ANNUAL REPORT 2009

Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

"The IBTS is committed to excellence in meeting patients' needs through the professionalism of our staff and the generosity of our donors."

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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 2009, in accordance with Appendix V of the Revised Code of Practice for the Governance of State Bodies

1. I, as Chairperson, acknowledge that the Board is responsible for the Body's system of internal financial control.

2. The IBTS system of internal control can provide only reasonable and not absolute assurance against material error, misstatement or loss.

3. The Board confirms that there is an ongoing process for identifying, evaluating and managing significant risks faced by the IBTS. This process is regularly reviewed by the Board via reports by 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 reports twice monthly on operational issues and risks and how they are managed to the Executive Management Team. 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 2009 at its meeting on 13th April 2010.

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 agreed a formal schedule of matters specifically reserved to it for decision and a list of matters delegated to the Executive. The Board agreed the content of a manual for Board members. The Board reviewed and 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, including a special Board meeting held in early April. Attendance by Board members was as follows:

	Jan	Feb	April (1)	April (2)	May	June	July	Sept	Oct	Nov	Dec
Ms Maura McGrath, Chairperson	✓	✓	✓	✓	✓	✓	✓	Term ceased 31.08.09			
Mr Sean Wyse	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mr Mark Moran	✓	✓	✓	✓		✓		✓	✓	✓	✓
Mr David Lowe	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓ Reappointed 10.12.09
Mr Dave Keenan	✓	✓	✓	✓	✓	✓		✓	✓ Reappointed 09.10.09	✓	
Dr Robert Landers	✓		✓	✓	✓	Term ceased 11.06.09					
Dr Margaret Murray	✓	✓	✓	✓		✓	✓	Term ceased 31.08.09			
Dr Cees Van Der Poel				✓	✓	✓	✓	✓	✓	✓	✓ Resigned 15.12.09
Dr Mary Cahill			✓	✓	✓	✓	✓	✓	✓	✓	✓
Ms Margaret Mullett	✓	✓		✓	✓	✓	✓	Term ceased 31.08.09			
Ms Jane O'Brien	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mr Gerry O'Dwyer	✓	✓		✓	✓		✓	Term ceased 31.08.09			
Ms Marie Keane					Appointed 31.05.09		✓	✓	✓	✓	✓
Ms Sinead Ni Mhaille								✓ Appointed 01.09.09	✓	✓	✓
Ms Katharine Bulbulia									Appointed 27.10.09	✓	✓
Ms Ann Horan											Appointed 18.12.09
Dr Paul Browne								✓ Appointed 01.09.09	✓		

Chairperson's Report

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.

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).

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

	January to April 30th, Annual Directors fee	May 1st to December 31st Annual Directors fee	Received 2009*	Expenses 2009
	€	€	€	€
Ms M McGrath Chair	24,000	21,600	16,652	919
Ms K Bulbulia Chair	N/A	21,600	4,071	1,415
Mr D Keenan	14,000	12,600	13,591	-
Mr M Moran	14,000	12,600	13,591	-
Ms J O'Brien	14,000	12,600	13,591	-
Mr S Wyse	14,000	12,600	13,591	287
Mr D Lowe	14,000	12,600	11,636	-
Ms M Mullett	14,000	12,600	9,278	-
Ms S Ní Mháille	N/A	12,600	3,828	-
Dr P Browne	N/A	N/A	N/A	-
Dr M Cahill	N/A	N/A	N/A	1,051
Ms M Keane	N/A	N/A	N/A	195
Dr R Landers	N/A	N/A	N/A	761
Dr M Murray	N/A	N/A	N/A	-
Mr G O'Dwyer	N/A	N/A	N/A	2,982
Ms A Horan	N/A	12,600	-	-
Dr C Van der Poel	14,000	12,600	-	3,915

* The Annual Director's fees were reduced as and from 1st May 2009 in line with government policy.

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 2009 was €181,648.

Medical Advisory Committee

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

Finance Committee

The Finance Committee met five times during the year and is comprised of 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, management accounts, insurance, procurement, treasury policy, capital expenditure, costing exercises and banking and financing arrangements. 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 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.

This monitoring ensures that the identified risks and controls are current and that new and emerging risks are identified and controlling measures put in place.

Chairperson's Report

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 its effectiveness. The Board's system of internal financial control comprises those controls established in order to provide reasonable assurance of:

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

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

- A comprehensive system of financial reporting
- Annual Budget prepared and presented to both the Finance Committee and the board and monthly monitoring of performance against budgets
- 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 carried out by staff independent of stores staff
- Payment verification of supplier invoices by senior staff independent of accounts payable staff
- Financial system possesses verification checks and password controls
- Regular monitoring of credit control function
- All purchase orders signed by purchasing officer
- Stock items are requisitioned by means of automatic ordering
- All non stock invoices signed and coded by budget managers
- All stock invoices independently matched with stores GRN and purchase order

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

Statement of Board Members' Responsibilities

The Board is required by the Blood Transfusion Service Board (Establishment) Order 1965, to prepare financial statements for each financial year which, in accordance with applicable Irish law and accounting standards, give a true and fair view of the

state of affairs of the Irish Blood Transfusion Service and of its income and expenditure for that year. In preparing those financial statements, the Board is required to:

- Select suitable accounting policies and then apply them consistently;
- Make judgements and estimates that are reasonable and prudent;

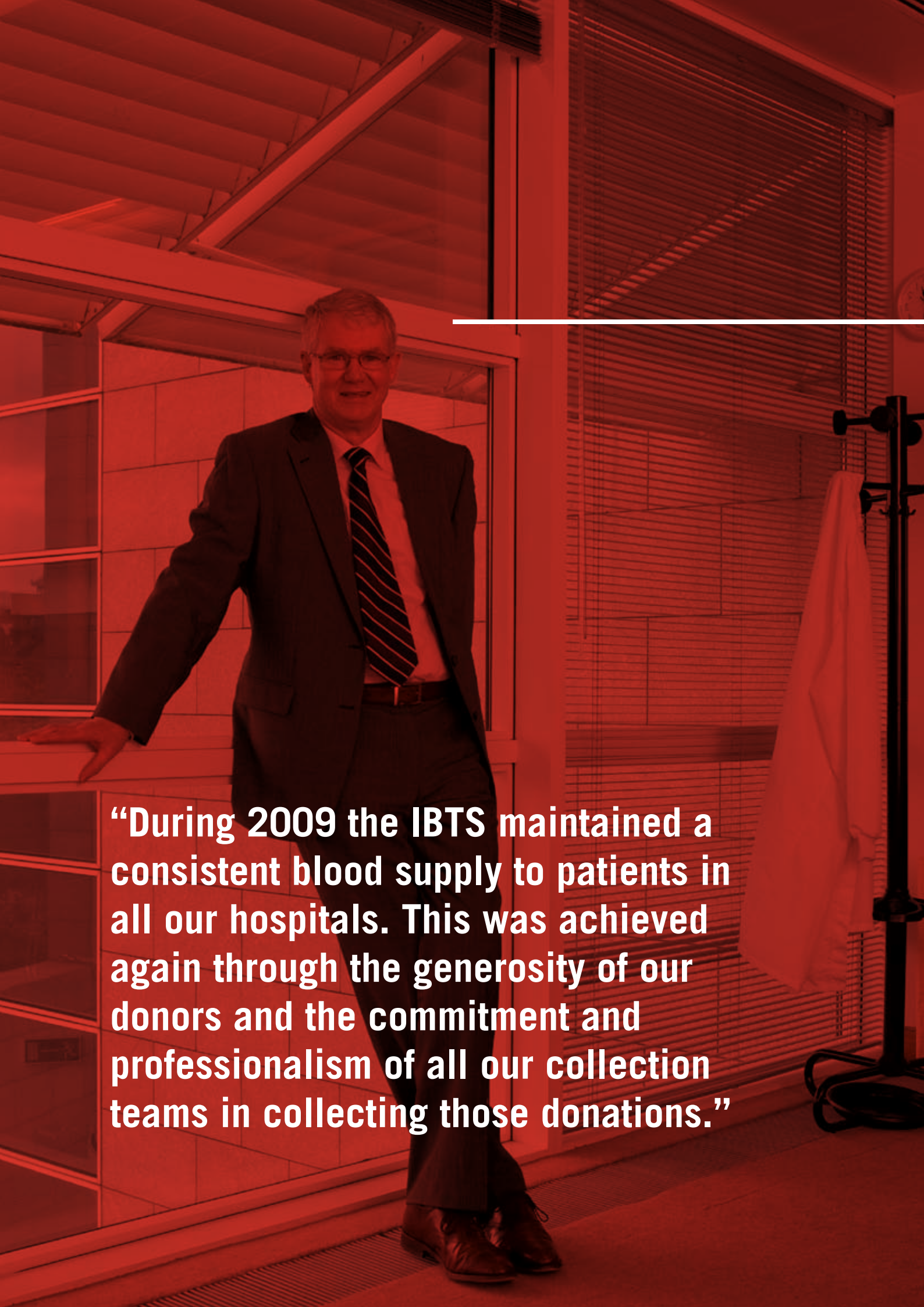
- Disclose and explain any material departure from applicable accounting standards;
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Irish Blood Transfusion Service will continue in business.

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

Commercially significant developments

Since 2001 the IBTS had not used the plasma collected as part of the whole blood donation as on of the measures taken to mitigate the risk of transmission of vCJD. Therefore, the plasma has been discarded. During 2009 discussions commenced with a commercial company who are involved in manufacturing control materials for blood analysers who were prepared to purchase the plasma. This was a major departure for IBTS so we decided to carry out a survey of our donors to gauge what their reaction might be to such a move. The donors had no major issues with this proposal and at year end the IBTS had agreed terms with two suppliers and this will be implemented by Quarter 1 2010.

Ms Katharine Bulbulia
Chairperson



“During 2009 the IBTS maintained a consistent blood supply to patients in all our hospitals. This was achieved again through the generosity of our donors and the commitment and professionalism of all our collection teams in collecting those donations.”

Chief Executive's Report

In presenting my report on the activities of the Irish Blood Transfusion Service (IBTS) in 2008 I referred specifically to a number of change programmes that were underway in the IBTS during that year which would have implications for how the Organisation operated into the future. Few of us could have foreseen the change in the economic environment that swept through the country in 2009 with implications across all sectors. The sharp fall in economic activity and the dramatic decline in the global economy seriously impacted on the public finances.

