy savings arising from those actions."

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; i.e 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 2010, IBTS consumed 11,814 MWh of energy, consisting of

- 5,903 MWh of electricity;
- 5,883 MWh of fossil fuels, including 5,229 MWh of natural gas and 654 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 within laboratories.

This means that 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 2010

In 2010 IBTS undertook a range of initiatives to improve our energy performance, including:

- Installation of new compressed air drier which resulted in 66 MWh of annual electricity savings.
- Installation of variable speed drive on water pump which led to 50 MWh of annual electricity savings.
- Installation of lower energy indoor and outdoor lighting which led to 20 MWh of annual electricity savings.

Actions planned for 2011

In 2011 IBTS intends to further improve our energy performance by undertaking the following initiatives:

- Lighting control upgrade in the main production laboratory which will save an estimated 61 MWh per annum.
- Changes to air conditioning operating mode in the main production laboratory which could save up to 80 MWh per annum.



Human Resources

The focus of these activities was to develop a stronger culture of accountability for the management of staff and to deliver efficient, effective, transparent processes to enable clarity of communication for team and one to one management.

Core Time and Attendance

 The swipe in system is incorporated for the most part throughout the organisation.

Business Information Reports

 A number of business information reports by department have been developed. These will inform the team and individual development and will be pivotal to the performance management system.

Recruitment and Selection Moratorium

- The Department of Health and Children issued a recruitment moratorium in 2009 which is to remain in place to end 2012.
- Only key roles critical to the maintenance of the safe, sufficient collection and processing of blood products and their derivatives have been protected within this moratorium.
- Competency framework for competency based recruitment will inform performance management and succession planning projects.

Change management projects

The objective of IBTS change management continues to be to improve service delivery to patients and donors. This is an ongoing priority for human resources. The promotion of a culture of continuous change in a timely manner will enable the delivery of a quality service in the times ahead. The operating environment changed significantly in 2010.

While the trade unions opted out of the partnership process, change management remains high on the IBTS business agenda. This agenda is being progressed under the Public Services Agreement. The status of a number of projects is as follows:

- Laboratory Cork Agreement
 Negotiations concluded, full implementation achieved.
- Donation Process Review Phase II
 Negotiations concluded, full implementation achieved.
- Transport Review
 Reaching conclusion. Although scheduled for negotiation in Q3 2010, this has been reprioritised to Q 2 2011.
- D'Olier Street Clinic Review
 Negotiations concluded, full implementation achieved.

Training and Development

The Training and Development function is responsible for ensuring that staff can develop the key capabilities and competencies required to create, implement and drive operations and change. The two main areas for training and development focus in 2010 were the conclusion of the Quantum Leap Team building and management programme and delivery of corporate mandatory training modules.

- All remaining relevant teams completed a team development day, team and personal development planning, with 1 to 1 coaching for team managers
- People management training for newlyrestructured clinic team managers
- HR Policy and Procedures

Human Resources

 Environmental Health and Safety training for managers and staff

IBTS Assisted Education Scheme

An assisted education scheme is provided by the IBTS to promote and foster continuous improvement of the organisation and professional development of individuals by financially investing in the education of employees and facilitating where possible the resources required for further education. The following new applications were approved in 2010:

- Fully Sponsored Financial Assistance 18
 Approved Applicants
- Limited Financial Assistance 5 Approved Applicants

Educational assistance included financial assistance for 18 ongoing applications in a variety of disciplines including healthcare, bio-medical science, nursing and medicine. Most educational assistance is for academically awarded programmes.

Library Services

The Library continued to drive and support the learning, research and information needs of the IBTS. Training by library staff was provided on how to source both quality medical and management information, with group and individual library and information skills sessions being maintained throughout 2010. In response to developing the library's alerting service, new subject specific email lists were set up for Web 2.0 technologies. Library staff developed enhancements to the intranet so that information can

now be more easily uploaded, resulting in a 42% increase in intranet traffic and usage.

A digital photographic archive of images outlining the history of the organisation from the 1940s was set up in 2010. The archive now numbers over 1,000 digital images and is a combination of images from the IBTS print photo archive and donated staff photos. A photographic exhibition entitled "Places I Remember: HQ Homes of the Blood Transfusion Service 1945 – 2010" was held in the NBC Atrium to mark the 10th anniversary at the National Blood Centre.

Environmental, Health and Safety

Comprehensive environmental health, safety and welfare programmes continue to be developed and adopted. Such programmes assist with legislative compliance and continue to promote an awareness of environmental, health and safety within the organisation.

National Environmental Health and Safety Steering Committee

The composition and terms of reference of the National Environmental Health and Safety Steering Committee was reviewed. The first meeting of the reconstituted Committee took place in September 2010.

