Witness Name: Dr M McClelland
Statement No.: WITN0892006
Exhibits: n/a
Dated: 26 January 2022

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF DR MORRIS MCCLELLAND

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 11 June 2019.

I, Dr McClelland, will say as follows:

Section 1: Introduction

1. **Please set out your name, address, date of birth and professional qualifications.**

Name: William Morris McClelland

Address: GRO-C, Belfast GRO-C

DOB: GRO-C 1945

Professional Qualifications: MB Bch BAO 1971

FRCPATH (Haematology) 1977

2. **Please give the dates that you were employed by the NIBTS.**

Dates of employment by NIBTS: August 1978 – July 2009

3. **Please explain the various roles and responsibilities that you held throughout your career at the NIBTS.**

Roles and Responsibilities

August 1978 – May 1980 Consultant and Deputy Director NIBTS. During this period, I had a number of short placements (1-2 months) to regional

	transfusion centres in GB – Edinburgh, Bristol and North East Thames.
June 1980 – May 1994	Director, NIBTS. Responsible for medical and scientific direction and also general management of the service (with support from Eastern Health and Social Services Board).
June 1994 – July 2009	Chief Executive and Medical Director, NIBTS Agency. Responsible to agency Board for the management of the service as well as medical/scientific direction.

4. **Please confirm whether you have provided any evidence or been involved in any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections in blood and/or blood products? If you have, please provide details of your involvement.**

I confirm I have not been involved in any other inquiries.

Section 2: Blood collection in Northern Ireland

5. **Please set out details of the system for collecting blood and blood components for use in Northern Ireland from 1970 to 1991, including the coordination and management structure of the NIBTS.**

The system during the period 1970-1991 was similar to the rest of the UK so NIBTS was / is a regional service responsible for donor recruitment, collection, processing, testing and distribution of blood and components. Each hospital has a blood bank responsible for storage of blood components and cross matching of blood for individual patients. NIBTS provided a reference laboratory service dealing with any problems encountered by hospital blood banks.

From 1972 the Eastern Health and Social Services Board (EHSSB) had responsibility for NIBTS (previously the Northern Ireland Hospitals Authority). While the Director had devolved responsibility for day to day running of the service, the budget was held by EHSSB, which also provided personnel services and other management services. When NIBTS was established as an independent special agency it assumed responsibility for all aspects of management including finance.

Section 3: NIBTS relationship with England

6. **Please explain the NIBTS's relationship with the Blood Products Laboratory ("BPL"), located in Elstree, England, in relation to the supply of blood and blood products to**

Northern Ireland, including the years that a relationship existed between the two countries.

I have little knowledge of this prior to my appointment in 1978 or any details of how the relationship was established. I do know that between 1970-1982 NIBTS did send a quantity of plasma to BPL. This plasma was in the liquid state and could be used for the manufacture of albumin and immunoglobulin, but not Factor VIII concentrate. No fresh frozen plasma was ever sent to BPL.

During this period, in addition to albumin and immunoglobulins, a small supply of Factor VIII concentrate was received from BPL which, by 1980, represented about 10% of Northern Ireland's needs.

7. **If you have not already done so, please elaborate on how this relationship operated, including all elements of the process, from the point of donation in Northern Ireland, to being sent to and processed at the BPL, and then ultimately the final product being returned for use in Northern Ireland.**

See 6 above.

<u>Section 4: NIBTS relationship with Scotland</u>

8. **Please explain the NIBTS's relationship with the Protein Fractionation Centre ("PFC"), located in Edinburgh, Scotland, in relation to the supply of blood and blood products to Northern Ireland, including the years that a relationship existed between the two countries.**

This relationship was established from 1982. Soon after my appointment as Director (in 1980), I began discussions with senior SNBTS/PFC personnel. It became clear that a link with PFC would offer obvious practical advantages for the transport of fresh frozen plasma (surface transport). PFC also appeared to have more spare fractionation capacity than BPL and they had moved into new, purpose-built facilities in the mid-1970s.

Strict contractual arrangements were established for the supply of plasma products from PFC whereby the quantity received was proportional to the amount of plasma provided. Furthermore, charges were directly related to the quantity of products received.

Plasma supplies (from NIBTS to PFC) were increased steadily during the 1980s.

9. **If you have not already done so, please elaborate on how this relationship operated, including all elements of the process, from the point of donation in Northern Ireland, to**

being sent to and processed at the PFC, and then ultimately the final product being returned for use in Northern Ireland.

See 8 above.

