HIV LITIGATION

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ORGANISATION AND FUNCTIONS OF THE NATIONAL BLOOD TRANSFUSION SERVICE

by

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I have been given a wide brief this morning, if I can use this term in the present company. It is to give an overview of the organisation and functions of the National Blood Transfusion Service. In doing this I have to refer to events which are now part of history. I have endeavoured to verify the dates involved as far as possible, but in some instances I have had to give an approximation, particularly in the uptake of policies which varied in RTCs, largely due to their regional rather than national management.

The transfusion services in the United Kingdom comprise the National Blood Transfusion Service (NBTS) which operates in England and Wales. Northern Ireland is managed by the local DH Office and the Scottish National Blood Transfusion Service is a separate organisation managed by the Common Services Agency of the Scottish Home and Health Department.

FORMATION OF THE NBTS

The NBTS was constituted in July 1946. During the second World War a Blood Transfusion Service operated under the Emergency Medical Service and the permanent Service was based on the University towns of Newcastle, Leeds, Sheffield, Cambridge, Oxford, Bristol, Cardiff, Liverpool and Manchester with two Centres to cover the Greater London area and South-East England.

The service was financed by the Ministry of Health and for the next two years the Service was truly a National Service, the only time in its history that it has been. The newly created Centres

were directed by a Regional Blood Transfusion Officer and they met monthly under the Chairmanship of Dr. Maycock who was the Director of the "Plasma Drying Plant".

TRANSFER OF ORGANISATION TO REGIONAL HOSPITAL BOARDS

In July 1948, the management of the Transfusion Centres was devolved to the Regional Health Boards created by the National Health Service Act. Initially, the Transfusion Centres were those cited previously. With the creation of the N.E. Thames and Wessex Regions there were 14 Regional Transfusion Centres in England and Wales. Thirteen Regions each had a Transfusion Centre, the exception being S.E. and S.W. Thames which were served by one Centre. The Welsh Office managed the RTC in Wales. There were two Central Laboratories, the Blood Products Laboratory (BPL) and its associated Plasma Fractionation Laboratory in Oxford and the Blood Group Reference Laboratory. The Central Laboratories were wholly financed by the DHSS and administered on its behalf by the Medical Research Council which, in the case of BPL, delegated day to day management to the Lister Institute of Preventive Medicine.

The Regional Blood Transfusion Officers, who became the Regional Transfusion Directors (RTDs) in 1949, continued to meet regularly to review the work of the Service. However, the meetings, although attended by some Department of Health Officers, were informal only, although attempts were made to put forward uniform policies for the NBTS.

However, this degree of co-operation constituted no more than a loose federation and RTDs could develop their own policies and employ staff, performing similar work, on different grades in accordance with agreements reached with their respective Regional Boards. Over the years divergent policies in the RTCs developed although core policies such as the medical selection of donors remained fairly uniform on a national basis.

MANAGEMENT BY REGIONAL HEALTH AUTHORITIES

Before the 1974 reorganisation of the NHS, a Working Party of the RTDs Committee prepared a report on the organisation of the NBTS. In this report, the growing divergence in the organisation and administration of the NBTS was pointed out, reflecting in part, the varying fiscal policies of Regional Boards. Furthermore there was no central body to co-ordinate policy for the NBTS in scientific, technical, administrative and financial fields. This lack of central direction, it was claimed, inhibited the achievement of a nationally uniform service of a desired standard of efficiency. Policies recommended to Regions may not necessarily be accepted, or, if accepted, were unlikely to be interpreted or implemented uniformly.

In the 1974 reorganisation of the NHS, the Government's White Paper left the responsibility for the provision of the blood transfusion service with newly created RHAs. It was recognised by the DHSS that the NBTS differed from other sections of the NHS in the services it provided and a degree of central co-ordination was desirable.

In 1973, on the recommendations of the Standing Medical Advisory Committee, the DHSS constituted a Committee with the following terms of reference: "to consider whether any changes should be made in the present organisation of the blood transfusion services in England and Wales and to make recommendations."

