Witness Name: Dr M McClelland

Statement No.: WITN0892001

Exhibits: WITN0892002-005

Dated:20 January 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR MORRIS MCCLELLAND

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 17 August 2021.

I, Dr McClelland, will say as follows:

Statement of Dr William Morris McClelland

Section 1: Introduction

1. **Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates or your membership.**

- Regional Transfusion Directors (England and Wales) Committee 1980 until Committee ceased.
- Northern Zone Committee
- UK BTS Forum – 1999 – 2009
- SNBTS Directors Committee (later SNBTS Medical and Scientific Directors Committee – 1982-2009
- UKBTS Guidelines (Red Book) Committee – (establishment – 2009)

- SHHD, Haemophilia Directors and Transfusion Directors Committee (Coordinating supplies of coagulation concentrates to Scotland and Northern Ireland – (1984 – unsure of date)
- Northern Ireland Advisory Committee on Blood Safety (approx. 2000 – 2009)
- NI AIDS Advisory Committee

2. **Please explain how you kept abreast of medical and scientific development and research in your field in the course of your career.**

Reading journals (Transfusion; Haematology; and general medical) – personal, in-house or copies of articles obtained via Queen's University Medical Library, PHLS and MMRR bulletins.

Relevant medical / scientific conferences – ISBT, AABB, British Society of Haematology, BBTS.

Membership of committees and societies (see 1. above).

3. **Please confirm whether you have provided evidence or have been involved in any other inquiries, investigations, criminal or civil litigation in relation to variant Creutzfeldt-Jakob disease ('vCJD') in blood and/or blood products.**
Please provide details of your involvement.

I confirm I have not provided evidence or been involved in any other inquiries, investigations, litigation etc. in relation to vCJD in blood or blood products.

Section 2: Your roles at The Northern Ireland Blood Transfusion Service and the Belfast Transfusion Centre

Northern Ireland Blood Transfusion Service

4. Please describe the roles, functions and responsibilities you had at the Northern Ireland Blood Transfusion Service ('NIBTS') during your period as:

A) Chief Executive; and

B) Medical Director

It should be understood that NIBTS and Belfast Transfusion Centre are one and the same service. There was a reorganization in 1994 which established NIBTS as an independent special agency. My role as director of NIBTS and later CEO / Medical Director of NIBTS Agency will be described:

A) As Director NIBTS, June 1980 – May 1994

B) As CEO/ Medical Director, NIBTS agency, June 1994 – July 2009.

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.

The role of CEO / Medical Director was similar to that of director, but there was now budgetary responsibility and also more in-house management functions such as HR and IT.

Under agency status I found there was a greater degree of monitoring than before (by the Agency Board and by Department of Health & Social Services and Public Safety ("DHSSPS"). The role of the NIBTS Agency Board was essentially to oversee all aspects of the service provided by NIBTS. It consisted of a Chair, two non-executive members (later three) and the CEO / Medical Director. The Senior Management Team also attended the Board as and when required.

5. Please describe the geographical remit of the NIBTS.

NIBTS provided blood and blood products and other relevant services to all hospitals and clinical units in NI- population 1.5M (now 1.8M).

6. Please describe the NIBTS' relationship with other blood services in the UK, including the scope of the NIBTS' decision-making power and whether it was accountable to any other organisations.

On my appointment, NIBTS was responsible to Eastern Health & Social Services Board ("EHSSB"), so I had a reporting relationship to the Chief Administrative Officer (EHSSB) and Chief Administrative Medical Officer (EHSSB). Managerial support was provided through a management services division of EHSSB.

There was also a reporting relationship to the Chief Medical Officer (CMO), Department of Health & Social Services Northern Ireland ("DHSSNI").

7. Please explain the organisation of the NIBTS during your tenure, including:

a) **the NIBTS's relationship with the Blood Products Laboratory ('BPL') and the Protein Fractionation Centre ('PFC') for the procurement of blood and blood products;**

There were no formal relationships with other blood services in the UK but policies and procedures were often shared with other RTC's in GB and adopted by NIBTS. This was particularly appropriate because policies adopted by DHSSNI typically followed those of DoH (London) since NI was under direct rule from London.

b) **Details regarding a proposal made in 1981 for NIBTS to switch from procuring manufactured plasma for BPL to PFC** (SCGV0000104_134; SBTS0000091_035) **and why NIBTS paid PFC for fractionating its plasma but not BPL** (NIBS0001698). You may also wish to refer to document SCGV0000104_106.

Under my new appointment as Director of NIBTS, one of my earliest and key priorities was to start the process of harvesting and supply of FFP to be used for the manufacture of Factor VIII concentrate. My initial plan was that, in addition to time-expired plasma, we would also begin to supply fresh frozen plasma to BPL (see correspondence from me to Dr Lane – 1980) **Reference: CBLA0005101**. Soon after this I became aware of capacity issues with BPL together with the apparent spare capacity at PFC. There were obvious practical attractions in the use of surface transport (Larne – Stranraer ferry) as opposed to air transport to BPL (the existing method for time expired plasma at that time). I remember a number of informal meetings I had around this time with inter alia Dr Lane (BPL), Dr Cash and Mr Watt (SNBTS) exploring a possible switch in fractionation arrangements and a proposal was made to EHSSB relating to this.

I also became aware of a meeting at Departmental level on the issue of self-sufficiency at which the possibility of PFC taking over fractionation of Northern Ireland plasma was mooted (Dec 1981). Later a formal

agreement in principle (between SHHD and DHSSNI) was agreed for the transfer of plasma fractionation from BPL to PFC and then more detailed arrangements agreed between the Scottish CSA and EHSSB including financial arrangements (see correspondence, minutes etc.) **References SCGV0000104-150; SCGV0000104-134; SCGV0000104-135.**

Regarding the last point (on charging for fractionation of plasma), I am unable to comment on how the arrangements with BPL were originally established (with no cross charging) as I had not been involved at that time. Under the new arrangements with Scotland it was made clear from the outset (by SHHD, CSA, SNBTS) that PFC costs would have to be recovered via a cross charging arrangement.

c) **Why BPL continued to supply the NIBTS with blood products after 1981.** (see NIBS0000384 dated 19 February 1998, in which you wrote that "Northern Ireland receives about 50% of its factor VIII (human form) for the treatment of haemophilia A from BPL. The remainder is obtained from Protein Fractionation Centre, Edinburgh").

Prior to 1982, NIBTS received a very small amount of Factor VIII, approx. 10%, from BPL. With the transfer to PFC (1982) Factor VIII supplies from BPL ceased, and I think this would have continued to be the case through the 1980s.

During the 1990s, Factor VIII usage continued to increase (to levels well beyond those provided by PFC). At some point in the 1990s BPL started to operate on a semi-commercial basis, i.e. marketing plasma products to users in competition with commercial suppliers and without reference to the source of plasma supply (i.e. the pro-rata principle). So by 1998 BPL Factor VIII had become, I believe, the major (non PFC) supplier of Factor VIII in NI.

8. Please describe the number of donations collected each year by the NIBTS

For most of my tenure, NIBTS collected in the region of 65,000 - 70,000 whole blood donations per year. For plasma and platelet donation, see later in this statement.

Belfast Transfusion Centre

9. Please explain when you became Director of the Belfast Transfusion Centre ('BTC'), the various roles and responsibilities that you held whilst Director and how theses (i) differed from your role as the Chief Executive and Medical Director of the NIBTS or (ii) overlapped.

See para 4 and 5 above.

10. Please describe the organization of the BTC during the time you worked there, including:

a) its structure and staffing in particular to whom you were accountable;

Staffing on my appointment

On my appointment as Director in 1980, I had two operational managers responsible for laboratories and the donor programme respectively. With fairly minor adjustments, these remained the two main operational posts. There was also a head nurse responsible for blood collection staff (Blood Donor Attendants) and a general administration officer.

Over subsequent years the management team evolved and changed very significantly as described below.

Medical

We were fortunate to recruit (in 1981) a very able person to the post of Deputy Director/ Consultant. My predecessor (*Colonel T.E Field*) Director (1969-1980) operated single handedly for most of his tenure – until my

appointment as Deputy Director in 1978. A third Consultant post was established in 1997.

Quality management

This role did not exist on my appointment. Then a Quality Control Officer was appointed - a relatively junior post and limited to laboratory end-stage testing. The role later evolved to the appointment of a Quality Assurance Manager overseeing and developing quality systems for all operational areas of the service with the help of an enlarged QA department. We were fortunate in recruiting an excellent person as QA Manager. Around 1995 an equally excellent deputy was appointed to the post of Head of Quality Control Labs and subsequently became Regulatory Affairs and Compliance Manager. By 2008, one of these individuals was appointed to the role of 'Responsible Person' as defined by the UK guidelines (Red Book).

Agency Status

Prior to the establishment of NIBTS as an independent special agency (directly responsible to DHSSPSNI), functions such as financial services and HR were provided by EHSSB later Belfast City Hospital (unit of management). On becoming an Agency in 1994, NIBTS appointed its own Finance Manager in February 1995 who later also became responsible for the IT department. An HR and Business Services manager was also appointed. However, there continued to be a number of functions for which external support was provided e.g. some HR services, supplies etc.

By early 1995 a greatly enhanced senior management team was now in place, consisting of CEO/ Medical Director, Deputy CEO/ MD, donor

services manager, laboratory manager, QA manager, finance manager and HR/ business services managers.

The CEO / Medical Director was responsible to the agency Board (meeting 6 times per year) with input from SMT members as appropriate. The CEO/MD also had a reporting relationship to the permanent Secretary, DHSSPS (as accountable officer) and to the CMO, DHSSPSNI for medical matters.

b) how the BTC was funded and whether this changed;

Until 1993-1994 all NIBTS activities were centrally funded via EHSSB (and NI Hospitals Authority before this).

With the establishment of Hospital Trusts and NIBTS as an independent special agency, new cross-charging/contracting arrangements were established – similar to those applying in England. For the supply of blood and most blood products, contracts were with hospital trusts (modified block contracts), but for haemophilia products central funding applied (from DHSSPS via EHSSB).

c) the type of administrative responsibility that the Eastern Health and Social Services Board ('EHSSB') had over the BTC (SCGV0000104_134)

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

d) its remit, including the geographical area it covered and the hospitals within its areas;

The EHSSB was the largest of the four area boards in NI. It was responsible for services in Belfast and surrounding areas and a range of Regional services. However, NIBTS provided services to all hospitals and clinical units in Northern Ireland.

e) whether the BTC was subject to any form of regulation and if so, what.

I would refer to paragraph 25 of my first witness statement:

By [regulation], 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) to NIBTS was delayed due to the inadequate premises. Indeed, this was a crucial factor in securing 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.

11. Were there ad hoc blood collection units ('ad hoc units') within Northern Ireland? Was the BTC or the NIBTS responsible for them? If not, who was? If so, can the NIBTS be accurately depicted as comprising the BTC and ad hoc units?

I had heard that such units may have existed in parts of the UK on a very limited basis, such as, use of 'directed' maternal blood for newborn babies. I have no recollection or awareness of such units existing in Northern Ireland during my tenure with NIBTS.

Section 3: Blood collection at the NIBTS

12. Please explain the system for blood collection at the NIBTS during your employment there, including at the BTC and ad hoc units across Northern Ireland, and how this changed over time.

Blood collection was carried out by three mobile teams who operated five days per week at venues throughout NI (15 sessions per week). In addition, there were collection sessions at fixed sites in Belfast including platelet/plasma apheresis sessions at the HQ unit.

Two significant developments in blood collection are worth noting. Firstly, in 1992-3 a mobile collection team based in, and covering, the west of the province was established. This team replaced one of the three teams based in Belfast but was still managed from Headquarters. Secondly, from around 2000, NIBTS commissioned a purpose-designed "bloodmobile" which enabled us to hold donation sessions at many additional venues.

The policies and practices for the selection and testing of donors 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 was carried out under the auspices of the Regional Transfusion Directors Committee.

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. From late 1984 it was presented to donors individually as part of the interviews and, once it became practically possible, (1985) the leaflet was included with a call-up letter. The approach followed is described in my letter to Dr A Smithies (DHSS London) of 25 January 1985. **Reference DHSC0101652_002.**

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 that they were not a member of a high risk group. At a later date, questionnaires covering all aspects of donor selection were introduced which the donor was required to read and sign. These were used to supplement the oral interview. This new process was

initially used for new and lapsed donors and subsequently (1993, I think) for all donors. I am unsure of the dates of these changes.

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

13. **As far as you are aware, how was blood collection at the NIBTS funded?**

Blood collection was an integrated part of the total service provided by NIBTS, so funding for this activity was covered by that for NIBTS as a whole.

14. **What if any steps did the NIBTS take to publicise itself to potential donor populations in order to increase donations? How successful were these steps?**

Maintaining of adequate numbers of volunteer donor panels has always been a key responsibility for NIBTS. This involved a carefully managed programme of marketing, publicity, advertising etc. Given the limited shelf life of blood components - three days, later extending to five days for platelets; three weeks, later extending to five weeks for whole blood / red cells - the challenge has always been to maintain collection at a steady level throughout the year.

The 'Troubles' in NI as well as the closure of many of the largest factories (which had been a very valuable source of donors), both had an adverse impact on donations. To compensate for this loss of donors, an important initiative was the schools programme. This involved a slight reduction in the donor age limit (to 17 and a half years with parental consent). Another initiative was the use of teams of telephone recruiters – telephoning eligible individuals immediately prior to donor sessions. The use of the general media (TV, radio, newspapers) could also be of great value but had to be used in a carefully controlled way in order to avoid peaks in response as well

as troughs. Despite our best efforts, there were times (uncommon) when supplies to hospitals had to be rationed or even rare occasions when elective surgery may have had to be postponed.

15. To what extent did the BTC and ad hoc units collect blood from prisons, borstals and similar institutions?

I would refer to paragraphs 36 to 42 of my first statement, relevant portions of which I have copied below for ease of reference.

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

[37] 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. These indicate that in the years prior to stopping prison donation sessions in October 1983, NIBTS visited two prisons – HMP Belfast (Crumlin Road jail) and HM Prison Magilligan, Limavady, Co. Londonderry.

[38] 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.

a) When did this practice cease?

The practice ceased in October 1983 (see Penrose Report 26.41 - WITN0892002).

b) What role, if any, did you have in this practice?

I inherited the practice but obviously as Director of NIBTS I had ultimate responsibility. Equally, I took the decision to cease the practice when I became aware of this approach being taken by many RTCs in GB.

c) What information, if any, was presented to donors before they gave blood?

As far as I remember the information presented to donors (prior to visiting the session) would have been similar to that for any workplace donor session. There was liaison with the Prison Medical Officer prior to the session and as far as I remember during the session as well. The interviewing, information etc. would have been the same as for any donation session, see NIBS0001871 previously provided.

d) Were hepatitis and HIV considered risks in these specific populations? If so, how were these risks managed?

I would refer to paragraph 41 of my first statement:

[41] I do not recall this being a significant issue until late 1982-1983.

...

I 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.

It is worth noting that our donor selection criteria were very strict - typically 10% of donors who visited sessions were excluded on medical/risk grounds. Even a small potential risk led to exclusion from donation irrespective of the collection setting or donor group. Indeed, I recall several doctors outside NIBTS expressed the view that our rules seemed unnecessarily strict.

e) Were donors provided with any form of incentive to donate blood? If so, What?

As per para 39 of my first statement.:

[39] 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.

f) What were the relative costs of collecting blood from prisons as compared to collecting blood at the BTC or ad hoc units?

The costs of collecting blood would have been proportional to the number of donations collected i.e. to efficiency in the use of staff resources. I do not have the donation figures for prison sessions to hand so cannot make a judgement on this.

16. Please describe the way in which donations were collected by the NIBTS during your time there. In particular:

a) What were the staffing arrangements during blood donation sessions? Were the staff involved medically trained?

See para 12 above.

b) Where did these sessions take place?

See para 12 above. Further, in 2000 NIBTS acquired a "bloodmobile" which could be driven to places which did not have suitable venues.

c) How frequently could a person donate blood?

This is determined by iron storage in the human body. Iron stores can become depleted and lead to anaemia in some individuals if donation is

carried out too frequently for that individual. Hence the routine practice of screening all donors for anaemia before acceptance for donation (on each occasion).

Until around 1990, donation frequency by NIBTS was limited to two times per year. It was then increased to three times per year, initially for male donors and later extending to female donors.

This change was broadly in keeping with international practice with many blood collections agencies in Western Europe and North America allowing three to six donations per year.

d) How were blood donors recruited?

This is answered under para 14 above with regards to publicity, advertising etc.

e) Did any of these matters alter during your tenure? If so, how?

See para 14 above.

17. Were there donation collection targets? If so, how were these set and by whom?

NIBTS did have blood donation / collection targets. These were determined by myself, the Donor Services Manager, and the Head of Blood Components. Targets were based on prior patterns of demand. Hospital demand for blood components, initially for whole blood and red cells but later platelets, became increasingly important in determining collection patterns. Collection had to be sufficient to maintain stock levels for each of the main blood groups at a minimum level.

The session programme had to be planned one to two months in advance i.e. which venues to be visited. For public sessions, existing donors were always invited to attend by letter. This did not normally apply to workplace

and other 'closed' sessions. Here, organisation of donors was normally carried out by a local volunteer based at the venue.

Immediately prior to donation sessions being held (one to two days before) and influenced by stock levels, additional recruitment activities could be carried out e.g. media publicity, individual telephoning etc. On very rare occasions - perhaps once every two to three years - if stock levels became dangerously low, blood components could be obtained from a UK Blood Transfusion Centre which had a surplus of this particular blood group. Equally unusually, blood could be provided by NIBTS to other UK centres who were in need.

18. Did the NIBTs meet its donation collection targets during your tenure? If not, why not? Were there any consequences for failing to meet them?

See para 14 above.

19. What was done to improve blood collection? What more could or should have been done? What were the barriers to meeting the targets?

Again, see paras 14 to 17 above.

With regards to barriers, I have already mentioned the negative impact of closure of major factories in NI, especially in the early 1980s. Also important, although harder to quantify, was the impact of the emerging AIDS epidemic and the publicity surrounding it. I believe this created negative associations in the minds of some donors or potential donors.

Section 4: Plasma procurement and production of fresh frozen plasma at the NIBTS

20. Did the NIBTS produce fresh frozen plasma ('FFP')? If not, where was this produced for Northern Ireland and what were the arrangements in place?

As with every other UK RTC, blood collected at donor sessions was returned to NIBTS HQ (laboratories) on the day/ evening of collection – for processing into components and storage. The routine components included FFP (as well as red cells and platelets).

21. If the NIBTS did produce FFP, please describe:

a) Where the production of FFP took place;

As per para 20, production of FFP took place at NIBTS laboratories.

Before the link with PFC was established in 1982, FFP was produced only for direct patient transfusion in Northern Ireland hospitals – either in the form of clinical FFP or as a starting material for preparing cryoprecipitate.

b) Broadly, the process that was undertaken, the capacity of the NIBTS to manufacture FFP and whether this changed during your tenure and why;

This was quite a simple process involving the use of refrigerated centrifuges and expressor devices to separate plasma from red cells. Until 1986-87 about two thirds of the plasma was removed from each unit, the remainder being required to re-suspend the red cells in order to maintain red cell function and to enable a satisfactory flow rate during transfusion to the patient. In 1986-87 optimal additive solutions (SAGM) were introduced. This development enabled almost 100% of the plasma to be removed from each unit of blood while the red cells were resuspended in the optimal solution - this being optimal for red cell function as well as allowing satisfactory blood flow during transfusion. This change thus allowed about 30% more FFP to be harvested from each unit of blood.

A proportion of units was required to prepare platelet concentrates. Each unit required to be suspended in 50-70mils of plasma.

Once plasma is separated, the individual units are "snap frozen" and stored at -20^{O}C until issued.

Transporting FFP to PFC

Another practical issue for NIBTS was the method of transport to the fractionation centre. During transport, FFP had to be maintained below -20^{O}C. To this end, NIBTS procured a specially designed vehicle enabling surface transport to PFC via the Larne – Stranraer ferry to be used, one to two journeys per month. For a short period at the start of the arrangement, PFC collected FFP from NIBTS using their own low temperature vehicle.

c) What proportion of blood collections were allocated to this process and how this decision was made, and whether this changed over time; and

The adoption of a strategy towards achieving self-sufficiency in plasma products led to a steadily increasing proportion of units being processed. In 1980 about 20% of units were processed, the remainder being issued to hospitals as whole blood. This proportion steadily increased during the 1980s and by 1990 almost 100% of units were processed. Over the same period, the amount FFP available for fractionation increased from 6 tonnes to almost 20 tonnes per annum.

d) How quickly the NIBTS could have increased its manufacture of FFP, had it wished to.

