

NHBT0002938 0001

## CONTENTS

- 3 General Manager's Report
- 5 Donor Facts and Figures
- 6 Products for Patients
- 7 Regional Transfusion Centres
- 11 Clinical and Laboratory Services
- 12 Protein Fractionation Centre
- 14 Medical and Scientific Directorate
- 16 Finance

Patients like Tom and Janet who have heart transplants lose a considerable amount of blood during their operations. It is thanks to blood donors that these life saving operations can be carried out.

## SERVING HEALTH CARE THROUGHOUT SCOTLAND

THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE exists to provide a comprehensive range of safe and effective blood and blood related products and services, and where appropriate other human tissues, for all patients throughout Scotland. We aim to do this:

by offering a comprehensive range of tigh quality products and services including tissue banking and cell manipulation;

by centaining at the toremost of developments in science, medicine and technology, and also in terms of value for money donor relations, human resource management and business Services, including information technology and resource management;

 by achieving and demonstrating an efficiency in the userol resources that compares favourably "with other of ganisations similar to ourselves visewhere in the world. by maintaining Scottich self-sufficiency in whole blood, sed cell concentrates, clinical fresh forcen plasma and all fresh and cellular, components of blood, also miclotring factors VIII and DC, albumin, intra-muscular, numbrogloballis, and intravenous immunoglobuling as well as decessary specific immunoglobuling and other specialised therapedoic blood produces.

and by responding rapidly and flexibly to the newly of our customers

We work for patients and the community at large, supporting the care provided by clinicians and other health care professionals; GP Practices, Health Service Trusts, Units and Hospitals. We also work in support of the NHS in Northern Ireland and a small number of other health care institutions outside Scotland.



## NHBT0002938 0003

PROTEIN FRACTIONATION CENTRE TEAM 203

312



123 SUPPORT SERVICES STAFF (including transport, domestic and catering staff)

RESEARCH SCIENTISTS 38

DONOR MANAGEMENT, RECORDS AND PUBLICITY STAFE 63

153

MEDICAL STAFF 88

BUSINESS MANAGEMENT, FINANCE, PERSONNEL AND OFFICE SERVICES TEAMS

MAINTENANCE AND ENGINEERING STAFF 7

DONOR NURSING STAFF (including donor attendants, bone bank nurses) INFORMATION TECHNOLOGISTS 17

тота 1,299









Thanks to blood donors, staff, and the many others who give vital support and encouragement, the Service has once again been able to meet the needs of patient care throughout Scotland. That this is being achieved at lower unit costs and to even higher standards of quality and service is testimony to the dedication, skill and sheer hard work of a great many people. The annual report is a welcome opportunity, on behalf of the SNBTS Management Board, to thank them all publicly for their contribution to another successful year – and in particular to thank blood donors for their continued generosity and commitment.

#### STRATEGIC CONTINUITY

The Scottish National Blood Transfusion Service team is acutely aware of the responsibility we bear for the safe, reliable and cost effective support of health care in Scotland, both day to day and in the long term.

The key concerns of this past year are also established as priorities in the Service's Strategic Plan for the rest of the century:

- The maintenance of Scottish self sufficiency is the key goal. This means the continued satisfaction of all appropriate clinical demands for blood and blood products for patients in Scotland by the provision of sufficient quantities of high quality, made from donors' gifts.
- Recruiting and caring for healthy voluntary non-remunerated donors in sufficient numbers to secure reliable supplies of all products.
- Maintaining and continuing to improve the safety of products in an increasingly challenging environment; with research, development and audit programmes to ensure that the SNBTS keeps fully up to date with all relevant technical and scientific advances.
- Meeting customers' needs with comprehensive, safe and efficacious product and service provision meeting all legislative and regulatory requirements and managed within very tight cost limits to ensure optimum value for money.

This can only be achieved by people working together unselfishly for the good of patients. We never lose sight of the great debt we owe to donors and to the community at large.

#### **GROWTH AND DEVELOPMENT**

In response to customer and patient needs – identified through day to day contact, supplemented by special surveys, research and in-house professional expertise – the SNBTS strives continually to develop both its therapeutic products and clinical services on the one hand and its services to donors on the other. Guided by proven scientific advances, by government policy and by customer requirements, the SNBTS thus seeks constantly to improve the services we offer in support of patient care throughout Scotland.

Concentrated plasma products, made at the National Protein Fractionation Centre, have shown a significant and challenging increase in demand. The PFC team has met these growing needs while simultaneously expanding production facilities in a major building programme. In addition, the establishment and scale up of the new high purity Factor VIII production process has made possible a most welcome enhancement of the care of people in Scotland with Haemophilia A. These have been significant achievements by the PFC team during an exceptionally demanding year. Processed plasma volume was a record – over 100kgs for the first time in any year; cause for congratulations and thanks for a job well done.