This Committee, with Dr. J.J.A. Reid, Deputy Chief Medical Officer as Chairman, considered the case for a centrally administered service proposed by the RTDs, but considered that the proposals in the 1974 reorganisation, i.e. the unification of the three existing aims of the NHS (hospital, local authority and family practitioner services) under the central control of the DHSS and then delegating as much as possible of the responsibility for administering the unified Service to RHAs, entailed a scrutiny of operations and planning in the Regions by DHSS. Furthermore, independently of the reorganisation, the DHSS had strengthened their administrative staff with the appointment of a Principal Grade Officer with responsibilities exclusively directed to blood transfusion matters.

The DHSS did not consider that central management or funding of the NBTS was necessary to increase the effectiveness of the service. It was conceded, however, that central co-ordination would be advantageous and a Central Committee for the NBTS was constituted with terms of reference as follows:

"to keep under review the operation of the National Blood Transfusion Service, including the Blood Products Laboratory and

the Blood Group Reference Laboratory in England and Wales and advise the DHSS and the Welsh Office on the development of the Service."

This Committee met on several occasions and was chaired by a senior doctor at DHSS and its members comprised representatives from DHSS, the NBTS and the clinical specialities for which the NBTS provided a service. The RTD Committee continued to meet on an informal basis.

By 1976, however, comments were being made by RTDs that the functioning of the Central Committee was disappointing in that co-ordination of the work of the RTCs and the differences in priority afforded by RHAs to their transfusion services had not changed.

FORMATION OF DIVISIONS

In order to improve communications within and between RTCs, in October 1976 the RTCs formed themselves into three Divisions.

These were:

Eastern: E. Anglia, N.E. Thames, N.W. Thames, SE/SW Thames

Western: Oxford, S. Western, Wales, Wessex, West Midlands

Northern: Mersey, Northern, N. Western, Trent, Yorkshire

Membership of the Divisions comprised all consultant medical staff working in the respective RTCs. The Divisional Chairman was an elected RTD. It was envisaged that meetings would be held

prior to the RTD meeting so that discussions could take place on agenda items in a wider forum than had occurred previously.

Regional Donor Organisers had met regularly since 1946 to discuss matters relating to Donor Recruitment and since central publicity funding still continued, they had representatives together with RTDs on a DHSS Central Publicity Committee. This Committee allocated funds for central publicity for donor recruitment. During the succeeding few years other groups of RTC managerial staff met two or three times per year and minutes of their meetings were sent to the RTD Committee. These Committees consisted of Managers/Administrators, Nurses and Head Laboratory Scientists.

The RTD Committee also created a number of Working Parties to examine certain aspects of the work of the Service. A number of these were also combined with the representatives of the Scottish NBTS. There were attempts to introduce some degree of standardisation and uniformity in the operations of the Service. There were some notable successes such as the introduction of machine readable labels, a uniform pack design for plasma for fractionation, guidelines for the medical selection of blood donors and guidelines for apheresis of blood donors.

ADVISORY COMMITTEE ON THE NATIONAL BLOOD TRANSFUSION SERVICE

The Central Committee on the NBTS was wound up during the latter part of the 1970's and a new Committee, the Advisory Committee on the NBTS was constituted. Again, it was hoped that this

Committee would provide advice which the DHSS and Welsh Office needed on the development and work of the NBTS.

The Committee was chaired by a Deputy Chief Medical Officer and its membership comprised the Chairmen of the NBTS Divisions, the Consultant Adviser to the C.M.O., the Director of the Blood Products Laboratory, a Regional Medical Officer, Regional Treasurer, Regional Nurse and Regional Administrator. Observers from SHHD, the Welsh and Northern Ireland Offices attended as observers.

This Committee, during its existence to 1988, performed three major tasks:

(1) A Working Party, established by the Committee, determined the quantity of plasma required for national self-sufficiency for the production of fractionated plasma products. This was an important matter since planning and construction of the new BPL was concurrently taking place.

(2) A survey of record-keeping in RTCs was performed by DHSS Officers on behalf of the Committee and, as a result of this survey, a health circular was issued to RHAs.