Section 5: Self-sufficiency

10. Please set out the extent to which Northern Ireland has been self-sufficient in blood and blood products since 1970.

As is the case with all issues in this statement, my knowledge of the period from 1970-1978 is second-hand i.e., based on reading of documentation, conversations about past events etc. and not on any personal experience or responsibilities. For most of the period 1972-1978 I was a trainee doctor in Haematology/ Laboratory Medicine.

When considering the issue of self-sufficiency in Northern Ireland during this period, I believe it is important to take account of the civil disturbances. The peak effects were probably in the early to mid-1970s but continued to be very significant during the 1980s and beyond. There were significant effects on demand for blood (arising from treatment of trauma) and also security difficulties for blood collection teams. It was particularly unfortunate that the relocated NIBTS headquarters (1969) proved to be close to a danger area, being damaged on four occasions by bomb explosions in one year (1972). Apart from security problems a major effect of the 'troubles' was the closure of many of the largest factories which had been important sources of blood donors.

In view of the above the achievement of self-sufficiency in blood components (whole blood, red cells, fresh frozen plasma, platelets and cryoprecipitate) was a very major challenge which I believe was remarkably well achieved in the circumstances.

Self-sufficiency in plasma products (factor VIII, other clotting factor concentrates, albumin and various immunoglobulins) relied, of course, on maximising the harvesting of plasma from donor blood. A significant quantity of plasma was collected and dispatched to BPL during the 1970s. But as noted, no fresh frozen plasma (suitable for factor VIII manufacture) was collected until 1982. By 1980 (when I became Director) 80% of blood was still issued to hospitals as whole blood.

When the new arrangement with Scotland (PFC) was fully established in 1982, the quantity of FFP harvested rapidly increased each year (from 6 tonnes to almost 20 tonnes per annum by 1990) with a corresponding increase in the amount of NHS factor VIII –2.25million international units (IU) by 1986. However, self-sufficiency was not fully achieved, mainly due to the rapid increase in demand (usage of factor VIII concentrates) during the 1980s. This arose from a combination of factors such as an increase in a number of patients with haemophilia, increase in orthopaedic surgical procedures and implementation of the home treatment programme in haemophilia.

11. Please explain the reasons why Northern Ireland has never been involved in fractionation.

The establishment of a plasma product manufacturing facility requires enormous investment in terms of expertise, facilities etc. of a level that would not have been feasible to service a population of 1.5 million. I think it would always have been regarded as a non-starter, certainly in my time as Director.

12. **Please explain how the demands for plasma changed from the 1970s onwards, and how transfusion and fractionation strategies adapted in response.**

Some of this is dealt with in 10 above.

The preparation of blood components, and harvesting of plasma from donated blood, became feasible with the introduction of plastic pack systems (replacing glass bottles). NIBTS introduced plastic packs in 1968. From then, and during the 1970s, increasing quantities of blood components (platelets, FFP and cryoprecipitate) were produced. From 1982, the objective of achieving self-sufficiency (in factor VIII concentrate and other plasma products) became a major priority for the service. This required the maximising of plasma collection from donated blood. This in turn required the acceptance by clinical users of blood in the form of concentrated red cells, as opposed to whole blood. A major educational programme was thus required. By 1990, red cell concentrates had increased from 20% to almost 100%. Two other significant developments towards increasing plasma supply are also noted:

a) The introduction of optimal additive solutions for the collection and storage of blood – this allowed a 30% increase in plasma collection per donation – from 1986.
b) A plasmapheresis programme was gradually established during the 1980s, reaching over 3000 donations by the end of the decade.

This level of plasma harvesting was further increased and then maintained during the 1990s until the impact of variant CJD arose.

13. **Please outline your knowledge and understanding of the efforts in the United Kingdom to achieve self-sufficiency in blood products, including but not limited to:**

a) the extent to which the United Kingdom was self-sufficient in the production of blood and blood products during the 1970s and 1980s;
b) the reasons that self-sufficiency was not achieved;
c) the consequences of failing to achieve self-sufficiency; and
d) how domestic supply of blood and blood products impacted the availability of cryoprecipitate.

Self-sufficiency depended on two factors.

a) Adequate fractionation capacity while meeting satisfactory standards of quality and safety
b) Harvesting of adequate quantities of fresh frozen plasma from blood donated by voluntary unpaid donors.

At the time of my appointment as Director, my awareness was that the main factor in failure to achieve self-sufficiency was the inadequate fractionation facility at BPL. It was also my understanding that a new facility was planned.

During my placement in 1979 with the Scottish BTS I became aware of the Scottish strategy for achieving self-sufficiency and that PFC had some spare capacity. My subsequent proposals to the Eastern Health Board and DHSS (NI) to establish a link up with the SNBTS were accepted and put into effect.