The IBTS, like all other organisations, had to embark on a series of cost cutting measures to reduce our cost base and ultimately the price of our products to customers. The Government also introduced austere measures to curb the overspend in the public finances and these measures impacted on how business could be done in the public sector and particularly the relationship between management and unions in negotiating change programmes and implementing the necessary change to achieve the cost savings required.

The other significant factor which impacted on the IBTS was the declaration in June 2009 by the World Health Organisation (WHO) of a flu pandemic. While a flu pandemic had been anticipated the announcement by the WHO certainly was earlier than had been expected by most countries and therefore major planning and finalisation of pandemic flu plans had to take place in a very short timeframe. As we now know the effect of the pandemic was much milder than expected. However, there was much energy and resources expended on preparing the IBTS for the full effects of a global pandemic and also liaising with hospitals regarding optimum use of blood and management of shortages should they arise resulting from the inability of donors to donate or of the IBTS to collect sufficient donations.

On the positive side it also provided an opportunity for the IBTS to revisit many of the deferral criteria for donors and also to stress test our contingency arrangements which had been designed for different purposes and make improvements on foot of this review.

Main Developments

I think it would be important to note that there were a number of very significant developments in the IBTS during 2009 despite the environment in which we were operating and the requirement to reduce costs. These were

a. The implementation of TIGRIS ~ April 2009
b. Continued changes in the donation collection clinics with a move to one Donor Attendant for two donors and Donor Attendants and Team Leaders carrying out venupuncture as well as doctors and nurses;
c. Implementation of the Blood Stock Management System in a number of hospital networks on a pilot basis and the drive to further reduce wastage;
d. The development of an ICT Strategy as part of the overall IBTS Strategy and a restructuring and refocusing of the ICT function;
e. The re-launch of our partnership with Vodafone which is essential in the maintenance of the blood supply;

Chief Executive's Report

f. The launch of the IBTS on Facebook as a medium to contact our donors and to target a specific audience and segment of our donor base;
g. The implementation of BOSS which allows us to make much more informed decisions given the timely availability of data and analysis and trending of the data for all of our activities.

All of these changes were implemented against a backdrop of a difficult industrial relations environment due to the macro economic environment changing significantly and the implementation by Government of a series of deductions and taxes on salaries.

One of the other significant factors affecting staff is the current state of the IBTS pension fund which was declared insolvent in March 2009 and this caused anxiety with staff who are paying a levy imposed by Government but yet the fund was not secured for the future payment of their pensions. This issue was being addressed actively by the Board and management in order to secure the future benefits of the staff concerned and the pensioners in the IBTS.

The economic environment in Ireland will continue to be difficult for the next 2 - 3 years and in that context the IBTS will be required to make further cost savings and reduce its prices. This will inevitably lead to significant change of work practices and how the organisation carries out its business if we are to realise those savings. This could involve outsourcing, identifying opportunities for shared services and will involve benchmarking against our peers to ensure that we deliver value for money. This can only be achieved through management and staff working together to identify the necessary changes, agree a mechanism for implementing them and ensuring that they are implemented and savings realised. It is essential that the IBTS controls the change programme necessary to deliver these cost savings rather than have those cost reductions imposed from external sources.

Even though the IBTS is focused on cost reduction primarily and will be so over the next 2 – 3 years we must continue to actively deal with the current threats to the blood supply and maintain a very strong vigilance on any emerging threats so that we can deal with them in a timely manner. Ultimately, the primary function of the IBTS is to provide a consistent and safe supply of blood to patients and this purpose must not be overlooked or compromised in the quest for cost reductions and price savings.

During 2009 the IBTS maintained a consistent blood supply to patients in all our hospitals. This was achieved again through the generosity of our donors and the commitment and professionalism of all our collection teams in collecting those donations. The changes that have been implemented and are in the process of being implemented throughout the organisation could only be achieved through the hard work of all staff across all sections and for this commitment I am deeply appreciative. We must also continue to develop our staff because of the need to maintain currency with the evolving knowledge in blood transfusion and the requirement to respond in a timely manner to any emerging threats or changes in our environment.

The IBTS will be seriously challenged to maintain international best practice standards given the changed environment with constrained resources. However, this must be done and the Executive Management Team will have to demonstrate the requisite leadership to address the many challenges that will need to be overcome to ensure that IBTS delivers on its purpose which is “to meet the transfusion needs of patients in Ireland”.

Andrew Kelly
Chief Executive

“Safety, supply, and efficacy are the drivers of the IBTS: safety of the products we produce from the donors’ gift, and safety of the donors themselves; supply of the right product at the right time every time to the hospital users, and ensuring that the product supplied is efficacious”

Medical and Scientific Director's Report

Safety, supply, and efficacy are the drivers of the IBTS: safety of the products we produce from the donors' gift, and safety of the donors themselves; supply of the right product at the right time every time to the hospital users, and ensuring that the product supplied is efficacious - fit for the job; making sure that it has been designed, manufactured, stored and shipped in such a way as to ensure that it is an effective medicine for patients requiring replacement of red blood cells to carry oxygen, platelets to prevent bleeding, or plasma products to promote blood clotting in bleeding patients.

It's a tall order to fill 365 days a year, 24 hours a day, and requires a skilled and committed team of scientific, nursing, medical, IT and support professionals. It requires an adequate regulatory framework and functioning regulatory process, and strong links into the global knowledge workplace to ensure that emerging threats and trends are seen, appraised and acted upon, and that new knowledge – either basic or applied, is harnessed appropriately. These links ensure that the IBTS can continue to provide products for Irish hospitals that reflect the best available quality and standards. They are formalised through the European Blood Alliance (EBA) which links closely the national blood services in the European Union, and the Alliance of Blood Operators, which in turn links the EBA with similar organisations in North America and Australia & New Zealand. The Council of Europe and professional scientific organisations and working groups also provide for a functioning exchange of information and knowledge.

This global network provided valuable and effective support in planning our response to the threat of pandemic flu in 2009. Flu probably can be spread by blood transfusion, but cases spread in this way are unlikely to contribute much to the overall numbers of cases in an epidemic. The real risks to the blood supply from flu in 2009 were that donors would be so reduced in numbers – either suffering from or recovering from the disease themselves, or caring for others in their households with the disease – and that there would not be enough well staff available to collect, test, process and distribute blood for hospitals. Close liaison with sister blood services in Australia, the UK, Europe and North America ensured that our planning and processes for dealing with the threat learned from the experience of others who were in the same position or, in the case of Australia in particular, had already weathered the first wave of infection. In the end, the epidemic did not reach the levels of community illness that were feared, and the second wave did not materialise. Nevertheless the effort and time we put into planning and preparing was time well spent in ensuring that the IBTS was capable of mobilising to meet such a threat in the future, and it was a clear demonstration of the worth and value of the international network in which we participate.

While flu dominated the agenda for much of the year, the threat of spreading variant Creutzfeldt Jakob disease (vCJD) has not yet receded. There have been no new cases of transmission of this disease by blood transfusion for several years, but the possibility remains that individuals who have been infected in the past – perhaps more than fifteen years ago or more – could still spread infection through blood

Medical and Scientific Director's Report

donation. It is very unlikely that there will be more than a handful of at-risk transfusion at most, but nevertheless it is essential to ensure that we continue to take every step available to us to minimise this risk. Over the years we have made several changes to our processes to counter the threat of vCJD from blood transfusion – removing the white cells from every unit of blood collected, a process known as leucodepletion; no longer accepting blood donations from people who have lived in the UK, including Northern Ireland, for upwards of a year between 1980 and 1996; not allowing people who themselves have been transfused to donate blood in the future. In addition, since 2003 we import plasma for transfusion from volunteer blood donors in Texas as a precaution against spreading vCJD through this blood component from Irish donors.

In 2009 we added another measure – replacing the blood component called cryoprecipitate, which is made from plasma from Irish donors, with a manufactured blood product (fibrinogen) made from US plasma by CSL Behring in Germany. In addition, in a study performed at Cork University Hospital, the first clinical safety assessment was completed in patients of a new filter for red cell transfusions that is designed to remove any infectious prion protein – the infectious agent of vCJD – from blood donations. Further operational assessment of this new filter were also done at Cavan General Hospital, and the question of whether to introduce this measure into routine use now rests with the Department of Health and Children, who have mandated a detailed assessment of the technology, its costs and its potential benefits, from the Health Information and Quality Authority.

A new donor test for vCJD appeared to be imminent during 2009, and a considerable amount of detailed planning for this advance took place, including extensive consultation with donors around the country. In the end, the new technology has yet to prove itself in field trials, and the prospect of a test has unfortunately receded for the time being.

Raising the upper limit of age for blood donors to 75 years, changes to deferrals for colds and cold sores, for blood pressure medication, and for migraine; concerns about the spread of the mosquito-borne disease dengue in the Americas, the Cape Verde Islands and elsewhere, and of the tick borne disease babesiosis in the USA, also required to be addressed during the year, along with the usual suspects of malaria, trypanosomiasis, Chikungunya and West Nile fever.

Blood transfusion is not optional – we do it because we have to, not because we want to. There is no alternative medicine for those who need blood replacements because of trauma, surgery or disease. It requires a continued sustained and high quality endeavour from the IBTS and from the community to continue to provide this medicine to the highest standards of safety and service.