(3) Funding was provided for the Regional Treasurer member of the Committee to employ consultants to advise the DHSS on a revised costing system for products prepared at RTCs. This costing system was accepted by the DHSS in 1984 and,

despite its imperfections, it was an advance on previous systems and has provided a basis for future policy on costings.

THE FORMATION OF THE NATIONAL DIRECTORATE

It became apparent during the middle 1980's that national aspects of the work of RTCs were assuming greater importance. The major factor was the need for increasing the plasma supply to meet the needs of the new BPL, the construction of which was nearing completion. RTCs varied in their ability to provide this plasma, and this situation was aggravated by blood shortages in the London area. RHAs were generally reluctant to approve blood collection in excess to their regional requirements. Neither the Advisory Committee nor the RTD Working Parties could address such detailed matters concerning the Service.

In response to a submission by the RTD Committee outlining these problems in the NBTS organisation, the DHSS commissioned a study of the NBTS by the NHS Management Services Branch of the DHSS and constituted a Steering Group to supervise the work.

The field work commenced in September 1986 and the report became available towards the end of 1987. Deficiencies were identified in the organisation and management of RTCs, particularly with respect to a lack of management information and poor co-ordination of the work of the RTCs on a national basis.

To rectify these deficiencies the DHSS formed the National Directorate of the NBTS and appointed a National Director, with a Deputy National Director, with a small supporting staff. The aims of the National Directorate, which was established in October 1988, were to:

1. Co-ordinate the work of the RTCs
2. Formulate a national blood collection policy
3. Ensure an adequate plasma supply
4. Establish a management information service
5. Promote cost-effectiveness in the RTCs

RTCs continue to be managed by RHAs who have the final decision on revenue and developments for their transfusion centres. Nevertheless, the coincidental introduction of the principle of cross-accounting has enabled surplus blood supplies to be sent to RTCs experiencing shortages without the exporting RHA suffering a financial penalty and the National Directorate is currently involved with the formulation of policies to implement the aims listed in this slide.

CONSULTANT ADVISER TO THE CHIEF MEDICAL OFFICER

Blood transfusion, like many other specialities, has a Consultant Adviser to the Chief Medical Officer of DHSS. There have been three in the history of the NBTS. Dr., later Sir William, d'A Maycock from 1948 to 1978, Dr. Geoffrey Tovey from 1978-1981 and myself from 1981 to the present.

The purpose of the Consultant Adviser is to provide advice of a personal nature to the CMO or nominated officers at DHSS as distinct from collective advice from the Speciality as a whole. The first two Advisers had an office and secretarial support provided by the DHSS, but when I was appointed this was changed by mutual agreement since as a Director of a Regional Transfusion Centre I could not maintain two offices as far apart as Manchester and London. This coincided with the wish of the DHSS who preferred the Consultant Adviser to advise on professional matters relating to Transfusion Medicine without purporting to be a member of the DHSS staff.

Events were to prove that my advice was required on many occasions during the next few years since within one year the relationship between AIDS and the transfusion of blood and its products was proven. It must be recognised that my advice on these matters was on a personal basis; responses from the Service to matters concerning HIV infection amongst other topics were elicited from the Chairman of the RTD Committee.

WORK OF THE NBTS

Each Regional Transfusion Centre has a core function of blood collection from volunteer, unpaid donors, the processing of the donations into blood products and the issue of these products to the hospitals in the region they service. Each RTC has staff responsible for the recruitment of blood donors, the maintenance

of donor panels, the organisation of blood collection sessions and the laboratory testing of donations and other products prior to issue.

Several products can be obtained from a donation of blood which consists of two principle components cells and plasma. Since the cells of different types have differing densities they can be separated by centrifugation from the plasma, and also from each other by the use of different centrifugal speeds. Thus platelets, which are cells important for blood clotting, can be prepared as a relatively pure product. They constitute important supportive therapy for patients deficient in platelets which may arise as a result of illness or by deliberately introducing the deficiency with drugs as part of a treatment regimen for patients, such as those suffering from leukaemia or in preparation for bone marrow transplantation.