During the 1980s, the quantities of NHS Factor VIII in all parts of the UK increased to a level that would have exceeded the usage at the beginning of the decade. But demand for product in the treatment of haemophilia also increased very rapidly so that there was still a reliance on some commercial product.

A further complicating factor was the onset of HIV/AIDS which led to the rapid development of viral inactivation/heat treatment techniques in the manufacture of clotting factor concentrates. These were introduced by all suppliers, NHS and commercial. In this new situation, the advantage of NHS products was less clear cut and the methods used in manufacture/viral inactivation became equally important factors in determining which product to use. This factor became relevant in Northern Ireland when some problems arose with the acceptability of the PFC Factor VIII product. Because of this I can recall periods in the 1980s when NI did not use its full allocation of Factor VIII (based on plasma input).

c) Consequences of failure to achieve self-sufficiency

It is likely that failure to achieve self-sufficiency in factor VIII supplies, and hence reliance on some commercial imports, had some effects on the incidence of transmissible infection in haemophilia patients. However, it is arguable that this would probably only have applied to HIV infection. Given the incidence of hepatitis C in the UK donor population and the large pool size used for NHS (as well as commercial) products it is unlikely NHS Factor VIII would have been much, if any, safer with respect to hepatitis C.

d) Cryoprecipitate availability

Fresh frozen plasma (FFP) used for fractionation and cryoprecipitate have the same starting material so clearly production of one would have influenced availability of the other. Once national decisions were taken (England and Scotland) to increase fractionation capacity with a view to achieving self-sufficiency in factor VIII, there presumably would have been pressures on regional transfusion centres to maximise their input of FFP. Given that total blood collection was fairly finite, this may have had some impact on cryoprecipitate production.

However, in the case of Northern Ireland I do not believe this was a significant factor in limiting supplies of cryoprecipitate. There were (fairly rare) occasions when supplies of cryoprecipitate would have been limited because of exceptional requirements for an individual patient.

Section 6: Knowledge of Risks

14. Please outline what was known by NIBTS and the relevant health authorities in the 1970s and 1980s about the risks of transmission of infections associated with blood and blood products.

I can only answer this by providing a brief outline of my personal knowledge as Deputy Director (1978/79) and then Director (from 1980). However, a few general points can be made. It was fully appreciated by medical and scientific staff in NIBTS that the prevention of transmission of infective agents, from donors to recipients, was a basic requirement in the provision of a safe and effective blood supply. Guidelines for the selection of donors were provided to staff and these were largely geared to this end. These guidelines were based on nationally agreed (UK) guidelines.

As screening tests for the carrier state for infections became available these were introduced in parallel with other parts of the UK e.g., syphilis serology (1940s), hepatitis B (1972), HTLVIII antibody (October 1985) and hepatitis C antibody (September 1991).

Another approach to preventing infection is the removal of infective agents or potential agents during the preparation of blood components. So NIBTS introduced leucodepletion (white cell removal by filtration) for all blood components (red cells, platelets, plasma) by November 1999 – a safety precaution related to variant CJD.

15. Please explain when and in what circumstances the NIBTS first became aware that hepatitis (including but not limited to HBV and non-A, non B hepatitis/HCV) was transmitted through blood and blood products.

In the case of hepatitis B, I and colleagues (from 1978) were aware there was a (small) residual risk related to the sensitivity of the screening tests. A more sensitive screening test for hepatitis B (radioimmuno assay) was introduced in 1982 (replacing the existing RPH assay).

Non-A, Non-B Hepatitis

I was aware of follow-up studies on transfusion recipients (mainly from the United States) published in scientific journals by the mid to late 1970s, indicating the existence of post-transfusion non-A non-B hepatitis in the region of 2-5% of recipients. However, in the UK at large, no properly controlled follow up studies were carried out, so while sporadic cases were reported the incidence of this problem in the UK was not known. Importantly, it was also unclear how serious the infection was i.e., how many cases would progress to chronic liver disease. Hospital clinicians and hospital blood banks were encouraged by NIBTS to report suspected cases to NIBTS but the numbers in the 1970s and 1980s were very small. We did recognize, from published studies, this would be an underestimate as the great majority of non-B hepatitis cases were mild or asymptomatic.

16. Please explain when and in what circumstances the NIBTS first became aware that HIV could be transmitted through blood and blood products.

