

IBTS Annual Report 2000

Mission Statement:

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

Irish Blood Transfusion Service

Annual Report 2000

FOREWORD

The year 2000 encapsulated a year of accelerated progress and exciting development for the Irish Blood Transfusion Service.

New practices and procedures continued to be implemented so that blood and blood products are as safe as they possibly can be.

New IBTS centres were opened in James's St. and D'Olier St. in Dublin and in Carlow. Additional staff were recruited in the past year - serving as a sign of the sterling efforts made to ensure not only a safe blood supply but that an adequate blood supply was available for our hospitals.

The physical manifestation of the commitment to the highest of standards was the opening of the National Blood Centre in October 2000. The Centre sets the standards in terms of transfusion laboratories and it is certainly among the very best internationally. Improved facilities allow us to undertake a wide range of highly advanced processes in the National Blood Centre which include cutting-edge tissue banking, cell-growing laboratories, sophisticated testing and quality control systems that are amongst the best, and most stringent in the world.

The National Blood Centre is truly an impressive facility. It will ensure that the IBTS remains at the leading edge in terms of transfusion services. It will also be a reminder to all who work in it, and those who visit, that we constantly strive to find new ways to improve both the standards of service and safety to the people of Ireland who will depend on blood either on a planned or an emergency basis.

During the year we celebrated our 50th anniversary. While not all of the events of the past fifty years gave us cause for celebration, our past will always be a reminder of our responsibility for the future.

The support of donors and the commitment of staff give us hope and a high degree of confidence, that the year under review, as the start of a new millennium marks the beginning of a new and positive era in transfusion services.

We remember the many people who gave generously of their time, and skills, to build and maintain this vital national service. We also remember all those who supported their efforts in any way. Their good work will continue in this millennium.

CHIEF EXECUTIVE OFFICER S REPORT

The continued availability of a safe and adequate supply of blood plays an essential part in supporting patient care in hospitals throughout the country. Maintaining the safety of blood products supplied for patient care continues to be a priority for transfusion services worldwide. Through our partnership with other national transfusion services and our involvement within scientific fora, we strive to stay at the forefront of international developments.

Ongoing change, which has been a feature of the service in recent years, gathered pace in 2000. September saw the opening of our new Donor Organisation centre in Carlow, which co-ordinates blood collection activities in the Southeast and South Midlands. In October we successfully completed the transfer of testing, production and administrative facilities from our old headquarters, Pelican House, to the National Blood Centre in James s Street. In November the Dublin Donor Clinic moved from Pelican House to a new centre in D Olier Street. Plans were put in place towards the end of the year to establish a donor centre for the Northeast and North Midlands to be based in Ardee, Co. Louth in 2001. We ended 2000 with a decision to enter negotiations with a designated company for the installation of Nucleic Amplification Technique (NAT) testing system at the National Blood Centre. NAT testing is the most advanced testing system available to blood banking.

The establishment of the new donor centres is a recognition of the need for change and of the fact that busy lifestyles and domestic responsibilities make it more difficult for many people to find the time to give blood. We will continue with our efforts to make it more convenient for people with busy lives to continue to donate blood in 2001.

To coincide with the many internal changes taking place we changed our name to the Irish Blood Transfusion Service. This reflects increasing involvement internationally, particularly in Europe. The change took place on 7th April 2000 to coincide with the World Health Organisation s (WHO) Safe Blood Campaign.

While continuing to work closely with local voluntary organisers and donors we continue to forge links with hospitals. The National Haemovigilance Office continues its close cooperation with hospitals to ensure the safe delivery of transfusion services. The appointment of additional transfusion consultants with hospital sessions will help to improve the links with major hospitals.

The tragedy of past events continued to receive attention throughout the year. Public hearings at the Lindsay Tribunal, which is inquiring into the infection with HIV, and Hepatitis C of people with haemophilia and related matters, commenced in May. At year-end the Tribunal had completed hearing evidence on the role of the Blood Transfusion Service in relation to the infections and in respect of related matters.

The threat of vCJD continued to be monitored closely throughout the year. At year-end we are examining what further steps, in addition to the removal of white cells from blood (leucodepletion), can be taken to minimise the potential threat of vCJD. While there is no scientific evidence that vCJD is transmitted through blood we are working on the assumption that it can be.

The gradual decline in the use of blood continued throughout the year. Ireland is now one of the lowest users of blood per head of population in the developed world. We will continue to work with hospitals to ensure the appropriate use of blood and blood products.

The many changes which have taken place in the past year would not have been achieved without the flexibility and commitment shown by staff throughout the organisation. Their commitment and enthusiasm augurs well for the future of the Irish Blood Transfusion Service as we enter the third millennium.

NATIONAL MEDICAL DIRECTOR S REPORT

As is now widely appreciated blood transfusion is a very difficult and demanding form of treatment. It is difficult to obtain, difficult to store, test and process and difficult to use. And though it saves lives, enables vital surgery to be done, cancer treatment to be given safely, serious accidents to be survived, it is difficult to keep safe. Hepatitis B, Hepatitis C and HIV have cut through the blood supply throughout the world killing thousands, leaving many more damaged and ill. The threats are not over and if we have learned anything, we have learned that we need always to keep vigilant and to be careful. We must ensure that as much effort and resources as we have at our disposal as a nation is used to ensure that patients who need a blood transfusion get a therapy that is as safe and effective as it can be.