Red cells can also be separated from both platelets and plasma. The plasma may be used for clinical treatment but most of the plasma separated from blood donations is used for the fractionation of purified plasma products.

PLASMA SUPPLY FOR FRACTIONATED PRODUCTS

For many years the principle use of plasma sent to the Plasma Drying Plant, later called the Blood Products Laboratory, was for the preparation of freeze-dried plasma. Purified albumin preparations, which were pasteurised, were substituted for this product in the late 1960s. These products were derived from

plasma pools from donations of whole blood which had time-expired.

The changing pattern of haemophilia care in the 1970s, which I am sure will be described by Dr. Rizza, led to a significant change in fractionation policy with the introduction of anti-haemophilic globulin as a fractionated product. This was derived from freshly collected plasma.

In 1973 it was estimated that approximately 230,000 donations per year were being used as a source of plasma or cryoprecipitate for the treatment of haemophilia. Cryoprecipitate is an impure form of Factor VIII which was prepared at RTCs as single donor units in the frozen state. At this time 20,000 donations per year were being sent to BPL for preparing AHG concentrate.

It was stated at that time that for total haemophilia care, fresh plasma, cryoprecipitate and AHG concentrate was required from between 400,000 and 700,000 donations per year.

RTCs began to increase supplies of fresh plasma sent to BPL and in December 1974 the DHSS provided £0.5M in order to provide 275,000 donations of fresh plasma annually for fractionation. RTCs were at this time given annual targets for plasma collection based on blood collection in 1973, not on regional populations.

In 1981 a system of pro-rata return of fractionated plasma products from BPL was introduced to encourage RTCs to increase

plasma production, i.e. the region received products equivalent to the quantity of plasma supplied.

It can be seen from this slide that the use of cryoprecipitate has declined over the years and the use of Factor VIII concentrate has increased, but much of the Factor VIII was derived from commercial sources. Blood collection increased between 1975 and 1985, but it can be seen that the significant change during this period was the use of plasma reduced blood which accounted for 50% of all blood issued.

Simple removal of plasma from a blood donation is limited to about 200 ml from each donation. In 1984 a red cell nutrient solution became available which allowed all the plasma to be taken from a blood donation (approximately 290 ml). Introduction of the use of this solution and of plasmapheresis, a procedure whereby the donor is connected to a machine, blood is collected and the red cells and plasma are automatically separated and the red cells are returned to the donor enabled a considerable increase in plasma supply and provided the means to collect sufficient plasma to achieve national self-sufficiency, a declared objective of the Government.

The quantity of plasma sent to BPL has increased steadily and exceeded the capacity for fractionation between 1986 and 1989. It was stored pending fractionation. Approximately 420,000 kg of plasma will be sent to BPL in the year ending March 1990.

This, together with plasma from store, should yield in excess of 75,000,000 iu of Factor VIII concentrate.

Another core function of RTCs is to provide clinical advice to hospitals on all matters relating to transfusion medicine. With regional development and management of RTCs and the diverse interests of the RTDs, a number of regional functions are performed at RTCs. The degree of involvement with each function varies considerably throughout the regions.

I should now like to concentrate in more detail on the selection of blood donors and tests performed on blood donors and blood donations.

PRE DONATION SELECTION AND TESTING ON DONORS

The NBTS has two aims with respect to the safety of the blood supply.

(1) That the collection of blood from a donor does not compromise the health of that person.

(2) When the blood or any of its products is transfused it has maximum efficacy and safety.

In some regions blood collection sessions are held in permanent sites, but most blood is collected by mobile teams. All the staff and equipment necessary for the blood collection are

transported to a suitable site which may be a public or church hall, a factory or other commercial premises.

The number of donations collected by a mobile team varies with the number of staff available, but can amount to 200 on one visit. Facilities are such that it is not possible to physically give a medical examination to every donor.

Each donor is given a screening test for anaemia since this is clearly a condition which is a contra-indication to blood donation. Donors who fail this test have a sample taken for a full blood count and those who have anaemia are referred for investigation and treatment.