The regional transfusion centres have also continued to break new ground this year against a background of increasingly stringent cost control and simultaneously rising demands for both services and products. Each of the five regional centres has made their own particular contribution to the excellent progress achieved overall.

The first phase of the Service's bone banking development has been completed, with bone banks in all Regions. Working in co-operation with orthopaedic surgeons, plans have been laid for further growth and improvement. Tissue typing and transplant services generally have been expanded to support the increased clinical activity including heart and liver transplantation, now being undertaken at home in Scotland rather than south of the Border.

During this year there has been a marked increase noted – and met – in the demand for platelets, essential for blood clotting and wound healing. With a shelf life of only a few days and unavailable from any alternative source, platelets are an especially precious part of the life saving product range that blood donors make possible. The constant need for platelets is a particular reminder of the vital need for 1000 donors to volunteer a pint of blood every day of every week of the year.

The year has seen the introduction, after extensive preparatory research and design work, of a new donor health check that has been well received, both by donors and by the medical staff responsible for donor and patient safety.

Quality assurance, audit and educational programmes have been enhanced. Further product licences have been attained, reflecting the proven effectiveness of SNBTS products in the treatment of a wider range of illnesses. Many staff representing all branches of the Service, have participated in seminars, workshops and training sessions in pursuit of improved quality and better ways

cont.

of working. Improvements have also been introduced in target setting and in performance monitoring and appraisal. The National Headquarters team have played an important role in supporting these and other developments.

#### QUALITY AND VALUE

In common with all parts of the NHS, the SNBTS has to face up to the difficult challenge of achieving increased output and enhanced quality, while at the same time continuing to find new and better ways of improving efficiency and value for money. With so many health care priorities competing for inevitably limited funding, the Service is deeply aware of its responsibility for making the very best possible use of every last pound. Management teams throughout the Service have made significant progress. More and better cost data is helping us to plan even greater improvements.

As part of this overall strategy, our research and development work is being reviewed and where necessary re-focused. Much of our long-term service to patients depends entirely upon these vital creative research activities and those responsible are working hard to ensure that they continue to be effectively harnessed for the optimum benefit of patient care in Scotland.

Medical audit activity is a further tool that is of course already making a significant contribution in many parts of the NHS. The disciplined application of sound audit principles has an established role in the development and improvement of many medical and surgical interventions. Transfusion medicine is no exception and the SNBTS Medical Audit Committee has a very full programme in hand.

All of these efforts are directed at helping to make sure that the Service continues to fulfil its Mission cost-effectively and in direct response to the needs of patients and other customers, including donors, hospital clinicians and other health care professionals, GP practices, Health Service Trusts, Units, Hospitals and the community at large.

#### **TEAMWORK FOR CHANGE**

The SNBTS recognises that the quality of our products and services depends upon the ability and effort of our staff. There is an established policy to support and encourage staff to share Service values and to feel valued themselves. This is very much a two way commitment and one which requires sustained effort over a long period to make it a genuine reality. Improved occupational health, and health and safety generally is, for instance, receiving increased emphasis. The achievement of a 'no smoking' policy in all public parts of the Service, and progress towards our goal of a Service-wide smoking ban has been one small but welcome improvement. A number of other projects are in train, designed to improve health and safety quality standards. These, and other improvements in the way we work, including communications, conditions of service, systems and methods, all contribute to our goal of bringing maximum benefit to patients, donors and taxpayers alike. It has been encouraging, during another year of significant change and development, to have been so well supported in these efforts by SNBTS staff teams and also by their Trades Union representatives. The going has not always been easy and there are no doubt some difficult times ahead, but there is a growing sense of shared understanding that the Service needs to adapt in order to continue to meet the needs of patients in a changing health care environment. Consistent progress depends on close multi-disciplinary teamwork in the delivery of our vital contribution to patient care.

#### THE CHALLENGES AHEAD

The background to SNBTS efforts again this year has been one of continually rising requirements for health care in Scotland and this seems set to continue in the years ahead. The NHS as a whole can be expected to place continued emphasis on

- more effective treatments for patients, including the development of new ways of tackling previously untreatable conditions.
- growth in the number of acute patients per year; in line with efforts to reduce waiting lists, increase provision of sophisticated surgery north of the Border and develop other improvements in health services.
- the safety and quality of all therapeutic products and services provided for patients.
- excellent value for money, with the need for everyone involved to keep costs to the absolute minimum necessary and to optimise efficiency.

Working closely with NHS colleagues, with customers and the community at large, the Scottish National Blood Transfusion Service intends to play its full part in helping to meet these health care challenges.

It is good to be able to report that, thanks to blood donors, the Service remains well placed to maintain Scotland's long tradition of excellence and self reliance in blood, blood products and blood transfusion services in the years ahead.

## GRO-C

David B McIntosh General Manager Thanks to the generosity of voluntary non-remunerated donors, Scotland is one of the few countries in the world able to meet the demand for blood and blood products from within its own population. Blood contains many precious life saving ingredients, these are separated into many different products for patients.