I was very aware of the early reports from the USA of AIDS in haemophilia cases. Then when the first case (or cases) where the only risk factor appeared to be standard blood transfusion were reported, this pointed to a transmissible agent being responsible. I/we had various sources of information – regular public health reports e.g., MMWR, several journals and attendance at international scientific meetings e.g., American Association of Blood Banks (attended annually in the early 1980s) and membership of national committees e.g., Regional Transfusion Directors Committee (England and Wales) and the Scottish BTS Directors' Committee. Through these various routes, I became quite rapidly aware when HTLVIII was discovered to be the causative agent.

The finding that a batch of PFC factor VIII had been responsible for transmitting the virus to a group of haemophiliacs in Scotland brought the matter closer to home. Fortunately, Northern Ireland had not received any of this batch. But this finding led to PFC introducing a dry-heat-treatment process to factor VIII concentrate (at the post manufacture stage) as a matter of urgency.

The various measures to screen donors and reduce risk of HTLVIII or HIV are described later, but it is noted here that there was very close coordination between the four UK blood transfusion services and, so far as I could see, between the UK DoH's. This ensured that each new safety measure was introduced by all Centres promptly and at the same time.

17. Please explain when and in what circumstances the NIBTS first became aware that variant Creutzfeldt–Jakob disease could be transmitted through blood and blood products.

In the mid 1990s (I think) there was a widespread outbreak of BSE in cattle and the subsequent appearance of variant CJD in humans in the UK. This led to alarm within the UK blood transfusion services about the possibility that the infective agent (prion) might be transmitted from human to human, including via blood transfusion. I closely followed reports of animal experiments, some of which began to demonstrate that such transmission was possible, especially by white cells and plasma components. Later I then became aware of the first case reports of variant CJD in a patient who had received blood from a donor who subsequently developed CJD. This was followed by two further such reports.

Meanwhile, following a decision by the Committee on Safety of Medicines (July 1998) a number of very radical steps were decided on i.e., that plasma products had to be manufactured using imported (non-UK) plasma and that white cells should be removed from all blood components. NIBTS had fully implemented the latter by November 1999. All regional transfusion centres (including NIBTS) also introduced a number of donor selection measures, and all were implemented in parallel. These included, at a slightly later stage, the exclusion from donation of anyone who had received a blood transfusion since 1980.

18. Please provide details of how reliant the NIBTS was on paid donations i.e., what percentage of blood and blood products came from international sources where donors were paid to give their blood.

To my knowledge NIBTS has always employed an entirely voluntary, non-remunerated system. Certainly, during my employment with NIBTS no form of material incentive was ever offered to donors. On the question of imported plasma products, this is dealt with elsewhere under "Self-sufficiency".

19. **Please outline what was known by NIBTS and the relevant health authorities in the 1970s and 1980s about the risk of transmission of infections associated with imported blood products compared to blood products manufactured in the United Kingdom.**

From my appointment in 1978, I was aware that plasma products, imported from commercial sources, were made from plasma collected from paid donors (mostly USA but also developing countries in Latin America). I knew that a safe blood supply relied on obtaining honest answers from donors about their state of health, risk behaviours etc. As such, there seemed to be a potential risk of infected donations entering plasma pools used for fractionation. I knew this was a specific hazard for viral hepatitis (and later HIV) at least in coagulation concentrates. On the other hand, albumin solutions, which were subjected to a pasteurisation step during manufacture, seemed very safe and I was not aware of any reports of infections with these products.

Section 7: Policy Making, Decision Making and Actions

20. **What decisions were taken and what policies were formulated by the NIBTS (whether alone or in conjunction with the Northern Ireland Department of Health and/or other Health and Social care ("HSC") bodies) in the 1970s, 1980s and early 1990s in relation to the risks arising from the following:**

a) the importation and use of blood products

In paragraphs 6-9 above, the arrangements to obtain supplies of plasma products from BPL (until 1982) and thereafter from PFC are described. The latter involved the setting up of a radical programme aimed at maximising the quantity of plasma made available for fractionation. To enable planning towards the achievement of self-sufficiency it was decided (1985) that all plasma products (NHS and commercial) supplies for Northern Ireland should be centralised at NIBTS. Previously, supplies of most commercial products were obtained directly from suppliers by individual hospitals. However, in the case of factor VIII and some other coagulation concentrates, supplies continued to be ordered by, and delivered directly, to the Haemophilia Centre at the Royal Hospital. But the budgets for these and all other plasma products were then held by NIBTS. This arrangement enabled NIBTS to plan better towards self-sufficiency and also assisted health authorities with financial planning with respect to an increasingly expensive item for the Health Service.

b) the collection and use of blood

During this period, blood was collected in keeping with nationally agreed guidelines for the selection and care of donors and for the collection and storage of blood. From 1982,

following the link with Scotland, external checks were introduced to the system as the donor selection/collection rules were required to comply with PFC requirements.