Every week over 1,000 people need a blood transfusion in this country; every year over 1% of the population receives a transfusion; and everyone in the country has at least a 1 in 4 chance of needing a transfusion in their lifetime.

The completion of the building and commissioning of the new blood centre at Dublin marked a major milestone in the development of blood transfusion in Ireland. This building serves as a physical manifestation of the commitment of this country to safe and secure blood transfusion in the future. It also serves as a physical manifestation of the shift of blood component manufacture to a pharmaceutical grade production and quality control philosophy. The building is the most advanced blood centre in Europe and is a very far cry from the

origins of blood component manufacture in the middle years of the twentieth century.

Blood component manufacture, the preparation of therapeutic components of red cells, platelets and plasma from blood donations is only one part of our operation. The others donor recruitment, blood collection, donation testing, blood storage and distribution and hospital liaison including supply, haemovigilance and support of best practice - all have equal importance in ensuring a safe and secure blood transfusion service. In all of these areas considerable development took place during the year, including new strategies in donor collection, developments in donation testing, particularly NAT testing for Hepatitis C, and development of national practice guidelines at the Blood Users Group.

The pace of change in blood transfusion has never been faster the year end found us meeting new challenges in the shifting paradigms of transfusion medicine; the threat of vCJD, the advent of more extensive NAT testing and the emergence of new chemical techniques for eradicating the threat of disease transmission by blood products.

The year was also marked by a very public schism within the IBTS over testing strategies the strategy of locating donation testing on a single site at the National Blood Centre in Dublin faced trenchant opposition. At year end the challenge of resolving this remains. In view of the huge demands on the Service to embrace far reaching changes, the urgency of resolving this issue is all the greater. The necessity to replace the old Cork buildings with state-of-the-art facilities also compounds the necessity to bring closure to this issue.

While facing the threat of vCJD remains our biggest challenge for the year ahead, achieving internal cohesion is an essential task to allow the IBTS to achieve its goals.

DONOR SERVICES & COLLECTION

Donor Attendances

174,738 people throughout the country attended our blood donor clinics in 2000. Of those, 18,848 were new donors.

New Southeast Centre

The Irish Blood Transfusion Service opened up its Southeast Donor Organisation Centre in Carlow in September. This new centre will organise clinics and collect blood in counties Carlow, Kildare, Kilkenny, Waterford, Wexford, Wicklow, South Tipperary and parts of Laois and Offaly. The opening times of clinics in these counties have been amended to make them more accessible to donors and a clinic will take place on every third Sunday in these areas.

New Dublin Blood Donor Clinic

President Mary McAleese officially opened the new Dublin donor clinic in D Olier Street in December. This is a prime city centre location with huge volumes of pedestrian traffic. Dublin donations have increased since the move to the city centre from Pelican House and we expect numbers to further increase in 2001.

Apheresis Platelet Programme

4,966 people donated platelets in the past year. Apheresis is a process whereby blood is taken from the donor, the platelets are extracted from the blood and the remaining blood components are then returned to the donor. Platelets, which have a shelf life of five days, are primarily used for the treatment of cancer patients and newborn babies. The Apheresis Platelet Programme is now based at the National Blood Centre.

Work Place Blood Drive

A broad range of government departments, semi-state bodies and public and private companies participated in our Work Place Blood Drive in 2000. This is where a company or organisation allows their employees (minimum of five) time off work to donate blood. Our thanks to all employers and employees for making this programme so successful.

Donor Interviews

An additional layer of donor screening was introduced by the IBTS in 2000 by the implementation of donor interviews at our clinics. All new and lapsed donors are now interviewed by a trained nurse or medical officer in advance of donation. This involves a detailed explanation of the Health & Lifestyle questionnaire by the nurse/medical officer who will answer any queries new donors may have.

Donor Award Ceremonies

One hundred and four 100-time and 603 fifty-time donors received their pelican and gold drop awards at ceremonies in Cork and Dublin during 2000. Our thanks to the Minister for Health & Children Michael Martin, Minister of State, Mary Hannifin and Cork Lord Mayor P.J. Hourican for presenting the awards.

Voluntary Donor Organisers

As always, the blood transfusion service could not be run without the help, support and commitment of our many Voluntary Donor Organisers who ensure good turnouts at our clinics throughout the country. We pay special tribute to those who retired in 2000 and keep up the good work to those working with us in 2001.

Donor Deferral Rates

In the past year, 17% of all donors were deferred from donating blood. This represents a 1% increase since 1999. In 1995 the deferral rate was 12.8%. Rising deferral rates puts greater pressure on the national blood supply as

it means a smaller pool of donors being available to give blood. The most common reason for deferral in 2000 were donors suffering from colds, flus, travel to a malarial country or donors who had not eaten before donation.

Complaints

The majority of complaints received by the Donor Services Department in 2000 concerned the opening times of, and delays encountered at clinics. The establishment of new regional centres will allow for a reorganisation of opening times in areas within their region.