There are blood donors in Scotland. donations were given during 1992/93.

#### WHERE DONORS GIVE BLOOD

For the convenience of donors, different types of sessions are organised. More donors are now giving at local community sessions than ever before.



#### APHERESIS DONATIONS

Some people donate by a process called apheresis in which the red cells are separated from the plasma by machine and returned directly to the donor. As the body replaces plasma quickly and naturally, these donors can give twice the normal volume, much more frequently. Important immunoglobulin treatments can be made from the plasma of donors who have natural antibodies or who have been sensitised through immunisation programmes. Platelets, essential for blood clotting can also be collected by apheresis and demand is steadily increasing.

#### APHERESIS PROCEDURES 1992/93

PLASMA

\_\_\_\_\_ PLATELETS



DIAGNOSTICS

WHITE CELLS

Blood collection is driven by the need for plasma products: Most of the plasma required is extracted from whole blood donations. During 1992/93 about 12% of the plasma required was collected by apheresis.

#### SCOTTISH NATIONAL BLOOD TRANSPUSION ASSOCIATION

The SNBTA is an independent charitable organisation which promotes, encourages and maintains the principles of voluntary non-remunerated donation and works to safeguard the interests of the voluntary donor.

## PRODUCTS PREPARED BY REGIONAL TRANSPUSION CENTRES

Over 20% of all whole blood donations are separated and processed to extract a wide range of VITAL BLOOD PRODUCTS. Fresh products with a limited shelf life are produced at Regional Transfusion Centres.

#### **RED CELL CONCENTRATES**



BUFFY COAT DEPLETED WHOLE BLOOD

350272

SPECIALISED RED CELL CONCENTRATES



**GED** 1,081

#### HOW SOME RTC PRODUCTS ARE USED

**RED CELLS** for routine surgery and anaemia, **PLATELETS** for some cases of leukaemia and for major surgery, **FRESH FROZEN PLASMA** for severe haemorrhage.

ISSUES FOR PATIENTS IN THE PRIVATE SECTOR OF MEDICINE These represent less than 1% by volume of all donations received.

#### 1992/93

Whole Blood 6	
<b>Red Cell Concentrates</b>	2,928
Platelet Concentrates	124
Fresh Frozen Plasma	120
Cryoprecipitate 72	

## PLASMA PRODUCTS

The Protein Fractionation Centre (PFC) manufactures a range of over 30 products from blood plasma collected by regional centres. The major volume ones issued are listed below, either by vials produced for patients, or in millions of international units (miu's), a standard measurement of biological potency. Plasma products are issued through regional blood banks and can be used up to 3 years after the blood was donated.

All these figures include products for Northern Ireland made from plasma donated there.

1992/93 PRODUCTS		% VARIATION from 1991/92
FACTOR VII (miu's)	. 13.5	+29%
FACTOR IX (miu's)	2.2	+14%
ALBUMIN (bottles)	86,365	- 6%
IVIgG (vials) (intravenous immunoglobulin)	25,287	+40%
IMIgG (vials) (intramuscular immunoglobulin)	32,332	+59%
ANTI-RHESUS (D)(vials)	17,440	+21%
FIBRIN SEALANT (vials)	52	NEW PRODUCT
ANTI TETANUS IMMUNOGLOBULIN (vials)	3,081	+66%
ANTI HEPATITIS B IMMUNOGLOBULIN (vials)	1,239	+29%
ANTIZOSTER IMMUNOGLOBULIN (vials)	972	- 4%

The large increase in issues of some specific immunoglobulin products shown above reflects planned increases in product availability.

#### HOW SOME PLASMA PRODUCTS ARE USED

ALBUMIN for the treatment of burns and other serious injury.

FACTOR VIII for haemophilia patients, IMMUNOGLOBULINS for the prevention and treatment of serious infection and illness, for example Anti-D which is used for the prevention of Rhesus disease in new born babies. Scotland is served by five Regional Transfusion Centres, each of which is responsible for blood collection and the supply of blood and blood products to hospitals and patients. Each region also provides extensive clinical support through a range of laboratory and clinical services, many of which are available twenty four hours a day, seven days a week.

These services range from procedures such as identifying blood groups, compatibility between donor and patient and tissue typing for organ transplantation, to services such as the rhesus disease prevention programme, therapeutic apheresis, bone banking and support for bone marrow transplant programmes.

This report highlights just a few aspects of the wide-ranging and important work carried out by staff at the Regional Centres throughout a busy year.



In addition to our own staff training and development programmes, SNBTS has a long tradition of providing training for visitors from overseas. During 1992/93 this included visitors from Thailand, Ethiopia, China, India and Russia. Support programmes for the transfusion service in Romania, begun in 1989, continues and assistance has also been provided for the former Yugoslavia.