Throughout this period, all donor sessions were overseen by qualified doctors.

With respect to the use of blood, this is covered under paragraph 21.

21. What did NIBTS do in response to the risks of transmission of infections arising from blood and blood products? In particular:

a) What steps were taken during the 1970s, 1980s and early 1990s?

With respect to education and training of doctors during this period, there were various opportunities from 1980. At undergraduate level, each medical year had two formal lectures on blood transfusion (delivered by me) and each year had a half-day visit to the transfusion centre in small groups (20+ attendees). All aspects of blood transfusion safety, including infection, were emphasised. At postgraduate level, every opportunity was taken to provide updates on transfusion matters including risks of infection e.g., by addressing specialist medical societies, hospital clinical meetings, Irish "Blood Club" Annual Meeting, etc. By providing information on what was known about non-A, non-B hepatitis. It was emphasised that the safety of blood could not be assumed. One area of particular emphasis was the importance of reporting any suspected transfusion transmitted infections to NIBTS so that appropriate action could be taken (see below).

b) What steps were taken to ensure that other HSC bodies, the medical profession and the public were informed and educated about the risks?

In every hospital, the blood bank and transfusion service were the responsibility of a Consultant Haemotologist. There was close liaison between these consultants and consultants in NIBTS, all being from the same medical specialty.

22. Please explain what consideration the NIBTS gave to increasing the use of cryoprecipitate or using a product with lower risks, in response to the risks associated with blood factor products.

Cryoprecipitate was first produced by the Haemophilia Centre, Royal Hospitals, in 1967, and as demand increased production was taken over by NIBTS in the early 1970s. Production levels were always demand-led – mainly by the Haemophilia Centre as well as by other hospitals. From memory, I believe production levels peaked in about 1978/79 at around 10,000 packs per annum and gradually reduced during the 1980s to around 5,000 packs per annum. By then, I think, its use in haemophilia (mild cases) accounted for a minority of its use. It was also used for Von Willebrand's disease and as a source of fibrinogen for certain acquired bleeding disorders.

23. What steps were taken by the NIBTS in response to information that a particular donor or a particular product was infected?

Prior to the introduction of HTLVIII antibody testing (1985) the two screening tests for infection were hepatitis B antigen and syphilis serology. On finding a confirmed positive for either of these agents, the procedure involved removal of all components from stock and destruction of the same and donor record flagged. The donor in question was written to with an explanation of the clinical implications, advice about not donating blood in future and requested to provide the GP contact details. On receiving this, the GP was written to with an explanation of the findings including advice about appropriate specialist referral.

With HTLVIII antibody screening, a different procedure was followed for the donor. A reactive result on the screening test would lead to immediate removal and destruction of any components as above, and the donor record flagged. Confirmatory testing on the sample was carried out by an independent laboratory in England. A true positive result (a minority) would result in a letter being sent to the donor (by an NIBTS consultant). This letter invited the donor to attend NIBTS for a meeting with the consultant. At this meeting, a full explanation would be provided to the donor, a blood sample taken for repeat testing, and appropriate support offered. This would include referral to a specialist – and informing the GP (both the with donor's consent).

The great majority of samples found reactive on screening tests (typically weakly reactive) were found to be not true positives by the independent confirmatory laboratory. In these cases, while the blood components were not used, the donor was still invited back to donate. In the case of repeat reactive donors (but confirmatory test negative) – a common scenario – the donor was written to with an explanation and reassurance that they should cease donation, an opportunity being provided to discuss the matter with a doctor in the centre if requested.

With the introduction of hepatitis C antibody screening (1991) a similar procedure was followed as for HTLVIII antibody testing, outlined above.

Furthermore, for both HTLVIII and hepatitis C testing confirmed positivity led to a look-back procedure being carried out – see paragraph 24 below.

Notification of possible transfusion infections to NIBTS:

NIBTS had procedures for dealing with this situation. On receipt of clinical details from the hospital the donor (donors) would be identified and flagged for possible additional testing. From November 1982, blood samples (taken for routine screening) were stored so they could be tested in future if required.

24. Please give details of any look-back or trace-back exercises that the NIBTS conducted in order to identify patients that may have been given infected blood and/or blood products.

This was introduced for HTLVIII. Thus, a confirmed positive would result in previous donations in the previous five years being identified and the hospitals to which any resulting blood components were issued, and the fractionation centre (PFC from 1982) to which plasma was sent. The procedure followed by the hospital would be coordinated by the

Consultant Haematologist in charge of the hospital blood bank to which the component had been issued (with advice from a NIBTS Consultant). Recipients/patients would be identified and advised and tested for HTLVIII antibody, if this was indicated.