The main determining factor was the pattern of demand for, and usage of, blood components - particularly the red cell/whole blood proportions. A major programme of education and persuasion of clinicians was required to change this. The introduction of SAGM red cells was important in helping red cell concentrate to become accepted in the vast majority of clinical situations.

The strategy throughout this period was to maximize plasma production and I believe that was achieved in respect of the whole blood programme. I believe significantly greater quantities of FFP could only have been achieved at the expense of a higher (and unacceptable) level of red cell wastage. So further increases in plasma collection could only be achieved from the plasma-pheresis programme. This is dealt with under para 28-31 below.

22. As far as you are aware, how was plasma procurement at the BTC funded?

Plasma procurement became an integral part of NIBTS operations and funding was covered from the NIBTS budget. However, significant increases in staffing, materials, and capital equipment were required especially during 1981-82 when the programme for fractionation by PFC was being established. A number of bids were made to EHSSB and DHSS NI which, in general, were met relatively promptly as the objective of achieving self-sufficiency was accepted at these levels.

23. Please describe the arrangements for supplying FFP to hospitals and haemophilia centres within Northern Ireland.

FFP was used in a wide range of clinical situations. Each hospital blood bank (about 16 in number) held a small stock to cover emergency needs. As with other blood components, supplies to hospitals were essentially demand-led.

This arrangement also applied to the regional haemophilia centre at the Royal Victoria Hospital, although usage of FFP for this group of patients was small.

Plasma Targets

24. Did the NIBTS have targets for the amount of plasma that had to be collected by the BTC and ad hoc units? If so, who set these targets and what were they? If not, why not? What was the purpose of the targets?

As noted above, plasma targets planned for each year were based on an overall strategy to maximize amounts to be sent (to PFC) for fractionation. The target was set by the Director. These targets were in the nature of projections and based on changing red cell /whole blood ratios. The projected annual volume of FFP was communicated in advance to PFC each year so as to be incorporated into manufacturing production plans.

25. What impact, if any, did the setting of targets for the collection of plasma have on decision-making at the NIBTS?

The first (essential) priority was that the requirements of each hospital for blood components were met. The collection of plasma for fractionation was also of great importance but the timeframes involved were different from supplies to hospitals.

26. What were the consequences, if any, of the targets not being met?

Given the nature of the contract/ agreement with PFC (see later) this could have resulted in a reduction in supply of plasma product in future years.

27. Were there any benefits, if any, of the targets being exceeded?

By exceeding the targets for one year, the excess could be carried forward into the following year and lead to more products being received from PFC if required.

Plasmapheresis

28. As early as 1981, plasmapheresis was being considered as a means of increasing the plasma supply to help achieve self-sufficiency (CBLA0001287). Please explain, as far as you are able, what consideration the NIBTS gave to implementing plasmapheresis including:

a) whether manual or machine plasmapheresis was preferred;

During the 1970s, manual plasmapheresis had been employed by NIBTS very occasionally to collect plasma from highly selected donors. One result of the new arrangements with SNBTS/ PFC was that NIBTS was required to establish an Anti- D programme i.e. provision of plasma with high levels of Anti-D for subsequent manufacture into Anti-D immunoglobulin (IG). Prior to this Anti-D IG to meet NI needs had been obtained from BPL – without the requirement to supply BPL with Anti-D plasma. An Anti-D programme was established in 1982 and an associate specialist, Dr J Scally, appointed to run the programme. Plasma collected from these donors was by manual plasmapheresis and this continued until 1986 when the first plasmapheresis machines were introduced.

With the early apheresis machines, it was a requirement that their use had to be restricted to a hospital setting where resuscitation facilities were available. This continued to be the case into the 1980s. The NIBTS centre (HQ) was not based in a hospital at that time. With the availability of a new generation of machines, this requirement no longer applied.

b) the relative cost differences between each method;

I am unable to provide an accurate assessment, but in general while the collection materials (disposables) for machines were more expensive, machine-plasmapheresis was more efficient (in terms of speed, staff costs etc). Machines were, therefore, more suitable for large scale collections. I should add that costs of either method would have been substantially higher than the cost (marginal) of plasma collected as a bi-product of whole blood collection and processing.

c) the infrastructure, expertise and capacity of the NIBTS to introduce plasmapheresis; and

By the late 1980s, NIBTS had reached the limit of its potential to provide FFP (for fractionation) from whole blood donations. So it was decided as well as Anti-D collections, NIBTS would commence a programme of recruiting 'ordinary' blood donors to donate plasma. Each plasma donation (approx. 500- 600ml) was equivalent to what could be collected from two whole blood donations.

d) whether, in your view, plasmapheresis would increase the amount of available plasma.

The plasmapheresis programme augmented supplies of plasma (and later platelet concentrate). By the early 1990s, NIBTS was collecting over 3000 plasma donations per annum. This was the maximum throughput that could have been achieved in the (old NIBTS) building and represented about 10% of total FFP being sent to PFC.

When NIBTS relocated to the new, purpose-designed centre (1995), the donation facilities were enhanced allowing more apheresis procedures. However, by this stage priority had shifted to platelet concentrate, the demand for which had been climbing very rapidly (as

in all regions). So the main increase in procedures was for plateletpheresis rather than plasmapheresis.

Regarding self-sufficiency I believe the position had changed somewhat. First of all, the usage/ demand for Factor VIII concentrate had increased to such an extent that self-sufficiency was no longer an achievable objective, certainly not without a radical change in approach. Secondly, the benefits of achieving self-sufficiency, given developments in viral inactivation, were no longer as clear cut. Thirdly, a further push to increase plasmapheresis significantly would by this time have had an adverse impact on other priorities e.g. meeting requirements for platelet concentrates.

29. Please set out the extent of the plasmapheresis programme within the NIBTS during your tenure. As far as you are aware, did this programme differ from other RTCs? If so, why?

See para 28.

As for other RTCs, I am unable at this distance to remember what most were doing in relation to plasmapheresis. I do recollect the very active plasmapheresis programme at Leeds RTC - spearheaded by Dr A Robinson - which she described at various meetings. It may be significant that Leeds was one of those RTCs based in a major hospital (see paragraph 28 a).

30. In an article published in either 1988 or 1989 in 'Focus – An annual report for the Eastern Health and Social Service Services Board', it was stated that the NIBTS was intending to extend plasmapheresis "beyond selected donors within the near future". (see page 32 of RHSC0000019). Please comment on whether:

a) this extension was implemented;

This extension was implemented. By the early 1990s, NIBTS was collecting over 3000 plasma donations per annum.

b) allowing more donors to undergo plasmapheresis increased the numbers of donors being transfused more regularly;

Allowing more donors to undergo plasmapheresis did increase the number of donations.

c) there was a significant rise in the levels of plasma being collected at NIBTS; and

There was. By the early 1990s NIBTS was collecting over 3000 plasma donations per annum.

d) whether this process made a material impact on the objective of achieving self-sufficiency in Northern Ireland.

I would estimate it led to an increase of approximately 10%.

31. Could you please explain whether cross-charging formed part of the contractual relationship between the NIBTS and PFC? If so please explain whether:

a) cross-charging applied to both cellular and plasma products; and

As part of the contract/agreement with PFC a tariff of charges was set (by PFC). There was discussion with PFC around 1991/1992 concerning changing the charging from one based on products received to one based on products of plasma processed. No cellular products were sent to or from PFC.

b) whether this had an effect on the plasma supply in Northern Ireland and the production of plasma via plasmapheresis

I cannot answer the question here since charging applied from the outset of our arrangement with PFC.

32. What steps, if any, did the NIBTS take to persuade hospital clinicians to use less whole blood and more red cell concentrates and/or plasma reduced blood to release more plasma for fractionation?

Education of clinical users of blood/ red cells and persuasion towards the use of red cell concentrates instead of whole blood was a key part of the strategy towards achieving self-sufficiency. Without this, the programme referred to above could not have been as successful. The most effective route of influence was via staff in charge of hospital blood banks (haematologists and laboratory staff). Dr Bharucha and I took every opportunity to influence these staff who, in turn, were in a position to influence the clinical users of blood in each specialty. I think it was helpful that Dr Bharucha and I had clinical sessions in the two hospitals which were the largest users of blood (Royal Victoria Hospital and Belfast City Hospital).

I was also responsible for teaching undergraduates (medical students) in blood transfusion – through lectures and small group visits to NIBTS. The proper use of blood components was an important part of this. We also took every opportunity to provide training on blood transfusion to post graduates and to doctors in various specialties. As noted above, the introduction of optimal addictive solutions (SAGM) was helpful in enabling red cell concentrate to be the preferred component in virtually all clinical situations, including major hemorrhage. This change did result in a gradual increase over this period in demand for clinical FFP in hospitals – so slightly less available FFP for fractionation.

Section 5: Arrangements for obtaining and allocating blood products at the NIBTS

33. Please describe the arrangements in place in Northern Ireland for the purchase and holding of, and the allocation to haemophilia centres within the country, of (a) NHS_factor concentrates and/or other blood products ("NHS blood products") and (b) imported factor concentrates and/or other blood products ("imported blood products"). In particular:

Throughout the period of my tenure, all NHS blood products i.e. those manufactured by PFC (or BPL before) were supplied to NIBTS from where they were issued to hospital blood banks on request.

Until 1985 all commercial plasma products were ordered and funded by the hospital concerned, either by the hospital pharmacy or blood bank. A disadvantage of the latter arrangement was the difficulty for NIBTS in obtaining accurate information on total usage/ demand for plasma products (by the 16 hospitals). This was, of course, essential information in planning towards self-sufficiency e.g. in setting plasma collection targets.

In 1985 there was a change in arrangements with respect to commercial products. As will be explained, this change was agreed (between EHSSB, NIBTS, Regional Haemophilia Centre, and NI hospital management) in order to (a) facilitate the strategy towards self-sufficiency and (b) to facilitate financial planning in the provision of blood (plasma) products.

The new arrangements (from 1985) differed between haemophilia related products and other plasma products. The latter (mainly albumin solutions and later IV immunoglobulin solutions) were to be funded, ordered, stocked and issued by NIBTS where there was a shortfall in NHS supplies from PFC. In the case of haemophilia-related products, it was agreed that because of their highly specialised nature, selection and ordering would remain with the Regional Haemophilia Centre although invoices would be forwarded to "NIBTS Finance Department". The latter was actually at EHSSB which held

the NIBTS budget at that time. BCH Unit of Management subsequently took over and then from 1994 the NIBTS Agency. Under this arrangement NIBTS had regular and up-to-date information on usage which facilitated planning towards self-sufficiency. It also meant that while the budget for haemophilia products sat with NIBTS, we had no influence whatsoever over the products ordered, either in terms of quantity or choice of supplier.

Over the course of subsequent years, the usage and cost of haemophilia products rose progressively and this was the cause of a recurring, large overspend on the NIBTS budget for which I was asked to account. While it was understood by management (EHSSB, DHSSPSNI) this was an area over which I had no control, finance managers wanted to keep all blood products under one budget as they felt it facilitated financial planning. The view taken by management was that this was an unavoidable area of expenditure and that it would not be appropriate to impose a ceiling on expenditure on haemophilia products or to require operation within a fixed budget. In later years, and certainly under independent agency status (1994), it became the practice in annual accounts to report income/expenditure with and without haemophilia products.

a. Please identify which haemophilia centres were supplied with such products by the NIBTS and over what period of time.

It should be noted that there is only one haemophilia centre in NI. Other hospitals who would occasionally treat haemophilia patients would receive blood products from the Regional Haemophilia Centre (Royal Victoria Hospital).

b. Please outline the respective responsibilities of the NIBTS, PFC/BPL, the relevant Health Boards, and haemophilia centre directors, and how these responsibilities changed over time.

This question is covered in para 33 above.

34. **Please explain whether any forums were established between the NIBTS, PFC/BPL, the relevant Health Boards, and haemophilia centre directors to discuss and facilitate these arrangements. Were meetings held regularly? Were they minuted? If so, by whom? What was discussed at these meetings?**

Within Northern Ireland, the EHSSB convened a forum (annual) attended by Dr Mayne, myself and managers from EHSSB. The forum was chaired by a public health consultant from EHSSB. I assume the meetings were minuted, but I have not seen the minutes for this Inquiry. The purpose of the forum was to review and plan usage of blood products used to treat haemophilia patients in NI.

In Scotland, the SHHD convened an annual planning forum attended by haemophilia centre directors, transfusion directors, PFC directors etc. to which Dr Mayne and I were invited.

35. **As far as you are aware, were arrangements for the purchase, holding, and distribution of (a) NHS blood products and (b) imported blood products similar across the United Kingdom, or was there a degree of differentiation (and if so, what?)**

I believe it was the practice across the UK for NHS plasma products (BPL/PFC) to be issued to RTCs and then issued to hospitals. For imported (commercial) products, I believe the arrangements varied but I cannot remember the details.

36. **Did you, or anyone else within the NIBTS, contract directly with any pharmaceutical company involved in the manufacture and/or importation and/or sale of imported blood products? If so, please describe:**

As explained in para in 33 above, this only would have applied to products other than those used to treat haemophilia and related conditions managed by Dr Mayne and the Regional Haemophilia Centre. It would also only have

applied after 1985 when the central procurement arrangements discussed in para 33 were introduced. As far as I can recall, during the 1980s and early 1990s imported blood products procured directly by NIBTS would have been restricted to albumin (4.5% and 20%) and intravenous immunoglobulin – in order to make up for shortfalls in supplies from PFC.

a) How and by whom the decision was made to contract with the particular pharmaceutical company

The head of NIBTS blood bank, Area Supplies Service officers and myself were the main people involved. The processes followed were based on advice from the Supplies Service which was independent of NIBTS.

b) the broad terms of the contractual agreements made; and

I am unable to remember the details at this distance but I believe there were agreements made annually for a fixed quantity of products for an agreed unit price.

c) the factors taken into account when determining whether to contract with one pharmaceutical company over another

For blood products generally, safety and efficacy would have been the most important factors. In the case of albumin solutions there was no known risk of transmissible infection so issues such as price and security of supply became more important. Risks to supply would have led us to contract with more than one supplier.

37. Further to question 36 above, you received a cash rebate from Baxter Healthcare in 1988 or 1989 "on the value of purchases such as blood products" by the NIBTS (see page 33 of RHSC0000019). Please explain how this came about? Was this a common occurrence? If so, please provide details.

I cannot recall any details of how this rebate came about but I believe it was as a result of a negotiation by the Area Supplies officer, EHSSB and Baxter who appear in the photograph. I suspect it may well have been a unique occurrence.

38. **The Inquiry understands that from 1 January 1985 the NIBTS assumed responsibility for centrally purchasing commercial blood products (RHSC0000066_024; RHSC0000066_003).please explain:**

a) **the purchasing arrangements for commercial blood products prior to 1985;**

b) **the change to the system of centralized purchasing of blood products in 1985; and**

c) **whether the change was to the source of funding only, form EHSSB to NIBTS, or whether the responsibility for managing the purchasing shifted to an individual within the NIBTS?**

The answers to questions a), b), and c) are covered in paragraphs 33 and 36 above.

39. **During the period of transition of supply from BPL to PFC, the Inquiry understands that NIBTS was not entitled to its 10% quota of Factor VIII from BPL (SCGV0000104_150). Therefore, arrangements were made to procure commercial Factor VIII until material from PFC was made available (SCGV0000104_135). As far as you can recall, was commercial Factor VIII sourced during this period? If so, in what quantities and for how long, for example, was it for an "interim period"? (SCGV0000104_135). What consideration, if any, did the NIBTS give to the risk of transmission of infections posed by commercial products?**

As explained in para 33 , any shortfall in NHS Factor VIII (from BPL or PFC) would have been made up by commercial supplies and this would have been

organised entirely by the Regional Haemophilia Centre, with no involvement by NIBTS.

40. **On 30 November 1988 you published an operational plan of the NIBTS for 1988/89 (RHSC0000066_031):**

a) **Could you please explain why there was an overspend by the NIBTS between 1987-89 on commercial products which were purchased ''mainly for the management of Haemophilia''?**

b) **In your plan, you state that you were ''most dismayed that the latter item, over which I have absolutely no control, continues to so dominate the BTS budget position''. Could you explain whether you were referring to the management of Haemophilia and if so whether the treatment of these patients accounted for a significant amount of NIBTS' annual budget.**

c) **You described this situation of ''huge expenditure on the purchase of commercial blood products'' as ''demoralising'' and that it tended ''to make a nonsense of any future planning''. Could you please explain what you meant by this?**

Again the answers to a), b) and c) are covered in para 33 above.

41. **A report prepared by the EHSSB in 1989 (RHSC0000066_024) indicates that Dr Mayne remained responsible for managing the supplies of ''all clotting agents'' which continued to be delivered directly to the Haemophilia Centre. Please could you explain this?**

The factual statement here is in keeping with para 33 above as is the explanation.

42. What was the impact on the NIBTS of shortfalls in NHS products coming from PFC/BPL? How frequently did this cover?

Again, I think this is covered in para 33.

43. Was the NIBTS in any way responsible for decisions about the choice of product used to treat patients in haemophilia centres and/or hospitals, for example the choice between one imported factor concentrate over another?

As explained above, NIBTS had no input into decisions about the choice of imported products to treat haemophilia related conditions.

44. If haemophilia centre directors were responsible for these decisions, did the NIBTS have any influence over their product choices? If so, please explain the extent of the NIBTS' influence?

As Director of NIBTS, I would have endeavoured to encourage, as far as possible, the use of PFC products and to facilitate their use, e.g. by providing estimates of factor concentrate each year that Northern Ireland would be entitled to (based on plasma input).

45. In your view, what were the key factors influencing the choice between NHS blood products and imported blood products?

In general, the allocation of NHS products received from PFC, were used in preference to imported products. I would have considered NHS products to carry a lower risk of transfusion transmissible infection because the source plasma of NHS products was derived from voluntary, non-remunerated donors. The relative safety advantages became less clear-cut with the introduction of various methods of viral inactivation.

46. Please explain what the impact of clinical freedom was on the relative use of NHS blood products and imported blood products in Northern Ireland.

This was a matter of clinical judgement. It was for the clinicians to consider what product was in the best interests of their individual patients.

As noted above, I believe NHS products would have normally been used in preference to imported products. In the "post viral inactivation era" other factors would have applied for certain clinical situations, e.g. the level of purity of the product.

47. **On 24 November 1989, you informed the National Medical Director of the Scottish National Blood Transfusion Service ("SNBTS") Professor John Cash, of a "major problem" in relation to recent batches of Factor VIII concentrates which the NIBTS Haemophilia Director did not consider to be satisfactory. A problem relating to solubility had made the concentrates unsuitable for home treatment resulting in several patients having to switch to commercial alternatives. You noted that PFC was experiencing difficulty in production capacity and that BPL may be able to fractionate Northern Ireland plasma instead. You stated that "[...] from our point of view, the current PBL Factor VIII would be more acceptable to the clinicians." Referring to SBTS0000194_020 and as far as you can recall, please describe whether:**

a) the NIBTS experienced recurrent problems with the quality of PFC-made Factor VIII concentrate; and

As noted above NIBTS was not involved in the processing of Factor VIII concentrate received from PFC. So any difficulties experienced were those fed back to NIBTS by the Regional Haemophilia Centre. The "solubility problem" of Factor VIII seemed to be related to enhancement of heat treatment – 80°C for 72 hours – which had become routine, I believe, from June / July 1988. It was a problem that seemed to be accepted by PFC/SNBTS as shown by correspondence during April / May 1990 involving Dr Mayne and PFC.

PFC agreed to replace two batches of Factor VIII because of this and issued an apology (letter from Dr Perry to Dr Mayne) for the problem.

Regarding production capacity there had been issues relating to Factor VIII and albumin. As a result of reduced Factor VIII yields (arising from heat treatment) supplies to NI were reduced around this time.

Regarding Albumin there had for a period been a problem with production capacity or funding leading to NIBTS not receiving its full allocation of product (around 1986/87).

b) steps were taken to enable BPL to fractionate Northern Ireland plasma.

The suggestion of asking BPL to fractionate Northern Ireland plasma was not followed through. Such a change would have been very radical and involved enormous logistical challenges. In any case the solubility problem was overcome to Dr Mayne's satisfaction as set out in Dr Mayne's letter to Dr Flett, DHSSNI (WITN0892003).

48. What was your view in 1989 as to the relative risks of transmission of infections between domestically produced blood products and the commercially available alternatives?