Dr William Murphy
Medical & Scientific Director
MD, FRCPEdin, FRCPath

Operations

Donor Services

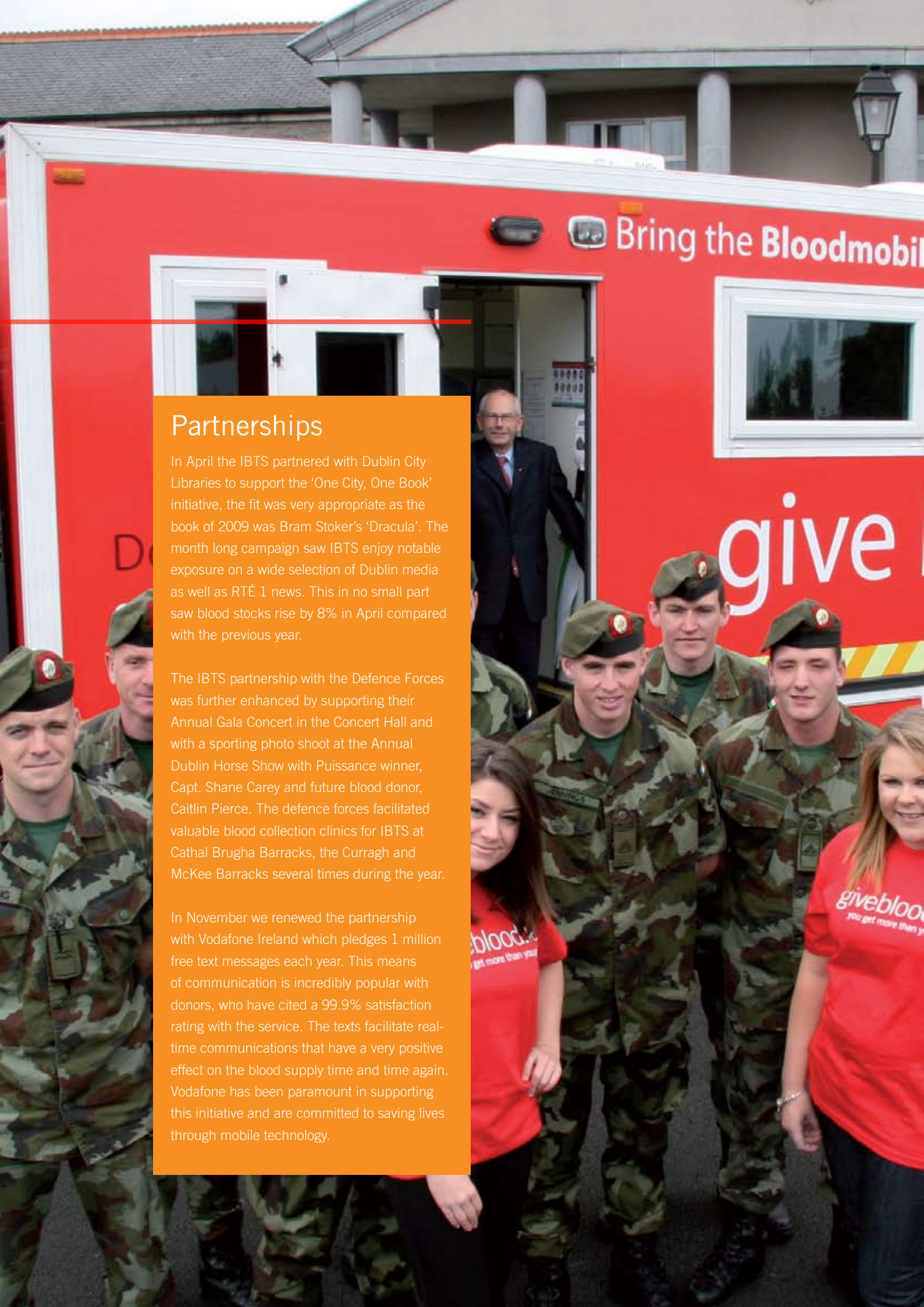
The combined efforts of Donor Services and Marketing ensure that 3,000 units of whole blood are collected each week. This is achieved primarily through promotions, awareness, direct communications, events, partnerships and advertising.

Donor Awards

Donor Award ceremonies took place in Dublin, Cork, Carlow, Kells and Ballybofey. In total 661donors were honoured with a gold drop for 50 donations and 61 donors were presented with a pelican for 100 donations. Award ceremonies are unique occasions whereby the organisation has an opportunity to thank donors for their long-standing loyalty and commitment to saving lives. At each of these events a patient who has received blood tells their story and brings real meaning to the donors about the value of their life-saving gift. 2009 saw the first award ceremony take place in the North-west, in Ballybofey, Co. Donegal, which was a huge success and well attended by donors from surrounding counties.

Branding

2009 saw the launch of a new TV advert which has advanced the brand development significantly along with press, radio, outdoor and online advertising. The current tag-line, “giveblood.ie - you get more than you give”, has proved popular with new and regular donors, who identify with the altruistic satisfaction they feel knowing that a single blood donation may save a life.



Partnerships

In April the IBTS partnered with Dublin City Libraries to support the 'One City, One Book' initiative, the fit was very appropriate as the book of 2009 was Bram Stoker's 'Dracula'. The month long campaign saw IBTS enjoy notable exposure on a wide selection of Dublin media as well as RTÉ 1 news. This in no small part saw blood stocks rise by 8% in April compared with the previous year.

The IBTS partnership with the Defence Forces was further enhanced by supporting their Annual Gala Concert in the Concert Hall and with a sporting photo shoot at the Annual Dublin Horse Show with Puissance winner, Capt. Shane Carey and future blood donor, Caitlin Pierce. The defence forces facilitated valuable blood collection clinics for IBTS at Cathal Brugha Barracks, the Curragh and McKee Barracks several times during the year.

In November we renewed the partnership with Vodafone Ireland which pledges 1 million free text messages each year. This means of communication is incredibly popular with donors, who have cited a 99.9% satisfaction rating with the service. The texts facilitate real-time communications that have a very positive effect on the blood supply time and time again. Vodafone has been paramount in supporting this initiative and are committed to saving lives through mobile technology.

Research

A second 'Topbox' survey was completed in 2009 which saw donor satisfaction levels rise in the majority of clinics nationwide. This survey is conducted in the UK and the Irish performance compares very favourably with the benchmarks set overseas. The research also shows gains in the donor commitment measurements which is encouraging in terms of behavioural changes amongst donors.

As part of the development of new and efficient means of by-product disposal, we surveyed donors to ascertain their reaction and consent to the supply of plasma by-product to a company that makes healthcare related laboratory tests. 92% of respondents said they would consent to the use of their plasma in this way, with 86% agreeing that this is a positive move for IBTS.

A short survey was undertaken on behalf of the Irish Haemochromatosis Association to measure the awareness of the condition amongst the Irish public, which resulted in 61% of respondents having heard of the condition and 41%, knew someone with Haemochromatosis; less than 5% actually had the condition.

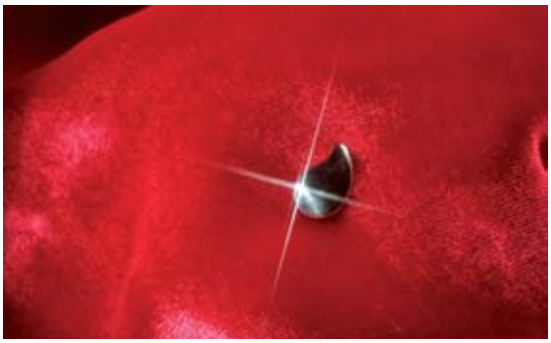
Media

2009 saw some new additions to media activities including a partnership with Spin 1038, aimed primarily at targeting the under 35 audience. The three month partnership helped secure promotions, awareness and increased donations during the H1N1 pandemic.

Q102's 'Blue Crew' promoted the clinic in Stillorgan, Dublin facilitating welcome publicity of the clinic during the challenging summer months.

The IBTS facebook page was launched and achieved almost 10,000 fans in the first 8 months without any advertising. This medium is a new venture for the organisation and proving very popular with donors, recipients and supporters alike. Social networking offers the IBTS real-time contact with donors in a very meaningful way.

"Our facebook page was launched and achieved almost 10,000 fans in the first 8 months"



World Blood Donor Day

World Blood Donor Day was launched in May with the help of a few Munster Rugby players and the IBTS mascot, using the theme 'Give Blood, Save Three Lives'. The celebrations of WBDD included a 2 week advertising campaign, on street promotions country-wide, donor award ceremonies and a corporate awards event at the National Blood Centre. A wide range of companies who support the work-ferry and bloodmobile initiatives were presented with an award by blood recipient and environmentalist Duncan Stewart.

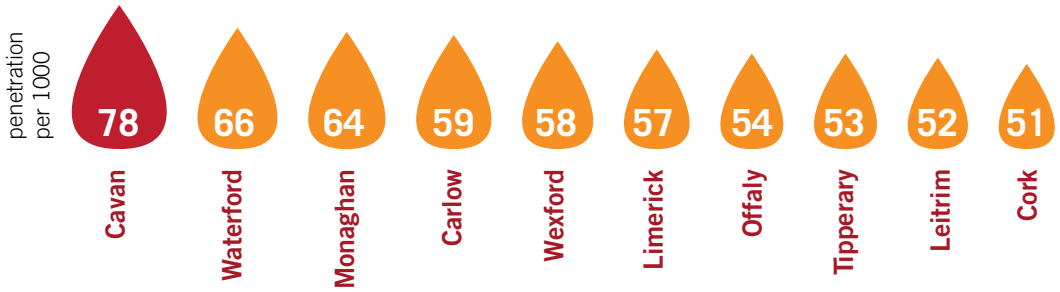
"World Blood Donor Day was launched in May with the help of a few Munster Rugby players and our own mascot, using the theme 'Give Blood, Save Three Lives'."

Donor Statistics

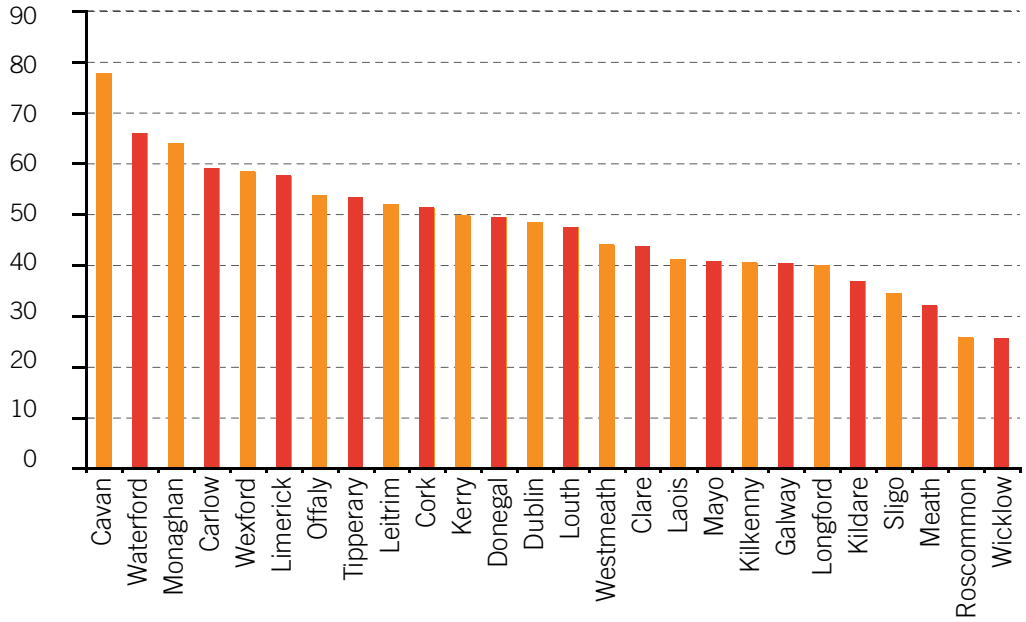
New statistics available demonstrate the prevalence of blood donation by county, which shows Cavan as the county with the most donors per thousand of population.