Emergency Actions Plans

Emergency Action Plans (EAPs) were developed for mobile clinics and rolled out to mobile clinic teams across IBTS. Evacuation chairs were introduced on

all mobile clinics as part of the emergency evacuation procedures outlined in the EAPs. 138 clinical staff received formal training in the implementation of Emergency Action Plans and use of emergency evacuation chair.

Environmental Health & Safety Risk Assessment Process

A Review of the Environment, Health & Safety Risk Assessment Process commenced in 2010. The aim of this process is to ensure that a standardised formal approach to Environmental, Health & Safety Risk Assessment is adopted by department. Seventy five staff within the organisation attended Risk Assessment Training which was organised for both managers and staff.

IBTS Contractor Management Programme

Work continued in 2010 on the implementation of IBTS Contractor Management Programme. The online Contractor Health and Safety Induction Training programme was further developed and trialled with a number of new external contractors to the IBTS.

Safety Statements

The Safety Statement and Building Evacuation Action Plan for the Cork Centre were agreed and signed off. Departmental Safety Manuals containing the Safety Statement, Building Evacuation Action Plan and associated documentation were distributed to all departments within the Cork Centre and training sessions held for managers and staff.

Use of Clinic IT System as a Health and Safety Information Reference Source

Improved access to health and safety documentation by staff working on mobile clinic was achieved by making health and safety documentation available electronically. This information source will be developed further in the coming year.

Certificate of Professional Competence (CPC) Training

The Road Safety Authority introduced Driver CPC in Ireland in 2009 in response to EU Directive 2003/59/EC. In addition to holding a current driving licence, professional drivers (Category D & C Licence) must obtain Certificate of professional Competence (CPC). IBTS drivers completed a further training Module 2010 in line with this requirement.

Bikes4Work Scheme

In 2009, the Irish Government introduced a benefit-in-kind tax break which supports employers in providing employees with bicycles and associated safety equipment to encourage people to cycle to work. The Bikes4Work Scheme was run for a second year as part of European Health & Safety Week. Eighty two staff have participated in the scheme since its launch.

Hepatitis B Vaccination Management Programme

A project commenced with IBTS Occupational Health Providers to amalgamate Hepatitis B vaccination status records for all IBTS staff onto one database.

Personal Protective Equipment

The wearing of safety glasses was made mandatory in the laboratory environment. The services of an external supplier was sought to provide prescription safety eyewear to facilitate this development.

Policies and Procedures in 2010

The IBTS occupational health policy was reviewed and further developed. A committee was established to develop policies in relation to occupational blood exposure. The following policies were developed;

- Policy on the Prevention and Management of Occupational Blood Exposure
- Handling and Disposal of Sharps Policy

Finance

Summary Accounts for the year ended 31st december 2010			
	2010 €'000	2009 €'000	
Income			
Recurring income	109,906	117,407	
Non-recurring income	854	540	
Total income	110,760	117,947	
Expenditure			
Total expenditure	106,814	112,136	
Surplus for year	3,946	5,811	
Actuarial gain / (loss) on pension scheme	(523)	577	
Transfer (to) / from Capital Reserves	-	(2,000)	
Transfer (to) / from Research Reserve	296	(273)	
Accumulated (deficit) at 1st January	(2,209)	(6,324)	
Accumulated surplus / (deficit) at 31st December	1,510	(2,209)	

Income

The Board's total income for 2010 of €110.76 million (2009 €117.94 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 €109.90 million (2009 €117.40 million). Non-recurring income of €0.85 million (2009 €0.54 million) includes interest on bank deposits and proceeds from the sale of fixed assets. For 2010 the Board reduced the price of Red Cells by 9% and the price of testing by 5%. Red Cell sales volumes fell by 3.26% in 2010.

Expenditure

Expenditure for 2010 amounted to €106.81 million (2009 €112.13 million). The reduction in expenditure mainly arises from the continuation of the 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 2010 was €7 million. In 2006 the Board set up a research reserve. In 2010 €296,000 was expended from the reserve. (In 2009 €273,000 was transferred to the reserve).

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

Finance

The Board invested €1.7 million in capital projects and equipment during 2010 (€1.4 million 2009). The main investments during the year included a replacement chiller, 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 government VPN and tape library upgrade.

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, is 45 days from receipt of the invoice or confirmation of acceptance of the goods or services which are subject to payment. It is the Board's policy to ensure that all accounts are paid promptly. During the year ended 31 December 2010, under the terms of applicable legislation, invoices to the value of €112,682 were late, by an average of 40.72 days. These invoices constituted 0.17 % by number and 0.14 % 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 €755.74. The Board continuously reviews its administrative procedures in order to assist in minimising the time taken for invoice query and resolution.

Contact details

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National Blood Centre James's Street, Dublin 8

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Cork Centre

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Dublin Blood Donor Clinic

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Stillorgan Blood Donation Clinic

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