#### WEST OF SCOTLAND (Glasgow)

The Regional Centre provides blood transfusion and related services for over 50% of the Scottish population in an area covering six Area Health Boards in Strathclyde and Central Regions.

The Centre has provided steady blood product and clinical service support for the new Heart and Lung Transplant Centre run by Professor David Wheatly at Glasgow Royal Infirmary.

Thirty-two transplants took place in the first 18 months of the programme and West BTS has provided round the clock support. Ten units of group O positive and ten units of group O negative cytomegalovirus-free blood are always on standby. News of each successful transplant reinforces the vital supporting role played by both blood donors and BTS staff in this important and complex surgery.

One of many SNBTS information technology developments is the West of Scotland print-on-demand system for blood group labels on blood packs. Efficient blood stock management includes inter-regional and sometimes national exchange of stock between blood banks, so label accuracy, quality and audit are essential. The West system employs computer monitoring, and the use of concatenated barcode label reading techniques to verify that the correct label is attached to the bag and that the label can be easily read.

The Centre was the first transfusion centre in the UK to receive full accreditation under the new Clinical Pathology Accreditation Scheme, confirming by exhaustive external audit the Centre's already well known ability to provide high quality of service.

Continuing progress has been achieved in the development of highly specific and potent monoclonal antibodies to human red cells. These are used for testing throughout the SNBTS and as the cell lines are selectively licensed to other major producers, this highly successful programme is contributing to world health care through some of the best monoclonal based blood grouping reagents available anywhere.

We were all greatly saddened by the sudden death of Dr Robert Crawford, who had made such an important contribution to the SNBTS in his 15 years as a consultant.

#### EAST OF SCOTLAND (Dundee)

The Dundee Centre provides extensive blood product, laboratory and clinical services support to hospitals in Tayside, North Fife and East Central Scotland. A decision is expected soon on the option appraisal for increasing and improving accommodation and facilities to meet expanding clinical services. The new Laboratory Manager, Keith Prior, will play a key role.

The sophisticated requirements of modern blood transfusion depend upon voluntary, non-remunerated donors who so generously give their blood and their time for the benefit of others.

Over 30,000 donors give blood regularly in the East of Scotland, approximately 80% of them at mobile sessions. To make donating convenient and easy, the BTS team visits towns and villages, educational establishments and a small number of industrial locations, usually twice a year.

Securing suitable accommodation is an essential part of the donor programme. The venue has to be easily accessible, so that the bus can park, allowing equipment access to the hall, and most importantly the hall itself must be large enough to accommodate the reception, donation and refreshment areas for a session of between 150 and 300 donors. Parking and other facilities for donors all contribute to the success of the donor session.

Community halls are popular and well booked, so forward planning is essential to guarantee regular visits for the donor team. In fact bookings are often made as much as two years in advance. The Blood Transfusion Service is extremely grateful to all those organisations which recognise its importance to the community and make BTS bookings a priority.

Some towns may not have a hall large enough to accommodate the session comfortably and donors may have to queue until there is a free donor bed. Despite this irritation, a cheerful camaraderie develops between donors and members of staff, and the session becomes something of a social occasion!

The Service is always looking for ways to ensure the long term future of the blood supply to patients and is especially keen to encourage more young people to become regular donors. This year the East BTS had its highest number of donors from schools and colleges and is currently planning an additional session with a local agricultural college.

There is also a busy apheresis programme in Dundee with around 300 donors regularly giving their plasma and platelets. Apheresis donors can donate much more frequently than whole blood donors as their red cells are returned to them. Some patients requiring long term platelet support often benefit from treatment with platelets from donors who have the same or similar tissue type. For them there is a special programme to provide ongoing support. On occasions tissue typed donations may be contributed by donors in other Regions of Scotland.

#### NORTH OF SCOTLAND (Inverness)

Dr Bill Whitrow retired after ten years as North BTS's Regional Director and handed over to Dr George Galea. Ian Gordon, Laboratory Manager, has also retired and Walter Mein has been appointed to succeed him.

The new team is settling in well and preparing for the challenges that lie ahead. These include the introduction of service level agreements with customers – including Raigmore Hospital, which acquired Trust status in April 1993 – and preparing for the dramatic upheavals of a welcome improvement soon to take place in accommodation and facilities.

Approval has been given by the NHS Management Executive for a new Blood Transfusion Centre. This will be a joint venture between the BTS and Raigmore Hospital Trust Haematology Department, and is due for completion in 1995.



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The new purpose-built Centre should enable North BTS to provide blood and blood products and clinical services to Medicines Inspectorate approved standards well into the next century. With new clinical challenges emerging, this commitment will also ensure that the Inverness Centre plays its full part in SNBTS development and continues to contribute significantly to the success of transfusion provision within Scotland.