It is noted that I am not aware of any cases of HIV infection in Northern Ireland that have been traced to the receipt of a blood component (as opposed to a plasma product-Factor VIII etc.).

When Hepatitis C screening was introduced, a look-back exercise was introduced which followed the national protocol coordinated by Dr A Robinson, National Blood Service. This UK wide exercise was implemented sometime after the screening programme commenced. The results for Northern Ireland were published by my colleagues, Drs Morris and Bharucha, as the first regional Hepatitis C look back exercise to be completed.

It may be relevant to mention here CJD tracing. The UK-wide tracing exercise (forwards and backwards) also included NIBTS.

25. **What regulatory regime was in place in Northern Ireland during the 1970s, 1980s and early 1990s, in respect of blood donors, blood donations, blood banks and transfusion centres, and how did this change over time?**

By this, I would understand a process by which an external/independent body would carry out regular inspections of all procedures with a view to bringing about continuous improvements to the service and achieving approval/accreditation/licensing etc. as appropriate. I am unaware of what (if any) such regimes existed during the 1970s.

The first approximation to such an external regulatory process occurred immediately prior to our link-up with PFC (1982) when an inspection of NIBTS processes and procedures was carried out by senior personnel from PFC (Quality Manager and Head of Microbiology). This was to ensure that quality standards for the collection, testing and processing of blood/plasma met the requirements of PFC. These inspections were repeated at intervals.

A process of inspection/licensing by the Medicines Control Authority (later MHRA) of all UK regional transfusion centres (including NIBTS) was introduced soon after. The first inspection of NIBTS by the MCA was in December 1982 and thereafter, I believe, at approximately two-year intervals. The granting of a manufacturing licence (by MCA) for NIBTS was delayed due to the inadequate premises, and this was a crucial factor in enabling the eventual funding for a new NIBTS Headquarters unit. The service relocated to the new (current) centre in 1995 and was granted a manufacturing licence after the first subsequent inspection.

26. **What donor selection, screening policies and practises were in place in Northern Ireland during the 1970s, 1980s and early 1990s? Who was responsible for formulating and implementing such policies and practises?**

The Director of NIBTS was responsible for formulating and implementing policies and practises for the selection and testing of donors. My comments below relate to the period from 1978 onwards.

The policies and practises were based on national "UK guidelines". I cannot recall what the exact status of these guidelines was i.e., what if any government input was involved in their production, or if they were professional/medical guidelines drawn up by representatives of the regional transfusion centres. I do remember at least once in the early 1980s a review of the guidelines under the auspices of the Regional Transfusion Directors committee was carried out.

At NIBTS, all blood donation sessions during this period were directly overseen by a qualified doctor who had undergone a period of appropriate training to carry out these duties. For every donor (new and repeat) a health screening interview was carried out by an experienced, appropriately trained, blood donor attendant. Any queries were referred to the medical officer who was also responsible for the venipuncture. Updates to medical officers on any changes (e.g., selection criteria) were provided via circular letters and/or update meetings at regular intervals.

The onset of AIDS and the increasing realisation that this could be transmitted by blood transfusion, led to important changes in 1983. These changes were aimed at discouraging people thought to be at higher risk of AIDS from donating blood. This involved the use of the national AIDS leaflet. Initially this was made available on donor sessions, then from late 1984 presented to donors individually as part of the interviews and, as this became practically possible, (1985) to include the leaflet with a call-up letter. The approach followed is described in my letter to Dr A Smithies (DHSS London) of 25 January 1985.

With the introduction of HTLVIII antibody testing in October 1985, donors were required to sign a statement indicating, inter alia, agreement to be tested and informed of the result and not being a member of a high-risk group. At a later date, questionnaires covering all aspects of donor selection were introduced – requiring the donor to read and sign. These were used to supplement the oral interview. This new process was initially used for new and lapsed donors and later (1993, I think) for all donors. I am unsure if the dates of these changes.

At a later date a change in procedure and staffing of donor sessions was introduced. This was to allow routine interviews to be conducted by medical officers while venipunctures were being done by qualified nurses.

27. What steps were taken by the NIBTS to screen blood donors for risks of infection?

The processes and how they evolved are described in Paragraph 26. Records of the detailed guidance in use may still be available but I have not seen these.

28. What steps were taken by the NIBTS to discourage donors thought to be at higher risk of transmitting infection, or to prevent them from donating?

These are described in Paragraph 26.