This question, in my view, is one for experts in what is a highly specialised field. I was certainly not an expert. I saw it as my role, at this time, to continue with our strategy of facilitating self-sufficiency in any way I could. By 1989 both domestic and commercial blood products were virally inactivated. Accordingly, whether there was a material difference between them in terms of risk of infection was debatable.

49. On 5 January 1984 you were copied into a letter from Professor John Cash addressed to Dr Elizabeth Mayne at the Department of Haematology, Royal Victoria Hospital, Belfast (NIBS0001714). It was

stated that commercial Factor VIII, probably purchased by the PFC, had been shipped to Belfast for use in ''exchange for the PFC material you have received via Morris McClelland". Professor Cash asked for clarification and expressed that: ''On the face of it this development looks a little worrying- AIDS etc- and I'm anxious to help as much as possible". Documents LOTH0000005_071 and LOTH0000005_085 confirm that these exchanges took place. Please could you explain:

a) who was this agreement made by?

As the correspondence indicates, this was an arrangement between Dr Mayne and Dr Ludlam during 1983. NIBTS was not involved.

b) Why PFC products were being exchanged for commercial ones? Was it because patients in Northern Ireland, unlike Scottish patients, had already been previously exposed to commercial products?

I presume the reason for the exchange would have been to enable patients to be maintained on the same product (PFC or commercial) which was considered desirable especially in the event of transmissible infection or other side effects occurring.

c) were the risks of blood borne infections known and taken into consideration when making this decision?

Although I and NIBTS were not involved, I have no doubt that issues around blood borne infections would have been central to this decision.

d) was this a long-term arrangement?

To the best of my knowledge, this was a short-term arrangement.

50. The inquiry understands that in 1988 a reallocation of 1m i.u of NFIS heat treated Z8 Factor product that was allocated to Northern Ireland was exchanged with Scotland, and in compensation for this supply,

Scottish Health Boards purchased an equivalent amount of commercial Factor VIII for use in Northern Ireland (PRSE0004030). Dr Mayne justified the exchange on the basis that it minimized the exposure of patients not previously treated with commercial products, which were used more widely in patients in Northern Ireland than in Scotland (NIBS0001767). To the extent not already covered in the previous question and as far as you can recall:

a) **who had the final decision- making power to approve this exchange?**

The answer is set out in a letter from CMO (NI) to Dr Mayne/ letter of 13th December 1988 (NIBS0001770).This basically points out that decisions such as this should be taken by agreement between relevant health authorities i.e. EHSSB and DHSS NI and in Scotland by CSA and SHHD.

b) **was it the decision of the NIBTS? If not, why not?**

NIBTS was not involved in this decision at any stage. This would follow from the explanation of roles set out in para 33 above.

c) **Was the NIBTS at this time responsible for purchasing all factor concentrates?**

Again as set out in para 33, decisions about purchasing the coagulation concentrate were always taken by the Regional Haemophilia Centre to where these supplies were sent directly. NIBTS was not involved in such purchasing decisions.

51. The Inquiry understands that on 10 November 1994 you attended a meeting of the SNBTS Medical and Scientific Committee during which it was recorded that the BTC was "not receiving the level of support it was entitled to expect" regarding the level of information and support for users for SNBTS products. Please confirm what impact this had on the BTC (STHB0000684).

I cannot recall what this referred to but my guess is it was related to clinical trials of new PFC Factor VIII products e.g. viral inactivated Factor VIII. I know PFC/ SNBTS did provide funding to allow the appointment of a medical post (temporary) to assist the Northern Ireland Haemophilia Centre with such trials.

52. As far as you are aware, what influence did pharmaceutical companies have in the way that the imported blood products they supplied to Northern Ireland were used? For example, can you recall whether pharmaceutical companies provided advise on the use of the products?

In the case of NIBTS albumin solutions and IV immunoglobulin were the products partly sourced from commercial suppliers as previously noted. There were occasional visits from representatives of these companies. As far as I recall, the main focus of these visits was on updates on their products and future development plans. As explained in para 36c, unit price and security of supply were the main factors determining choice of these particular products.

Section 6: Production of cryoprecipitate at the NIBTS

53. Did the NIBTS produce cryoprecipitate? If not, where was this produced for Northern Ireland and what were the arrangements in place?

Cryoprecipitate was originally produced at the Regional Haemophilia Centre (from 1967), but from the early 1970s the production was taken over by NIBTS which then supplied the needs of all hospitals in NI for this component.

54. If the NIBTS did produce cryoprecipitate, please describe:

a) where this production of cryoprecipitate took place;

Production of Cryoprecipitate was at the NIBTS laboratories based at the HQ Unit – initially at Durham Street, Belfast and from 1995 in the new centre based at Belfast City Hospital.

b) broadly, the process that was undertaken, the capacity of the NIBTS to manufacture cryoprecipitate and whether this changed during your tenure and why;

The method of production was the standard one used by most RTCs – using triple plasma pack systems, centrifugation and expressers. The starting material was FFP collected from individual units of blood, slow thawing of same (overnight), followed by separation of supernatant plasma into the third transfer pack and storage of the individual units of cyro at -20°C to -30°C. Stocks of individual cryo were held by hospital blood banks which were responsible for pooling the units of cryo prior to transfusion to patients. From 2006-07, pooling of cryoprecipitate was carried out by NIBTS and issued as such to hospitals on demand.

c) what proportion of blood collections were allocated to this process and what sent to RFC and/or BPL and how this decision was made, and whether this changed over time;

The quantity of cryo produced was entirely demand-led, i.e. determined by clinical requests. As far as I recall, the maximum quantities were in the mid to late 1970s when production reached about 10,000 units (packs) per annum. I believe most of this was used to treat haemophilia A. During the 1980s as increased quantities of Factor VIII concentrate were used for haemophilia A, I believe an increasing proportion of cryo was used to treat patients with Von Willebrand Disease and as a source of fibrogen e.g. in the treatment of DIC. I think annual production fell to around 2000-3000 packs per annum.

d) how much, if any, funding was provided by the EHSSB for the production of cryoprecipitate: and

As this activity was integrated with general blood component preparation no special funding was identified for the purpose.

e) how quickly the NIBTS could have increased its manufacture of cryoprecipitate, had it wished to, during the early 1980s

As I recall, in the early 1980s NIBTS could have readily returned production to what it had been in the late 1970s (around 10,000 packs per annum). I believe there would have been the capacity to increase this substantially to, say, 20,000 packs per annum (at a guess). Some additional equipment and staffing would have been required, but this had already been acquired in order to produce the large increases in FFP going to PFC.

55. Please explain what consideration the NIBTS gave to increasing the production and use of cryoprecipitate in response to the growing awareness of the risks associated with Factor VIII concentrate products in the 1980's.

As noted above and elsewhere, the products used to treat haemophilia were entirely determined by the Regional Haemophilia Centre as this was a

specialist area of transfusion practice. The role of NIBTS in this area was to meet the clinical demand. For that reason, we did not consider increasing the production of cryoprecipitate. I do not recall any discussions with the Haemophilia Centre about increasing cryoprecipitate production for treatment of haemophilia A patients. As far as I recall, usage of cryo for patients with Von Willebrands disease increased as the numbers of these patients increased.

56. **Please describe the steps taken by NIBTS to increase the production of cryoprecipitate during this time. If no steps were taken, please explain why.**

The answer to this question is provided in 54 and 55 above.

57. **Please describe the arrangements for supplying cryoprecipitate to hospitals and haemophilia centres within Northern Ireland.**

The Regional Haemophilia Centre would have held a stock of cryo (in the Royal Victoria Hospital Blood Bank). As far as I remember, most other hospitals were not provided with a holding stock but were provided with cryoprecipitate when specific clinical need arose.

58. **On 3 September 1981 you were copied into a letter by Dr John Cash with regards to beginning the contractual relationship between NIBTS and PFC for plasma production in which it was suggested that you may have favored cryoprecipitate over Factor concentrates. Is this correct? If so, why?** (**NIBS0001698**).

The letter is actually from Mr John Watt to Dr Cash. My reading of the comments relating to cryo is different to that implied by the question. As noted above, production of cryo by NIBTS was demand-led and this would continue after the arrangement with PFC was established. Clinical demand for cryo was the determining factor.

59. On 21 November 1997, you attended a meeting of the United Kingdom Blood Transfusion Service National Institute for Biological Standards and Control for the first time. During discussions relating to virally inactivated plasma, it was noted that trials would proceed on methylene blue cryoprecipitate in the South East Zone and Edinburgh to establish whether "the process is suitable for production of cryoprecipitate". Please describe, as far as you are aware, the outcome of these trials and whether this process was later adopted for the production of cryoprecipitate at PFC. You may find JPAC0000105_007 of assistance.

I do not recall the outcome of the trials on this product, but I believe it may have been later adopted for use by UK RTCs. However, I cannot remember the details.

Section 7: Self-sufficiency

60. During your time at the NIBTS, what did you understand by the term 'self-sufficiency' to mean? Did this change over time?

In the context of blood products for human therapy, I understood this to mean that all supplies should be prepared using donations from voluntary, non-remunerated donors from within the UK. As an aspiration, I think it altered somewhat with the introduction of various methods of viral inactivation (from 1984), especially as these methods became increasingly complex and sophisticated. In terms of safety, it was no longer a "given" that a product made from UK-derived plasma was safer. With the onset of vCJD, the concept was completely reversed, i.e. UK plasma ceased to be used for the production of blood products

61. In your experience at the NIBTS, to what extent was 'self-sufficiency' a concept that informed the following:

a) plasma procurement:

From shortly after my appointment as Director, plasma procurement was entirely driven by a strategy to achieve self-sufficiency. This continued to be the case throughout the 1980s and early 1990s and I believe we reached the maximum level of procurement that could be practically achieved. From this stage, annual plasma collection had reached a plateau.

b) decisions with regard to cryoprecipitate production:

As explained under Section 6, production of cryo was determined by clinical demand by Northern Ireland hospitals, more particularly the Haemophilia Centre.

c) purchases of commercial blood products; and

As explained elsewhere, purchases controlled by NIBTS were to cover shortfalls in non-haemophilia related NHS products.

d) the funding of NIBTS.

As explained elsewhere, additional funding secured by NIBTS in order to establish the new arrangements with PFC - staff and equipment.

62. What was your view on the prospect of the UK achieving self-sufficiency?

I think once the new BPL was commissioned I probably expected that the English regions would follow a similar trajectory towards self-sufficiency as we had in Northern Ireland – obviously on a massively larger scale.

63. The Inquiry understands that in 1986 you wrote a paper entitled 'Plans for future blood product requirements' in which you stated that England and Wales should be self-sufficient in blood products by the end of 1986 (as applies already in Scotland). It would seem highly undesirable if Northern Ireland were to become the only part of the UK still importing blood products'/ Could you please explain if and when

Northern Ireland became self-sufficient in blood products? (RHSC0000065_001; RHSC0000065_002).

This depended on a number of factors i.e. plasma procurement (NIBTS), pattern of clinical usage (the demand for Factor VIII increased rapidly), fractionation capacity, and clinical preference.

During the period 1982-88, there was a progressive increase in plasma supplies to PFC after which the level started to plateau. This should have been sufficient to achieve the predicted requirements for blood products in Northern Ireland. Demand for Factor VIII and other products, however, proved even higher than the projections. As noted elsewhere in this statement, there were occasions when capacity at PFC was exceeded (e.g. impact on Albumin supplies). There were also quality issues (e.g. with PFC Factor VIII) which were not acceptable to the Haemophilia Centre. Accordingly, there were occasions where either NIBTS did not receive its full allocation (based on plasma input), or did not use its full allocation of PFC product due to clinical acceptability.

For the various reasons outlined above, Northern Ireland reached a position by the mid-1980s where most plasma products were NHS derived but never reached 100% self-sufficiency.

64. **As far as you are aware, did your views on self-sufficiency accord with the views of your peers and the UK Blood Service?**

I am unable to give a meaningful answer to this question.

65. **On 22 May 1984 you wrote a letter to Professor J.M Bridges at the Department of Haematology of the Royal Victoria Hospital regarding supplies of plasma protein fraction (NIBS0001719). With reference to the letter could you please explain exactly when the NIBTS became self-sufficient in Factor VIII and whether this was maintained post 1984?**

As noted, the letter referred mainly to a specific problem with plasma protein fraction supply, thus arising mainly from a temporary operational/capacity problem at PFC. The questions referring to Factor VIII are covered in my answer to question 63.

66. **The Inquiry understands that around 1986 the SNBTS could not process additional plasma from Northern Ireland because "funding from SNBTS development fund will not be made available for this purpose" SCGV0000104_026. It was suggested that if PFC could not process all of Northern Ireland's plasma then Northern Ireland might consider approaching the ROI and/or England:**

a) **Was additional plasma sent for processing to other centres for example in ROI/ England/ Wales?**

One of the drawbacks of the UK model for achieving self-sufficiency was that as a plasma collection centre, we were effectively tied to a particular fractionation centre - at least, for a considerable period of time. The logistics of supply were complicated. It would not have been practically possible to chop and change fractionation arrangements for operational, and undoubtedly (had it arisen), for administrative and contractual reasons.

While it would have been a possible option to send some or all NIBTS plasma to BPL instead of PFC, this course of action was never followed through, partly for the general reasons alluded to above (question 65) but in this specific case because solutions were found to deal with the problems in a reasonable timeframe.

b) **Could you please explain what steps you took to ensure that Northern Ireland received the correct level of blood products from PFC and whether blood products were procured from other sources, including commercial, to make up for any shortfall?**

As explained elsewhere, the agreement with PFC was that supplies of plasma products were pro-rata with the input of plasma and this arrangement was adhered to throughout. I consider that the relationship between NIBTS and PFC was very constructive. Failure to meet allocations was rare and where this ever arose, there was "carryover" into the following year to make up for the shortfall. In the event of a shortfall, commercial product was procured.

For each year a detailed agreement which covered each plasma type (and supplies of each product) was arrived at, as can be seen from correspondence between Dr Perry and myself.

c) Was the NIBTS ever informed whether ''development money" was required for PFC to process additional plasma? If so, did this have and impact on Northern Ireland's ability to achieve self-sufficiency?

On the specific issue of albumin supplies and PFC fractionation capacity, (funding etc.) NIBTS was informed in writing about the resolution of this problem. I am seeking to locate a copy of the relevant correspondence and shall provide it to the Inquiry if possible.

Section 8: Services for donors at the NIBTS

67. What counselling was offered to donors prior to (i) HIV testing (ii) HCV testing and (iii) HBV testing taking place? Please describe the process.

In general, I can say that NIBTS followed closely a nationally (UK-wide) agreed approach. I do not have the relevant documentation, forms etc. to hand and cannot recall the detail although these should presumably be available.

(i) HIV testing:

By the time this was introduced, the AIDS leaflet had been in use in various ways for almost two years. When HIV testing started (October 1985) I do recall that all donors were required to read and sign a

statement to the effect that *inter alia* they were not in a high risk group (for AIDS), they agreed to be tested for AIDS antibody (anti-HTLV III), and, in the event of a positive result, they would be contacted by NIBTS. This process was carried out during the routine pre-donation health check interview which at that time was undertaken by an experienced and appropriately trained blood donor attendant. All donation sessions were supervised by a qualified doctor (appropriately trained and updated) to whom any queries could be referred.

(ii) HCV Testing:

I am less clear in my recall about this, but as far as I know we used a variation of the above process (for HIV) when HCV testing was introduced.

(iii) HBV Testing:

This was introduced well before my tenure at NIBTS (1972). As far as I know no specific counselling was provided about this on donor sessions. This would have continued to be the case at least until HIV testing began. At some point after this, counselling about HBV testing would have been incorporated into the process used for HIV and HCV testing, but I cannot recall any details about when and how this happened.

68. **In 1983, there appeared to be resistance from English Transfusion Centre Directors to the initiative of distributing a UK leaflet on AIDS to all donors attending a transfusion session (PRSE0002617). Please describe what the position was in NIBTS to the distribution of this and any other leaflets aimed at reducing the risk of donations from high risk donor categories. You may also wish to refer to DHSC0101652_002 for further information. In your view, were the steps taken by NIBTS to**

prevent high risk donors from donating adequate? Could or should more have been done? If so, what?

There was widespread concern that publicity about AIDS, including the use of the AIDS leaflet, would have a deterrent effect on donor attendances. It was a concern shared by my blood donor recruitment / administration staff especially given the conservative nature of society in Northern Ireland. There was indeed some evidence (hard to quantify) of negative associations of blood with AIDS which led to loss of donors or potential donors.

The process of introducing the AIDS leaflet by NIBTS is described in my letter to A. Smithies, DOH London (29 January 1985) i.e. initially displaying the leaflet prominently in all sessions and then by late 1984 presenting it to each donor (I think at the reception desk). At this stage, there was a difference in approach between public sessions to which donors were invited individually by postcard and "closed" donations (workplaces etc.), to which donors were not called individually, but which were organised by a local volunteer. The local volunteer was provided with a supply of AIDS leaflets to use as appropriate prior to the donor session.

In the case of public sessions, at which the largest number of donations were given, inclusion of the leaflet with a call up letter had to await procurement of an automatic enveloper which was introduced along with a new computerized system (1985). I would point out that suddenly switching from mailing 600-1000 postcards per day to letters with inserts, using a very small team of clerical staff, was not practical. However, the automatic system allowed each donor to receive an AIDS leaflet with a call up letter.

Apart from the practical difficulties that delayed sending the leaflet to donors in advance of the session, I feel there may have been benefits in the more gradual approach taken as this allowed NIBTS to assess the impact of this major change.

Regarding the effectiveness of the measures taken, two pieces of evidence emerged. First of all, with HTLV testing it became apparent that the (admittedly small) number of positives in most cases belonged to "atypical" risk groups who would not have been aware of their risk. Secondly, in subsequent years, it became apparent that the NIBTS incidence of Hepatitis B positive donors dropped dramatically (I think from 1984 onwards) – Hepatitis B being associated with similar risk activities to HIV. See **Ulster Medical Journal 58 Number 1 page 72-82 April 1989. WITN3082021**

I believe these two pieces of evidence pointed to the likelihood that donors in the main high risk groups were excluding themselves from donating blood. Whether this was mainly due to the use of the AIDS leaflet or to more general publicity around this time I do not know. Either way, I am sure these measures were very important during the approximately two year period before HTLV-III antibody testing began and would have contributed to the fact that there was no conclusive evidence of HIV transmission in Northern Ireland by "standard" blood transfusion (excluding Haemophilia related treatment).

69. You were present at a meeting of the Screening and Early Detection Sub-group of the HIV Advisory Groupon 12 November 1986 (NIBS0000061). The meeting minutes stated that donors who were found to be HIV positive following a blood donation were contacted by a "senior doctor in the Blood Transfusion Service" and "advised to involve their GP and/or to contact the GUM clinic" The meeting minutes also noted that "further counselling should be provided for these individuals."

a) What counselling and psychological services were available for donors who tested positive for HIV at the NIBTS?

Confirmed positive donors were contacted by a consultant at NIBTS (Dr Bharucha or myself) and initial counselling provided at NIBTS. I had attended a training day in London to enable me to take on this role and as far as I can remember Dr Bharucha did as well.

b) **Which other agencies were involved in counselling and psychological services in Northern Ireland?**

With their agreement, these donors would be referred to one of two consultants, (an STD physician and immunologist) at the Royal Victoria Hospital who had been given responsibility for the care and support of these patients. Counselling and psychological support services were established at these departments, but I cannot remember any details.

c) **Were the same services available to donors who tested positive for HCV? If not, why not?**

The same process was followed at NIBTS as for HIV positive donors. With their agreement, these donors were then referred to a consultant hepatologist with a special interest in their condition. I cannot recall the nature of the psychological support services that were available at these departments.

70. **What counselling and psychological services were available for recipients of infected donations? Were such services delivered by NIBTS or were referrals to other agencies made? Please describe the process.**

Counselling and psychological services for recipients were the responsibility of the hospital attended by the patient concerned and not NIBTS. The process for dealing with such patients is described in section 13 on look back programs.

71. **were the arrangements for donor counselling and psychological services sufficient in your view? If not, why not?**

I believe the initial counselling and support NIBTS provided for donors was adequate but cannot comment on services provided beyond this.

72. **On 4 March 1999, you were copied into a written letter by the Medical Director of the National Blood Authority ("NBA"), Dr Angela Robinson, in which it was noted that the NBA had a legal duty to inform donors who were potentially carrying of infected with vCJD of their diagnosis and to arrange counselling/treatment. Did the NIBTS have a similar duty? If so, what measures were taken to address both diagnosis and counselling of donors? Please refer to NHBT0007217_001 in answering this question.**

Although we did not seek independent legal advice on this matter, we assumed the advice in question applied to NIBTS. The same policy would have been implemented as for the NBA, the process being put in place by my colleague Dr Bharucha and later by Dr Morris.