PROCESSING & TESTING

When units of blood are brought into our laboratories in Cork and Dublin each unit is entered onto our IT system. The units are then brought to the Components Laboratory where the red blood cells are filtered to remove white cells to reduce the risk of vCJD and then stored in quarantine. Platelets are stored in a controlled temperature 'agitator' which maintains consistent motion to prevent platelets from settling.

All samples of blood are simultaneously tested for HIV, Hepatitis B & C, syphilis and rare viruses called HTLV 1 & 2 in our Virology Laboratories in Cork and Dublin. At the same time, the Donor Grouping Laboratory is testing a sample of each donation to determine its blood group and Rhesus type.

A significant development during the year was the introduction of NAT (Nucleic Amplification Technique) testing which was contracted to the Scottish National Blood Transfusion Service pending the development of in-house facilities at the National Blood Centre. A sample of every unit of blood collected in Ireland was sent to Edinburgh for this additional more sensitive test for Hepatitis C in 2000. NAT testing will use the latest DNA technology to detect viruses at any stage of their development, rather than looking for the symptoms in the immune system after they have already developed.

HOSPITAL SERVICES

The Hospital Services Department of the IBTS continued its essential link in the distribution chain needed to ensure that blood reaches the people who need it most during the past year. The key function of the Department is to provide safe, and secure distribution of all products released for issue to hospitals. This involves critical product management and the maintenance of accurate and comprehensive records of both received and issued blood, blood components, and derivatives.

The Hospital Services Department is responsible for monitoring stocks of blood and blood products on an ongoing basis. The IBTS provides a 24-hour service to all hospitals throughout the country 365 days a year. A regular weekly delivery service to hospitals is also in permanent operation.

BLOOD & BLOOD PRODUCTS ISSUED

Product

1999

2000

Red Cells & Whole Blood

132,115

124,797

Platelets

43,987

41,207

Frozen Plasma

23,335

24,811

Cryoprecipitate

2,188

1,848

Albumin 20% 50ml

1,056

1,464

Albumin 20% 100ml

2,741

1,058

Albumin 4.5% 400ml

0

1,013

Albumin 4% 500ml

2,660

7

Normal Immunoglobulin 2ml

637

298

Anti D Immunoglobulin

42

38

Anti HepB Immunoglobulin Heptatect 2ml

23

22

Anti HepB Immunoglobulin Heptatect 10ml

84

77

Anti Varicella Immunoglobulin Varitect 5ml

57

13

Anti Varicella Immunoglobulin Varitect 20ml

54

14

Factor VII

5,000

0

Factor VIIA (xIU)

228,300

260,040

Protein C (x IU)

324,970

11,570

Anti Thrombin III (x IU)

23,000

28,500

Factor VIII Recombinant (x IU)

10,908,740

15,737,440

Von Willebrand Factor Haemate P (x IU)

329,500

146,500

Factor IX Recombinant (xIU)

4,888,470

7,889,820

Prothromplex (x IU)

310,800

266,400

Fibrinogen (x Ig)

235

119

Factor XIII Fibrogammin P

6,750

4,750

QUALITY ASSURANCE

2000 was a year of major change in the context of quality within the IBTS. The appointment of Marie O Connell as National Quality Assurance Manager in May 2000 added to the existing quality group, and gives a new emphasis to the national role required in defining, implementing and maintaining standards throughout the organisation.

Integral to ensuring compliance with relevant quality standards and regulatory requirements is the development of an effective validation programme. The appointment of a full time Validation Manager in the National Blood Centre (NBC) and the appointment of a permanent validation technician in the Cork centre during the year, will ensure we maintain a validated environment for our products and services.

Central to the move from Pelican House to the National Blood Centre, was the validation work done to commission and ready equipment and utilities to enable the IBTS work within a GMP validated environment.

A total of 278 validation protocols were executed before, during and after the move to the NBC. The principle of a planned validation programme has been incorporated into the day to day thinking of operating a quality service

within the IBTS.

Due to an extensive Y2K compliance programme, there was a smooth transition in the roll-over to year 2000.

Closure was achieved on the retrospective validation of the Blood Bank Computer System (BBCS) by year-end, and validation is still ongoing on the new computer software system Progesa.

A total of eight inspections were carried out by the Irish Medicines Board (IMB) of the IBTS during 2000, including full GMP inspections of the sites in the National Blood Centre, Cork IBTS and new clinics in Carlow, and D Olier Street.

The IBTS will continue to implement a safer, more efficient quality service in 2001.

NATIONAL HAEMOVIGILANCE OFFICE

The National Haemovigilance Office (NHO) is now firmly established in its role of collecting and analysing voluntary confidential information relating to adverse transfusion events at hospital level. This year marked the first complete year of reporting with the number of reports received surpassing original expectations. This excellent response reflects a developing and positive attitude towards Haemovigilance in Ireland, which can only be of long term benefit to all involved in the transfusion process. A more detailed breakdown and analysis of these reports will be contained in the Annual Report of the NHO.

A major part of the remit of the NHO is education/training and support in relation to best transfusion practice at hospital level. Considerable time has been invested working with hospital appointed Transfusion Surveillance Officers, (TSO) and promoting improvements in transfusion practice. When appointed, Hospital TSOs attend induction and general training at the National Blood Centre. Information packs, quarterly newsletters, correspondence and training days have also been arranged to encourage uniformity of practice and a free, open exchange of information.