Donors are asked to read a list of illnesses and other conditions such as contact with persons suffering from certain diseases, inoculations and travel abroad. Positive answers may lead to the permanent or temporary deferral of the donor. This interview is normally conducted by a trained receptionist; in cases where this person is unable to make a decision the donor is referred to the medical officer or nurse in charge of the session.

TESTS PERFORMED ON BLOOD DONATIONS

Serological

Each blood donation is tested to determine the donor's blood group and the plasma is tested for irregular blood group antibodies. An antibody is a property which develops in the blood as a result of stimulation with a foreign substance. Most

antibodies develop as a result of bacterial or viral infections but can also occur as a result of stimulation with red blood cells which contain blood groups which are absent in a given individual. This stimulation may be either from transfusion of blood or pregnancy, which in effect is the same causative factor since small leaks of blood from the foetal to the maternal circulation are common, particularly in the later stages of pregnancy. The foetal blood groups differ from the mother's since the father makes a contribution to the genetic make-up of the child.

In certain instances the blood is tested for rare groups or the white cells are tested for the tissue groups which they carry.

Microbiological

Microbiological screening of blood donations is now an important part of the work of the RTC since it is by this means that transmission of an infection can be minimised.

The potential number of infections transmissible by blood is considerable. On this slide are shown the viruses which may potentially be transmitted. It will be noted that this includes the hepatitis and herpes viruses, the human immunodeficiency viruses, the human B lymphotropic viruses which have been associated with certain leukaemias and others which are less common.

Bacteria and parasites may also be potentially transmitted by blood. On this slide are shown the principle ones. They include Treponema, the causative agent of syphilis and Plasmodium the parasite which causes malaria.

It is not necessary, fortunately, to routinely screen all donations for these infectious agents. Some are eliminated by taking a history from the donor, e.g. foreign travel for malaria, and infection with others, e.g. Salmonella would make the donor too ill to donate. In other instances, such as the herpes viruses shown in the previous slide, the level of immunity to the virus in the community is high and only certain patients require blood free from the virus, e.g. patients whose immune status is compromised through illness or drug therapy.

Before the introduction of routine screening for an infectious agent certain criteria have to be considered:

1. The prevalence and epidemiology of the agent in the country.
2. The incidence of carrier states. When a person recovers from an infection but still retains the virus in the tissues, particularly the blood, then they may be perfectly healthy yet can transmit the infection to a susceptible patient.
3. The morbidity, mortality and long term effects of the infection.
4. The availability of suitable screening tests.

5. The immune status of potential recipients which may be compromised through illness or drug therapy.

When a screening test is available it must comply with the following criteria:

1. It must be easy to perform.
2. It must be rapid, reliable and reproducible.

   Many RTCs test up to 500 donations per day and tests which take a long time or are complex in nature are not practical.

3. The test must have high sensitivity and high specificity. Sensitivity of a test is the ability of the test to detect the antigen and antibody for which it is designed. All tests have a level of sensitivity and may fail to detect antigen and antibody below a certain concentration. Specificity is the ability to detect the antigen or antibody without giving a positive reaction with other antigens and antibodies which may be present as contaminants.

4. Finally, the test should be cost-effective.

Tests for syphilis have been performed on blood donations since 1946. The organism survives poorly in stored blood. However, some products are now used in the fresh state and may be transmitted in such products if they are infected. Also, syphilis is a sexually transmitted disease and screening for it

can constitute a surrogate test for other sexually transmitted diseases.

I will consider hepatitis B and anti-HIV screening in more detail, but to complete this section, anti-CMV is tested for in a proportion of donations. Cytomegalovirus is a Herpes virus and approximately 60 per cent of the adult population are immune. However, certain patient groups may be susceptible, e.g. newborn infants, patients undergoing transplantation, and children with leukaemia or undergoing open heart surgery. These patients are usually transfused with blood which is free from CMV.

Other antibodies to infectious agents are screened for their usefulness in the preparation of a fractionated plasma product called an immunoglobulin which will contain a high concentration of the antibody. Anti-D which is used to prevent haemolytic disease of the newborn and anti-tetanus are examples of specific plasmas.