Section 9: Meetings of various committees

Meetings of Regional Transfusion Centre Directors

73. **The Inquiry understands that you attended the final meeting between the Directors of Regional Transfusion Centres ("RTCs") in January 1989 (NHBT0018188). What do you consider to have been the purpose(s) of those meetings?** Please refer to the schedule of documents for a full list of the minutes of meetings you attended.

I think the purpose was that of information sharing and co-ordination of activities between the English and Welsh RTCs with the Northern Irish and Scottish Transfusion Centres being represented as observers. For me, it was

very valuable as a means of keeping abreast of developments in the other UK RTC's.

74. **Please explain, as far as you are able, the decision-making remit of the group. Were the RTC directors empowered to make collective decisions that affected the policies and procedures of all RTCs? If yes, please describe the decision-making process and how decisions were disseminated.**

As far as I recall, a common concern of RTDs in England was related to the difficulty of implementing decisions across the country. This arose from the fact that each RTC was individually and separately managed by the respective RHA. This greatly limited the ability of RTC directors to make collective decisions that were binding.

75. **Do you consider that these meetings were conductive to fulfilling the purpose(s) for which they were established?**

I have no further comment here. At all times, I was attending as purely in the capacity of an observer.

76. **What was your understanding of why the meetings were abolished?**

I was not involved in this decision in any way but it seemed as far as I can remember to be related to the establishment of a national directorate in England (National Director and Deputy National Director).

77. **Did meetings between RTC Directors continue after this date in a different forum? If so, please give details?**

A new format was established by which England and Wales was divided into three zones and a forum was established for each zone to which all medical consultants were invited. My colleague and I were invited to attend the Northern Zone meetings. There was also established National Management Committee meetings for the BTSs in England. I was not invited to attend nor do I recall receiving minutes.

78. If the meetings were not replaced with another forum, please advise, as far as you are able, why that was the case and what impact that had on NIBTS.

See para 77.

Membership of other professional bodies

79. The Inquiry would be grateful if you could further describe the roles of the following groups and your position within them. Please refer to the schedule of documents for a full list of the minutes of meetings you attended:

a. The Scottish National Blood Transfusion Service - Directors' Meetings;

b. The Coagulation Factor Working Party; and

c. The SNBTS Medical and Scientific Committee.

These are my impressions but I do not have to the hand the terms of reference for these groups.

a) The Scottish National Blood Transfusion Service- Directors' Meetings;

This group consisted of the SNBTS National Medical Director, National Administrator, five regional transfusion directors (all medical) and Director of PFC. It was the senior management and coordinating group for SNBTS, certainly with respect to medical issues. As SNBTS was a National Service the group was empowered to take certain decisions which would be implemented, but there also seemed to be a significant degree of autonomy exercised by individual RTC's.

I was invited to join this group after our link with PFC was established. I found this very valuable with respect to information sharing. In

general, there was no requirement for uniformity on policies and practices between the two services (SNBTS and NIBTS) except with respect to relationships with PFC e.g. common quality standards for plasma supplied to PFC was a requirement.

b) **The Coagulation Factor Working Party; and**

I do not recall being a member of this SNBTS group although the minutes would have probably been included in the SNBTS Directors Meetings papers. As I recall, it dealt with scientific research on Factor VIII, Factor IX etc. and would have had a significant role in the development of new Factor concentrates by PFC.

c) **The SNBTS Medical and Scientific Committee.**

This was really a successor to the SNBTS Directors Committee (paragraph 79a) above), established in 1990 and followed the appointment of a general manager for the SNBTS. From my point of view, it would have had a similar function to the Directors Committee. This group included additional members who had been appointed to national roles by SNBTS e.g. quality management, operations, donor management and virology reference service.

80. **The Inquiry understands that you attended the meetings of the following committees/groups. In each case please explain the primary objective and scope of each organisation. Please refer to the schedule of documents for a full list of the minutes of meetings you attended:**

a) **The Screening and Early Detection Sub-Group of HIV Advisory Group;**

This was a Northern Ireland group. I am not sure if the main group was advising the DHSSNI or the EHSSB. I think the purpose of the sub group is fairly self-explanatory from the title. Screening would have included blood donor screening on which I would have reported.

b) **The UKBTS/ NIBSC Joint Executive Liaison Committee/ The Red Book Executive Committee;**

The key purpose of this committee was to oversee the production and regular review of the Red Book. This was carried out through a number of expert sub-committees which between them covered all aspects of transfusion practice. Between editions of the Red Book, it also provided detailed guidance on specific issues.

c) **The SNBTS Co-ordinating Group;**

This had similar membership to the SNBTS Directors Committee (paragraph 79a above). I received the minutes of this committee but only attended one of the meetings each year - this was the annual supply/ demand meeting, the purpose of which was to discuss the supplies of products from PFC.

d) **The UK BTS Forum**

This was established in 1999. The purpose was to coordinate activities of the four UK BTS. The membership was Chief Executives and Medical Directors of each of the four services. A significant role was appointment of chairs to certain other UKBTS committees- JPAC, SHOT.

e) **The Joint UKBTS/NIBSC Professional Advisory Committee**

This was the same committee (under a different title) as per para 80 b above and had the same role.

f) **The HIV Sub Committee of the regional Communicable Diseases Liaison Group (''RCDLG"); and**

I have no recollection of this group -was it for NI or UK wide?

g) **The BBMPDP Working Party.**

NIBTS was a significant contributor to this national programme. The objective was to recruit and organise a panel of volunteers (from existing blood donors) who agreed to be HLA (tissue) typed and have their name included on a national register (based in Bristol). When a donor was selected as the best available match for a patient, the subsequent contacting, counselling and, general "work up" was carried out by the RTC. This committee was set up to plan and coordinate this programme and, as a contributor, I was invited to attend.

81. Please confirm whether you were a member of the following organisations and if so describe your role and position:

Both groups referred to were sub-committees of the main "Red Book" Committees under paragraph 80 b) and c) above and of which I was a member. As such I was not a regular attendee of the sub-committees, but I would have received the minutes. NIBTS would have been represented at some of these meetings.

a) Joint Meeting of the Standing Advisory Committees on Blood Components and Transfusion Transmitted Infections (NHBT0001972)

I appear to have attended one meeting here, probably because it was joint meeting involving the two groups but I did not attend the individual sub committees

and

b) The UK Standing Advisory Committee on the Care and Selection of Blood Donors (NHBT0002548).

I did not attend this but NIBTS was, I think, represented at various times – Dr Bharucha, Dr Morris and later Dr Murdock.

82. **On 23 December 1994, you were asked whether the NIBTS would like to be represented on the recently created Working Group for Reporting Serious Hazards of Transfusion whose objective was to implement a system of reporting the serious complications of transfusion such as post transfusion hepatitis and other viral transmission (NHBT0007851_011). Did a representative of the NIBTS join this group? If so, please provide details of the NIBTS' involvement in the group. If not, why?**

I do recall attending meetings of the steering committee for this scheme. I do not recall whether NIBTS was otherwise represented. NIBTS, and indeed all hospitals in NI, were always very active participants in this scheme. I always considered it to be an excellent initiative. It played a significant part in improving transfusion safety.

Section 10: Information handling and sharing

83. **Please describe the record keeping system in place for blood donations and blood donors at the time of your directorship of both the NIBTS and the BTC.**

In particular, please explain:

a) What records were kept;

Traceability: this is a key aspect of record keeping. The purpose is to ensure traceability forwards from donor to any recipient of blood components (or to PFC) and backwards from the recipient to the donor. This was achieved via the use of unique donor numbers, donation numbers and component numbers.

Other information recorded:

- donation outcome- including deferrals and reason for deferral
- date donor eligible for recall.
- Test results e.g. blood group, hepatitis/ HIV test.
- Product history – e.g. blood component issues to hospital blood banks or PFC.
- Flagging system against donors not eligible to donate including those positive for infectious disease markers.

b) In what form they were kept;

Until 1985 records were entirely manual i.e. donor record cards, donation sheets and laboratory work sheets. By 1985 the beginning of a computer system was introduced, initially for donor records and later for blood component issues.

c) Where they were kept;

Records were kept within the relevant department i.e. donor administration department, laboratory testing and blood issue (blood bank) department.

d) Who had access to them;

This was on a need to know basis by the relevant operational staff and medical officers.

e) For how long they were kept, and

I believe the most important records, e.g. those required to enable future traceability, test results etc. were kept indefinitely.

I was aware at one time of the evolving recommendation for certain records to be kept for at least 15 years. Later we did develop a record storage strategy including a policy for destruction.

f) The policy or practice adopted in relation to their destruction.

As far I know the critical records on donations, issues etc. described above (paragraph 83a) were never disposed of during my tenure.

84. **Please describe the record keeping system in place for ad hoc centres in Northern Ireland. Did each ad hoc centre follow the same record keeping practices at the BTS, or did each centre implement its own system?**

As noted above there were no such ad hoc centres in NI.

85. **What were the record keeping arrangements SLRTC had with the hospital blood banks to whom SLRTC provided blood and blood products? What information were the blood banks expected to feedback to SLRTC about the use of products supplied to them, and in what form? Was this information routinely feedback, or were there problems with the hospital's compliance? IF so, what if any steps were taken to remedy this.**

I assume this should be NIBTS. All individual issues of blood components and plasma products for individual patients were carried out by the hospital blood banks. It was the responsibility of the latter to maintain the records that would enable full traceability as noted in paragraph 83 a). Such records do not require to be returned to NIBTS. Any blood components or products that were unused/ time expired by the hospital were returned (with records attached) to NIBTS.

86. **Do you consider that the record keeping measures in place within the NIBTS (including at the BTC and at the ad hoc centres) were adequate to prevent donors who were suspected of carrying blood borne infections from continuing to give blood donations at that centre?**

I believe the systems in place were adequate for this purpose. A number of such measures were in place and these were gradually strengthened during my tenure. In many cases, I cannot recall the details as I was not the doctor in day-to-day charge of this area. Some of these measures would have

flagged individuals at the donor session – if included on a permanent donor deferral file that was available at each session. Apart from this, measures were in place to detect potentially infected individuals post-donation, e.g. reactive but unconfirmed positives and suspected carriers of NANB Hepatitis – see procedure by C Bharucha (WITN0892004). The introduction of personal computers on donor session – late 1990s(?) meant that relevant information on the entire NIBTS donor panel became available on each donation session.

I believe the systems in place were adequate for this purpose. This area would always have been audited by the MCA/ MHRA and other external agencies e.g. PFC/SNBTS, CPA accreditation (UK). I do not recall any major issues being raised in this specific area. A general concern raised by MHRA was a lack of a fully integrated IT system. This concern was not fully addressed until after the move to the new transfusion centre in 1995.

87. **The Inquiry is aware of a Northern Ireland Communicable Disease Surveillance Centre ("CDSC") (BHCT0000275_004). What was their role in preventing donors suspected of carrying blood borne infections from continuing to give blood donations?**

I cannot think of any significant role this centre would have had in relation to preventing donors suspected of carrying blood borne infections from continuing to give blood donations.

88. **Did this Centre maintain a database to keep track of reporting of blood donor who tested positive for HIV? If so, please answer the following questions:**

a) **Were you aware of the database, if so, when did you become so aware?**
b) **Who proposed the creation of the database?**
c) **Did the NIBTS/ BTC contribute data on HIV positive donors to the database? If not, why not?**

d) Are you aware of whether other RTCs contributed data on HIV positive donors to the database?

(a-d) I am wondering if this question should refer to the national CDSC at Colindale? I believe some data was forwarded to the national centre, but this would have been in a coded form with donor identifiers removed. My colleague, Dr Bharucha, was the consultant responsible for this area and might have a better recollection.

89. Did the NIBTS/BTS maintain a separate, or additional, database to track HIV positive blood donors?

NIBTS did have a system to flag donors positive for HIV aimed at ensuring these donors were not accepted for donation. I am unable to remember the details at this distance. Dr Bharucha may be able to do so.

90. In 1989, the NBTS reintroduced a database called the "J" donor system to identify donors involved in cases of post-transfusion hepatitis (NHBT0005388). Were you aware of the existence of such a system? Was a similar system ever implemented within the NIBTS/BTC to identify donors involved in cases of post-transfusion hepatitis? If so, what was the purpose of the system, what information was it intended to collect as far as you are aware, does the system still exist?

I do not recall this system as such, but NIBTS did have a system designed for the same purpose. See procedure by Dr Bharucha, 24 November 1983 (WITN0892004 - same exhibit as Question 86). This was to flag donors possibly implicated in being the source of post-transfusion hepatitis (NANB). Such donors would have been identified as a result of reports of PTH from hospitals. Depending on subsequent information, donors considered to carry a risk could be deferred from donation.

91. In addition to the database(s) mentioned above, did the BTC or ad hoc centres share information between themselves about excluded donors, donors that posed a risk to the safety of the blood supply, of infected

blood donations? If so, was this a formal or informal basis? Please describe the mechanisms the BTC and ad hoc centres used to share this information, if any.

Since NIBTS is / was the only blood collection centre in NI, this question is not applicable.

92. **Did the NIBTS have information sharing measures with other RTCs within Great Britain? Please provide details.**

As far as I recall, we did not have sharing arrangements with other RTCs i.e. with regard to NANB hepatitis.

Section 11: Knowledge of risk of infections while at the NIBTS

HIV/AIDS

93. **During your time at NIBTS, what was your knowledge and understanding of HIV (HTLV-III) and AIDS and, in particular, of the risks of transmission from blood and blood products? How did your knowledge and understanding develop over time?**

HIV/AIDS

My earliest recollection of HTLV III/AIDS was of reading reports from the US about AIDS being associated with Haemophilia. I believe these reports were in MMWR bulletins (1981/82). I also recall an AABB meeting (in or about 1982, I think) at which AIDS and its possible relevance to blood transfusion was discussed on the fringes of the meeting. Subsequent to this, I would have been aware of reports appearing in the scientific literature which provided increasingly convincing evidence of a single infective agent, including the first report of a child, in which the only risk factor appeared to be blood transfusion.

I then remember reports on the search for a virus including an association with HTLV I (as it later became known) before the first reports from Montagnier and Gallo that HTLV III was the likely causative agent.

94. How and when did you first become aware that there might be an association between AIDS and the use of blood and blood products?

See para 93 above.

95. What, if any, enquires and/or investigations were carried out at NIBTS in respect of the risks of transmission of HIV/AIDS? What was your involvement? What information was obtained as a result?

NIBTS was not involved in any research or investigative work on AIDS prior to the introduction of HTLV III screening. In the absence of any proven cases of AIDS in Northern Ireland at that stage, I saw my role as ensuring I was as fully informed of developments as possible, e.g. by accessing any available scientific reports, any literature, meetings etc.

96. Did the testing of blood donations for HTLV III antibody become mandatory in Northern Ireland from October 1985? You may wish to refer to NIBS0000049 for further details.

This became mandatory from mid Oct 1985.

97. On 17 April 1986, Senior Medical Officer G. Lawson sent a letter to a representative of the Scottish Home and Health Department (SHHD) expressing concern at a proposal to limit the amount of plasma processed at PFC and therefore supplies to Northern Ireland (SCGV0000104_029). Regarding the knowledge of risk of blood borne infection, the following was noted: ''Patient safety could be threatened if blood products produced from local voluntary donors are replaced by commercial materials produced from paid donors from areas at high risk for hepatitis, AIDS etc. This particularly applies to haemophiliacs, representing a risk in spite of the introduction of heat-treatment of

Factor VIII". Could you please comment on whether the NIBTS received fewer blood products from PFC than it needed in 1986-87 and, if so, whether commercial material was in fact procured to make up for this shortfall.

As far as I recall and from reading the relevant correspondence, there was a temporary capacity problem at PFC around this time. I understand that this mainly affected PFC's ability to meet our entitlement (based on plasma supply) of albumin solutions rather than Factor VIII. This issue seemed to be resolved within 6 months to 1 year after which normal supplies of albumin resumed.

98. **In April 1991, you co-authored an article for The Ulster Medical Journal titled ''Human Immunodeficiency Virus infection in Northern Ireland" (WITN3082020) which stated that: ''The lower figure for infection of haemophiliacs in Northern Ireland may be explained by the use of more factor VIII derived from European sources. All Factor VIII products became infected eventually but the European material became contaminated at a later date compared to that imported from the United States of America". Please outline whether American Factor VIII products were ever used by the NIBTS. Did the NIBTS understand American products to carry a higher risk of HIV than domestic products.**

As noted elsewhere, the choice of Factor VIII used was entirely decided by the Regional Haemophilia Centre. NIBTS was only involved in the supply of NHS Factor VIII (as described elsewhere) as part of the drive towards self-sufficiency. Factor VIII products imported from the US were not used by NIBTS.

<u>Hepatitis</u>

99. **What was your knowledge and understanding of hepatitis (including hepatitis B and non A non B hepatitis (NANB)/ hepatitis C) and in**

particular of the risks of transmission from blood and blood products during your time at NIBTS? How did your knowledge and understanding develop over time?

I was aware of the probable existence of NANB hepatitis from the time of my initial appointment as a consultant in 1978 and of its association with blood transfusion. However, most of the information and research seemed to come from the USA, Japan and other countries that would later prove to have a higher incidence of hepatitis C than the UK. There seemed to be a lack of any studies in the UK that systematically followed up recipients of blood transfusion – as took place in the US. Because of this dearth of good quality research in the UK, there was uncertainty as to the incidence and (long-term) severity of this condition.

As indicated, I was aware of the debate concerning the possible role of surrogate markers in decreasing the risk of NANB Hepatitis and of the introduction of such measures in some countries. We did encourage reporting of possible cases of NANB Hepatitis to NIBTS so that appropriate action could be taken – see paragraph 90.

With respect to Hepatitis B, I was aware at the time of my appointment of residual issues related to the sensitivity of the existing tests. NIBTS introduced the more sensitive RIA test in 1982.

100. **How and when did you first become aware that there might be an association between hepatitis (including Hepatitis B and NANA/hepatitis C) and the use of blood and blood products?**

See para 99 above.

101. **In a letter you wrote on 30 May 1984 to Dr Gunson of the Manchester RTC, you described that the reason for post-transfusion cases of hepatitis having 'increased strikingly' may have been due in part to under reporting. Please explain what you meant by this. Further:**

a) what did you mean by ''post-transfusions hepatitis'' (ie hepatitis B, NANB, hepatits C etc)?

PTH would have included any type of hepatitis that occurred within two weeks and 6 months of receiving a blood transfusion and therefore included hepatitis B, NANB, and other causes. A better term to have used may have been transfusion-associated hepatitis. This is because hepatitis following a blood transfusion was not necessarily caused by the blood transfusion. It could have been acquired in the hospital from another source. I believe by that time (1984), the majority of transfusion-associated hepatitis B cases were in this category.

b) were there specific organizational issues which led to its under reporting? (please see NHBT0094549_007).

It became apparent that 90% of NANB hepatitis cases have no jaundice (anicteric), or no symptoms at all, in the acute phase. Apart from this, there was an educational issue among some clinicians about the importance of reporting, and in some cases even about the existence, of NANB hepatitis. Hospital blood bank and haematology staff were well aware of this, but not necessarily other users of blood and blood components. Every opportunity was taken to educate clinical staff about this and also through publications e.g. Ulster Medical Journal volume 55.1, page 23-26, 1986.

102. You co-authored an article (WITN3082021) in the Ulster Medical Journal in April 1989 in which it was stated ''Transmission of hepatitis B virus by blood and blood products such as cryoprecipitate and Factor VIII has almost ceased following the screening of blood donors and the development of more sensitive and specific tests. There was no evidence that haemophilia patients became infected after 1982 and

patients who received multiple transfusions after 1980 did not have acute hepatitis B Virus infections".

a) **to the best of your knowledge, after 1980 were there any patients who received transfusions and went on to develop chronic hepatitis B?**

I am not aware of any data to answer this question but I do not recall any proven cases. As noted, under para 101a association with transfusion is not the same as causation. The latter would have required identifying one of the donors concerned as being a hepatitis B carrier.

b) **Please also explain the apparent contradiction between an increase of port-transfusion cases of hepatitis mentioned in your letter from 1984 to Dr Gunson (see question 101 above) and your 1989 journal article which implies that there were very few, if any, cases of transfusion associated infections after 1982.**

This is not really a contradiction. As noted above the 1989 journal article refers to hepatitis B only while the letter to Dr Gunson refers to all cases of PTH, mainly NANB.