Top ten counties include Waterford, Monaghan, Carlow, Wexford, Limerick, Offaly, Tipperary, Leitrim and Kerry. Dublin is showing just 40 per thousand give blood compared with almost 78 per thousand in Cavan.

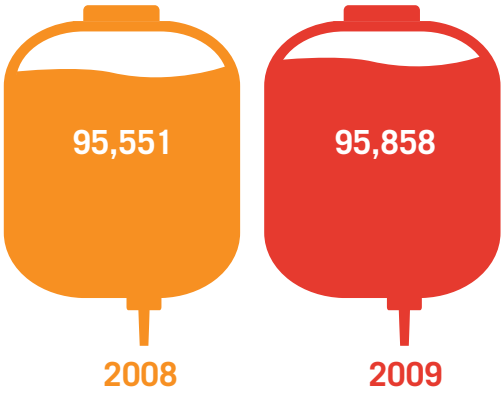
Top 10 donor counties



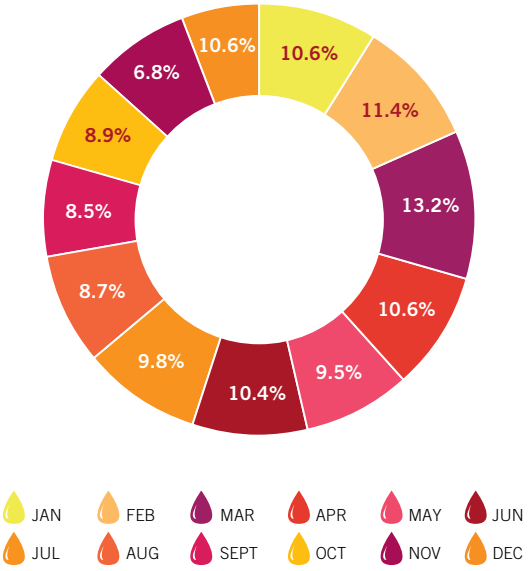
Counties with most donors per thousand of the population



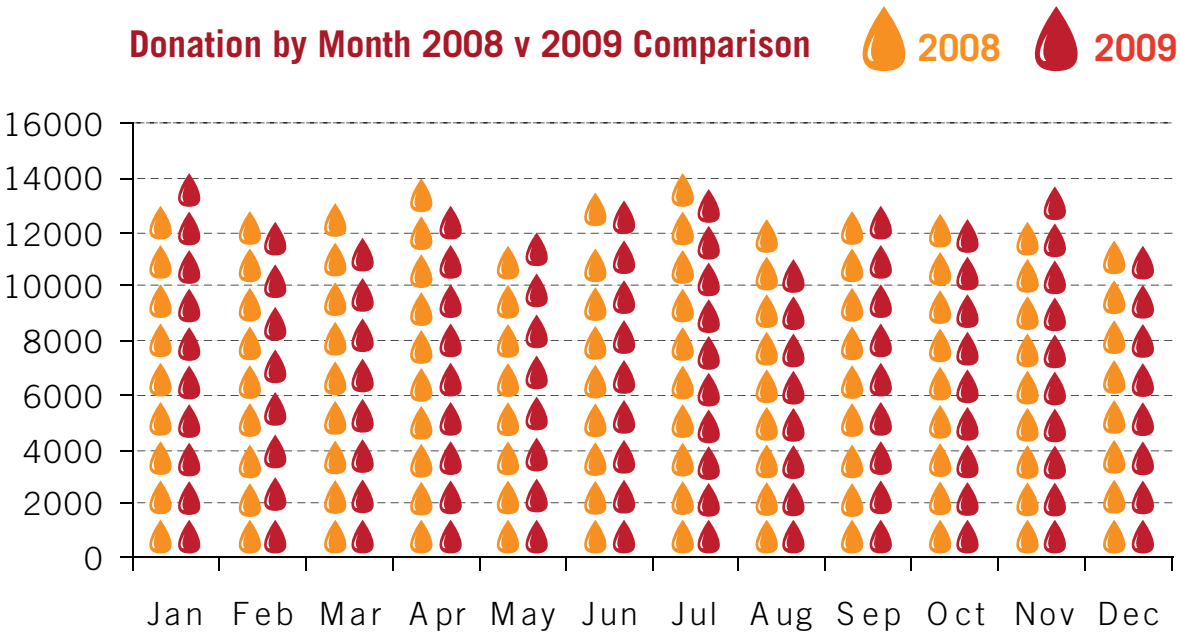
Donors 2008 vs 2009



% of first time donors by month



Donation by Month 2008 v 2009 Comparison



Hospital Services

Hospital Services incorporates the management, storage, packaging and distribution of blood, blood components and manufactured therapeutic products. It provides the essential link in the supply chain between the hospitals and IBTS Hospital Services located in both the NBC and the Cork Centre.

This team is responsible for the safe and secure distribution of all products released for treating patients and works closely with Components. 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 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 in 2009. 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 Products Issued		
Product	2009	2008
Red Cells & Whole Blood	142,459	141,364
Platelets - Therapeutic Doses	26,256	24,415
Frozen Plasma	447	474
Octaplas	23,401	23,856
Cryo Depleted Plasma	39	-
Cryoprecipitate	1,316	2,717
Factor VIIA (xIU)	286,950	276,120
Anti Thrombin III (x IU)	-	1,500
Factor VIII Recombinant (x IU)	30,979,500	30,521,500
Von Willebrand Factor (x IU)	1,057,500	752,000
Factor IX Recombinant (xIU)	8,912,250	10,486,500
Prothromplex (x IU)	481,200	480,600
Factor XIII	6,000	4,000

Testing

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.

In the first quarter of 2009, the NAT laboratory tested donations (in mini-pools of 8 donations; MP-NAT) using the Novartis Procleix HIV-1/HCV Assay. This Duplex assay is a qualitative in-vitro Transcription Mediated Amplification (TMA) nucleic acid testing assay system for the detection of Human Immunodeficiency Virus type 1 and/or Hepatitis C virus RNA in human plasma. This assay is highly sensitive and specific for viral nucleic acids and is capable of detecting infection earlier than other screening methods, thus narrowing the window period. Prevention of cross-contamination within the laboratory itself and also between processed samples is critical to the success of NAT testing.

From the 27th April 2009, the NAT laboratory introduced 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 October 2009.

An archive sample is retained on all donations. Every donation collected in 2009 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 (Ultrio assay only)), Bracket Controls (Ultrio assay only) and Internal Control (IC). IC is added to each test sample via the addition of working Target Capture Reagent (wTCR). The IC is used to control sample processing, amplification and detection steps and used to ensure all manufacturer testing processes are operating correctly. Tigris Bracket Controls are used following testing of every 100 samples in each worklist. Calibrator results must meet assay specifications.

Interlaboratory comparisons using EDCNet software and participation in External Quality Assurance Schemes (EQAS) in 2009 allowed the IBTS to perform peer review with other Novartis and non-

Virology

Novartis users of NAT assays worldwide. These were all satisfactory with no discrepancies to report. EDCNet is an initiative by the National Serology Reference Laboratory, Australia (NRL) (see www.nrlqa.net).

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. Also, participation in the Quality Management System within the IBTS enables implementation of changes through Change Controls and Change Orders to improve NAT processes.

"The NAT laboratory is committed to continuous improvement of the NAT process"

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 2009.

These tests are performed using the latest cGMP (good manufacturing practice) compliant equipment. 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 following serology tests are carried out in the virology laboratory and are mandatory for all donations.

- Hepatitis B surface antigen (HBsAg) and antibody to Hepatitis B core
- antibody to Human Immunodeficiency Virus 1/2
- antibody to Hepatitis C virus
- antibody to Human T-Lymphotropic Virus I & II
- antibody to Treponema Pallidum the causative agent of Syphilis

Selected donations are tested for Cytomegalovirus (CMV) in order to have a supply of Cytomegalovirus negative donations for those patients who need it e.g. immunocompromised patients. A serum sample (archive sample) is also stored frozen from each donation.

The laboratory performs screening tests for viral markers for various departments within the IBTS, including stem cell donors, heart valve tissue

Diagnostics

donors and samples from recipient tracing testing programmes

The quality of the testing system is ensured by using standards from the 'National Institute of Biological Standards and Controls U.K.', 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 two proficiency programmes, one circulated by the National Institute for Biological Standards and Control in the UK and the second by VQC-Acrometrix in association with National Serology Reference Laboratory (NRL, Australia).

Diagnostics laboratory Dublin

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

The services provided by the Diagnostics Laboratory include:

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

In total, over 2300 samples were referred in 2009. Increases were observed with, ABO/D Typing (16%), Rh D workup (33%), DAT (21%), Compatibility Testing (28%), Antibody Investigation (18%) and phenotyping of patient samples (9%).

The Emergency Reference Red Cell Immunohaematology On-Call Service, for patients with a clinically urgent requirement for antibody Investigation / Compatibility testing, continues to operate well. There were over 80 cases where a Scientist was required to provide service in 2009.

A Diagnostics Laboratory 'User manual' was made available on the IBTS website www.giveblood.ie in the first Quarter 2009. It is planned to have Diagnostics User Satisfaction Surveys conducted in 2010, to identify significant areas in the laboratory service for improvement and development.

The laboratory carried out preparatory work to apply for ISO15189 accreditation.

"A Diagnostics Laboratory 'User manual' was made available on the IBTS website www.giveblood.ie in the first Quarter 2009"

Diagnostics Laboratory Cork

Clinical and Laboratory immunohaematology services are provided by the Diagnostics Laboratory at Cork which include routine serology services for Cork City hospitals, reference service for hospitals in the Munster region on a 24/7 basis, secondary processing out of hours, component modification and special preparations for paediatric patients. The Diagnostic Laboratory also investigates suspected transfusion reactions in all hospitals for which we provide compatibility services. The Diagnostics Laboratory has responsibility to ensure that platelet components are negative by bacterial testing at time of issue.