Bone banking developments in orthopaedic surgery in the last five years, particularly in the areas of major reconstruction procedures and the surgical management of bone cancer, have resulted in a pressing need for supplies of high quality bone fragments to assist the healing process in the event of substantial tissue loss.

Much of the expertise and technology involved in bone banking is familiar to blood transfusion services – donor recruitment, safety testing, product identification, processing, storage and patient issue – all vital aspects which must be subject to good manufacturing practice standards.

The completion of the SNBTS Phase I development, with the appointment of a Bone Bank co-ordinator for North BTS, means that this service is now available for all patients throughout Scotland.

#### NORTH EAST SCOTLAND (Aberdeen)

North East BTS has been closely involved in the successful development of the bone marrow transplant programme at Aberdeen Royal Hospitals NHS Trust and has laid plans for a fully equipped bone marrow bank at the new Regional Blood Transfusion Centre, which is due to open during 1993-94.

The first autologous bone marrow transplant in Aberdeen (i.e. using the patient's own bone marrow) was carried out in June 1992 by Dr Derek King, Consultant Haematologist, on a young girl suffering from Non Hodgkins Lymphoma. Two further transplants were performed during the year, and several other patients had their marrow harvested for future use. The BTS assists with the bone marrow harvest and provides platelet and red cell support during the recovery period.

In the new Transfusion Centre NEBTS will undertake the freezing of the bone marrow (in liquid nitrogen below -80°c) and storage for up to three years before transplant. The SNBTS programme for recruiting marrow donors for the British Bone Marrow and Platelet Donor Panel is already well underway. Some of these donors have already helped to support the developing transplant programme in Aberdeen.

The donor laboratory services of the SNBTS provide essential scientific and technical resources for a safe and sufficient supply of blood. Blood component separation and manufacture is an essential routine Regional function. All donations are tested for ABO and Rhesus D blood groups, and for a range of microbiological and virological markers indicating the presence of certain transmissible diseases – Hepatitis B & C, HIV I & 2 and syphilis.

Clinical laboratory services include: cross matching blood for patients; serological tests for the prevention and

treatment of haemolytic disease in new born babies; investigation of auto immune haemolytic anaemias; and tissue typing and histocompatibility testing for bone marrow and organ transplantation. Quality control and research activities in Aberdeen – as elsewhere – are integral to successful and effective laboratory practice.

#### SOUTH EAST (Edinburgh)

The new Liver Transplant Unit for Scotland in the Royal Infirmary of Edinburgh opened in November 1992. With plans to carry out 50 liver transplants every year, the Unit has transplanted 31 patients in its first seven months.

Blood transfusion support is vital for this very major surgical operation and SEBTS was closely involved with staff of the Unit in planning the details of the transfusion support (usually using both red cells and fresh frozen plasma). As a result of this collaboration the blood bank has so far had no difficulty in meeting the Unit's transfusion needs.

The bone banking programme of the SEBTS has been expanding to meet increasing clinical needs, and now hospitals in the Borders, Fife and Edinburgh each have their own dedicated members of the BTS bone banking team. New developments in the field of tissue banking include the replacement of damaged heart valves in young children with valves retrieved from multi-organ donors, and SEBTS is now working closely with the local transplant team and cardiac surgeons to provide the vital heart valves which may help to restore a young person to prolonged good health.

Infants, especially if they are premature, often have complicated blood problems and need frequent transfusion of just 5 to 10ml of red cells (the baby's total blood volume may only be 200ml). SNBTS is introducing a special system of blood packs, called "pedipacks" – for these very small children. One donor will, at a single donation, be able to provide five small packs of red cells, which will then be available to meet the transfusion needs of a single infant. This method brings a further improvement in the margin of safety against viral or immunological risks.

Edinburgh is one of several centres around the world investigating the possibility of a new blood collection system which will allow single donations to be separated at the time of collection into red cells, plasma and platelets – each stored in separate packs.

BTS is working with the Haematology Department in the Royal Infirmary, Edinburgh, to provide a new way of collecting special white cells from the blood (known as 'stem cells'). These cells have the capacity to act as the seeds from which new bone marrow is formed. This is of great significance for patients with leukaemia or cancer, who must be treated by chemotherapy. As well as killing malignant cells, the therapy also destroys healthy bone marrow. Donated stem cells can help restore this vital tissue.

This treatment is rapidly replacing the former method of collecting the patient's own bone marrow and providing an effective method of supporting recovery that is much less troublesome for the patient. Transfusion Centres in Scotland provide a number of clinical and laboratory services directed towards patients. These include blood group compatibility between blood donation and patient, and tissue-typing for organ transplants. Many of these services are available 24 hours a day, 7 days a week.

## PATIENT SAMPLES TESTED



## PATIENT/DONOR SAMPLES TESTED





1990/91

## DONOR LABORATORY SERVICES

Blood donations undergo a series of tests to ensure the maximum safety of products to patients. All donations are tested for ABO and

Rhesus (D) Group, HBs Ag, Syphilis, and antibodies to HIV I and 2, and to the hepatitis C virus.