In order to achieve a national standard in transfusion practice for all patients nationally the ultimate goal of the National Haemovigilance programme, - the office has continued to extend its involvement by being pro-active in two-way interaction with hospitals. Extensive visits, educational support, and the development of in-service training programmes have continued. This aspect of the programme has been most rewarding, with a steady building of mutual trust between the NHO staff; hospital based TSO and others throughout the country.

As the majority of TSO appointments were located in centres with a sizeable blood usage the NHO has developed in-service training sessions within smaller centres, in an attempt to standardise patient care before, during and on completion of transfusions.

A major part of the remit of the NHO is the development of audit functions at hospital level. NHO staff designed an audit tool to assist in identifying areas of transfusion practice where difficulties exist or could arise. The tool is loosely based on the NHO detailed questionnaires, and is designed to allow ease of completion both by observing practice and from archived patient records. Resulting recommendations will be used to promote improvements in transfusion practice by identifying areas of educational need.

The NHO continues to develop haemovigilance further in the year ahead by expanding a programme of regional seminars and study days in the interest of improving the care and welfare of transfusion patients throughout the country. The excellent progress made in the first fifteen months of this programme, has provided a firm foundation for these future developments and augers well for the future.

IRISH UNRELATED BONE MARROW REGISTRY

A total of 1,224 applications to join the Bone Marrow Registry were received during 2000. Of these, 79% were recruited with the remaining 21% being deferred due to our strict medical guidelines.

During 2000, the Bone Marrow Registry facilitated transplants to eleven Irish patients and two patients abroad. Donors on the Irish panel donated marrow to two Irish patients and two international patients.

The Irish Unrelated Bone Marrow Registry is affiliated to the National Marrow Donor Program, the largest registry in the U.S and European Marrow Donor Information System.

TISSUE BANKING

The Tissue Bank of the Irish Blood Transfusion Service is comprised of the National Eye Bank and the Homograft Heart Valve Bank. The Tissue Bank is a member of the Irish Donor Network, the European Eye Bank Association, the British Association of Tissue Banks and the American Association of Tissue Banks.

Bone Bank

The IBTS Bone Bank is based in our Cork Centre. In the past year 45 processed bone slices (900g) were issued for use in hospitals in addition to 5 half femoral and 4 femoral heads. These issues are used by hospitals for patients who would have previously had hip replacement operations and who need further bone replacements due to wear and tear.

National Eye Bank

The role of the Eye Bank is to supply organ cultured corneas to ophthalmic surgeons throughout Ireland. 87 corneas were donated to the Bank in 2000 of which 56 were issued for transplant.

Homograft Heart Valve Bank

The Homograft Heart Valve Bank received 19 heart valve donations in 2000. In total, 54 heart valves were issued in the past year. The valves are primarily used for children with congenital heart disease and women of child bearing age.

RECIPIENT TRACING PROGRAMMES

The Recipient Tracing Unit of the IBTS continued to trace recipients of infectious or potentially infectious blood or blood products.

To year end December 2000, 65,980 were screened for Hepatitis C under the national Anti D HCV Programme of which 64, 954 tested negative for Hepatitis C antibodies. Under the Anti D Reassurance Programme 3,879 recipients were re-tested.

Under the Targeted Look back Programme, 246 people have been tested of which 106 have evidence of continuing Hepatitis C infection. Up to December 2000, 14,865 people were screened under the Optional HCV Screening Programme of which 41 tested PCR positive. All 2,146 people screened under the HIV Screening Programme tested negative.

BUILDINGS AND ESTATES

National Blood Centre - James s Street, Dublin 8

The new Headquarter of the Irish Blood Transfusion Service opened its doors for business in October 2000. Located on James's Street, Dublin this state-of-the-art facility has been purpose-built to ensure that the IBTS can keep abreast of developments in medical science over the coming decades.

The site covers an area of 2.85 acres which includes the main building of 10,957 square metres consisting of a two story rectangular laboratory section with a curved three story office block, an enclosed service yard and parking spaces for donors, staff and visitors. The Minister for Health and Children, Micheal Martin TD, officially opened the National Blood Centre on the 23rd November 2000.

The National Blood Centre, its equipment and processes are validated on an ongoing basis to ensure that blood processing is conducted in compliance with the PEU Good Manufacturing Process (GMP) standards similar to those applicable to the pharmaceutical industry.

The National Blood Centre is one of the most modern facilities of its kind in the world. It will enable the Irish Blood Transfusion Service to be at the forefront of transfusion medicine and to offer the highest standards available internationally in terms of safety and quality in testing procedures.

Cork Centre

The Board of the IBTS agreed a draft Design Brief for a new Cork centre in December 2000. It is planned to progress this development in 2001.

Carlow Centre

The Irish Blood Transfusion Service opened its new centre in Carlow in September 2000. The centre, which will employ 27 people, will organise and operate mobile blood clinics in the Southeast region covering counties Carlow, Kilkenny, Waterford, Wexford, Wicklow, Kildare, South Tipperary and parts of Laois and Offaly. Blood collected is transported to the National Blood Centre for testing and onward distribution to hospitals.