During 2009 the Cork Centre Diagnostics laboratory activity was as follows:

- 5,983 samples were referred to the Laboratory; compatibility testing was undertaken for 2,871 samples and 6,613 corresponding red cell preparations were issued.
- 672 Antibody Investigations were carried out, of which 409 were reference samples received from hospitals with blood banks. These required the Cork Centre Diagnostics staff specialist knowledge and experience in order to identify unusual antibodies and for other investigations.
- 600 patients had Rhesus Phenotype determined and a further 5,504 Antigen typing tests were performed.
- 1,708 Direct Antiglobulin Tests were undertaken, of which 643 required a Mono-Specific DCT.
- 20 suspected transfusion reactions were investigated.

NHIRL

Of the samples received 929 were managed as emergencies within the working day (i.e. outside routine batches) and in addition 983 were processed as out of hours emergency by evening/night duty staff.

910 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. 895 (98.4%) of these were subsequently transfused at CUH.

100% Traceability Compliance was achieved with the Bag & Tag Traceability System. The traceability manual is available at www.giveblood.ie/clinical_services/hospital_services/traceability

National Histocompatibility and Immunogenetics Reference Laboratory (NHIRL)

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

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

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

In 2009 the NHIRL HLA typed 197 newly diagnosed patients and 488 of their relatives. 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 2009 the laboratory HLA typed 988 new volunteer donors to add to the registry.

Between 2007 and 2009 the IUBMR facilitated 103 unrelated donor transplants for Irish and international patients, the same number as had been facilitated in the preceding seven year period. This upward trend in patients requiring transplants from unrelated donors has significantly increased the necessity for high resolution HLA typing by the NHIRL.

The NHIRL also provides a routine disease association HLA typing service. The demand for this service continues to increase and represented over 40% of the laboratory's samples in 2009. 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 (NAITP), post transfusion purpura (PTP), platelet refractoriness, alloimmune thrombocytopenias and adverse transfusion reactions is provided. The number of new platelet donors requiring HLA-A and B typing in order to support the provision of an optimal platelet product to the hospitals increased by 14.5% in 2009. Selection of HLA matched platelets for patients with alloimmune platelet refractoriness has been greatly enhanced by the introduction of the Blood Operations Support Software (BOSS) report incorporating the HLAMatchmaker algorithm.

The NHIRL saw an overall increase of 5.2% in the number of tests performed by the laboratory in 2009 as compared to 2008 and there has been an increase of 34% since 2005.

The laboratory has performed several studies with Irish hospitals to demonstrate the role of HLA genes in disease susceptibility. In particular, the NHIRL has published its findings in relation to Multiple Sclerosis and Hepatitis C. At the 23rd European Immunogenetics and Histocompatibility Conference, Ulm, Germany in May 2009, the laboratory presented the following abstracts based on collaborations with St. Vincent's University Hospital and St. James's Hospital respectively:

- HLA-Cw*0602 and treatment of Psoriasis with TNF-∝ inhibitors. J Kelleher, C Ryan, M Fagan, R Hagan, E Lawlor, B Kirby. Tissue Antigens 2009; 73: 385-523.

- Factors impacting the outcome of matched unrelated donor (MUD) transplants: the Irish experience. J Kelleher, M Fay, R Hagan, E Lawlor, C Flynn. Tissue Antigens 2009; 73: 385-523.

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.

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.

Donor Grouping Dublin

In 2009 almost 123,000 donations were tested at the NBC in Dublin and each red cell unit requires certain mandatory tests before they may be released for issue. These include ABO & RhD types and a screen for irregular antibodies. During this year there were over 10,000 new donors bled, which represent 8% of the total donations.

The blood group and RhD type of this group will reflect the true blood group characteristics of the donor population which is:-

O POS	44%
O NEG	10%
A POS	26%
A NEG	5%
B POS	9%
B NEG	2%
AB POS	2%
AB NEG	1%

Over 45% of donors receive a full Rh phenotype (C, c, E, e, type) every time they donate and 20% of these will go for further antigen screening or typing. These donations are then available for issue to patient who are known to have produced multiple red cell antibodies.

2009 saw the take over of Olympus Diagnostics Division by Beckman Coulter, who will now supply the PK7300 blood typing machine. It is hoped that the installation and validation of this equipment will be complete by mid 2010. 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.

During 2009 the donor grouping laboratory in Dublin trialled the latest technique in antigen typing. This PCR technique involves the extraction of DNA and using it to establish the genotype of many various blood group antigens. Antigen typing of donors is currently performed using haemagglutination techniques, which is severely restricted in some cases due to the lack of suitable anti sera. This PCR technique using BeadChip technology will

antigen type donors at genetic level, allowing for the detection of antigens which are very rare, weakly reacting or undetectable using current serological typing methods. The project yielded valuable information into the true genetic nature of some antigen types, which were found to be undetectable using conventional serological tests. At the moment PCR typing techniques are changing rapidly and it is planned that in the future that PCR antigen typing may be performed on a more routine basis. This will keep the Irish Blood Transfusion Service at the fore front of blood typing techniques.

Donor Grouping Cork

Over 47,000 donations were tested at the Cork Centre and each red cell unit requires certain mandatory tests before they may be released for issue. These include ABO & RhD types and a screen for irregular antibodies. Over 4,000 of these donors were new donors.

All red cell units are now routinely typed for the Kell antigen, to minimise the number of females of child bearing age stimulated to produce Anti-K post transfusion of red cell units. This in turn will reduce the cases of Haemolytic Disease of the Newborn (HDNB) due to Anti-Kell.

Over 20% of donors receive a full Rh phenotype (C, c, E, e type) every time they donate and a percentage 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.

All red cell units for transfusion to neonates and sickle cell patients are now tested for the haemoglobin S trait and issued with negative red cell units. This screening is important not only for the recipient, but also from a donor care perspective and allows the early identification of donors, who may be unaware that they carry the sickle cell trait. To date no such cases have been detected with the Sickle cell trait at the MRTC. If donors are identified they will be provided with information and advice, so they are aware of all aspects and implications of the sickle cell condition.

An increase in demand for typed paediatric blood was seen for the year 2009, due to an increase in cases of HDNB.

Over 650 red cell products were discarded in 2009 due to expiry along with over 1100 platelet products. The current blood typing analyser in use at the Cork Centre is the Galileo, which was introduced in 2004.

Additional Services

Tissue Bank

The tissue bank was inspected in accordance with EU directive 2004/23/EC and reaccredited for ocular, cardiovascular and umbilical cord blood stem cells banking. The IBTS continues to import all tissue supplied for ophthalmic surgery from the US due to the possible risk of vCJD. 2009 saw a continued increased demand for pre cut (DSAEK) corneas for endothelial keratoplasty. DSAEK corneas now account for 32% of all corneas issued.

There was a change in supplier of freeze dried amnion tissue from Celgene to Surgical Biologics, who are based in Georgia, US, as Celgene withdrew from the market. The IBTS also provides autologous serum eye drops for patients when requested by an ophthalmologist.

The IBTS in association with the ophthalmic director of the eye bank, Mr. William Power, RVEEH and DCU are collaborating to bring cultured limbal stem cells from the bench to a clinical application. This project will continue in 2010 with the transfer of the technology from DCU to a GLP and ultimately a GMP setting in the IBTS. This work is being funded from monies received under a bequest.

The IBTS continues to process and cyropreserve human cardiovascular tissue on behalf of the Mater Misercordiae University Hospital under the auspices of the cardiothoracic director of the heart valve bank, Mr. A. E. Wood.

The Directed/Sibling Cord blood bank collects and cryopreserves cord blood on request from the oncology/haematology team in OLCHC. The main indications for collection during 2009 were malignancy and sickle cell disease. The Irish Unrelated Bone Marrow Registry (IUBMR) 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 treating Haematologist/ Oncologist.

The cord blood is stored in the National Blood Centre for the intended recipient's use only. In 2009, eight cord blood units were collected with 105 units stored to date of which two have been transplanted.

National Haemovigilance Office (NHO)

Haemovigilance plays an essential role internationally in developing safe clinical transfusion practice. In the nine years of its operation (2000-2008) a total of 1860 serious adverse transfusion reactions/events have been reported to the NHO.

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

The NHO collects SAEs relating to the quality and safety of blood which are mandatory under the EU Blood Directive 2002/98/EC. Non mandatory SAEs, termed Incorrect Blood Component Transfused (IBCT), relating to errors in clinical areas are also reportable under professional responsibility. The total SAEs IBCT reported to the NHO in 2008 was 147 representing 51% of all incidents (147 of 290). Of these events 53 (36%) were classified as 'mandatory' serious adverse events.

Serious Adverse Reactions (SARs)

In 2008, 143 SARs were accepted by the NHO, mainly in Acute Allergic, Anaphylactic Transfusion and Febrile Non-Haemolytic Transfusion Reactions categories.

Eight cases of Suspected Transfusion Transmitted Infection (two viral and six bacterial) were reported. Transfusion transmitted infection was excluded, or considered unlikely, in four cases (2 bacterial and 2 viral) and in the remaining four cases were considered possible as bacterial infection could not be excluded. The patients suffered no sequelae as a result of these incidents

Annual Notification of Serious Adverse Reactions and Events' (ANSARE)

In compliance with Commission Directive 2005/61/EC Annex II D and III C an ANSARE form must be completed by all hospitals transfusing blood and blood establishments (BE). The ANSARE form for reporting year 2008 was issued in January 2009 to 76 reporting centres (72 hospitals and 4 BE).

No. of sites	reported in 2008
21 (28%)	one or more SAR
6 (8%)	one or more SAE
22 (29%)	both SAR and SAE
27 (36%)	no SAR or SAE

As ANSARE does not collect non mandatory clinical IBCT incidents, which account for 32% of the total number of reports analysed by the NHO in 2008, these returns underestimate the overall rate of hospital reporting to the NHO.

NHO 10th Anniversary Conference (2009)

"Haemovigilance in Ireland-The First Decade– Promoting safety in Transfusion"

The NHO 10th Anniversary Conference was held in the Royal Hospital Kilmainham in October 2009 with

190 delegates from medical, nursing and scientific backgrounds attending the event. The Conference was opened by the Minister for Health and Children, Ms Mary Harney, TD.

Key speakers on aspects of patient safety were Dr Tony Holohan Chief Medical Officer (CMO) Department of Health and Children (DOHC), - Patient Safety in Ireland and Dr. Clare Taylor Medical Director of UK SHOT - Haemovigilance and the Junior Doctor. Dr. Kieran Doran, Senior Health Care Ethics Lecturer, University College, Cork spoke on Consent to transfusion.