We test for **Zoster** antibody because blood from people exposed to chicken pox or shingles can be made into precious anti-Zoster immunoglobulin, essential for some very ill patients.

#### TISSUE TYPING

1992/93 24

Numbers of patient/donor samples tested.

Bone Marrow and Platelet Donor Panel.

1991/92 3,3

UNRELATED BONE MARROW DONORS

donors have been registered on the British

## **BONE BANKING**

Since January 1992 there have been 🤞



of bone material, mainly femoral head bones from hip replacement operations. At 31 March 438 issues had been made from SNBTS bone banks and 350 units were

in stock.

The PFC is the sole producer of fractionated plasma products in Scotland. Using sophisticated pharmaceutical processes, the Centre manufactures a wide range of vital products for patients, from the precious blood provided by blood donors in Scotland and Northern Ireland. Last year record production of plasma products was achieved with no increase in staffing reflecting the successful introduction of shift working in 1991 and the efforts of all staff employed at the Centre. Some of the increases in output are shown below and on page 6.

#### BUILDING DEVELOPMENTS

An extension to the existing building was completed and opened. This extension includes new warehousing, engineering facilities, plasma deep freeze facilities at -40° c and product packaging facilities.

In officially opening this phase of the building programme Minister of State, Lord Fraser of Carmyllie said: "Liver and heart transplant patients, burns victims and people with haemophilia are just some of the many patients who will benefit from the blood products made here.

"Scotland is rightly proud of its reputation for a progressive transfusion service and for the very high quality of the blood products produced here at the Protein Fractionation Centre"

The final phase of this £6m development is now in progress with the phased refurbishment and modernisation of the original manufacturing facility, which will contribute to increased production capacity.

#### PRODUCT DEVELOPMENT

Clinical trials of the new product **fibrin sealant** are progressing successfully. This plasma derived product described as the 'biological super-glue' is designed to help seal wounds and prevent bleeding during and after surgery Also planned for clinical trial is **fibrinogen for infusion**, which may eventually replace cryoprecipitate. The **high potency Factor VIII** product described in last year's report has lived up to high expectations in terms of quality and rapid solubility, and is now being used successfully in clinical trial. In addition to the introduction of a new Factor VIII product, the SNBTS also managed to meet a significant increase in demand for this product.

1992/93 also saw the completion of product design and development of a **new high purity Factor IX product** (for patients with haemophilia B). This product will be transferred to production during 1993 with a view to clinical trials at the end of the year.

#### INCREASED DEMAND

The SNBTS successfully met significant increases in demand for a number of other products, especially:

- Intravenous immunoglobulin; one of the most extensively licensed products of its type. It is used in treatment of a range of immune disorders and neurological diseases. Demand continues to increase due to a combination of new patients and new uses for the product.
- Intramuscular immunoglobulin, which is widely prescribed for travellers to areas of the world where diseases like Hepatitis A are endemic. Demand has increased dramatically in recent years probably due to increased foreign travel and greater awareness of our products.

#### QUALITY AND SAFETY

These remain our dominant consideration in the nanufacture and supply of therapeutic plasma products. A strong research and development programme continues to ensure that products and processes reflect best practice The SNBTS development programme includes investment n'modern technology and in staff training to ensure that relevant scientific advances are harnessed for the benefit of patients.



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#### PROTEIN FRACTIONATION CENTRE

Blood contains many precious life saving ingredients. These are separated into many different products for patients.

**4 BLOOD DONATIONS** 



PLATELETS

WHITE CELLS

WHOLE BLOOD

**HOSPITALS & BLOOD BANKS** 

I LITRE PLASMA

**CLOTTING PRODUCTS** 

Factor VIII (1 bottle) Factor IX (1 bottle) Fibrin Sealant (1bottle) ALBUMIN (I bottle)

TREATMENT OF BURNS PATIENTS AND MAJOR BLOOD LOSS

USE IN SURGICAL PROCEDURES

TREATMENT OF HAEMOPHILIA

IMIg G (10 bottles)

Normal

Immunoglobulins

IVIg G (I bottle)

IMMUNOGLOBULIN PRODUCTS

Anti CMV Anti Hepatitis

**Specific Antibodies** 

(various quantities)

Anti D

Anti Tetanus Anti Zoster Anti Rabies

TREATMENT OF IMMUNESUPPRESSED PATIENTS AND IMMUNE DISORDERS

TREATMENT OF PREGNANT WOMEN (RHESUS DISEASE)

PREVENTION OF INFECTION

TO HOSPITALS AND CLINICS FOR PATIENTS

PLASMA EXCHANGE

#### MEDICAL AND SCIENTIFIC CO-ORDINATION

SNBTS has been at the forefront of medical and scientific research and development in many aspects of blood transfusion products and services. Not surprisingly, there is very considerable scientific and medical expertise within the different Regions and Units – exemplified annually at the Scotblood Conference, which attracts over 40 scientific papers each year.