103. **What, if any, further enquires and/or investigations were carried out within the NIBTS in respect of the risks of the transmission of hepatitis? What was your involvement? What information was obtained as a result?**

I was very interested in the possibility of doing a prospective study on transfusion recipients to determine the incidence of PTH in NI - perhaps in collaboration with other UK regions. I remember writing a proposal but we were unable to get this off the ground. I also remember a discussion with Dr Brian McClelland about the possibility of contributing to a proposed study of liver function tests post-transfusion, that he and Dr Gunson had put to the Medical Research Council. Unfortunately funding could not be obtained. As

indicated, this would have involved repeat measurement of liver function tests in a cohort of transfusion recipients and compared to a control group.

The only NI study I can point to is a publication by two of my colleagues based on reports of PTH received by NIBTS, Ulster Medical Journal, volume 55, number 1, page 23- 27 (WITN0892005).

104. What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time?

By the mid-1980s I was aware of follow up studies that were starting to indicate that a proportion of cases of NANB Hepatitis were showing evidence of chronic liver disease and even cirrhosis e.g. transfusion recipients in the US, UK haemophiliacs (recipients of Factor VIII from the US). There was much less information about recipients of blood from UK donors. More locally (NI) and anecdotally, I recall some discussions with one of our liver physicians who had a special interest in this area and at that time he had no evidence of cases of Chronic Active Hepatitis or cirrhosis that could be traced to previous blood transfusion.

105. In a scientific paper dated October 1986, Dr Gunson stated that the best estimate of the incidence of transfusion- associated NANB hepatitis in the UK from published data at the time was 3% (SBTS0001120). He further noted that "if one assumes that the 2.3 million donations in the UK are transfused to 750,000 recipients annually then one would expect 22,5000 icteric or anicteric cases of NANB hepatitis each year." Please answer the following questions:

a) Were you aware of this paper and these findings at the time of publication? If so, when and in what circumstances did you become aware of the findings of this paper? If not, when did you become aware of it and/or the conclusions set out within out

I cannot recall this paper although I most likely would have seen it around this time. Having reviewed the paper for the purpose of the Inquiry, I would have been familiar with several of the references therein. I feel the conclusions were limited by (a) lack of any sufficiently large and well-controlled prospective studies in the UK and (b) by the impact of the (HIV related) self-exclusion measures.

b) **Were these figures regarding the prevalence of NANB post-transfusion hepatitis ever discussed by RTC Directors? If so, please describe the general response to these figures.**

I cannot recall specific discussions by RTC Directors. But I would have thought most, if not all, RTDs would have been familiar with the published findings relating to NANB hepatitis. I think there still would have been uncertainty about the size of the problem in the UK at that point in time.

106. **Please provide details of any other information that informed your understanding of the severity and prevalence of HCV in the UK donor population.**

I have nothing further to add to the points set out about.

General

107. **How did your understanding of the seriousness of HCV and HIV/AIDS impact the donor selection policies and practice in place at the NIBTS?**

NIBTS has always followed national guidelines for the selection of blood donors. The latter were quite detailed and even in the 1980s updated from time to time. I recall the NBTS guidance (Memorandum on the Selection, Medical Examination and Care of Blood Donors).Documents **PRSE0004358, DHSC0003734_066.**

The impact of HIV/AIDS led to new exclusion categories as per the AIDS leaflet. While the process in the 1980s relied on self-exclusion, blood collection staff received special training in dealing with any issues that might

arise, such as queries that might be raised by donors. I do not recall any new exclusion criteria relevant to HCV – there were already selection rules relating to a history of jaundice / hepatitis etc. IV drug use and other use of needles such as tattoos.

108. What advisory and decision- making structures were in place, or were put in place within the NIBTS to consider and assess the risks of infection associated with the use of blood and/or blood products?

NIBTS had very close links to the other UK BTS and was always included as part of the national structures in England and Scotland. As the only transfusion centre in NI, we did not have formal structures to consider and assess infection risks. This would be dealt with informally e.g. at a weekly meeting with consultant medical staff.

109. What role, if any, did the NIBTS have in advising those hospitals and haemophilia centres that it provided blood and blood products to, as to the risks associated with blood and blood products? Please give details of any steps taken in this regard.

NIBTS consultant staff had a well-accepted role in providing education and advice to medical and other clinical staff on transfusion practice and associated risks. Examples include, undergraduate lectures and classes, lectures to specialist societies, regular visits to hospital blood banks and later - 1990s-2000s, regular hospital user meetings at NIBTS, and NIBTS membership of hospital transfusion committees. The Handbook of Transfusion Medicine was funded by NIBTS and distributed to all junior hospital doctors.

As Haemophilia was a specialist area, NIBTS had a very limited role in providing advice to the Regional Haemophilia centre.

Section 12: Reduction of risk of infections

Donor Selection

110. What donor screening processes were in place during your tenure at the NIBTS, and how did these change following the emergence of:

a. HBV;

b. AIDS/HIV

c. NANB/ HCV

It is assumed this question refers to the selection of donors at donation sessions rather than the laboratory screening of donor blood.

There are two aspects to this, firstly the donor selection criteria followed and secondly the processes in use on donor sessions to enable these selection criteria to be enforced.

NIBTS has always followed the UK guidelines for the Selection, Medical Examination and Care of Blood Donors. On appointment we were following the 1977 version, then 1982, 1987 etc. I do not have documentation to hand relating to subsequent versions. These guidelines were used to inform NIBTS donor selection processes and procedures on which blood collection staff were trained.

During the 1980s and 1990s all blood donation sessions 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 venepuncture. Updates to Medical Officers on any changes (e.g. selection criteria) were provided via circular letters and / or regular update meetings.

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

With the introduction of HTLV-III antibody testing in October 1985, donors were required to sign a statement indicating agreement to be tested and informed of the result and not being a member of a high risk group. At a later stage (I am unsure of the date) questionnaires covering all aspects of donor selection were introduced and required 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 (again I am unsure of the date) introduced for all donors.

Later still a change in procedure and staffing of donor sessions was introduced. This was to allow personal interviewing to be conducted by Medical Officers while venepunctures were being done by qualified nurses.

With respect to NANB Hepatitis, there had (from 1980) been relevant selection / exclusion rules e.g. relating to history of jaundice / hepatitis, IV drug use and other exposures to needles such as via tattoos, body piercing, acupuncture etc. These rules were refined and adjusted with each version of the national (NBS) guidelines and adopted by NIBTS accordingly.

111. **You were present at the Regional Transfusion Directors' Meeting on 9 April 1984 at which it was highlighted that high-risk groups should be discouraged from donating blood. To the best of your knowledge could you describe these categories of individuals and the steps the NIBTS**

took in order to dissuade them from donating? You may wish to refer to item 4C of CBLA0001836.

The statement is made in the context of HIV/ AIDS. So the categories would have been those listed in the AIDS leaflet at that time (see 107 above).

The method of using the AIDS leaflet on donor sessions is described elsewhere in this statement. In addition various initiatives were made to communicate the exclusion policy to relevant clinical staff and to the general public. On the former, I was an invited speaker at several AIDS update symposia for medical staff in NI. All opportunities were also taken to publicise and explain the policy to the public via the mass media.

112. **The Inquiry understands that the Department of Health and Social Security (DHSS) was to issue a list of categories of donors in 1985 that were at high risk of having AIDS and who should therefore not donate blood. In a letter you wrote in 1986 to the Royal College of Practitioners, you indicated that this policy had "been in operation for about 2 years" (NIBS0000030). Please explain your recollection of the policy, including how it was implemented by the NIBTS. Please also answer the following questions:**

The exclusion categories referred were those listed in the AIDS leaflet which had been introduced by 1983 and subsequently updated at intervals. The cornerstone of this policy was the use of the AIDS leaflet and self-exclusion and paralleled that in used throughout the UK. See para 68 on implementation.

a) **Was the decision to implement the policy taken by central government, or the NITBS?**

The policy was taken by central government.

b) As far as you can recall, did the policy have any noticeable effects? For example, was there a decrease in the number of donations testing positive for the HTLV III antibody?

As noted elsewhere the policy was associated with a marked reduction in donations testing positive for hepatitis B antigen. HTLV III antibody testing was introduced approximately two years after the exclusion policy (October 1985)..

113. How were decisions made within the NIBTS as to which donors were high risk and should be excluded from donating? What was your role in this process? Were these decisions reviewed and, if so, how often? You may wish to consider NHBT0003681.

These decisions were taken by a central government group (DOH London). The letter to Dr Gunson, 22 April 1988, would have followed a request from him to all RTCs to provide samples from donors who had visited West Africa since 1977. There was emerging evidence that this sub-type of HIV (HIV2) was mainly found in West Africa.

Decisions about risk categories were under constant review by DOH (London). My role was one of overseeing NIBTS implementation of these decisions.

114. Were there any difficulties in implementing the exclusion of high-risk donors at the BTC? Please explain your answer.

This is answered under para 68 above which refers to the use of the AIDS leaflet. As noted there were initial practical difficulties in sending this leaflet to donors in advance of the sessions (later resolved) which in any case could not be achieved with 'closed' sessions and for new and lapsed donors at any sessions.

There was evidence, hard to quantify, that the policy had an adverse impact on donation numbers. Despite efforts to compensate for this, e.g. expanding the number of donor sessions, it did at times lead to blood shortages.

115. What national guidelines (if any) informed the donor selection policies and processes at SLRTC? In the event that the SLRTC processes departed from any such guidelines, please explain how and why.

It is assumed this should be NIBTS. Apart from the new AIDS related guidance there were in existence national guidelines for the care and selection of donors. I am unable to remember the source of these guidelines or on whose authority these were issued. But these guidelines were followed strictly by NIBTs and incorporated into the training of blood collection staff including routine donor interviews and literature used on donor sessions.

116. What information (either written or oral) was given to donors about the risk of them transmitting infections via their blood? When was such information provided? In particular, was there a nationally agreed leaflet or did each RTC produce its own leaflet?

From 1983 the information provided was in the form of the AIDS leaflet provided by DOH (London). The method of using the leaflet is described in para 68. When HIV testing was introduced, donors were required to sign a statement stating they had read the AIDS leaflet and are not in a high-risk group, agreed to be tested and to understand they will be contacted in the event of a positive result.

117. How often were donor leaflets updated, and how was their content decided?

This was determined by DOH London.

118. How effective, in your view, were leaflets and other communications at reducing the risk of donations from high-risk individuals?

I believe the use of the leaflets was effective in deterring high risk donors from donating. See para 68 for evidence.

119. On 1 September 1983, the SHHD announced the publication of a UK-wide leaflet on AIDS and blood donors (BPLL0007247). What, if any, involvement did you have in the production of this leaflet?

I was not involved in the production of this leaflet.

120. In 1991, you wrote a letter to John McKeever, the then Development Officer at the Northern Ireland AIDS helpline, outlining the approach of the NIBTS in respect of donor selection (NIBS0000176). You noted (page 1) that at the ''health check interviews donors are not asked directly about high risk behavior but are asked to sign a statement indicating that they have read the AIDS leaflet and are not in high risk group" Please explain:

It was considered essential that a balance was struck between (1) imparting information to donors and potential donors effectively so that those at risk could exclude themselves and (2) avoiding being so direct and intrusive that individuals not at risk were deterred from attending donation sessions.

a) why this was the approach of the NIBTS at the time;

The letter would accurately describe the approach taken at that time.

b) whether you agreed with this as an approach;

I would have approved that approach at that time.

c) whether this was always the approach taken by the NIBTS. If not, when and how did things change, and for what reasons?

As noted above, the approach was an evolving one commencing in 1983 and as described in para 68 above.

Introduction of virally inactivated products

121. What role did you consider the NIBTS had (or should have had) in pushing for factor concentrates to be virally inactivated in the late 1970's and early 1980s? In particular, was the need for safe products raised by you or anyone else within the NIBTS with BPL and/or pharmaceutical companies (or anyone else) during this period? If so, please give details. If not, why not?

Viral inactivation of coagulation concentrates is a highly specialized field and leading scientists at PFC and BPL were engaged in finding ways in doing this as a top priority. Transfusion medicine doctors like me were not experts, so any scientific contribution we could make would have been minimal.

122. Could you please explain what role solvent detergent had on FFP and whether this process rendered the end product safer? You may find NHBT0003460 of assistance.

I have not received the letter in my pack from Dr Robinson to which I was replying. I know this product was developed and marketed by a commercial company (Octapharma). Solvent detergent was used to inactivate certain viruses (those with a lipid envelope) but did not inactivate all viruses. It was therefore an additional safety enhancement in the event that any donations escaped the screening tests in use. The product was made from donor pools but I cannot recall the size of each pool.

According to an annual report it is recorded that NIBTS started supplying this product to hospitals in 2006/07 issuing approximately 600 units per annum. Again, from the issue figures NIBTS continued to issue a significant quantity of standard FFP produced by the transfusion centre.

123. Did the NIBTS use solvent detergent FFP and/or methylene blue plasma? If so, please explain the advantages and disadvantages, in

your opinion, of both products. You may wish to refer to NHBT0041966_009 and item 1C of document NIBS0000404_005.

At this distance and without any available data to hand I am unable to make any comparison between these two products. I think MBT may have killed a similar range of viruses to Octoplas but not at all sure. MBT did have the advantage of being a single donor derived product and was suitable for manufacture by a RTC. From annual reports NIBTS began producing MBT FFP for use in neonates in 1998.

124. **On 20 October 1987 the Director of PFC, Dr R J Perry, informed you that for a short while the PFC could only supply NIBTS with Z8 that had been heated to 75 instead of 80 degrees because heating the product to the latter temperature had led to problems of solubility (NIBS0001753). In a similar but separate letter to Scottish Haemophilia Directors, Dr Perry stated that ''the decision to reduce heating conditions to 5 degrees has been taken to preserve balance between product safety (virus kill) and product solubility characteristics.'' Did you agree with Dr Perry's assessment that heating to 75 degrees balanced safety and solubility? Did the NIBTS accept this product? Please provide details.**

The point made para 121 about expertise applies here. Without satisfactory solubility the product could not be prepared for transfusion either by the hospital blood bank or by the patient at their home (home-treaters). It would also, probably, be less effective due to loss of Factor VIII activity.

Apart from this point, I would have had no basis to question the assessment made by PFC.

125. **In a letter dating to May 1986 and addressed to Dr R Maw, Consultant Physician at the Royal Victoria Hospital (NIBS0000046), you noted that ''some blood products which have been prepared from source plasma collected 3-4 years ago are still being issued. Whilst the highest-risk**

products are being heat- treated (probably effectively) some others are not." Please answer the following questions, as far as you are able.

a) **Was the '' plasma collected 3-4 years ago" unscreened? If so, what was the rationale behind using it?**

Plasma collected 3-4 years before this date could not have been screened for HIV or hepatitis C.

b) **which blood products were and were not being heat treated at this time? Please give as much detail as you are able, with particular reference to product type and the quantity or proportion of product which was unheated.**

I think I must have been referring to immunoglobulins – for both intramuscular and intravenous use.

c) **what was the rationale at this time for not heat treating all blood products?**

These products had an excellent safety extending back many years, even before source plasma could be screened for hepatitis B. So fractionators did not consider it appropriate to heat treat these products at this time. I believe in later years IV immunoglobulin was manufactured by techniques that reduced the risk of viral transmission but I do not have any details to hand.

d) **why did you consider heat-treatment to be ''probably" effective?**

This was at a time when methods of viral inactivation were still in evolution especially with regards to inactivation of hepatitis C (NANB). It was therefore not possible to state in absolute terms that heat treatment was completely effective in all circumstances.

e) **were you aware of any instances of infection following use of these heat-treated products?**

I do not have any data (from that time period) that would enable me to answer this.

Recall of unheated product

126. In terms of recalling unheated products, the English and Scottish blood services had differing approaches: BPL did not recall any unheated Factor VIII, whereas PFC recalled all of its Factor VIII for heat treating in January 1985. Please outline:

NIBTS would only have been involved in recall procedures for PFC Factor VIII and IX as these were supplied to the Regional Haemophilia Centre via NIBTS. We would not have been involved in the recall of commercial Factor concentrates.

a) the approach of the NIBTS as far as recalling unheated blood products. Were unheated blood products recalled en masse? Please discuss Factor VIII and Factor IX in particular.

NIBTS followed exactly the same recall process as that of SNBTS which would have been directed and coordinated with PFC.

b) If such recalls did take place, how were they affected? How much product was recovered?

I am unable to remember details of the process. It would have been carried out in conjunction with the Regional Haemophilia Director who would have been kept informed of the process to be followed by PFC directly (as well as by NIBTS).

c) Your opinion at the time in relation to recalling unheated blood products.

My opinion at the time was that the approach taken by SNBTS was appropriate.

Recall practice and procedure at the NIBTS

127. Please give an overview of product recall practice at the NIBTS, and how this changed during your tenure

This was a very carefully controlled process in coordination with hospital blood banks. I do not recall any details of the procedure but it would always have been managed by NIBTS QA department and been subject to audit by the MCA/MHRA.

128. What, if anything do you remember about any formal recall of notification procedures in place?

As noted above (para 127) I cannot recall any details.

129. In your opinion, were such practices and procedures effective? From your experience did clinicians generally comply with recall requests and if not, do you recall why not?

The most significant examples here were Factor concentrates used by the Regional Haemophilia Centre. As far as I recall this was always carried out effectively. The process was coordinated by the hospital blood bank at RHC which had tightly controlled procedures in place. I believe Dr Mayne and her colleagues at RHC would have fully complied with all requests.

Provision of diagnostic screening kits

130. Please describe the arrangements in place at the NIBTS regarding the provision of diagnostic testing kits for donation screening ('screening kits').

These required to be procured from commercial manufacturers. One exception I can think of was a hepatitis B test which was provided by BPL in the early 1980s. I do not recall much about the processes involved but these would have followed procedures required by the Area Supplies Service (part

of EHSSB). I do recall prior to HTLV III screening we would have had the opportunity to evaluate each of the available test in our own laboratory on a free trial basis.

131. **Did you, or anyone else at the NIBTS, contract directly with any pharmaceutical company involved in the manufacture and/or importation and/or sale of screening kits, or were contracts negotiated on a national basis? You may find NHBT0000188_039 of assistance.**

I do not remember there being national (UK wide or England/ Wales) contracting arrangements at this time to which NI could join. The main individuals involved in the contracting process would have been the head of microbiology testing laboratory (NIBTS), administrator and supplies officer (Area Supplies Service).

132. **What were the key factors influencing choice of screening kit and/or pharmaceutical provider?**

These were (a) sensitivity and specificity (as technically defined) (b) ease of use and compatibility with existing laboratory processes and (c) cost.

Introduction of HIV testing

133. **In a letter you wrote on 31 January 1985, you mentioned the cost implications of introducing HTLV III testing to the NIBTS (RHSC0000042_093). Please expand on your comments, in particular whether financial constraints delayed the implementation of HTLV III testing in the NIBTS?**

The timing of implementation (October 1985) was in parallel with all other RTCs in the UK and was not delayed by financial constraints. In the first instance this was achieved by using existing resources of staff. There was an inevitable lead time with the appointment of staff.

134. **Please explain:**

a) **whether the Regional Virus Laboratory was or is located Northern Ireland: and**

The RVL referred to was located in NI (Royal Victoria Hospital, Belfast)

b) **why the NIBTS began Anti-HIV testing in October 1985, 6 months after the Regional Virus Laboratory. You may wish to refer to page 2 of WITN3082020.**

The RVL was a diagnostic laboratory and as such would have been testing samples (in small numbers) from patients suspected of being infected with HIV and therefore with a relatively high incidence rate of positivity. This is very different from the mass screening of very large numbers of samples from donors which had a low likelihood of being positive. Diagnostic virology laboratories were thus able, throughout the UK to begin HIV testing in early 1985 but mass screening by RTC had to await the completion of the necessary evaluations, pilot studies, confirmatory tests etc.

Also noteworthy is that there was a real risk and concern that RTCs would act as a magnet for individuals attending in order to obtain a test, hence the importance of having an alternative testing laboratory for HIV in place.

135. **In a letter to Dr Darragh at the EHSSB in August 1985, you wrote 'if the mid-October deadline for commencement of (the AIDS testing programme) is to be met it is imperative that immediate steps are taken to appoint the laboratory staff [...] and that funds are released to enable purchase of the capital equipment" (RHSC0000042_072). As far as you can recall, were staff and funding obtained in time to commence testing in October 1985? Please provide details.**

HTLV antibody screening of all donations at NIBTS did commence by October 1985 in line with the rest of the UK. The necessary equipment would have been funded and commissioned to enable this to happen. I cannot

recall timescales for appointment of additional staff but it did happen around this time.