HEPATITIS

It has been known for many years that hepatitis could be transmitted by the transfusion of blood and blood products. It was formerly called homologous serum jaundice and the major product which led to transmission was freeze-dried plasma since this was prepared from plasma pools and one infected donation contaminated the pool. The substitution of purified albumin products which are pasteurised, eventually eliminated this as a

causative factor, but the occasional transmission from blood donations remained.

There are three types of hepatitis. Hepatitis A is the commonly acquired community hepatitis and is rarely transmitted by blood transfusion. Hepatitis B is an infection which can be transfusion transmitted and to take the story further, when this infection was largely eliminated through donor screening a third type of hepatitis was found, known as non-A, non-B.

In 1969 the Australian Antigen derived from the serum of an Australian Aborigine, was shown to be part of the causative agent of Hepatitis B. I am sure that Dr. Craske will refer to this agent in more detail and I will be content to state that from this discovery a test for the detection of this antigen, now known as the hepatitis B surface antigen, was developed. The test was applied to the routine screening of blood donations in England and Wales during 1971 and 1972.

The test first used in the NBTS to detect hepatitis B was the counter-immunoelectrophoresis. This was not particularly sensitive, although it was the most sensitive test available at that time. By the mid-1970s this was replaced by the reverse passive haemaglutination assay, which had greater sensitivity. Both of these tests may have given negative results with donations containing trace quantities of HBsAg. The so called third generation tests, radioimmunassay and ELISA have been used

Part 6: Taken from P- HIV Litigation: Organisation and Functions of The National Blood Service, report by H.H. Gunson, possibly 2 December 1989

in the NBTS since 1979/80 and both are highly sensitive and highly specific.

On this slide I have detailed the HBsAg results found in new or first time donors between 1979 and 1986. It can be seen there are three distinct groups of positivity rates. In 1979 and 1980 it was approximately 1 in 1000. Between 1981 and 1983 it was 1 in 1200; the reason for this was probably due to the decision to discontinue blood collections at H.M. Prisons in 1981 since prisoners showed a significantly higher rate of HBsAg positivity than the general population.

Finally, the rate has progressively reduced to 1 in 3000 by 1985. Hepatitis B is also a sexually transmitted disease and during this period the NBTS has been actively promoting self-exclusion of donors in risk categories for AIDS, another sexually transmitted disease. One can argue that the AIDS leaflets given to blood donors have been effective in persuading those at high risk for HIV infection to self-exclude.

Testing for HBsAg reduced the incidence of transfusion transmission of this virus, but instances of hepatitis transmission by blood transfusion still occurred. This was due to the presence of non A, non B hepatitis virus or viruses in blood, but more particularly plasma pools fractionated into the coagulation factor products, notably Factors VIII and IX used to treat haemophilia. A specific test has not been available to detect this virus until this year. Studies performed in the USA

in the late 1970s indicated that this was the commonest type of transfusion transmitted hepatitis.

Although the disease itself tends to be mild, there is a tendency for liver damage to result over a period of years in up to 50 per cent of patients. Studies in 1981 and 1986 suggested a relationship between transfusion-associated NANBH with a raised level of a liver enzyme, alanine aminotransferase and the presence of an antibody to the core of hepatitis B virus. ALT screening has been performed on donors in the Federal Republic of Germany and in some parts of Italy, where there is a high incidence of the disease, for some years and became routine in the USA in 1986. It has not been employed in the UK, but a study to evaluate these tests in blood donors has been recently concluded and the results are currently being analysed.

HIV INFECTION IN BLOOD DONORS

The first case of transfusion-transmitted AIDS was reported in 1983 in an infant transfused in late 1982. At this time there was no test available for blood donations for the presence of HIV. During 1983 a leaflet asking persons in certain risk categories to self-exclude as blood donors was prepared and issued in September of that year.

It must be realised that the exclusion categories were worded according to the best information available at that time.