Irish Medicines Board

The IMB is the Competent Authority for implementation of all aspects of the EU Blood Directive. The IMB held quarterly case review meetings with the NHO to discuss reported incidents.

Education, promotion and developments

The NHO continues to support the development of hospital in-service training programmes and transfusion education for nursing and medical laboratory science students by working closely with hospital based Haemovigilance Officers (HVOs).

Open days

All newly appointed hospital HVOs are invited to the NHO Open Day where the function of the NHO is explained. One open day was held in 2009 with 14 people attending.

Haemovigilance Education Initiatives at DCU

The NHO, in partnership with Dublin City University (DCU) continued to deliver both professional development degree level and postgraduate modules, aimed at clinical and laboratory staff working in blood donation and transfusion practice.

Students from both the Irish Blood Transfusion Service and from hospitals through out the country have undertaken the professional development modules for both 2008-2009 and 2009-2010. These modules are particularly well evaluated from a professional development perspective. Additionally students from the Irish Blood Transfusion Service currently completing the graduate diploma in nursing practice will graduate in 2010.

The availability of both degree and post-graduate options at DCU afford a unique opportunity to progress to post graduate study in blood donation and haemovigilance practices and delivers a recognised pathway for practitioners to develop their roles to advanced specialist level.

E-Learning

The roll-out to Irish hospitals of the LearnProNHS e-learning programme developed by the Effective Use of Blood Group of the Scottish National Blood Transfusion Service continues. The NHO also participated in the e-learning editorial group which reviews and updates materials on an annual basis, in addition to contributing and reviewing proposed programme content for new modules.

Irish Unrelated Bone Marrow Registry

The e-learning programme facilitates continuing professional education for clinical practitioners involved in the transfusion process. The e-learning programme offers learners an alternative way to keep up to date with current best practice at a time and place convenient to them and for those learners successfully completing the assessment modules provides standardised evidence of staff training in transfusion practice as required by the Irish National Accreditation Board.

Recommendations for a unique health identifier in Ireland

Data from reports received to the NHO since 2000, was used by the Health Information and Quality Authority to support the introduction of a unique health identifier in Ireland. This was the only available data within an Irish context.

A copy of the report is available at http://www.hiqa.ie/publications.asp

At present allogeneic stem cell transplantation is the only curative therapy for some leukaemias, bone marrow failure syndromes and for some inherited metabolic disorders. The ideal donor is a tissue matched sibling but due to falling family sizes fully HLA matched sibling transplants will not be possible for many patients.

Matched Unrelated Donor (MUD) transplants provide an alternative for such patients with no family donor and increasing numbers are being performed each year aided by the availability of volunteer bone marrow registries throughout the world.

The Irish Unrelated Bone Marrow Registry (IUBMR) was set up in 1989 to meet the need for unrelated donors for Irish and international patients. The panel currently consists of 19,926 donors 99% of whom are fully AB, DR typed. Since 2001 all donors going on the unrelated panel are typed exclusively by DNA methods by the National Histocompatibility Immunology Reference Laboratory (NHIRL).

The registry 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 (OLCHC).

In addition, in conjunction with SJH, the Registry co-ordinates donations from Irish donors for both Irish and international patients. The registry is covered by the IBTS tissue licence 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.

Donor Recruitment

The IUBMR recruited 906 new donors to the panel in 2009.

National Activities

In 2009 fifty five patients were referred to the IUBMR for unrelated searches from the Irish Transplant Centres at SJH and OLCHC. Fifteen were paediatric referrals and 40 were adults.

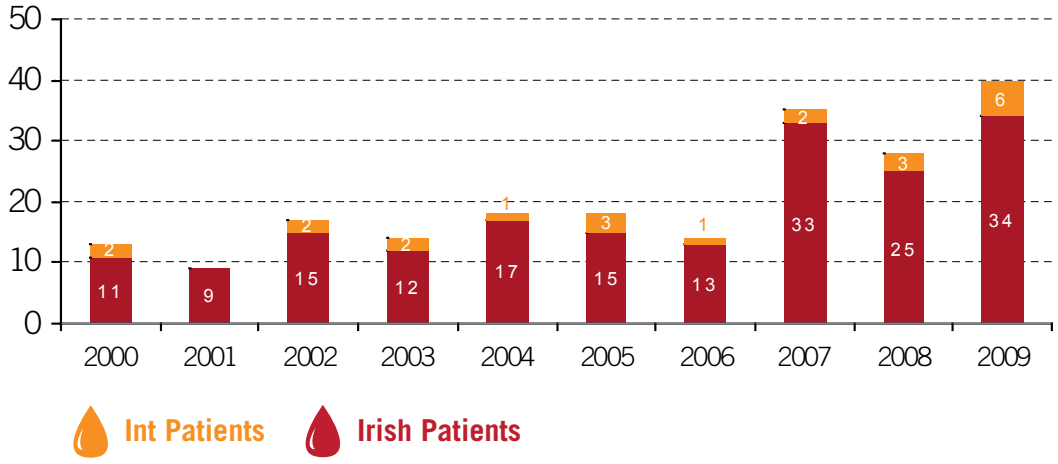
The number of searches for unrelated transplants for Irish patients has increased over the last 3 years due to increased number of indications for matched unrelated transplants and the extension of the upper age limit for patients.

Donors were activated for 52 of the 55 patients referred for an unrelated search. Samples were requested from 171 international and Irish donors for typing in the NHIRL. Typing was also requested from international registries on 180 donors.

Thirty four patients received a transplant in 2009. Twenty nine stem cell donations were sourced from Europe including Ireland and 5 from outside the EU.

Sixteen patients received peripheral blood stem cells (PBSC) and fourteen patients received bone marrow. Four of the patients received unrelated cord blood units (CBU) as a source of stem cells.

IUBMR Transplants Facilitated From Irish And International Donors 2000 - 2009



International Activities

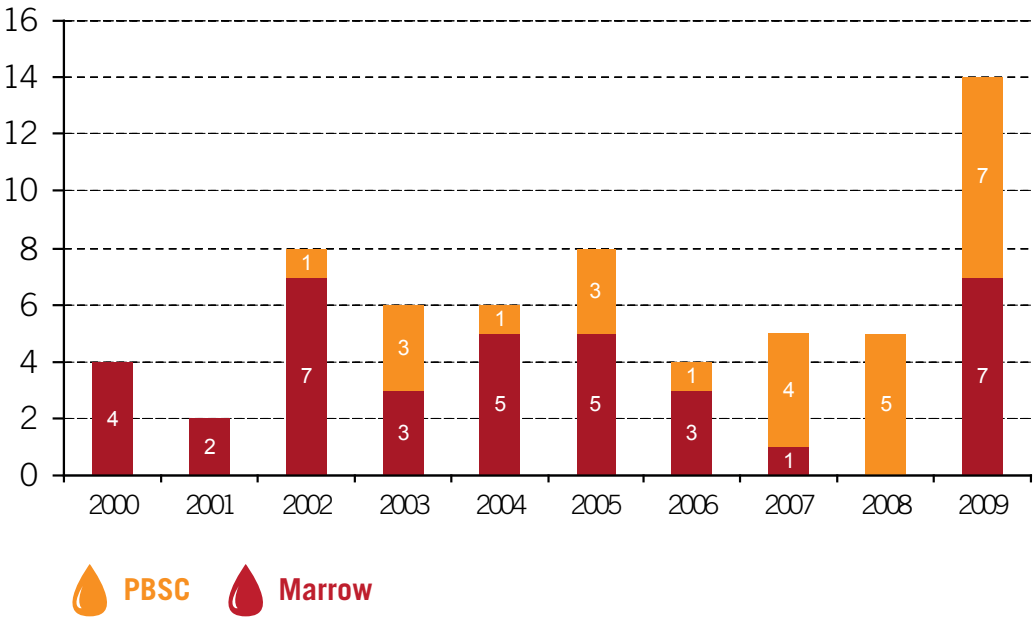
Preliminary searches were received on behalf of 348 international patients of which 124 were activated. Irish donors donated for 3 international patients. The IUBMR also facilitated workups for 3 international donors who were residing in Ireland.

Irish Donations

Since 2000 the mean number of donations from Irish donors was 6 per year but in 2009 the number of collections increased by 36% from 2008.

There were fourteen donations in 2009. The donations went to patients in Europe including Ireland (12) and outside the EU (2).

Irish Donors Donations 2000 - 2009



Therapeutic Apheresis

The therapeutic apheresis teams in the IBTS provide a demand led service on location in Dublin and Cork. Apheresis procedures are performed on patients with rare and often life threatening Haematological, Renal or Neurological blood disorders. The majority of procedures are Plasma Exchanges but other treatments include, Red Blood Cell Exchange, Red Cell Depletion, Leucodepletion and Platelet Depletion.

The respective teams are led by consultant haematologists and treatments are provided by specially trained apheresis nurses.

Case Load

A total of 473 procedures were carried out in 2009, a decrease of 31 from the previous year. This compares to previous years as follows;