Dublin Donor Clinic - D Olier Street

The new Dublin Blood Donor clinic is ideally situated on the second floor of the former ICS building which fronts onto O Connell Bridge. The new Clinic was officially launched by President Mary McAleese in December 2000.

INFORMATION TECHNOLOGY

The continuation of the development and upgrading of the Information Technology (IT) system has been a priority for the IBTS during 2000. Our objective is to have in place an IT system that provides an efficient and effective service to the organisation, which supports the maximum safety of our donors and quality of our products. In this regard, our IT system is integral to the tracing of blood and blood components from donor to patient.

Blood Bank Control System (BBCS)

The validation of the existing Blood Bank Control System (BBCS) was completed during the year.

The Progesa System

The existing Blood Management System (BBCS) is being replaced by a new system, Progesa, which is designed to replicate industry best practice in respect of process flow, operating procedures and quality management. It is currently the leading system in transfusion services internationally. Following extensive testing and validation, it is to be implemented by mid 2001.

PCR Project

The implementation of PCR testing required a system to ensure results of such tests could be received back from Scotland. This required the provision of a system to record the sending of samples to Scotland and the return of the results. This resulted in a detailed testing and validation program to ensure our high standard of safety was adhered to.

Network Infrastructure

The move of the IBTS to the National Blood Centre along with the opening of the new Donor Clinic in D Olier Street and the regional office in Carlow required the provision of new Local Area Networks (LAN) in each location. This in turn resulted in an increased Wide Area Network for the organisation.

STAFFING & HUMAN RESOURCES

Senior Appointments

The following senior appointments were made in 2000:

Mairead Nalty Human Resources Manager

Marie O'Connell National Quality Assurance Manager

Bernie Connolly Director of Nursing

Breda Mulvihill Area Organiser, Limerick Centre (Midwest)

Miriam O'Neill Area Organiser, Carlow Centre (Southeast)

John Healy Area Organiser, Ardee Centre, (Northeast)

Arthur Corrigan Management Services Officer

Employee Numbers by Centre 2000

Ardee 16

Cork 119

Carlow 27

National Blood Centre (inc. D Olier Street) 317

Limerick 30

Total 509 (full & part time)

Policies

The Following policies have been agreed with the Trade Unions representing Staff in the IBTS:

Grievance and Disputes Procedure
Respect and Dignity in the workplace

Transfer Talks

The Human Resources Department was critically involved in talks with staff organisations on the successful transfer from Pelican House to the National Blood Centre throughout 2000.

COMMUNICATIONS & PUBLICATIONS

Corporate Identity

The Blood Transfusion Service Board was renamed the Irish Blood Transfusion Service in April 2000. The new name reflects the increasing involvement of the national blood service at European level and its interaction with transfusion organisations in other European countries. The change of name, while minimal, will reflect our country of origin at international blood transfusion service meetings and conferences. Following the change of name, all IBTS stationary, vans, donor leaflets and publications were re-branded.

Web-Site

The IBTS web-site continued to provide information on our activities to the general public, hospitals and members of the media in the past year.

Freedom of Information

A total of 34 requests for information were received by the IBTS under the Freedom of Information Act in 2000.

Publications

A number of publications were issued by the IBTS in 2000 intended primarily for our donors and hospitals.

Handbook of Transfusion Medicine

The Handbook on Transfusion Medicine was re-issued in 2000 due to demand from hospitals. The Handbook is a reference book for NCHDs who transfuse blood at hospitals

Donor Digest

The Donor Digest is a bi-annual newsletter for donors. It provides information on donating blood, clinics, the use of blood for patients and also invites contributions from our donors. The Donor Digest is available at all our clinics and is also posted on our website.

FINANCE

2000 1999

£ £

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Income

Recurring 47,107 59,814 39,691 50,397

Non- Recurring 3,000 3,809 2,252 2,859

Total Income 50,107 63,623 41,943 53,256

Expenditure

Total Expenditure 51,438 65,313 41,452 52,633

Deficit/Surplus for year >1,331 >1,690 49,1 623

Balance at 1 January 1,484 1,884 993 1,261

Balance at 31 December 153 194 1,484 1,884

NOTE: The above figures are based on unaudited accounts for the years 2000 & 1999.

The Board's total income for 2000 of £50 million (1999 £42 million) is analysed into recurring and non-recurring. Recurring income consists of revenue generated from products and services provided to hospitals totalling £46

million (1999 £38 million). Also included is direct funding of £1.3 million (1999 £1.8 million) received from the Department of Health & Children in relation to expenditure incurred on the Hepatitis C programme. Non-recurring income includes a grant of £2.4 million in relation to Information Technology projects.

Expenditure of £51 million for the year 2000 is £10 million more than the 1999 figure. This reflects the continuing costs of implementing the Board's Reorganisation Plan and the costs of the introduction of new technologies and procedures such as Recombinant Products, leucodepletion, PCR Testing and the establishment of new IBTS centres in Carlow and D Olier Street, Dublin etc.

The Board's capital programme in 2000 amounted to £4.3 million. The majority of this investment was for the equipping of the National Blood Centre. That project has been fully funded by the Department of Health & Children.