This work is essential for the SNBTS to keep abreast of the rapid advances in science and technology which are taking place all the time: a recent demonstration of our critical approach was the Consensus Conference on leukocyte depletion in blood and blood components, sponsored by the Royal College of Physicians of Edinburgh.

Important research and development work is going on in all the Regional Centres, and is co-ordinated by the National Medical and Scientific Directorate.

The SNBTS must demonstrate that blood products are safe and effective before licences are granted – in the same way as the pharmaceutical industry . In addition to new product validation, the clinical trials team plays a crucial role in establishing data for the extension of existing product licences to embrace new clinical applications. Products currently in clinical trial include Factor VIII, fibrin sealant and intravenous immunoglobulin.

Collaboration with fellow NHS professionals, academic institutions, research councils and pharmaceutical concerns, both in this country and overseas, is becoming increasingly common as a means of improving health care. Examples include the development (in conjunction with the University of Edinburgh) of a screening test to detect a condition called neo-natal alloimmune thrombocytopenia – a serious bleeding disorder in new born babies. Another is the monoclonal antibody research for the production of blood grouping reagents – for which Glasgow and the West of Scotland BTS has won much praise.

Everyone within SNBTS is conscious of their role in ensuring that the service achieves and maintains the highest quality standards. There are active quality programmes operating in each of the regional centres, co-ordinated by the National Quality Group – which has itself taken a lead in training through the British Standards Institute.

Our internal audit programme helped prepare us for the Medicines Control Agency's inspections and accreditation, and the recently introduced Clinical Pathology Accreditation scheme. Key aspects of quality, such as defining customer needs and meeting expectations, are important challenges, not least because part of our job is to question the appropriate uses of our products and services.

Our medical audit programme is now well established and involves the systematic and critical analysis of medical aspects of transfusion practice. Several major projects have been undertaken with additional funding from the Scottish Home and Health Department Clinical Resources and Audit Group (CRAG). These have focused on four broad sectors of transfusion activity: the blood donor programme, laboratory diagnostic services to patients, blood banking, and patients' perception of transfusion. These projects have involved close collaboration with many colleagues in the NHS.

Full reports of several projects have already been submitted to CRAG.

Using information technology, we have undertaken a detailed analysis of blood usage, so that optimum regional blood bank stock levels can be established. Work is underway on a computer system for clinical services which will provide greatly improved facilities for stock control, product support, laboratory reporting and clinical audit.

#### THE NATIONAL SCIENCE LABORATORY

NSL provides scientific research and specialist services to other branches of the SNBTS. Much of its work is basic applied science directed towards important blood product development. – both new products and improvements to existing product specifications.

Important projects during the year included:

- Continued collaboration with the PFC on the development of improved coagulation Factor VIII and IX concentrates.
- Assessing methods of isolating and recovering Von Willebrand factor from otherwise unused plasma fractions.
- Developing cell culture models for detecting thrombogenic agents in Factor IX concentrates.
- Developing novel gels for purification of plasma proteins (supported by a DTI 'LINK' grant).
- Purification methods and the development of cells for the preparation of alpha-I antitrypsin, for the possible treatment of certain kinds of lung disease.
- Developing a method of banking keratinocytes (from human tissue) which may be used in future for treating wounds and even skin grafting.
- Investigation of further applications for fibrin sealant, a biological glue.

NSL is also working closely with colleagues in the local academic community towards the development of expertise in gene therapy. This is seen as a natural development from established SNBTS procurement and supply of cell products.

#### MEDICAL AND SCIENTIFIC DIRECTORATE

#### THE SNBTS REAGENTS PROGRAMME

The National Reagents Programme provides a wide range of high quality reagents for use in SNBTS and other Scottish Health Service laboratories. These reagents are derived both from donated red blood cells and antibodies in donor plasma and from the use of modern bio-technology processes.

In 1992/93 product issues increased by 25% to over 200,000 units and there are now 51 different products available. This is largely due to further progress in concentrating manufacture on one site.

During the year the SNBTS undertook an extensive review of the manufacturing costs of monoclonal reagents. This confirmed that SNBTS can manufacture these important products more cheaply than they can be purchased. It also identified areas in which improvements could be made to reduce manufacturing costs without affecting product quality. Follow up work set in motion this year should bear fruit in 1993/94.

A student from the Thai Red Cross has just spent twelve months training in monoclonal cell line development and reagent manufacture at the National Reagents Unit and the West of Scotland Transfusion Centres. Her study was sponsored by the British Council. Not only did she acquire the skills necessary to develop and produce monoclonal blood group grouping reagents for the Thai Red Cross, but she developed several new cell lines which will be of use in Scotland. The SNBTS will be sending to Bangkok, under licence, several monoclonal secreting cell lines to help the reagent production programme in the health service in Thailand.