136. **On 25 October 1985, a representative of the DHSS, Dr Alison Smithies, asked you to test remaining stocks of blood and blood components sent to blood banks or stored at NIBTS and blood components sent to blood banks or stored at NIBTS for Anti-HTLV III (DHSC0000481). This was because there had been considerable public and UK parliamentary concern about blood and blood products not being tested for the infection and ministers needed assurances 'that no untested blood or blood components are being given to patients'. Was all blood and blood products distributed by the NIBTS tested for the HLTV III antibody from 25 October 1985? If not, what date did this begin?**

I believe we took appropriate action to comply with this request. I do not have information to hand as to how exactly we did this but I presume that information would be available in my reply to Dr Smithies.

137. **In a letter you wrote to Mr Damien McNeill on 19 July 1991 you described screening for HIV type 2 as "more complicated (additional steps) than HIV-1". Please explain your views. You may find NIBS0000194_006 of assistance.**

This variant of HIV, prevalent in parts of West Africa would sometimes have been missed by the existing tests for the much more widely distributed HIV 1. Although rare in the UK, it was decided to enhance the test system so that the antibody to HIV 2 could be reliably detected. I cannot remember much about the technical details beyond what is mentioned in the letter.

138. **Please describe the implementation of HIV screening within the NIBTS. In particular:**

a. **What was the process for screening donors and/or blood donations?**

In the absence of relevant documentation, what follows is an outline of the process as far as I can recall.

The introduction of routine anti HTLV 3 screening was accompanied by an information and consent process for each donor. Thus donors were required to sign a statement to the effect that:

(i) They had read the AIDS leaflet and were not in a high risk group.
(ii) A blood sample would be tested for AIDS antibodies.
(iii) In the event of a positive result they would be contacted by a doctor from NIBTS.

In the laboratory any donor samples that produced a reactive result with a screening test (above the cut-off) resulted in the test being repeated twice and if two or more tests were found to be reactive this was considered a positive result. In this case samples would be taken from the blood bag for further testing by the same method. Any blood components prepared from the donation would be quarantined (at the first positive result) and if repeat reactive the components would be destroyed (by autoclaving).

Samples from this (initially positive) donation were then sent to a reference laboratory in England (PHLS I think) for confirmatory testing. Tests here would include repeat screening tests and a Western Blot test.

For management of confirmed positives (see 138 D below).

Donors found reactive but not confirmed (the vast majority) were kept on the donor panel but had their records flagged. They would be invited to attend the next donation session but although blood would not be used to make components all routine tests would be performed. If negative for HIV blood from the following donation could be used with their components (if still HIV negative).

Donors who gave reactive results but confirmatory test negative on repeated occasions were, after a certain number of such occasions (I have forgotten

the number) were written to with an explanation of why their blood could not be used and advised not to attend in future.

b. What impact did the introduction of HIV screening have on the NIBTS?

This was not possible to quantify but as far as I recall there was an impression, among my donor admin and recruitment staff that AIDS generally and its association with blood transfusion may have a negative effect on donor attendances.

c. What happened to all the unscreened blood that had been collected prior to HIV screening being implemented?

For each type of blood component there had to be a cut-off date for this. I recall that every effort was made to ensure that by the official start date (14 October 1985) any blood component issued from NIBTS had been tested. I cannot remember the details but this would have been achieved by commencing testing at some point before the official start date which would have enabled components with a relatively short shelf-life to have been tested by the 14th October (red cells and platelets). For long shelf-life components FFP and Cryoprecipitate destruction of any unscreened units would have been required. I cannot recall in detail how we managed this but it would have involved judgments based on continuity of supply for each component set against safety considerations.

d. What happened when a donation was found to be infected with HIV? Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor. You may wish to refer to item 3A of NIBS0000061.

If found to be positive on confirmatory testing the donor was written to by a medical Consultant and invited to attend the Transfusion Centre for a discussion / initial counselling. At this visit a blood sample would be taken with a view to confirming the results. Issues covered at this meeting and at follow-up visits would include clinical implications of the results, transmissibility of the infection, possible risk factors and an assessment of the possible date of exposure to infection. Confirmed positive donors were encouraged to be referred to one or other of the two Consultants in Northern Ireland who had developed a special interest in the clinical management of Aids and with the donors consent, to have their GP informed of the result.

With respect to passing information to third parties, as far as I remember some information was provided to the CDSC but to protect donor confidentiality a coded system was used.

With respect to previous donations from a confirmed positive donor, a look-back process was followed from the outset. Given the rarity of such an occurrence a relatively informal and ad-hoc process was followed. This would have involved contacting the haematologist in charge of the hospital Blood Bank, providing them with donation numbers of any previous components issued to the hospital and advice on the importance to trying to identify recipients in conjunction with the clinician involved. Further action would then have been taken by the clinician responsible for the patient.

139. The Inquiry understands that you were present at a meeting of the Scottish Transfusion Directors on 12 May 1987 at which it was recorded that the Directors had decided that "it was not appropriate to commence routine HIV antigen screening" (PRSE0000633). Could you please explain the rationale for coming to this view?

From materials provided, this was referred to, in passing, at a meeting I attended on the 10th June 1987 but the decision was taken by the SNBTS

coordinating meeting on the 12th May 1987 which I did not attend. This test was being developed as a means of trying to reduce the "window period" for HIV antibody testing i.e. the period between exposure to HIV and the test becoming positive. I assume that the SNBTS Directors would have judged that at the time this test would not have resulted in a significant reduction in the "window period" and thus would not justify the costs involved.

140. Please clarify whether blood products sent from PFC to NIBTS after November 2002 were tested for HIV using a stricter ("combi") testing kit. You may wish to refer to NHBT0088306 in answering this question.

The issue here is again related to the "window period" referred to under para 139 above. The Combi Test was designed to detect HIV antigen and HIV antibody in a single test. As far as I know NIBTS did not introduce the Combi Test at this time but along with SNBTS introduced, during 2003 an additional test for HIV RNA (using HIV NAT technology). At this time NAT testing (for HCV and HIV) was outsourced to SNBTS to which batches of samples were sent each day for testing.

141. What was your opinion of surrogate testing as a potential method of donor screening, and how did this change over time? Please comment on each infection with reference to specific surrogate tests for:

a. HIV;

In relation to HIV I have no recollection of any tests that would have been seriously considered as likely candidates for surrogate testing of donors.

b. NANB/HCV.

I was well aware of the debate, in general terms, about the pros and cons of surrogate testing, namely ALT testing and anti-hepatitis B core. However, I was far from being an expert and would have had to defer to those who were and in government departments who would have had access to all relevant and up to date information.

I think I felt that appropriately controlled and large scale clinical trials within the UK would have been very important to enable an assessment of the benefits of surrogate testing and that this was lacking. We did know it would have involved a significant loss of donors / donations and entail complex issues around the provision of advice to excluded donors.

I was aware of studies in the US (and possibly elsewhere) which were able to quantify the benefits of surrogate testing (at least at a particular point in time) but from what we knew about NANB hepatitis there seemed to be wide variations in the incidence geographically and thus of the likely benefits of surrogate testing.

142. **At an SNBTS Directors meeting on 3 March 1987, the Directors agreed to "recommend to the SHHD that surrogate testing for NANB should be implemented with effect from 1 April 1988 as a national development requiring strictly new funding. Each Director should let Dr Cash know what funds would be required in his/her region, assuming that both core testing and ALT would be undertaken in the Transfusion Centres" (PRSE0004163). Please expand on the following:**

a. **How this recommendation was taken forwards to SHHD;**
b. **What response was anticipated from SHHD;**
c. **What response was received from SHHD;**

a to c. I cannot really answer these questions other than that I understood that the bid was not approved by SHHD.

d. **Whether surrogate testing (namely ALT or anti-HBc testing) was introduced at the NIBTS during your tenure;**

Surrogate testing for NANB hepatitis was not introduced during my tenure. The reference to its introduction in the NIBTS operational plan for 1989-90 (written 3rd November 1988) was based on an emerging anticipation of it becoming a UK-wide requirement at that time but this did not come to pass.

e. **If so, whether this had any impact on the NIBTS;**
f. **How the surrogate testing was performed;**
g. **What the process was for screening donors and/or blood donations;**
h. **What, if anything, happened to the unscreened blood that had been collected prior to surrogate testing being implemented; and**
i. **What happened when a donation tested positive. Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.**
You may wish to refer to RHSC0000066_031.

e to i. In view of the above these questions are not applicable.

143. **In July 1987, many SNBTS Directors wrote to the Lancet to state that surrogate testing was "inescapable." They stated that "no large study to answer this critical question has yet been presented, and we agree that the size of the benefit to be gained from surrogate testing cannot be accurately established without such a study. However, the time for this study has already passed" (PRSE0001444). Were you aware of this article? If so, did you agree with the reasoning provided in this article? If not, why not?**

I would have been aware of this article. The reference to surrogate testing being 'inescapable' seemed to be related to:

(i) Concerns about the impact of legislation on product liability
(ii) Issues around competition with suppliers of commercial plasma products which may have posed a threat to PFC.

The first point revolved around the legal interpretation and I would not have been in possession of any independent legal advice on this.

My main concern would have been the benefits to safety of blood transfusion in Northern Ireland. I do not think I would have been convinced of the benefits in the absence of the necessary studies, as per 141b above.

144. **A report prepared by Dr Gunson in August 1987 set out the conclusions of a Working Group established by the Council of Europe Committee of Experts on Blood Transfusion and Immunohematology to consider the introduction of routine surrogate testing ("the Working Group report") (NHBT0008816_002). The Working Group concluded it could not provide a recommendation on the introduction of surrogate testing in light of the following considerations:**

a. **the use of surrogate tests to reduce the incidence of transfusion associated non-A non-B Hepatitis (NANBH) and its possible value as a public health measure remained controversial;**

b. **there was no guarantee, in a given country, that there would be a significant reduction of NANBH;**

c. **the introduction of surrogate testing in some countries could lead to a severe depletion of donors which could compromise the blood supply; and**

d. **if surrogate testing was introduced, provision would have to be made for interviewing, counselling, medical examination and treatment of anti-HBc positive donors and donors with raised ALT.**

Please advise whether you were aware of the Working Group report. If you were, did you agree with the conclusions reached by the Working Group? If not, why not?

I would have been aware of this report. I think the conclusions would have been a fair summary of views at the time. In particular I would have agreed with the requirements for each country to assess the likely risk or benefits of surrogate testing which would have required the carrying out of appropriate clinical trials (see 141b and 143 above).

145. **If surrogate testing was introduced by the NIBTS, please explain what impact this had on the Service. In particular:**
   a. **How was the surrogate testing performed?**
   b. **What was the process for screening donors and/or blood donations?**
   c. **What happened to the unscreened blood that had been collected prior to surrogate testing being implemented?**
   d. **What happened when a donation tested positive? Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.**
   e. **What were the circumstances in which the NIBTS stopped surrogate testing?**

As noted in 142d above, surrogate testing was not introduced by NIBTS (so questions a to e are not applicable).

146. The Inquiry understands that you were present at a meeting of the SNBTS Medical and Scientific Committee on 18 May 1994 at which it was discussed that the Standing Advisory Committee on Transfusion Transmitted Infections had decided to re-evaluate whether donations should be tested for anti-HBc. Could you please explain the difference between this type of test compared to anti-HBsAg, for instance whether it is more reliable/accurate and whether core testing was adopted after this re-appraisal? (PRSE0003685)

From the minute this issue was not actually discussed but merely noted as something SACTTI intended to revisit. It should be noted that the test for carriers of the hepatitis B virus was for hepatitis B surface antigen (HBSAg) not anti- HBSAg – positivity for the latter actually implies immunity to the hepatitis B virus (depending on the titre.

There was a debate later as to whether testing for anti-hepatitis B core antibody as an additional test to that for HBSAg (not instead of) would result in the detection of some hepatitis B carriers missed by HBSAg alone.

Later a major study (published in 1999) was carried out in the UK and this is discussed at length by Dr L Williamson (WITN0643001) and Dr P Hewitt (WITN3101006) in their statements to the Inquiry.

147. You were present at another meeting of the SNBTS Medical and Scientific Committee on 10 November 1994 at which it was stated that the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) had concluded that ALT testing "had nothing to do with blood safety". During the meeting it was noted that this issue was a policy decision for ministers to consider and that

"all 4 will have to agree to proceed with ALT testing before it can be introduced" (section 5(i) STHB0000684):

a. **What did you understand about the reasons why the MSBT considered that ALT testing had nothing to do with blood safety?**

I am unable to say what MSBT membership might have meant by the expression "nothing to do with safety".

b. **Was ALT a reliable/effective marker for detecting the presence of NANB in your view?**

I have given my views on this (surrogate testing) in paras 141, 143 and 144 above.

c. **Was a political decision made to introduce this form of surrogate testing?**

I have seen documentation indicating that BPL introduced ALT testing and that this was influenced by this test becoming standard among the main commercial manufactures of plasma products. Perhaps this was justified as it was still considered important to encourage the usage of Factor 8 etc. that was manufactured from UK non-remunerated donors. Other than that point I am unable to make any comments.

Hepatitis Testing

148. **On 25 September 1980 you wrote a letter to Dr Lane at BPL stating that you were going to introduce R.I.A. for hepatitis testing of FFP (CBLA0005101).**

a. **Could you please describe what steps led you to this decision and whether this decision was taken in coordination with other UK blood services?**

Until 1981/82 NIBTS used an RPH assay for hepatitis B screening. RIA was a somewhat more sensitive test but relatively expensive from commercial suppliers of the test. BPL undertook to produce this test for use by RTC's and I believe at a competitive price and NIBTS in common with most UK RTC's (I think) adopted it. Around this time NIBTS established links with PFC for plasma fractionation which required RIA as a method of hepatitis B screening. NIBTS continued to use RIA until 1993 when we switched to an ELIZA method which was equally sensitive, avoided the use of radioisotopes and as far as I remember was no more costly.

b. **Was R.I.A testing for hepatitis of FFP introduced?**

Hepatitis B screening by RIA was used for all blood donations which therefore included FFP.

c. **Could you please also explain what impact this decision had?**

As noted above it was a requirement to comply with PFC policy. Although a more sensitive test than RPH I do not recall that NIBTS ever detected a positive for hepatitis B that would have been missed by the previous RPH method.

149. **In June 1980, you were present at a meeting of Regional Transfusion Directors, at which the Directors were informed that BPL's RIA test would be delayed due to Burroughs Wellcome developing their own RIA (SBTS0000290_004). Some RTDs wrote to their Regional Treasurers**

to protest this (CBLA0001261). Ultimately, BPL RIA was not rolled out to RTCs until March 1981.

a. What was your view on this delay at the time?

As far as I remember NIBTS was not affected by the delay because we would not have been in a position to commence testing using it until after March 1981. This was related to the completely new (to NIBTS) technology involved which required the use of radioisotopes. This in turn involved the creation of a new microbiology testing facility at NIBTS – incidentally this proved fortuitous as a few years later we were able to take on HIV testing within the same, larger space.

b. Did you contact your Regional Treasurer on this issue? Are you aware of anyone else doing so?

I do not recall raising this with our treasurer (EHSSB). Any extra cost involved in this area would have been covered by a package of funding to cover the self-sufficiency strategy.

150. On 30 November 1988, you authored an operational plan in which you stated that NANB hepatitis screening would likely become mandatory between 1989-90 (item 3 RHSC0000066_031). Please could you confirm if and when screening became mandatory and how such screening was undertaken (for example, by way of measuring ALT markers)?

This summarised annual plan to EHSSB included a bid for ALT testing. The latter was anticipated in view of developments within NBS and SNBTS which indicated ALT testing was likely to become mandatory, hence the pilot study carried out by NIBTS. However this was not proceeded with. Soon after the position was superseded by the announcement by Chiron Corporation of the

discovery of a viral agent (Hepatitis C) which seemed likely to be the cause of at least a proportion of NANB cases.

151. When did the NIBTS begin anti-HCV screening? Document LOTH0000181 suggests that HCV testing may have been implemented from 1 July 1991 at all SNBTS RTCs. Did this take place and did it include the BTC?

In keeping with the national decision at Health Department level (by DOH, SHHD and DHSS (NI) and at BTS level (NBS, WBS, SNBTS, NIBTS) this was 1st September 1991.

The question refers to a document indicating an SNBTS start date of 1st July 1991. The document provided to me is actually a report for 1984/85 so a mistake appears to have arisen here.

However I have two comments:

Firstly I am aware that the Glasgow RTC was one of the UK centres engaged in the evaluation of available screening tests and that evaluation would have continued into the start of routine testing. Secondly, many centres in order to ensure that all or most components in stock were screened by the official start date would have commenced testing on an earlier date. As far as I recall NIBTS also did this but I am unable to remember details nor have I seen relevant documentation.

152. Please explain the role of HCV confirmatory testing using Recombinant immunoblot (RIBA-2) in Northern Ireland. When and by whom was such testing introduced? You may wish to refer to SBTS0000012_033.

Any donor sample found to be a repeat reactive on a screening test (ELIZA) required to be sent to a reference laboratory for further confirmatory analysis. For anti-HCV testing this involved the use of a recombinant immunoblot test

(RIBA). Positives for RIBA were further tested by a PCR test. NIBTS requested the hepatitis reference laboratory in Glasgow, under Dr E Follett to provide this service – on a contract basis. This arrangement would have commenced in parallel with the commencement of anti-HCV screening in September 1991.

153. What impact did HCV testing have on the NIBTS? In particular:

a. What was the process for screening donors and/or blood donations?

In the absence of relevant documentation this is an outline of the process as far as I can recall it.

Process. Screen positive samples would result in the corresponding blood components being quarantined. If repeat reactive (in at least two out of three tests) the components would have been autoclaved and then discarded. Prior to this the screening test would be repeated on samples drawn from the blood bag. Repeat reactive samples would be sent for confirmatory testing as described in para 152 above.

b. What happened to all the unscreened blood that had been collected prior to the HCV testing being implemented?

As far as I recall this would have been managed in a similar way to that described for the introduction of anti-HIV screening (para 138C). Thus I recall every effort was made to ensure that by the official start date (1st September 1991) any blood component issued from NIBTS had been tested. I cannot remember the details but this would have been achieved by commencing testing at some point before the official start date – would have enabled components with a relatively short shelf life to be tested by 1st September 1991 (red cells and platelets).

For long shelf life components e.g. FFP, Cryoprecipitate, this would have required destruction of any unscreened units. I cannot recall in detail how we managed this but it would have involved a judgment based on continuity of supplies for each component against safety considerations.

c. **What happened when a donation tested positive? Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.**

The process followed would have followed a similar course to that described for anti-HIV testing. Thus, if found to be positive on confirmatory testing the donor was written to by a medical Consultant and invited to attend the Transfusion Centre for a discussion/initial counselling. At that visit a blood sample was taken with a view to confirming the result.

Issues covered at this visit and / or a follow-up visit would include clinical implications of the results transmissibility of infection, possible risk factors and assessment of possible date of exposure to infection. Confirmed positive donors were encouraged to be referred to one or other of two Consultant Hepatologists and with their consent to have their GP informed of the results.

With respect to identifying recipients of previous donations the initial approach differed from that undertaken when HIV screening was introduced. So in keeping with DOH/DHSSNI policy look-back was not introduced until 1994 when it was launched as a formal policy and followed a standard process. The latter was coordinated nationally by Dr A Robinson, NBS and for NIBTS by Dr C Bharucha in conjunction with Consultant Haematologists in charge of each hospital blood bank. The results of the lookback were published by Dr Bharucha and Dr K Morris (as the first completed regional lookback in the UK).

Donor information to third parties; as far as I can recall as with HIV positives some information was passed to PHLS/CDSC but to protect donor confidentiality a coded system was used.

154. You were present at a meeting of the SNBTS Medical and Scientific Committee on 16 May 1991 at which it was discussed that the "NIBSC would prefer that anti-HCV donations should be excluded from plasma pools" (PRSE0002912, page 5). Please could you explain whether positive HCV donations were being included in plasma around this time.

Regrettably, from the minute I cannot really understand the point at issue here (as in 155 below). Obviously all anti-HCV positive units of plasma would be excluded once screening became fully implemented but this seems to refer to an interim period, shortly before full implementation. By this stage (1991) I believe viral inactivation methods would have been effective in producing safe plasma products of all types. I think this is an issue for fractionators to answer.