The accounts of the IBTS are audited by the Comptroller & Auditor General. When the accounts for 1999 & 2000 are audited they will be submitted to the Department of Health and Children and subsequently laid before the Houses of the Oireachtas.

CORPORATE GOVERNANCE

The IBTS is committed to maintaining the highest standards of corporate governance and is accountable to the Minister for Health & Children. This statement describes how the principles of corporate governance are applied.

Compliance with the Combined Code

The Board is committed to complying with the relevant provisions of the combined Code of the Hempel Committee on Corporate Governance.

The IBTS established the Audit Committee during the year and received reports on internal control and going concern issues. The Board regularly reviews the reports of the IMB 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.

Workings of the Board

The non- executive Board is comprised of a Chairman and members appointed by the Minister for Health & Children. The Board is committed to achieving a range and balance of skills and competencies in its membership to permit it to execute its governance role to the highest standard. It is our objective that each member brings to Board an independent mind to judge on issues of strategy, performance, resources and standards of conduct.

The Board meets monthly. To enable the Board to discharge its duties, all members receive appropriate and timely information. The board takes appropriate independent professional advice as necessary.

The following committees deal with specific aspects of the IBTS s affairs:

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 meets monthly and is comprised of suitably qualified members of the Board, the Finance Officer and Management Accountant. The Committee reports to the Board on management and financial reports and advises it on relevant decision making.

Going Concern

After making appropriate 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 the financial statements.

Internal Financial Control

The Board is responsible for establishing and maintaining the Group s system of internal financial control. Internal control systems are designed to meet the particular needs of the Board and the risks to which it is exposed, and by their nature can provide reasonable but not absolute assurance against material misstatement or loss. The Board has no reason to believe that the internal control systems are inadequate, but is committed to reporting more fully in future years.

Statement of Director s Responsibilities

We undertake to prepare financial statements for the financial year which give a true and fair view of the affairs of the IBTS and of its income and expenditure for the year. In preparing those statements we have:

Selected suitable accounting policies and applied them consistently

Made judgements and estimates that are reasonable and prudent and

Explained any material departures from applicable accounting standards

We are responsible for keeping proper accounting records that disclose with reasonable accuracy at any time the financial position of the Board. We are also responsible for safeguarding the assets of the Board and for taking reasonable steps for the prevention and detection of fraud and other irregularities.

We undertake to publish the annual financial statements with the Annual report and to ensure, where possible, that the report of the Comptroller and Auditor general be appended.

IRISH BLOOD TRANSFUSION SERVICE

Members of the Board Dr. Patricia Barker, Chairman

Mr. Gerry Coffey

Mr. Pat Farrell 1/6/2000

Dr. Rosemary Hone Dr. Mary Horgan 1/6/2000

Dr. Fred Jackson

Dr. Elizabeth Keane 20/4/2000

Mrs. Valerie Mannix

Dr. Karen Murphy 1/6/2000

Professor Shaun McCann

Mr. Tony McNamara 1/6/2000

Dr. Ann O Connor 1/7/2000

Auditors: Comptroller & Auditor General

Treasury Building

Lower Castle Yard

Dublin Castle

Dublin 2

Solicitors: McCann FitzGerald Solicitors

2 Harbourmaster Place

Custom House Dock

Dublin 1

Bankers: Allied Irish Bank

Dame Street

Dublin 2

Mission Statement:

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The physical manifestation of the commitment to the highest of standards was the opening of the National Blood Centre in October 2000. The Centre sets the standards in terms of transfusion laboratories and it is certainly among the very best internationally. Improved facilities allow us to undertake a wide range of highly advanced processes in the National Blood Centre which include cutting-edge tissue banking, cell-growing laboratories, sophisticated testing and quality control systems that are amongst the best, and most stringent in the world.

The National Blood Centre is truly an impressive facility. It will ensure that the IBTS remains at the leading edge in terms of transfusion services. It will also be a reminder to all who work in it, and those who visit, that we constantly strive to find new ways to improve both the standards of service and safety to the people of Ireland who will depend on blood either on a planned or an emergency basis.

During the year we celebrated our 50th anniversary. While not all of the events of the past fifty years gave us cause for celebration, our past will always be a reminder of our responsibility for the future.

The support of donors and the commitment of staff give us hope and a high degree of confidence, that the year under review, as the start of a new millennium marks the beginning of a new and positive era in transfusion services.

We remember the many people who gave generously of their time, and skills, to build and maintain this vital national service. We also remember all those who supported their efforts in any way. Their good work will continue in this millennium.

CHIEF EXECUTIVE OFFICER S REPORT

The continued availability of a safe and adequate supply of blood plays an essential part in supporting patient care in hospitals throughout the country. Maintaining the safety of blood products supplied for patient care continues to be a priority for transfusion services worldwide. Through our partnership with other national transfusion services and our involvement within scientific fora, we strive to stay at the forefront of international developments.