#### NATIONAL MICROBIOLOGY REFERENCE UNIT

Manufacturers are continually seeking to improve screening tests for blood borne viruses such as Hepatitis and HIV. Better and better tests – properly validated – will no doubt further enhance the margins of safety associated with blood and blood products in the years ahead.

A formal national evaluation procedure has been established by the SNBTS with the Microbiology Reference Unit and the West of Scotland Transfusion Service taking the lead role. All new test kits are now formally assessed against a defined standard before they are approved for use within the SNBTS. During the first year of their programme six new kits were assessed, providing a unique service in the UK.



12,6744

10 CELL AD IDENTIFICATION 761

ANTI-D 5,125

3 CELL Ab SCREEN

#### **GRANTS AND PUBLICATIONS**

Much of the research done by SNBTS is part funded by other institutions. This year we were delighted that the Scottish Office Home and Health Department funded an in-vitro study into the placental transfer of IgG allo antibodies causing haemolytic disease of the new born and the inhibitory effect of intravenous immunoglobulin preparation. The grant is for one year and is worth  $\pm 18,383$ . It has been awarded to SJ Urbaniak, S Armstrong, D Broamovich, and K Page.

A UK Blood Transfusion Service team has recently completed a pocket-sized 2nd edition of the Transfusion Medicine Handbook. This has become an important and much valued reference book for clinical staff. A computer disk version is planned which will supply more detailed background information and self learning facilities. An SNBTS compendium of data sheets giving important information on blood products and blood components has been published and will be regularly updated for customers. The South East BTS has also introduced a monthly bulletin of information for local clinicians about key aspects of using blood safely. This is distributed to all customers.

Many SNBTS staff are regular contributors to medical, scientific and other journals. Details of published articles are listed in a separate booklet available from any of the Regional Transfusion Centres and National Units.

#### THE FINANCIAL YEAR 1992/93

The SNBTS receives its funds from the NHS in Scotland as a discrete part of the overall allocation for the Common Services Agency. The figures are extracted from the Statutory Accounts of the CSA and have been prepared on an income and expenditure basis.

#### MAJOR WORKS

Several of the building projects initiated in 1991/92 have now been completed, including the new Blood Components Separating Suite in Edinburgh and the new Central Boiler facility at the Glasgow and West of Scotland Regional Laboratories. Work continued on the new Regional Transfusion Centre for Aberdeen, and on Phases III and IV of building developments at the Protein Fractionation Centre in Edinburgh. The new Aberdeen RTC is scheduled for completion in August 1993. Phase III of the PFC development was completed by January 1993; Phase IV is currently underway and is scheduled for completion by the end of 1994.

## MINOR WORKS PROJECTS UNDERTAKEN IN 1992/93 INCLUDED:

the upgrading of laboratory accommodation and facilities for the National Science Laboratory and National Reagents Unit; and projects at various regional centres to ensure their facilities meet current legislative and Medicines Control Agency requirements.

## SUMMARY OF CAPITAL EXPENDITURE FOR THE YEAR ENDED 31 MARCH 1993

Capital Expenditure Projects.







VEHICLES



EQUIPMENT

# £7,926,616

TOTAL

#### **REVENUE EXPENDITURE 1992/93**

AN	ALY	SIS	OF	EXP	ENDI	TURE	1992/93
40.3.00							



DONOR AND BLOOD COLLECTION PROGRAMME



LABORATORIES

# 32%

BLOOD COMPONENT SEPARATION AND PRODUCT MANUFACTURING



CLINICAL SERVICES (e.g. tissue typing, bone banking, National Rare Cell Panel)



PRODUCTS AND SERVICES SUPPORT, DEVELOPMENT AND RESEARCH

SALARIES & WAGES	
OPERATIONAL EQUIPMENT	
OPERATIONAL SUPPLIES	
RENT & RATES	
HEAT & LIGHT	
MAINTENANCE OF PREMISES	
DONOR SESSION EXPENSES	
TELEPHONES & POSTAGE	
PUBLICITY & MARKETING	
PRINTING & STATIONERY	
VEHICLE RUNNING COSTS	
FURNITURE & OFFICE EQUIPMEN	E £229,531
TRAVEL & SUBSISTENCE	
CLEANING MATERIALS	
OTHER	£566,838
TOTAL EXPENDITURE	





## SNBTS SCIENTIFIC PUBLICATIONS 1992/93

Every year SNBTS scientists and clinicians publish the results of their research in scientific journals and books. They also present their findings at scientific meetings, both national and international. Previously these publications have been listed within the Annual Report. From now on they are being published in this booklet which we hope will prove to be a useful resource for those interested in blood transfusion-related research. It will also allow a cumulative record to be built up, year by year, of SNBTS scientific publications. For publications prior to 1992, readers are referred to past Annual Reports.

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