This approach was supplemented by general publicity via the local media etc. and in the case of closed sessions (workplaces etc.) by the provision of written material to local contacts prior to the donation sessions taking place. There was evidence (indirect) of the effectiveness of changes introduced from 1983 (Paragraph 26), thus there was a marked reduction in the rate of Hepatitis B positivity, coinciding with this change, and this decrease was sustained in future years. The data was published in the Ulster Medical Journal, Vol 58, No. 1, PP 72-82 April 1989 (WITN3082021) . There was published data from another UK centre describing similar findings.

Section 10: Screening of donations

29. What policies and practises were developed in relation to the testing of blood donations during the 1970s, 1980s and early 1990s? Who was responsible for formulating and implementing such policies and practises?

During this period, NIBTS policies and practises for testing were in keeping with the other regional transfusion centres throughout the UK. The timescales for implementing this testing were also similar in all UK centres. From documentation, I believe this was the case during the 1970s as well as the period for which I was responsible (1980s and 1990s). The director was responsible for formulating and implementing such policies and practises.

30. What decisions and actions were taken by the NIBTS in relation to the testing of blood donations during the 1970s, 1980s and early 1990s?

The following tests were carried out on blood samples collected (separately) on all blood donations:

Blood grouping (A, B, O and rhesus) and red cell antibody screening – using automated blood grouping equipment e.g. TECHNICON BG15 until 1982 and TECHNICON AG16C (1982 to 1993?);

- Syphilis serology;
- Hepatitis B antigen;
  - IEOP method from 1972;
  - Reverse passive haemagglutination 1975;
  - Radioimmunoassay 1981-1993;
    ELIZA 1993 onwards;
- HTLVIII antibody – October 1985;
- Hepatitis C antibody – September 1991;

In addition to the above mandatory tests on all donations, from 1984?, a proportion of donations were tested for antibody to cytomegalovirus.

CMV antibody negative blood components were issued for transfusion of selected patients e.g., neonates, bone marrow transplant recipients and others with a severe immune deficiency. It later became a mandatory requirement to provide CMV negative blood for this group of patients. The procedures for dealing with donations/donors that were positive for an infectious disease marker are described in Paragraph 23 above.

31. From what date did the NIBTS implement screening of blood donations for HIV and how did this compare with the rest of the United Kingdom?

NIBTS implemented screening for HIV (HTLVIII antibody) from October 1985 as in other UK regional transfusion centres.

32. From what date did the NIBTS implement screening of blood donations for HCV and how did this compare with the rest of the United Kingdom?

NIBTS implemented screening for hepatitis C antibody from 1 September 1991 as in other UK regional transfusion centres. While this was the official start date, two or possibly three sites began testing on a pilot basis a short time (1 / 2 months?) before the official start date in order to check on any operational issues associated with either of the two available tests.

33. Could further steps have been taken to prevent patients from the risks of transmission of HIV and HCV infection from blood and blood products; if so, what were those steps?

HIV infection

I believe that, given the state of knowledge at the time, the actions taken (from 1983) to discourage individuals in high-risk groups from donating blood were as timely as was reasonable. Furthermore, I consider the findings regarding hepatitis B positivity (see Paragraph 28) provide evidence of the effectiveness of these actions. This view is based on the known association between HIV and Hepatitis B with respect to risk factors.

Once HIV (HTLVIII) antibody screening was introduced, the main remaining risk of HIV transmission was from donations collected during the "window period" i.e., between exposure and the test becoming positive. The other risk could arise from a system or human error, leading to inadvertent issue of a positive blood component.

As more sensitive antibody tests became available, the "window period" was reduced and eventually closed when HIV Nucleic Acid Testing (NAT) became available.

As noted above, I am unaware of any incidences of HIV (AIDS) in Northern Ireland being caused by the transfusion of a blood component (as opposed to plasma products).

Hepatitis C

There are two main issues here:

a) The use of surrogate testing prior to the discovery of the hepatitis C virus; and

b) The date of implementing HCV antibody screening.

a) The use of surrogate testing

I am aware that a few countries, including the USA, introduced (during the 1980s) screening tests aimed at reducing the risk of Non-A, Non-B hepatitis. These were for the liver enzyme, ALT, and antibody to hepatitis B core antigen. As far as I remember, most of the clinical research leading to surrogate testing was carried out in the USA. Research in the mid to late 1970s demonstrated the existence and incidence of Non-A, Non-B hepatitis and later research was carried out on the effect of surrogate testing. The latter, I believe, showed some reduction in incidence of post-transfusion hepatitis in those communities (approximately 30%) albeit with a substantial loss of donations from false positives. No such research (controlled trials on transfusion recipients) had been carried out in the UK. Yet there was evidence that Non-A, Non-B hepatitis varied widely between countries. I am not convinced there was enough evidence on which to base the introduction of surrogate screening of blood donations in the UK at that time.