Ongoing change, which has been a feature of the service in recent years, gathered pace in 2000. September saw the opening of our new Donor Organisation centre in Carlow, which co-ordinates blood collection activities in the Southeast and South Midlands. In October we successfully completed the transfer of testing, production and administrative facilities from our old headquarters, Pelican House, to the National Blood Centre in James s

Street. In November the Dublin Donor Clinic moved from Pelican House to a new centre in D Olier Street. Plans were put in place towards the end of the year to establish a donor centre for the Northeast and North Midlands to be based in Ardee, Co. Louth in 2001. We ended 2000 with a decision to enter negotiations with a designated company for the installation of Nucleic Amplification Technique (NAT) testing system at the National Blood Centre. NAT testing is the most advanced testing system available to blood banking.

The establishment of the new donor centres is a recognition of the need for change and of the fact that busy lifestyles and domestic responsibilities make it more difficult for many people to find the time to give blood. We will continue with our efforts to make it more convenient for people with busy lives to continue to donate blood in 2001.

To coincide with the many internal changes taking place we changed our name to the Irish Blood Transfusion Service. This reflects increasing involvement internationally, particularly in Europe. The change took place on 7th April 2000 to coincide with the World Health Organisation's (WHO) Safe Blood Campaign.

While continuing to work closely with local voluntary organisers and donors we continue to forge links with hospitals. The National Haemovigilance Office continues its close cooperation with hospitals to ensure the safe delivery of transfusion services. The appointment of additional transfusion consultants with hospital sessions will help to improve the links with major hospitals.

The tragedy of past events continued to receive attention throughout the year. Public hearings at the Lindsay Tribunal, which is inquiring into the infection with HIV, and Hepatitis C of people with haemophilia and related matters, commenced in May. At year-end the Tribunal had completed hearing evidence on the role of the Blood Transfusion Service in relation to the infections and in respect of related matters.

The threat of vCJD continued to be monitored closely throughout the year. At year-end we are examining what further steps, in addition to the removal of white cells from blood (leucodepletion), can be taken to minimise the potential threat of vCJD. While there is no scientific evidence that vCJD is transmitted through blood we are working on the assumption that it can be.

The gradual decline in the use of blood continued throughout the year. Ireland is now one of the lowest users of blood per head of population in the developed world. We will continue to work with hospitals to ensure the appropriate use of blood and blood products.

The many changes which have taken place in the past year would not have been achieved without the flexibility and commitment shown by staff throughout the organisation. Their commitment and enthusiasm augurs well for the future of the Irish Blood Transfusion Service as we enter the third millennium.

NATIONAL MEDICAL DIRECTOR S REPORT

As is now widely appreciated blood transfusion is a very difficult and demanding form of treatment. It is difficult to obtain, difficult to store, test and process and difficult to use. And though it saves lives, enables vital surgery to be done, cancer treatment to be given safely, serious accidents to be survived, it is difficult to keep safe. Hepatitis B, Hepatitis C and HIV have cut through the blood supply throughout the world killing thousands, leaving many more damaged and ill. The threats are not over and if we have learned anything, we have learned that we need always to keep vigilant and to be careful. We must ensure that as much effort and resources as we have at our disposal as a nation is used to ensure that patients who need a blood transfusion get a therapy that is as safe and effective as it can be.

Every week over 1,000 people need a blood transfusion in this country; every year over 1% of the population receives a transfusion; and everyone in the country has at least a 1 in 4 chance of needing a transfusion in their lifetime.

The completion of the building and commissioning of the new blood centre at Dublin marked a major milestone in the development of blood transfusion in Ireland. This building serves as a physical manifestation of the commitment of this country to safe and secure blood transfusion in the future. It also serves as a physical manifestation of the shift of blood component manufacture to a pharmaceutical grade production and quality control philosophy. The building is the most advanced blood centre in Europe and is a very far cry from the origins of blood component manufacture in the middle years of the twentieth century.

Blood component manufacture, the preparation of therapeutic components of red cells, platelets and plasma from blood donations is only one part of our operation. The others – donor recruitment, blood collection, donation testing, blood storage and distribution and hospital liaison – including supply, haemovigilance and support of best practice – all have equal importance in ensuring a safe and secure blood transfusion service. In all of these areas considerable development took place during the year, including new strategies in donor collection, developments in donation testing, particularly NAT testing for Hepatitis C, and development of national practice guidelines at the Blood Users Group.

The pace of change in blood transfusion has never been faster – the year end found us meeting new challenges in the shifting paradigms of transfusion medicine; the threat of vCJD, the advent of more extensive NAT testing and the emergence of new chemical techniques for eradicating the threat of disease transmission by blood products.

The year was also marked by a very public schism within the IBTS over testing strategies – the strategy of locating donation testing on a single site at the National Blood Centre in Dublin faced trenchant opposition. At year end the challenge of resolving this remains. In view of the huge demands on the Service to embrace far reaching changes, the urgency of resolving this issue is all the greater. The necessity to replace the old Cork buildings with state-of-the-art facilities also compounds the necessity to bring closure to this issue.

While facing the threat of vCJD remains our biggest challenge for the year ahead, achieving internal cohesion is an essential task to allow the IBTS to achieve its goals.

DONOR SERVICES & COLLECTION

Donor Attendances

174,738 people throughout the country attended our blood donor clinics in 2000. Of those, 18,848 were new donors.