155. At the same meeting it was suggested that "even with several anti-HCV positive individual units included in a plasma donation neither the pool or the final product would likely to show up positive assay; positive donations would be diluted" (PRSE0002912, page 5). What did you understand was meant by his statement?

I presume this is a statement of fact that in plasma pools of several thousand units the presence of a single or even two to three anti-HCV positive units would probably not be detected by available tests due to the high dilution factor. The same would apply to the final product. It is not clear to me what the significance of this statement is – if for example it is a reason for not excluding these units from the pool.

156. Please confirm whether the NIBTS was testing anti-D immunoglobulin and other plasma for HCV at source before the end of December 1992. If not please confirm whether, in light of the Committee of Safety of Medicines' position, these products had passed their quality release tests before manufacturing. You may wish to refer to item 3.4 of NHBT0071593_001.

All anti D plasma (and other immune plasmas) collected by NIBTS from 1st September 1991 would have been tested for anti-HCV as would have been the case in the other UK RTCs. The issue here would relate to stocks of this very valuable plasma that was collected prior to September 1991 and which even by December 1992 (as per the minutes) had still not been fractionated. The decision by CSM would I assume have been influenced by the excellent safety record of anti D immunoglobulin with no instances of hepatitis caused by either the BPL or PFC products.

157. To the best of your knowledge and referring to section 4.7.1 of SBTS0000450_010 were hyperimmune immunoglobulins made from non-HCV tested plasma banned from being released after 1 January 1993? If not, why not? When was all plasma for the production of blood products screened for HCV?

I cannot answer the specific questions posed here – referring to dates. I would speculate that insofar as non-HCV tested plasma may not have been banned from release after 1 January 1993, the same general point in 156 above is relevant, namely that these specific immunoglobulins all had an excellent safety record, even when manufactured from plasma untested for hepatitis C and indeed I believe for hepatitis B before that. It seemed that the PFC manufacturing process itself resulted in the removal of the viruses.

158. You were present at a meeting of the SNBTS Medical and Scientific Committee on 9 March 1993 at which it was stated that PFC had lodged an application "for continued use of anti-D IgG made from non-HCV screened plasma". As far as you recall please confirm:

a. Whether this application was successful;

The minute does not give dates for which the approach was made. In any case I do not recall the outcome.

b. If so, how long did PFC continue issuing anti-D IgG made from non-HCV screened plasma;

Again I cannot recall the answer but as for 158a above this should be readily available from the records.

c. Whether NIBTS submitted non-HCV screened plasma to PFC; and

As noted above (156) all plasmas submitted to PFC from NIBTS would have been screened for anti HCV following the September 1991 start date.

d. Whether NIBTS received and issued anti-D IgG made from non-HCV screened plasma from PFC?

All supplies of anti D from PFC would have been in compliance with regulatory requirements with respect to screening etc. that applied at any material time.

Please refer to section 4.7.4 of STHB0000677 for reference.

159. On 10 October 1995 you were present at a meeting of the SNBTS Medical and Scientific Committee at which it was reported that HCV had been transmitted by an intramuscular immunoglobulin and that the FDA had "introduced a requirement that all such products which had not been subjected to a viral inactivation process should be tested prior to release for HCV RNA by PCR". Furthermore, it was anticipated that the Committee for the Proprietary Medicinal Products would adopt this policy, which would "affect PFC's specific immunoglobulin products, possibly by 1 Jan 1996" (STHB0000687). As far as you are aware:

I think the minute here should have read intravenous immunoglobulin and not intramuscular Ig - the Baxter product, Gammagard was an IV product. There is a difference between IM and IV immunoglobulin with respect to hepatitis transmission. Hepatitis transmission by the IM product to my knowledge was rare.

a. At this time were immunoglobulins blood products (i.e. not recombinant)?

Immunoglobulins were blood products (not recombinant).

b. At this time, was PFC issuing blood products such as immunoglobulins which had not been virally inactivated? If so, were these received and issued by the NIBTS?

As far as I recall, the PFC IV Ig was virally inactivated at this time.

160. You were a member of SNBTS Medical and Scientific Committee in the early 2000s. The Committee discussed whether routine anti-HBc screening should be introduced as a risk reduction measure (PRSE0000874). Other committees such as SACTTI and MSBT also discussed this matter from the early 1990s into the early 2000s (e.g. MHRA0020214 and JPAC0000089_020).

a. What do you recall about the arguments put forward, both in favour of and against the introduction of routine anti-HBc screening?

During much of the 1980s this was mainly under consideration as a surrogate marker for NANB hepatitis but was superseded by anti-hepatitis C screening. Following the introduction of the latter its use was under consideration as a means of detecting the very occasional carrier of hepatitis B that was missed by HBsAg screening – so called "tail end" cases. The arguments are fully discussed in Dr L Williamson's statement (WITN0643001) – the latter including an important study (1999) which did show a very small number of additional hepatitis B carriers would be detected if anti-HBV screening was added to HBsAg screening. While being revisited from time to time by various advisory committees (JPAC, MSBT). As far as I recall it was not supported for reasons related to cost effectiveness. Among fractionators there was even an argument that removal of anti-HBV positive units from plasma pools might actually increase the risk of hepatitis B associated with plasma products. However, by the 1990s I understand that viral inactivation methods had become effective enough to prevent such a risk.

b. **What was your personal view on this issue? Did this change over time? If so, how?**

Clearly the arguments for and against the introduction of anti-HBc screening were complex and finely balanced and even among the experts there may well have been different views. As a non-expert, I was not in a position to reach a definite conclusion or to disagree with the conclusion that anti HBc screening was not justified by the evidence.

c. **In your view, why was this issue revisited so often by the committees without a final decision? Do you feel that this continued reassessment was appropriate?**

I think my views on this are covered by the points made in 160a above.

Autologous blood transfusion

161. **On 23 September 1987, you wrote a memorandum on the viability of introducing autologous transfusion ("AT") within the NIBTS, in which you explored respective logistical and cost implications (NIBS0000091). You stated that "there is a danger that the existence of an AT programme could lead to an exaggeration of the risks of ordinary blood transfusion. This in turn may lead to an undermining of confidence in the safety of blood transfusion for the majority of recipients." Could you please state when autologous transfusion became available within the NIBTS and what effect, in your opinion, this had on the public's perception of regular blood transfusions?**

I cannot recall much about this memo, although I assume it was submitted to EHSSB as a bid for funding. If so, it was not approved. Incidentally, the reference to "exaggeration of risks etc." was not necessarily a personal view but simply part of a listing of identified pros and cons of AT.

NIBTS did not during my tenure provide an AT service on any remotely significant scale so there would have been no significant impact on public perception of regular blood transfusion.

At a later date (1990s I think) stimulated by the CMO's Better Blood Transfusion Initiative, NIBTS did offer the service (pre autologous deposit type) and it was included in the NIBTS user guide for hospitals. However, the uptake was never other than minimal. In practice it was only really used for bone marrow donor volunteers, selected to donate –only about two to four per annum. Even this would have reduced as the method of collection changed from bone marrow harvest to blood stem cell collection.

162. At a meeting of the Northern Ireland Advisory Committee on Blood Safety held on 6 September 2001, a report from the Autologous Blood Transfusion Working Group was circulated (BHCT0000143). In this report various transfusion methods were assessed for feasibility, including autologous pre-donation, inter-operative cell salvage, and acute normovolaemic haemodilution (ANH):

a. How did this report impact upon the usage of these autologous transfusion methods?

As far as I know, of the three methods the only one that became established in clinical practice was intra operative cell salvage, albeit on a very small scale and probably limited to vascular surgery. This would have been beneficial in limiting blood exposure to the individual patients involved but would have had no significant impact on overall blood usage. I do not think PAD was continued into routine use at Musgrave Park Hospital.

b. **The report noted that ANH "proved extremely difficult to implement" but that "the majority of patients did not meet the inclusion criteria**

suggesting that a more appropriate population should have been studied." In light of this, were any further studies done on ANH to reassess its feasibility?

Regarding ANH, I cannot recall if any further progress was made in this area. My Consultant colleague Dr Morris was responsible for hospital liaison and would have been much more aware of this although NIBTS would not have had responsibility for that area.

c. **Do you believe that these autologous transfusion techniques could have been implemented on a larger scale earlier, in order to reduce the risk of disease transmission? How early do you think these techniques could have been utilised?**

Our experiences of trying to implement or pilot these technologies demonstrated that there were so many practical disadvantages as to preclude their use on a large scale.

d. **Why, in your opinion, were autologous transfusion techniques not used as frequently in the UK compared to other countries such as the USA?**

As it turned out, a much more effective approach to limiting exposure to blood transfusions was to reduce the threshold for patients to receive blood. This approach followed the publication of results of controlled clinical trials. For example, operative procedures, previously requiring cover with one to two units of blood routinely seldom required any blood transfusion. As a result of many similar initiatives total blood (red cells) usage steadily decreased – by at least to ten to fifteen percent.

As for AT in other countries, I was not sufficiently familiar with actual practice internationally to give a meaningful answer to this question.

Recombinant products

163. The Inquiry understands that you were present at a meeting between NIBTS and PFC on 18 December 1998 at which it was stated that "Although it is planned to change to all recombinant FVIII in Scotland before mid-1999 there are no similar plans in NIBTS." Please could you explain whether the NIBTS procured recombinant FVIII from PFC and why the NIBTS was not planning to treat all patients with recombinant FVIII before mid 1999? Please refer to NIBS0001602.

NIBTS did not procure recombinant products from PFC as PFC did not manufacture recombinant products.

Decisions about transferring all patients on to recombinant Factor VIII would have been dependant on negotiations between the Regional Haemophilia Centre and EHSSB/DHSS NI who provided the funding.

164. When were all haemophilia patients given access to recombinant factor concentrate products in Northern Ireland?

I cannot recall when all haemophilia patients were given access to recombinant factor concentrates in NI.

General

165. Please describe all other steps or actions taken by the NIBTS during the time you worked there to ensure blood safety and to reduce the risk to recipients of blood or blood products of being infected with a transfusion transmitted infection.

Those that I can recall are listed below and explained very briefly.

i. Cytomegalovarus (CMV). Provision of CMV antibody negative blood components for selected patients i.e. neonates and severely immune-suppressed patients e.g. bone marrow transplant recipients – early 1980s, later becoming mandatory.

ii. Bacterial contamination/infection in components. Risk reduction measures included:
   - Routine bacterial testing of platelets. These were the highest risk components due to storage requirements –around 2004
   - Sample diversion techniques during blood donation.

iii. T cell leukaemia virus (HTLV1/2) – routine screening – 2002.

iv. Nucleic Acid Testing (NAT) testing – HCVRNA (1999) and HIV RNA) (2003).

v. Malaria antibody testing – selected donors based on travel history.

vi. Donor selection – a range of precautions in keeping with UK Guidelines (Red Book) and JPAC Guidelines.

vii. Use of selected donors to prevent transfusion related Lung Injury (TRALI) - 2004

166. Was blood safety ever subject to cost, time, staffing or any other constraints? If you felt a particular course of action needed to be taken to ensure blood safety, were you free to take it?

I cannot recall any specific example where an agreed or mandated UK wide safety precaution (transmissible infection related) was constrained due to lack of or delay with funding. My impression was that DHSSPSNI always took the view that in these areas they were in no position to second guess national decisions and that funding had to be found. Other safety precautions mentioned under 165 above e.g. bacterial testing of platelets, CMV testing, (non-mandatory at the time) were self-financed.

An important, more general exception to the above was in the area of general environmental and quality standards because the building occupied from 1970 to 1995 became increasingly unsatisfactory for a Regional Blood Transfusion Service. From the time when I became Director in 1980, while there was an acceptance of the need for a new building, we were faced with a total moratorium on any major new capital developments within the Health Service in NI and this continued for many years. Input from the Medicines Inspectorate helped to break the impasse by declaring that NIBTS would not receive a manufacturing licence while still occupying the previous facility. Issues relating to agreement on a site caused some further delays but eventually we were able to relocate to the new purpose designed centre located in the campus of one of the two main teaching hospitals in Belfast.

167. To what extent were you and other RTDs reliant on the decisions of other bodies (advisory committees, directorates, SNBTS, NBTS, SHHD, DHSS) to achieve blood safety? Who or what was responsible for defining what constituted safe blood? What happened if your own opinion conflicted with the decision or advice of that person or body?

NIBTS was heavily reliant on other bodies with respect to major safety issues. In the pre-AIDS era we seemed to have considerable autonomy in our operations but, unsurprisingly, with the onset of AIDS our policies and practices on e.g. donor selection, testing, look-back etc. were determined by decisions taken by DOH (London). The same applied to hepatitis C testing and later vCJD. In these major areas I had a clear understanding (from DHSS NI) that we would be required to follow nationally determined decisions and time scales.

In the case of plasma fractionation there was an obvious reliance on the fractionators – in our case PFC/SNBTS.

NIBTS inevitably was required to apply the same standards with respect to the quality and safety of source plasma and hence of donor selection/testing.

With respect to finished products, there were occasions (dealt with elsewhere in this statement) when the needs of PFC/SNBTS took preference over NIBTS when these came into conflict. Many of the bodies on which NIBTS was reliant I looked upon in a positive light.

The MI/MHRA inspection system (starting 1982) enabled us to develop increasingly rigorous quality management systems such as those applied to the pharmaceutical industry. The JPAC system was / is an excellent system by which quality standards in all aspects of transfusion were continually reviewed and updated by the leading experts and this was greatly facilitated by the revolution in communication. Through these means NIBTS became more directly involved in the decision making process e.g. by membership of JPAC and its Sub-Committees and later of the UK BTS Forum which had an oversight role in relation to JPAC.

Section 13: Look back programmes at the NIBTS

168. Were you involved in setting up any national or local HIV look back programmes during your time at the NIBTS? If so, please describe this process, your role in it and how it was funded.

I was involved in setting up the Policy and Procedures at NIBTS for HIV Lookback. The process is described under para 138d. As noted, the finding of a confirmed positive donor was a rare event for NIBTS and no additional funding was sought or obtained.

169. Were you involved in implementing any HIV look back programmes during your time at the NIBTS? Please give details.

I did personally manage the donor counselling and look back process in respect of the first confirmed positive HIV positive donor – having attended a

training course at, I believe, St Mary's Hospital London. Subsequent HIV positive donors / donations were managed by my colleague Dr C Bharucha who would also have managed the look back arrangements.

170. Were you involved in setting up any HCV look back programmes during your time at the NIBTS? If so, please describe this process and your role in it and how it was funded.

The policy followed that decided by DOH (London) and hence by DHSS NI and to the same agreed timescale. The procedure was coordinated nationally (at least for NBS) by Dr A Robinson and NIBTS followed this procedure using similar forms (appropriately adapted). For NIBTS the procedure was managed by Dr Bharucha in conjunction with the haematologists in charge of each hospital Blood Bank and as described previously in para 153c.

171. Were you involved in implementing any HCV look back programmes during your time at the NIBTS? Please give details.

I had ultimate responsibility for ensuring that the programme was appropriately implemented by NIBTS.

172. You were present at a meeting of the SNBTS Medical and Scientific Committee on 19 February 1991 at which it was stated that due to national events no look back exercise would be undertaken in relation to HCV. Could you explain whether this decision included NI and the context surrounding this approach? (PRSE0003568)

As noted above (153c) look back was implemented in Northern Ireland in 1995 as part of a national (UK wide) policy not because of the SNBTS decision.

173. On 6 November 1991 you were present at another meeting of the SNBTS Medical and Scientific Committee where it was agreed that

RTCs were to "assess the possibility of retrospective screening of normal plasma stocks" in relation to HCV. Could you please clarify whether this meant testing plasma stocks for HCV? If so, please confirm whether this occurred at the BTC, and if it did:

a. **The remit and chronological scope of the exercise; and**
b. **What approach was taken for HCV positive plasma stocks? (SBTS0000446_007, page 17)**

Regrettably, I am unable to remember the details in relation to these questions and in the absence of any further (follow up) documentation I am unable to answer them. I assume this information would be readily available from PFC/SNBTS.

174. **On 14 February 1995 you were present at a meeting of the aforementioned committee where it was agreed that an implementation date would be determined from which all SNBTS centres would begin an HCV lookback exercise. In particular it was noted that, "This will ensure a unified Scottish (though not necessarily UK) implementation date". Was an HCV lookback programme started soon after and did it include NIBTS? If not, why not? Please refer to SBTS0000462_085.**

As noted in 172 above, NIBTS followed the NBS procedure (rather than SNBTS) although as far as I remember both NBS and SNBTS followed the same UK-wide policy.

175. **Please confirm your involvement in look back processes relating to any other infection during your time at the NIBTS. If so, please provide an overview of the relevant programmes and detail your involvement.**

I cannot recall being involved in look back processes other than for HIV and Hepatitis C. The National Policy (which did include NIBTS) with respect to vCJD is dealt with under Section 17.

176. Did you consider whether there was an ethical obligation to inform patients who may have received transfusions from infected donations? If not, why not?

I do consider that there would have been an ethical obligation to inform such recipients. There was however a view at the time that this would have been particularly the case once it became clear that an effective treatment for the infection had become available or when effective precautions in reducing transmission to family members or other close contacts had become known.

177. On 7 April 1997 the NBA contacted you asking whether the NIBTS would like to join a UK wide national HCV Registry. Could you please explain what this was and whether the NIBTS participated? (NHBT0036422)

I cannot recall in any detail the purpose of this registry. I assume we would have participated and if so my colleague Dr Bharucha would have provided the relevant data to CDSC/PHLS. However in the absence of my response to the letter or other documentation I cannot be certain about our involvement. I assume full information on the registry, including its purpose, participants etc. would be readily available from NBS sources.

Section 14: Your relationship with commercial organisations

178. Have you ever:

a. **provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products?**

No

b. **received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture, sale and/or importation of blood products?**

No

c. **sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture, importation or sale of blood products?**

No

d. **received any financial incentives from pharmaceutical companies touse certain blood products?**

No

e. **received any non-financial incentives from pharmaceutical companies to use certain blood products?**

No

f. **received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.**

No

179. What regulations or requirements or guidelines were in place (at any time relevant to your answers above) concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?

Since no member of NIBTS staff were involved, as stated under 178 above I do not recall any internal/NIBTS regulations being in place. Our parent organisations, DHSSPS and EHSSB may have had such regulations / guidelines in place but I cannot recall.

180. Have you ever undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture, importation or sale ofblood products? If so, please provide details.

No

181. Have you ever provided a pharmaceutical company with results from research studies that you have undertaken? If so, please provide details.

No

182. If you did receive funding from pharmaceutical companies for research, did you declare the fact that you were receiving funding and the source of the funding to your employing organisation?

Not applicable

Section 15: Relationship between the NIBTS and SNBTS

Relationship between the NIBTS and SNBTS

183. Please explain the NIBTS' relationship with the SNBTS in relation to the supply of blood and blood products to Northern Ireland. 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.

NIBTS and SNBTS were under separate Health Departments and operated within separate management structures. Under direct rule during most of the 1970s 1980s and 1990s the DHSSPS in NI followed decisions taken by London. So as a general rule if there was a conflict in decision making between DOH London and SHHD, NIBTS would follow the former. During the 1980s and 1990s only the most important issues required significant DHSSPS involvement e.g. plasma fractionation arrangements, HIV, Hepatitis C and major capital spending and budget setting. For most other issues NIBTS in conjunction with EHSSB (until 1994) were relatively autonomous.

The link with PFC/SNBTS established in 1982 was on a strict contractual basis whereby the quantity of plasma products received was based on the volume supplied of each plasma type – on a pro rata basis. As noted previously the quality of plasma supplies from NIBTS had to comply with the same standards as applied to all the Scottish RTCs. It follows that this requirement had an impact on all operations – donor selection, testing, processing of plasma and general quality and environmental standards. With respect to processes that did not impact on the PFC contract or PFC requirements there was no requirement for NIBTS to follow SNBTS policies and procedures.

Apart from the PFC contract NIBTS also took up the option of contracting for (outsourcing) some other services with SNBTS of which the most important were for hepatitis C confirmatory testing, routine NAT testing for hepatitis C RNA and HIV RNA. On the other hand NIBTS decided to adopt the same IT systems for its core activities as used by the NBA (NHSBT) – from 1996.

184. **Please outline the arrangements in place to enable cooperation between the NIBTS and SNBTS during your tenure, including any forums or reporting lines established to aid this cooperation. You may wish to refer to document NIBS0001680 for further assistance.**

The major forums were the SNBTS Directors Committee (later replaced by SNBTS MSC) and the annual Supply and Demand meeting which dealt with PFC supply issues. Apart from issues related to the PFC supply contract, attendance at these meetings provided an excellent opportunity to keep abreast of wider developments in the fields. This was assisted by the attendance at these meetings of representatives from NBS but also involvement of SNBTS in many UK Advisory Committees which were reported on.