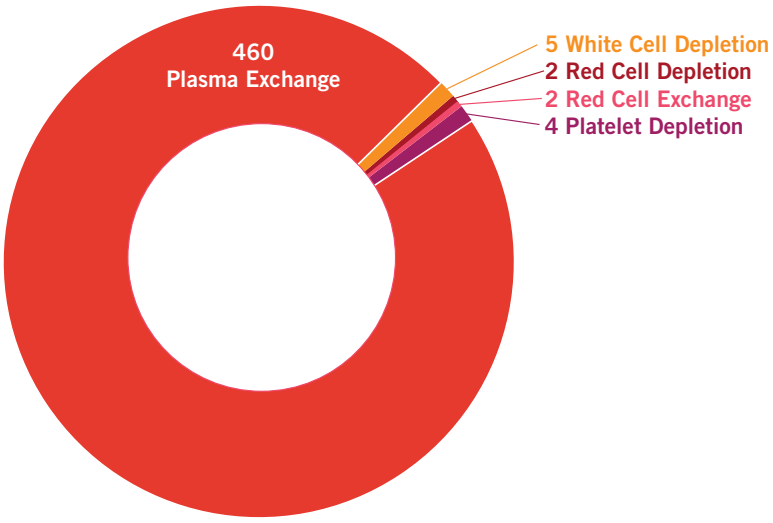
2008 - Total procedures = 504

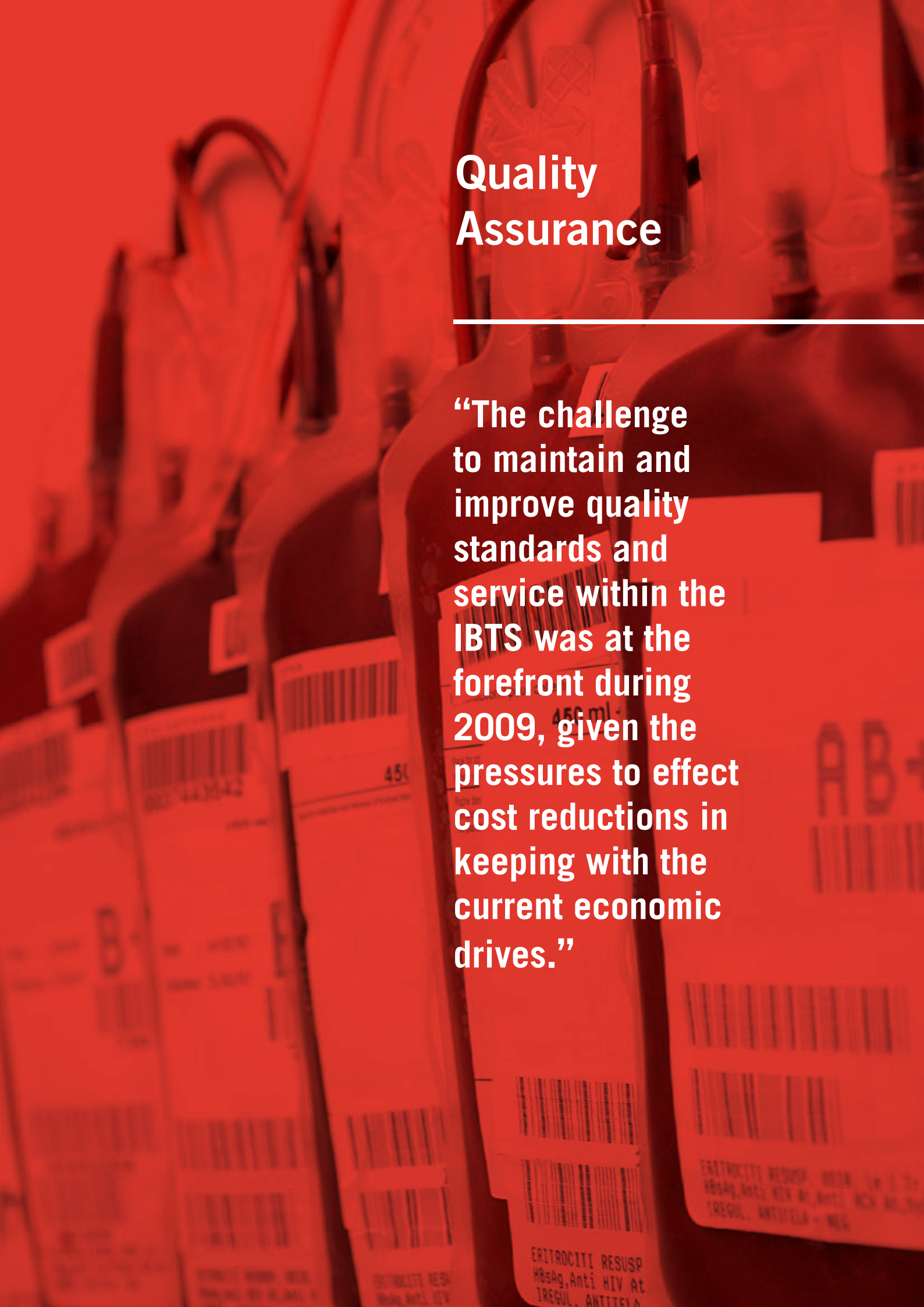
2007 - Total procedures = 428

The hospitals involved where patients were treated are Tallaght Hospital (AMNCH), St Vincents Hospital (SVUH), Mater Hospital (MH), Cork University Hospital (CUH), Mercy University Hospital (MUH), and others.

The therapeutic apheresis teams provided emergency cover and on call service at weekends and public holidays.

Types and frequency of procedures





Quality Assurance

“The challenge to maintain and improve quality standards and service within the IBTS was at the forefront during 2009, given the pressures to effect cost reductions in keeping with the current economic drives.”

Regular reporting on established compliance metrics both to the Executive Management Team and the Audit and Compliance Committee was an essential element of making progress transparent.

During 2009, the IBTS was subject to 4 IMB inspections, two for the Blood Establishment (BE) activities, one for the Tissue Establishment (TE) activities and one inspection of the National Haemovigilance office. The outcome was satisfactory for both the BE and TE inspections.

The Quality Audit programme completed a total of 50 Internal Audits during the year covering a sample of all the IBTS activities. Good progress was made on achieving the metric of >80% closure of incident reports (IRs) with an average of 84.5% of IRs closed out by year end. It is envisaged that the introduction of SMART®CAPA during 2010 will further enhance the transparency of IR close out.

The rate of change in the IBTS is measured in the Quality Management System through the numbers of change controls (CC) and change orders (CO) raised, processed and implemented. The target of >80% closure on change orders was exceeded for centre based changes during 2009, with IBTS/National changes coming in under target at 66%. This will be closely monitored during 2010 to effect improvement.

The rate of change controls raised, processed and implemented during 2009, met the close out target of >60% for centre based changes but showed a 55% closure for IBTS/national changes.

Analysis of this data shows that implementation of major/significant national changes e.g. introduction of new technologies (Tigris; single donor NAT testing), changes in critical materials (new bag introduction, change in donor arm cleaning materials) is done in a planned validated way over a period of time to ensure the reliability and robustness of systems and practices.

The preparations for the H1N1 swine flu virus pandemic was the focus of major work during the year, with preparations covering all aspects of the IBTS business from supply of critical stocks to plans for staff/resource cover. The robustness of the Quality Management system ensured rapid changes could be made in a controlled way.

As well as having a system to capture product complaints, the IBTS developed a particular system for donor and service complaints that was introduced in January 2009. By year end, 94.8% of donor and service complaints were closed. The IBTS will build on improving this in the coming years as the system matures.

The number of product complaints received by the IBTS increased in 2009 over 2008 figures, with DAT + complaints increasing and a new category of short dated/service complaints emerging. The target of achieving closure >90% within 30 days for product complaints is currently not being met; the quality function has a challenge to improve on this.

The combined number of recalls for both MRTC and NBC was 357 (for 2008) and 363 (for 2009). Recalls in this business are preventive in nature and

Quality Assurance

in the main are instigated on foot of post donation information from the donor, or due to precautionary recalls associated with the incubation of bacterial testing of products.

There is a Donor Vigilance, Haemovigilance and Tissue Vigilance system in place within the IBTS to ensure that both Serious Adverse Reactions (SARs) and Serious Adverse Events (SAE's) are reported to the NHO/IMB. During 2009, the Donor Vigilance System was centre based with 127 donor vigilance events captured in MRTC and 186 in NBC. From 1st January 2010, a national system of reporting such donor events will be in place.

There were 3 Tissue Vigilance Reports identified to the IMB during 2009, relating to tissues such as heart valves, imported corneas and cord blood.

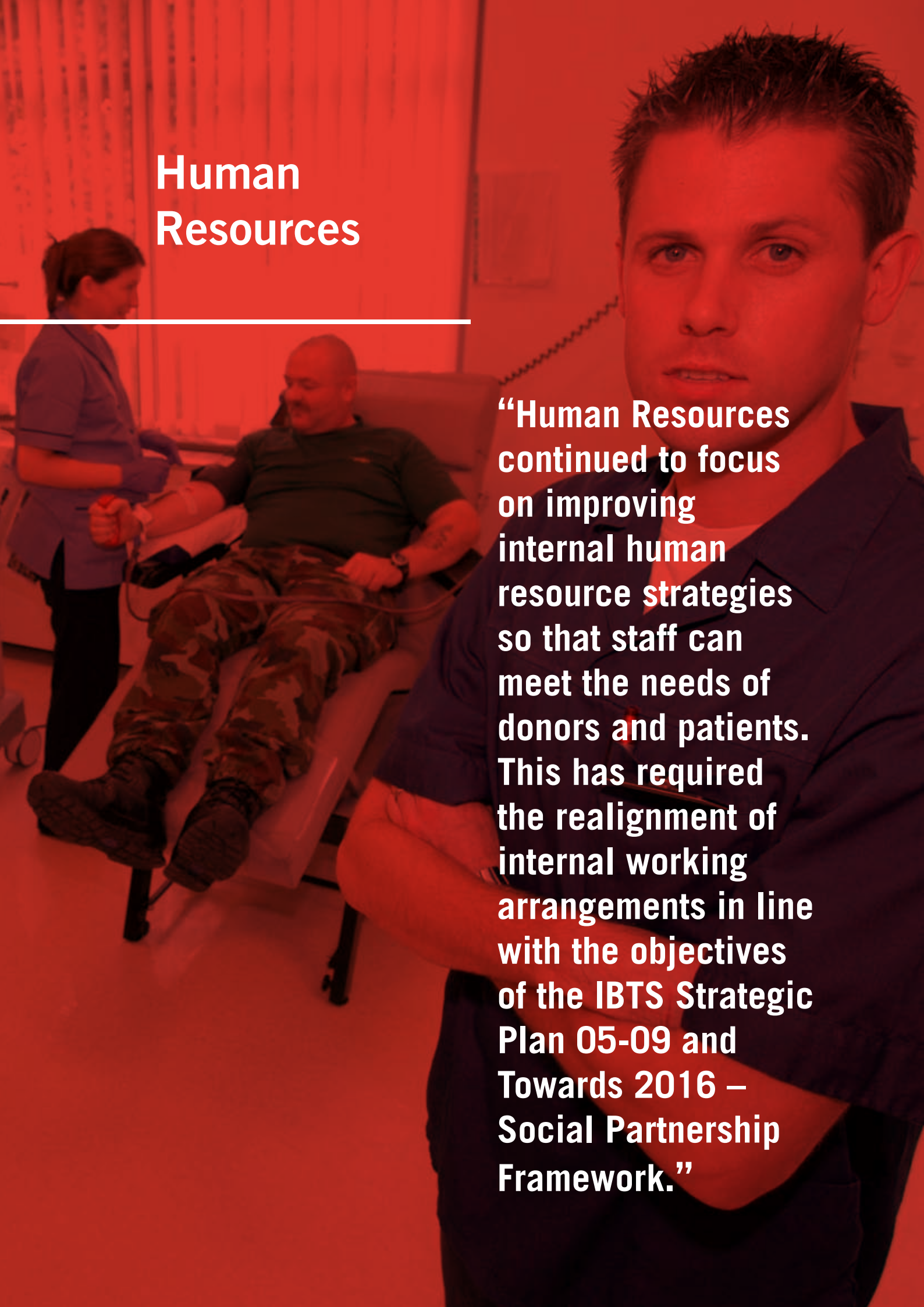
The number of quality system haemovigilance reports to the NHO were similar in number for the NBC for both 2008 and 2009, but there was an increase in reported numbers from the MRTC.