New Southeast Centre

The Irish Blood Transfusion Service opened up its Southeast Donor Organisation Centre in Carlow in September. This new centre will organise clinics and collect blood in counties Carlow, Kildare, Kilkenny, Waterford, Wexford, Wicklow, South Tipperary and parts of Laois and Offaly. The opening times of clinics in these counties have been amended to make them more accessible to donors and a clinic will take place on every third Sunday in these areas.

New Dublin Blood Donor Clinic

President Mary McAleese officially opened the new Dublin donor clinic in D Olier Street in December. This is a prime city centre location with huge volumes of pedestrian traffic. Dublin donations have increased since the move to the city centre from Pelican House and we expect numbers to further increase in 2001.

Apheresis Platelet Programme

4,966 people donated platelets in the past year. Apheresis is a process whereby blood is taken from the donor, the platelets are extracted from the blood and the remaining blood components are then returned to the donor. Platelets, which have a shelf life of five days, are primarily used for the treatment of cancer patients and newborn babies. The Apheresis Platelet Programme is now based at the National Blood Centre.

Work Place Blood Drive

A broad range of government departments, semi-state bodies and public and private companies participated in our Work Place Blood Drive in 2000. This is where a company or organisation allows their employees (minimum of five) time off work to donate blood. Our thanks to all employers and employees for making this programme so successful.

Donor Interviews

An additional layer of donor screening was introduced by the IBTS in 2000 by the implementation of donor

interviews at our clinics. All new and lapsed donors are now interviewed by a trained nurse or medical officer in advance of donation. This involves a detailed explanation of the Health & Lifestyle questionnaire by the nurse/medical officer who will answer any queries new donors may have.

Donor Award Ceremonies

One hundred and four 100-time and 603 fifty-time donors received their pelican and gold drop awards at ceremonies in Cork and Dublin during 2000. Our thanks to the Minister for Health & Children Michael Martin, Minister of State, Mary Hannifin and Cork Lord Mayor P.J. Hourican for presenting the awards.

Voluntary Donor Organisers

As always, the blood transfusion service could not be run without the help, support and commitment of our many Voluntary Donor Organisers who ensure good turnouts at our clinics throughout the country. We pay special tribute to those who retired in 2000 and keep up the good work to those working with us in 2001.

Donor Deferral Rates

In the past year, 17% of all donors were deferred from donating blood. This represents a 1% increase since 1999. In 1995 the deferral rate was 12.8%. Rising deferral rates puts greater pressure on the national blood supply as it means a smaller pool of donors being available to give blood. The most common reason for deferral in 2000 were donors suffering from colds, flus, travel to a malarial country or donors who had not eaten before donation.

Complaints

The majority of complaints received by the Donor Services Department in 2000 concerned the opening times of, and delays encountered at clinics. The establishment of new regional centres will allow for a reorganisation of opening times in areas within their region.

PROCESSING & TESTING

When units of blood are brought into our laboratories in Cork and Dublin each unit is entered onto our IT system. The units are then brought to the Components Laboratory where the red blood cells are filtered to remove white cells to reduce the risk of vCJD and then stored in quarantine. Platelets are stored in a controlled temperature 'agitator' which maintains consistent motion to prevent platelets from settling.

All samples of blood are simultaneously tested for HIV, Hepatitis B & C, syphilis and rare viruses called HTLV 1 & 2 in our Virology Laboratories in Cork and Dublin. At the same time, the Donor Grouping Laboratory is testing a sample of each donation to determine its blood group and Rhesus type.

A significant development during the year was the introduction of NAT (Nucleic Amplification Technique) testing

which was contracted to the Scottish National Blood Transfusion Service pending the development of in-house facilities at the National Blood Centre. A sample of every unit of blood collected in Ireland was sent to Edinburgh for this additional more sensitive test for Hepatitis C in 2000. NAT testing will use the latest DNA technology to detect viruses at any stage of their development, rather than looking for the symptoms in the immune system after they have already developed.

HOSPITAL SERVICES

The Hospital Services Department of the IBTS continued its essential link in the distribution chain needed to ensure that blood reaches the people who need it most during the past year. The key function of the Department is to provide safe, and secure distribution of all products released for issue to hospitals. This involves critical product management and the maintenance of accurate and comprehensive records of both received and issued blood, blood components, and derivatives.

The Hospital Services Department is responsible for monitoring stocks of blood and blood products on an ongoing basis. The IBTS provides a 24-hour service to all hospitals throughout the country 365 days a year. A regular weekly delivery service to hospitals is also in permanent operation.

BLOOD & BLOOD PRODUCTS ISSUED

Product

1999

2000

Red Cells & Whole Blood

132,115

124,797

Platelets

43,987

41,207

Frozen Plasma

23,335

24,811

Cryoprecipitate

2,188

1,848

Albumin 20% 50ml

1,056

1,464

Albumin 20% 100ml

2,741

1,058

Albumin 4.5% 400ml

0

1,013

Albumin 4% 500ml

2,660

7

Normal Immunoglobulin 2ml

637

298

Anti D Immunoglobulin

42

38

Anti HepB Immunoglobulin Heptatect 2ml

23

22

Anti HepB Immunoglobulin Heptatect 10ml

84

77

Anti Varicella Immunoglobulin Varitect 5ml

57

13

Anti Varicella Immunoglobulin Varitect 20ml

54