b) Hepatitis C antibody screening

I was well aware of the discovery/announcement of the hepatitis C virus in 1989 by scientists at the Chiron Corporation. I was also aware that some countries started screening for HCV antibodies earlier than the UK. The approach to HCV testing in the UK was closely coordinated and involved UK transfusion services, Departments of Health and with advice being provided by world leading hepatitis virologists. There were important issues to be resolved, including the false positivity rate with the initially available screening tests, and the development of confirmatory tests to enable the management of positive testing donors. Whether a greater awareness at that time of the incidence and long-term seriousness of hepatitis C in the UK should have led to earlier introduction of screening, I am unsure at this distance from those events.

With respect to (a) and (b) above I should note that I personally was not part of the 'inner circle' who took the (UK wide) decisions.

Section 11: Viral inactivation/heat treatment

34. What decisions and actions were taken by the NIBTS in respect of heat-treatment?

It is assumed this refers to heat-treatment of Factor VIII and other clotting factor concentrates. NIBTS had no input into decisions concerning heat-treatment of these products. Such decisions were the responsibility of PFC and the SNBTS. As noted above (Paragraph 20A)), PFC products were issued to hospitals by NIBTS but decisions on which products to use clinically were taken by the NI Haemophilia Centre. NIBTS would have had a role in facilitating the "swapping out" of products i.e., heat treated with untreated products.

35. When did the NIBTS introduce heat-treated blood products?

As I recall, the first heat treated Factor VIII provided by PFC was in 1984 (month?). This was a dry heat-treated product which was rapidly introduced following the discovery in Scotland of HIV infections among recipients of a batch of PFC Factor VIII.

Section 12: Blood donation sessions in prisons

36. Please state, to the best of your knowledge, the date that the NIBTS started blood donation sessions in prisons.

I have no knowledge of when NIBTS started blood donation sessions in prisons.

37. Please list all of the prisons in which blood donation sessions took place.

I am unable to answer this. I recall that NIBTS held donation sessions in the early 1980s, and I recall discussions about a discontinuation of this. For details on prison visits, dates, number of donations collected etc. I would need to refer to documentation held by NIBTS. More specifically, I note details recorded in the Penrose Inquiry report. This states that in the years prior to stopping these donation sessions (October 1983) NIBTS visited two prisons – HMP Belfast (Crumlin Road jail) and Magilligan HM Prison, Limavady, Co. Londonderry.

38. Please state, to the best of your knowledge, how many times the NIBTS would visit each prison and how many blood donations would be collected, on an annual basis.

It is stated in the Penrose report that in the preceding years (prior to discontinuing donation sessions in prison) NIBTS collected approximately 120 donations per annum from prisons, representing less than 0.2% of the 70,000 donations collected annually. I am unable to add to this information but suggest the documentation be rechecked.

39. Please give the details of any NIBTS policies or incentives that were in place at that time to encourage prisoners to donate blood.

During the period of my responsibility there were no incentives, other than the obvious ones of providing the necessary time off to donate and providing the opportunity for an altruistic activity. To the best of my knowledge, this would always have been the case.

40. Please explain what methods were used to screen prisoners for infectious diseases like HIV, HBV and HCV.

Prison donors would have undergone exactly the same screening for infectious disease markers as all other donors (see above).

41. Please explain what was known, and when, about the risk of transmission of infection from the prison population compared to the general donor population.

I do not recall there being a significant issue with this until around late 1982/1983. I recall this matter being raised as an issue by the Medicines Inspectorate during inspections of SNBTS centres. I cannot recall if it was raised during the first inspection of NIBTS (December 1982). I also became aware of some surveys in Great Britain indicating a higher incidence of

hepatitis B markers in prisoners. I do not think there was any obvious increase among Northern Ireland prison donors or indeed if there were any hepatitis B positives detected during my time as Director. However, our total number of prison donations was small.

42. When and why did the NIBTS stop donation sessions in prisons?

From my recollection, the main reasons would have been:

a) Some concern about prisoners fulfilling the criteria for voluntary donation and thus concern about the reliability of obtaining truthful information about risk activity;
b) A higher incidence of hepatitis B markers among prison donors – although by the early 1980s very sensitive tests (third generation) were in use;
c) Views expressed by the Medicines Inspectorate and a general consensus emerging among the UK transfusion services.

Section 13: Other issues

43. Please explain, in as much detail as you are able to, any other issues associated with your work at the NIBTS that may be of relevance to the Infected Blood Inquiry.

I refer to my first written statement.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed ..GRO-C

Dated ....26/1/02.....