Three categories were defined:

1. Homosexual men with many partners
2. Persons, male or female, who inject drugs
3. Sexual contacts of the above groups

Policy for distribution of this leaflet varied throughout the regions. The majority of RTCs made the leaflet available at blood collection sessions. Four RTCs distributed the leaflet with call-up letters in order that donors could read this before coming to the blood collection session. Donors were asked if they had read the leaflet.

The second leaflet was issued in January 1985 and the exclusion categories were changed to:

1. Practising homosexual and bisexual men
2. Drug abusers, both men and women who inject drugs
3. Sexual contacts of people in these groups

Reference was also made to HIV infection in Haemophilia patients and to the increased infection in certain ethnic groups.

This leaflet, and future ones, was distributed to prospective donors by mail with call-up letters or the information was included on computer-derived call up letters.

During 1985 the test for the antibody to HIV became available and was licensed in the USA in March of that year. It was not immediately introduced for routine screening of blood donations in the U.K.

At this time the prevalence of anti-HIV positives was unknown but it was estimated in the USA that about 70% of positive test results may be false. Concern was expressed that the withdrawal of HIV seropositive units may actually lead to shortages of blood and that the effect on donor recruitment may be serious if potential donors were aware of a significant false positive rate. It was important, therefore, that highly specific confirmatory tests should be available within a short time after routine screening of blood donations commenced so that false positive reactions could be identified and the donor called for a further donation.

Critics of this policy who argued that at least positive reacting donations could be eliminated, did not recognise the practical problems involved with the avoidance of further blood collections from donors without advising them of the reasons for not requiring their donations in the future.

A further consideration was that, since the anti-HIV test had received wide publicity, it was feared that some persons at high risk would present as blood donors as a convenient way of finding out their anti-HIV status. Although their blood may have been

eliminated by the screening test there was a greater risk that these persons presented as blood donors in the "window" between contracting HIV infection and the presence of detectable anti-HIV - a period generally of a few weeks to a few months. This would have been counter-productive and made the blood supply less secure rather than safer. It was essential, therefore, that alternative test venues were available for such persons.

The test only became regularly available in the U.K. in March 1985. There had been no experience with its use in the NBTS and the appropriate test systems for screening donations had not been defined. Staff had not been trained in its use and it was important that senior medical staff were trained to counsel confirmed seropositive donors.

The appropriate conditions existed for the introduction of the test in the U.K. in October 1985 and all RTCs started testing on the same day.

Since the test detects an antibody to HIV and not the virus itself it was considered important to continue the issue of leaflets to prospective donors. A further leaflet was introduced immediately prior to testing and the exclusion categories now included haemophiliacs who had been treated with blood products. In these new leaflets donors were informed that the test would be performed on their donation and they were asked to agree to this by signing a consent form.

An updated leaflet was issued in September 1986 and this was more explicit with respect to homosexual and bisexual men and for intravenous drug users. The reason for this arose from questioning donors who were found anti-HIV positive. Some donors attended who had discontinued their homosexual activities or drug use months or years earlier and who did not regard themselves now as an HIV risk. A statement with respect to sexual contacts with persons living in Africa was also included.

The current leaflet, issued in July 1987 included sexual partners of haemophiliacs and prostitutes.

Finally, I thought you may be interested in a summary of the results of screening blood donations and blood donors between 1985 and 1988 in the U.K. (this data includes Scotland).

Approximately 2.5 million donations have been screened each year and the HIV seropositive rate has declined. This is not surprising since one donor may donate several times and, therefore, with elimination of infected donors the rate per donation falls. The rate is one of the lowest in the World. You will note a preponderance of males in the seropositive donors, when new or first-time donors are tested the rate is higher but also has been declining.

It can be seen that the seropositives are largely under the age of 40 years, which is a typical distribution for a sexually transmitted disease.

Of the anti-HIV positive donors interviewed the majority can be allocated to groups with high risk activity with respect to HIV infection. Although 14 donors denied risk this data must be interpreted with care since some donors did not admit risk activity until several interviews had been held.

I hope that this presentation has been useful for your understanding of the organisation and work of the National Blood Transfusion Service. Despite the length of this presentation there are many other items which I could have included or existing topics that could have been dealt with in more detail. If there are any questions I will be happy to respond to them.