The development of a single, unified, quality system within the IBTS has been facilitated by the implementation of Pilgrim, SMART®SOLVE electronic quality management system. The first module, fully implemented Smart Doc has made transparent the tracking of SOPs being nationalised, from a starting point of 318 IBTS SOPs (September 2008) of a total of 1545 SOPs, to 664 IBTS SOPs (December 2009) of a total of 1514 SOPs. A target of 815 IBTS SOPs by end 2010 has been set.

During 2009 two further modules of SMART®SOLVE were validated and introduced, SMART®AUDIT and SMART®TRAIN The latter is being rolled out throughout the IBTS to achieve electronic training record keeping for all Quality Management System procedures.

As part of the IBTS Quality Management System, the testing laboratories participate in external quality assurance schemes throughout the year. During 2009, both NBC and MRTC results were satisfactory with one exception.

Human Resources



"Human Resources continued to focus on improving internal human resource strategies so that staff can meet the needs of donors and patients. This has required the realignment of internal working arrangements in line with the objectives of the IBTS Strategic Plan 05-09 and Towards 2016 – Social Partnership Framework."

Human Resources

Change management

The operating environment changed significantly through 2009. The break down of social partnership saw the return to a more turbulent industrial relations environment, including industrial action ranging from work to rule culminating in a day of action involving the withdrawal of labour. The status of a number of projects is as follows:

Extended Working Day Laboratory NBC Review – implemented and reviewed
Laboratory Cork Agreement - under negotiation
Donation Process Review Phase Two – centre by centre implementation commenced
Transport Review – reaching conclusion, next stage negotiate the changes in 2010.
D'Olier Street Clinic Review – complete review and negotiate changes in 2010.

The objective of IBTS change management continues to be to enhance service delivery to patients and donors.

Recruitment

Ensuring we hired and promoted the right people, at the right time, in the right role to support the delivery of, and provide an excellent service to our donors, patients and key stakeholders continued for the first quarter of 2009. In quarter two, a moratorium on recruitment was introduced which is to remain in place until the end of December 2010. Only key roles critical to the maintenance of the safe, sufficient collection and processing of blood products have been protected within this moratorium.

Training and Development

One of the IBTS' Core Values is Learning - 'we are committed to ongoing organisational learning, professional and personal development and research'.

A fundamental element of progress in any organisation is to have responsible and capable management and staff to facilitate the organisation meeting its key operational and strategic objectives. The Training and Development function within Human Resources is responsible for ensuring that the staff have the capabilities and competencies required to create, implement and lead change. The major development intervention in 2009 was the Team Management & Development programme "Quantum Leap", which saw the completion of the Executive, Senior Management & Clinic Management 12 module training programmes, undertaken in conjunction with IBEC and the IMI. Clinic teams also completed their team development days. This was a significant resource and logistical commitment on the part of the organisation and participants.

Quantum Leap continues into 2010, where the remaining support and laboratory teams complete their team development day. The outcomes of all team development, in the form of team and personal development plans and team continuous improvement projects will form the basis for ongoing development.

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 2009:

- Fully Sponsored Financial Assistance – 14 approved applicants
- Limited Financial Assistance – 7 approved applicants

During the year, the support included financial assistance and leave for study and exams for 15 ongoing applicants 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. The collection of non-medical material held was expanded to reflect the needs of employees undertaking the Quantum Leap programme while the training needs of staff undertaking further studies were also addressed.

Training by library staff was provided on how to source both quality medical and management information and how to reference and cite sources with group and individual library and information skills sessions being maintained throughout 2009.

In response to developing the Library's alerting service, new subject specific email lists were set up for Chikungunya and Babesiosis. Library staff continued to develop and update the IBTS Intranet and produced guides for same.

Environmental, Health and Safety

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

IBTS Contractor Management Programme

A Contractor Management Programme was written to establish Environmental, Health & Safety responsibilities in relation to Contractors. As part of the Contractor Management Programme a Contractor Induction Management System was established.

Certificate of Professional Competence (CPC) Training

The Road Safety Authority introduced Driver CPC in Ireland 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).

Human Resources

IBTS drivers completed Module 1 of CPC training in 2009 in line with this requirement.

Portable Appliance Testing

In compliance with the Safety, Health & Welfare at Work (General Application) Regulations 2007 the IBTS Portable Appliance Testing Programme was revised with testing rolled out for portable electrical appliances in all IBTS Centres.

Bikes4Work Scheme

The introduction of this scheme by the Government offered 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 launched in the IBTS during European Health & Safety 2009 with Road Shows being run in IBTS Centres nationwide.

Flu Vaccination

The annual seasonal flu vaccination was provided in IBTS centres at the beginning of the flu season. In addition in 2009 with the emergence of the Pandemic H1N1 influenza virus (Swine Flu), vaccination was provided for IBTS employees. Twenty nine per cent of IBTS employees received the swine flu vaccination.

Finance

Draft Accounts for 2009

	2009 €'000	2008 €'000
Income		
Recurring income	117,407	116,714
Non-recurring income	540	853
Total income	**117,947**	**117,567**
Expenditure		
Total expenditure	**112,136**	**119,540**
Surplus for year	5,811	1,027
Actuarial gain / (loss) on pension scheme	577	(15,673)
Transfer (to) / from Capital Reserves	(2,000)	-
Transfer (to) / from Research Reserve	(273)	296
Accumulated (deficit) / reserve at 1st January	(6,324)	8,026
Accumulated (deficit) at 31st December	**(2,209)**	**(6,324)**

Income

The Board's total income for 2009 of €117.94 million (2008 €117.56 million) is analysed into recurring income and non-recurring income. Recurring income consists of revenue generated from products and services provided to hospitals of €117.40 million (2008 €116.71 million). Non-recurring income during 2009 includes interest earned on bank deposits and proceeds from the sale of fixed assets. The Board did not increase its prices for 2009.

Expenditure

Expenditure for 2009 amounted to €112.13 million (2008 €116.54 million). The reduction in expenditure mainly occurred as a result of the implementation of a cost reduction programme and price reduction in blood products. Costs incurred buying out remaining laboratory work practice in 2009 were at a lower level than those incurred in 2008.

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

In 2006 the Board set up a research reserve. In 2009 €273,000 were transferred to the reserve. (In 2008 €296,000 was expended from the reserve).

Finance

The Board also has a Capital reserve fund 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 2009 was €7 million.

Capital Expenditure

The Board invested €1.4 million in capital projects and equipment during 2009. (€1.7 million 2008). The main investment during the year included freezer modifications, NAT lab modifications, MRTC production centrifuges, liquid nitrogen tank upgrade, Anti D (Anti C) quantitation equipment and completion of the BOSS project.

There was recurring expenditure for the replacement of I.T. infrastructure, medical and other plant and equipment. In addition, expenditure was incurred on laptop and USB encryption, and HR time & attendance system.

Financial Systems

In 2009 an upgrade of hardware, software and the Oracle platform took place for our integrated HR/ Payroll system.

Prompt Payment Legislation

The Board complies with the requirements of Prompt Payment Legislation except where noted below. The Board's standard credit taken, unless otherwise specified in specific contractual arrangements, are 30 days from receipt of the invoice or confirmation of acceptance of the goods or services which are subject to payment. It is the Board's policy to ensure that all accounts are paid promptly. During the year ended 31st December 2009, under the terms of applicable legislation, invoices to the value of €460,921 were late, by an average of 35 days. These invoices constituted 0.39% by number and 0.56% by value of all payments to suppliers of goods and services during the year. Total interest paid in respect of all late payments amounted to €1,052.92. The Board continuously reviews its administrative procedures in order to assist in minimising the time taken for invoices query and resolution.

Members of the Board in 2009

Ms Katharine Bulbulia
(Chairperson, appointed 27.10.09)

Ms Maura McGrath
(Chairperson, term expired 31.08.09)

Mr David Keenan (reappointed 09.10.09)

Mr David Lowe (reappointed 10.12.09)

Mr Sean Wyse

Ms Jane O'Brien

Dr Robert Landers (term expired 11.06.09)

Dr Margaret Murray (term expired)

Ms Margraet Mullet (term expired 31.08.09)

Dr Mary Cahill

Dr Cees van der Poel (resigned 15.12.09)

Ms Marie Keane (appointed 01.05.09)

Ms Sinead Ni Mhaille (appointed 01.09.09)

Dr Paul Browne (appointed 01.09.09)

Ms Ann Horan (appointed 18.12.09)

Mr Gerry O'Dwyer (term expired 31.08.09)

Mr Mark Moran

Contact details

Auditors

Comptroller and Auditor General
Treasury Building
Lower Castle Yard
Dublin Castle
Dublin 2

Solicitors

McCann Fitzgerald Solicitors
Riverside One
Sir John Rogerson's Quay
Dublin 2

Bankers

Allied Irish Bank
Dame Street
Dublin 2

Irish Blood Transfusion Service

National Blood Centre
James's Street, Dublin 8
t: 01/4322800
f: 01/4322930
e:info@ibts.ie
www.giveblood.ie Donor infoline 1850731137

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

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

Stillorgan Blood Donation Clinic
6 Old Dublin Road
Stillorgan, Co Dublin
t: 1850 808 808

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

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

Limerick Centre
Carrig House
Cloghkeating Ave
Raheen Business Park
Limerick
t: 061/306980
f: 061/ 306981

Tuam Centre
Unit 49
N17 Business Park
Tuam, Co Galway
t: 093/70832
f: 093/70587

Irish Blood Transfusion Service

Seirbhís Fuilaistriúcháin na hÉireann

National Blood Centre
James's Street, Dublin 8.
Tel: 00 353 1 4322800
Fax: 00 353 1 4322930
Email: info@ibts.ie

www.giveblood.ie
Donor Infoline 1850 731 137

Designed by catalyst