Assurance of NIBTS compliance with PFC requirements were met by regular audits by the PFC Quality Department.

185. **Please explain the NIBTS and SNBTS' approach to policy development and implementation. Was policy developed and implemented on a UK-wide basis unless otherwise agreed, or was the approach discussed on a case by case basis? For assistance please refer to document NIBS0001680.**

I think this is largely answered under para 183 and 184 above.

186. **Did the SNBTS share information with the NIBTS about excluded donors, donors that posed a risk to the safety of the blood supply, or infected blood donations? If so, was this on a formal or informal basis?**

Please describe the mechanisms in place to share this information, if any.

I do not recall there being such an arrangement with SNBTS.

Relationship between PFC and BPL

187. **Please explain your understanding of the relationship between PFC and BPL (NB: Reference to BPL also includes the associated Plasma Fractionation Laboratory in Oxford). In particular:**

a. **What was the extent of collaboration and coordination between BPL and PFC? What impact did this have, if any, on the operation of the BTC within the NIBTS?**

I had no particular insight into the extent of collaboration between the two centres. From casual conversation I think I was vaguely aware of collaboration at some levels but also aware of competition between the two facilities.

b. **Do you consider there would have been merit in a joint UK approach to Factor VIII production and research, particularly given that PFC and BPL were both engaged in the development of similar severe heat treated products (8Y and Z8) in the 1980s?**

It seems obvious that such a joint approach to research and development for the production of safer and more effective products would have had benefits – given that both facilities had the same objectives. However my opinions on this very specialised area are not based on any real knowledge or expertise.

Section 16: Quality control at the NIBTS

1980s

188. In September 1981, the SNBTS published a preliminary report in response to the request from Northern Ireland for plasma to be fractionated at PFC (SCGV0000104_117). The report identified the following concerns in relation to quality control that needed to be addressed before any formal arrangement for plasma fractionation could be agreed:

a. The plasma quality assurance programme was unsatisfactory;

b. Refrigeration facilities were inadequate;

c. The environment in which plasma was procured needed improvement;

d. The Hepatitis B Antigen testing was not of the adequate sensitivity recommended in the Third Report of the Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody (1981);

e. The NIBTS needed to produce Standard Operating Procedures (SOPs).

With reference to the report and to SCGV0000104_090, please answer the following questions:

a. The report suggests that you were responsible for development of policy decisions regarding plasma procurement and fractionation for the NIBTS within this joint programme with SNBTS. Could you explain

your role within this programme and what steps you took to address the above issues?

As Director I was responsible for putting in place new arrangements for plasma procurement and fractionation within this joint programme with SNBTS.

With respect to quality control NIBTS did not, at that time, in common with most if not all UK RTCs have a quality manager. Day to day responsibility for quality rested with the head of the laboratories (laboratory manager) and heads of each of the six sections of the laboratories – four of which were concerned with the provision of blood products i.e. blood component processing, microbiology testing, donor blood grouping and blood group reference laboratory. The other sections were concerned with patient testing / (diagnostic) services. As Director I had ultimate responsibility for quality. As such I would, in conjunction with the laboratory heads referred to above, have developed an action plan to address the various issues. These would have fallen into two broad categories, firstly the procurement of equipment involved in the enhancement of refrigeration equipment and the introduction of RIA for hepatitis B testing (described elsewhere under para 149). My role would have included securing the necessary funding for this equipment. Secondly, issues related to the QA programme, standard operating procedures, environment etc. would have involved detailed discussions with PFC staff as alluded to in the report.

b. To what extent did new provisions of the Medicines Act 1968 impose stricter quality assurances with regards to the collection of blood products sourcing and collection?

The most obvious impact was that during the early 1980s for the first time RTCs became subject to formal inspections by the MCA (later MHRA) to

check on progress with the development of QA programmes. Before that time RTC laboratories and hospital Blood Banks basically operated in accordance with the principles of good laboratory practice, similar to that followed by hospital diagnostic laboratories. Professional staff manning these laboratories (scientific and medical) followed similar training programmes whether working in diagnostic laboratories or RTCs. Shortly after my appointment I started to become aware of an emerging requirement for RTCs to operate more like pharmaceutical manufactures than hospital laboratories with respect to the provision of therapeutic components for patients.

Initially this development had the greatest effect on fractionation facilities (PFC and BPL) and it was through my early discussions with PFC that I became increasingly aware of the significance of these changes. I understood that PFC had for some time undergone inspections by the MCA with a view to obtaining a manufacturing licence and they had a requirement to provide assurances on the quality standards of the source plasma from RTCs. Hence the first audit/inspection by PFC in 1981. The latter was followed soon after by the first inspection of NIBTS by the MCA. Such inspections became a fairly regular feature subsequently approximately every two years, I think.

While MCA inspections could be quite stressful events for staff it was a development that I came to welcome. The inspections of UK RTCs were all led by the same individuals who thus acquired considerable expertise in blood transfusion practices and processes. They were able to transmit examples of particularly good practice to all other centres which for a relatively isolated centre like NIBTS was welcome.

c. What was the outcome of the Medical Inspector's report of the Belfast Centre on 9 September 1982?

I cannot recall any of the specific issues raised in the first inspection by MCA and have not been provided with a copy of the report however NIBTS would have provided a corrective action plan for MCA which I believe was accepted and that these corrective actions were carried out to MCA satisfaction.

189. **On 3 September 1981, Mr John Watt (Scientific Director of the SNBTS) copied you into a letter to Professor John Cash of the SNBTS in which he stated that there would need to be "modification in the area of quality control" before the collection of FFP from the BTC could commence. Of biggest concern to him was the fact that there were "no in house facilities" for microbiological monitoring (NIBS0001698). Please explain, as far as you are able, what Mr Watt meant by microbiological monitoring. Why were such facilities not available at the NIBTS? As far as you can recall, were they subsequently introduced?**

This refers to testing that was carried out to reduce the risk of blood components becoming contaminated by bacteria from the environment – e.g. from the donors arm during venepuncture, centrifuge buckets, positive pressure cabinets and other critical processing and storage areas. Such testing would be carried out on a proportion of samples from finished blood components and by swabbing of processing and storage equipment. This is a relatively specialised area of activity and NIBTS sourced the actual testing to a hospital bacteriology department which had experience of this kind of monitoring. As far as I recall this type of arrangement was common among RTCs. It remained in place until the move to the new Transfusion Centre, when an in house facility was later established at NIBTS.

190. **In the same letter (NIBS0001698), Mr Watt stated that "looking at the centre with an inspector's eye it was clear that Dr McClelland had problems getting access to adequate standard and sufficiently fast response so far as building and equipment maintenance was**

concerned." Did you agree with Mr Watt's statement? Please provide details.

I cannot remember in detail the specific issues here. Certainly building maintenance was provided by a department of the EHSSB that was not under NIBTS control and the former would hire private firms to carry out any building work. There could often be delays although if work was necessary for clinical or safety reasons this would normally be given priority. Equipment maintenance would have been covered by contracts and would have been carried out on a regular basis.

191. **Also in the same letter (NIBS0001698), Mr Watt suggested that PFC would need an undertaking from you or the board to "bring the [BTC] to a position that would meet the need of PFC so far as the centre was a supplier of raw material for fractionation. No doubt the Medicines Inspectorate would hold the same view." Could you explain what steps you took in order to ensure that quality standards were raised in order to come to a contractual agreement with PFC?**

Para 188 above referred to the actions related to the PFC inspection. A limited amount of additional QC testing was introduced and this involved end-stage testing on a proportion of blood components (red cells, platelets, FFP and cryoprecipitate) to ensure that the specification for each component was being met.

An important capital item was the purchase of a liquid nitrogen blast freezer which enabled very rapid freezing of plasma units, thus preserving Factor 8 activity. We also commissioned, somewhat later, a new purpose designed, temperature controlled vehicle which was used to transport FFP from Belfast to PFC.

192. **Is it right to understand that from at least 1985, the PFC required an increase in quality control testing on source plasma, however, the**

NIBTS was unable to meet this standard, in part due to a lack of funding for senior personnel to oversee the process (NIBS0001460)? If so, please describe whether additional funding was subsequently made available and whether there was any impact of the collection of blood at the NIBTS.

I would accept that PFC raised a number of quality control issues at the time but I am unable to recall the detail.

I cannot remember the exact source of funding but around this time a separate Quality Control (QC) department was established. This department was the beginning of a separate Quality Assurance (QA) department which later became responsible for quality management systems covering all NIBTS activities in the 1990s.

1990s

193. **On 27 November 1991, Professor Cash wrote to you expressing his concerns regarding a recent audit of the BTC that had taken place between 20-22 November 1991 (SBTS0000070_025). He stated that "your Centre has significant quality assurance deficiencies which seem to relate not only to facilities and equipment but to management performance and general staff attitudes to quality." He suggested that the audit raised "important issues regarding the plasma fractionation contract." Could you please explain how many times a QA audit had taken place between the beginning of the contract with SNBTS for plasma fractionation in 1981 and this audit, and whether this was the first time that an external audit had found significant deficiencies?**

I do remember this audit clearly because I believe it was the first audit in which significant deficiencies (against rising standards) were identified. I

believe we were able to put in place a corrective action plan that was found satisfactory to PFC/SNBTS.

I cannot remember details on dates of audits carried out by SNBTS between the beginning of the contract and this audit.

194. **On 23 July 1992 Dr Perry sent you a letter regarding the Belfast audit in which he suggested a follow up audit take place "to confirm that the necessary standards have been met" (SBTS0000645_103). Could you please explain whether this occurred and what steps you took to address the quality control issues?**

In the absence of any further documentation I am unable to provide any details on the audit or NIBTS corrections. However, I believe from memory the process was completed to the satisfaction of PFC/SNBT by the end of 1992.

195. **On 4 March 1992 the Medicines Control Agency sent you a letter regarding their inspection of the BTC between 22-24 February 1993 (SBTS0000457_066). During the visit they identified some "deficiencies" and requested your proposals to remedy these deficiencies to facilitate the Agency's report to the Licensing Authority regarding the NIBTS. The Agency noted that deficiency 2.1 would only be resolved with the creation of a new centre. Could you explain whether this was a new Transfusion Centre and whether this was achieved?**

The correct date of the letter is in fact 4 March 1993.

This did indeed refer to a new Transfusion Centre. By this stage plans would have been well advanced for the building of a new purpose designed Transfusion Centre. NIBTS relocated to this centre approximately two years

later summer 1995) so by this stage funding would have been agreed, a site selected, architects plans completed and I think builders selected.

It is noted that the first MCA inspection following this relocation resulted in the granting of a manufacturing licence in 1996.

2000s

196. **The Medicines and Healthcare products Regulatory Agency ("MHRA") inspected the Belfast City Hospital Complex between 31 March and 4 April 2008 pursuant to the Blood Safety and Quality Regulations 2005 (SI 2005/50) (DHSC0007467). The MHRA inspector "identified a critical deficiency in relation to compliance with the requirements of good practice" at the NIBTS, including:**

a. **incidence management**

b. **document control**

c. **equipment management**

d. **temperature controlled storage**

e. **processing**

f. **laboratory operations**

g. **Training**

h. **document completion**

i. **self-inspection**

j. other areas

The MHRA informed you that it was "gravely concerned at the risk to public health" and considered that the NIBTS was "failing to comply with its responsibilities as a blood establishment under the Regulations." The MHRA informed you that "the NIBTS has failed to maintain an adequate quality system as required by regulation 7(1)(b) of the Regulations" and reminded you, as director, that such a contravention was "a criminal offence" under regulation 18. The MHRA gave you notice as the Responsible Person that the NIBTS was in breach of the requirements of the regulations and ordered the NIBTS to prepare a root cause analysis to present along with a corrective action plan by 10 June 2008. The MHRA informed you that you would be relieved of your duties if the NIBTS failed to comply. Following the MHRA's inspection, you wrote a letter to the chairperson of the MHRA, Ms Bernadette Sinclair-Jenkins, dated 21 April 2008, in which you accepted "the extreme seriousness of the outcome of this inspection" and that "In the 28 years since I have been Director of this Service this is the most serious crisis for our Service." Please explain what factors, in your opinion, contributed towards the "systemic deficiencies" within the NIBTS identified by MHRA. (Please see DHSC0008844).

Before answering this specific question I would like by way of context to make a number of points:

a. This was the first occasion in which a critical deficiency was identified.

MCA/MHRA inspections of NIBTS had been carried out at regular intervals, typically every two years from 1992. The outcome of all previous inspections had been generally satisfactory (apart from the specific issue on the facility as per 195 above).

b. Other regulatory authorities had carried out inspections of NIBTS which were generally satisfactory.

As well as its core business, NIBTS was responsible for other services which were subject to regular external inspection by bodies other than MHRA. These were patient testing (diagnostic) services which were covered by the CPA Accreditation Scheme and cord blood banking covered by the Human Tissue Authority. In both cases there was a strong focus by the inspections on quality management systems and in both cases all previous inspections had been satisfactory. These services were under the same (laboratory) management as the core business of NIBTS.

NIBTS (through our QA manager) provided a high degree of support and direction to the Belfast Bone Bank based at Musgrave Park Hospital and enabled this service to achieve compliance with HTA requirements.

c. NIBTS had introduced a number of non-mandatory safety initiatives prior to 2008.

As well as ensuring full compliance with all mandatory testing requirements (hepatitis, HIV etc.) over the years, NIBTS introduced a number of additional safety measures that were not mandatory, or before they became mandatory. These included:

- Provision of CMV antibody negative blood for selected patients (from the early 1980s).

- Bacterial testing of platelet concentrates as a release criterion.

- Full blood counting on all blood donors – as a supplement to the routine pre-donation thumb prick test for anaemia (which could miss cases of anaemia on occasions).

I mention these points to demonstrate that NIBTS has always had a strong focus on safety over the years and that I consider this particular inspection in March/April 2008 to have been a temporary and short-term setback and not indicative of long term systemic failings.

As regards factors that contributed to "systemic deficiencies" identified by MHRA, I believe the Blood Safety and Quality Regulations (2005) which followed EU legislation on blood transfusion led to a substantial increase in the standards against which MHRA inspected blood services and also led to an increase in the rigor of the inspection process. The new regulations and how they were interpreted required a huge increase in documentation – in relation to operating procedures, quality incidents, change control, training, equipment maintenance etc. NIBTS found it difficult to implement the very significant additional administrative burden that the new regulations created. These difficulties were exacerbated by staffing and resource issues.

We were aware of the majority of the issues raised in advance of the inspection but lacked the resources for a period to take the necessary corrective action. I believe this was partly due to insufficient staff time and partly to failure of management to ensure this was given the priority it required. As the person with ultimate responsibility I include myself in this failure. It is unavoidable in this context to mention that the person with responsibility for the quality system had GRO-C GRO-C of which I had not been made aware and led to him having to take GRO-C leave at a critical time – from 3rd April 2008 for the next six months.

197. On 30 May 2008, you produced a draft version of the NIBTS' response to the MHRA inspection, in which you stated that "the Chief Executive/Medical Director and Senior Management Team fully accept

the extreme seriousness of the outcome of this inspection" and that the first priority was to establish and deploy a "corrective and preventive action plan" (DHSC0007461). You noted that, since its last inspection, the NIBTS had received additional funding for more staff posts but that there had been recruitment difficulties leading to serious delays in filing these extra roles. Please elaborate on these difficulties. What steps, if any, did you take to resolve these difficulties? In your opinion, what effect did a reduced staff have on implementing the corrective action plan?

Apart from extra posts (see below), a key vacancy was a replacement IT manager which continued for over a year. This arose from the competitive market for IT staff at the level required. I believe two unsuccessful interview panels were held before an appointment was made – despite an enhanced salary level being agreed for the post. Fortunately, an excellent appointee was selected and who remained with the service long term.

A similar situation applied to the new post of risk manager and an appointment was only made around the time of the inspection.

A new post of laboratory training officer led to an internal (laboratory) appointment and so would have required the filling of a more junior post.

We created additional resources in the area of document control (within the QA department) and I have forgotten the details of how this was achieved. These additional staff resources played a significant role in implementing the corrective action plan but equally important was the enhanced understanding of and priority given by all operational staff.

198. **Also in your draft response to the MHRA, you stated that "a key objective is to improve the quality culture within the organisation" and that "success in this area is dependent on leadership provided by all senior staff" (DHSC0007461).**

Please explain what steps you took to improve the "quality culture" at the NIBTS.

An important initiative involved the engaging of external Consultants who were able to provide different types of specialist expertise (four in all). Some of these individuals had provided SNBTS with support for a similar purpose and so had relevant knowledge. A key role of the lead Consultant was to support the new acting QA Manager (previously Deputy QA Manager).

In developing the corrective action plan a tool called root cause analysis was used. This involved inputs from staff at various levels, thereby instilling a sense of ownership for the action plan. From documentation I am reminded that one Consultant provided support on incident management, equipment management, temperature control storage and Q-Pulse (IT system) and another provided training in GMP and self-inspection (internal audit). Through an intensive period of work on the part of staff at all levels things were turned around in a relatively short period of time.

199. **On 16 June 2008, you wrote a memorandum entitled "External support to NIBTS following MHRA inspection, April 2008" which detailed external support that had been obtained, been committed to or needed to be committed to in order to implement "the corrective action plan" (DHSC0007448). You stated that NIBTS planned to recruit an expert to the Responsible Person Role on an interim basis. How did this role differ from your existing responsibilities as Chief Executive and Medical Director of, and also the Responsible Person for, the NIBTS? By whom was the role eventually filled?**

Under the BSQR each blood service was required to appoint someone to-the role of "responsible person". As I recall there was at least initial confusion about the appropriate person to appoint. The title and the fact that the holder carried legal responsibility for the quality management system suggested it should be the person with overall responsibility for the organisation i.e. Chief

Executive. On another interpretation, the role could be delegated to the QA manager. Initially I agreed with my Board to assume the role (from November 2005). Following the April 2008 inspection and subsequent communications with MHRA, it was proposed that the acting QA manager – later Regulatory Affairs and Compliance Manager, could appropriately undertake this role and this was accepted by the MHRA. Before this, consideration had been given to the nomination of the lead external Consultant to this role on an interim basis but as far as I remember this did not happen.

Comparing the roles of Chief Executive/Medical Director and responsible person role, as noted above, the latter was responsible for the quality management system (which included legal responsibility) but the Chief Executive/Medical Director would remain responsible for the management of the service as a whole and, as Medical Director, for medical and scientific policies.

200. **When was the concept of the "Responsible Person" under the Blood Safety & Quality Regulations established? From when did you hold this position? What were your regulatory responsibilities as Chief Executive and Medical Director of the NIBTS prior to the establishment of the "Responsible Person" role? You may wish to refer to DHSC0007463.**

I think the answers to these questions are covered in para 199 above.

201. **In your statement in response to the MHRA's inspection, you stated that "the role of Responsible Person requires a level of attention to detail in relation to the quality management system and GMP compliance which is challenging for someone with responsibilities of Chief Executive and Medical Directors" (DHSC0007463). What steps did you take during your tenure to mitigate the challenges posed by being both the Chief Executive and Medical Director of the NIBTS? What steps, if any, did you take to delegate or otherwise manage your responsibilities? During your tenure, did you consider stepping down**

from one of your positions to enable you to focus more completely on the other role? Please provide details.

My role on first appointment as Director in 1980 included responsibility for both general management of the service and medical direction. So on appointment as Chief Executive and Medical Director of the NIBTS Agency (1994) this was really a continuation of the previous responsibilities although the agency role involved having ultimate responsibility for areas such as finance. As explained elsewhere during this period I was able to delegate an increasing number of responsibilities, particularly in the medical area (having two additional Consultant posts) and in quality management. As a result my pattern of work changed a great deal over this period from dealing with day to day clinical issues (individual patients and donors) to a more medical policy-making role. In view of the increased level of delegation referred to, I considered the combined role was appropriate.

With respect to the 2008 inspection, I believe I was able in the CE/MD role to generally oversee the corrective action programme required and to achieve a successful outcome. This included securing the necessary resources and providing general oversight. Thus at a follow-up inspection in September 2008 NIBTS was as far as I recall commended for the action programme as I believe was the case after a further inspection in 2009, before returning to a normal inspection cycle. I retired in August 2009 which was somewhat later than I had originally planned.

202. **The Inquiry holds draft letters that indicate the MHRA relieved you of your duties as the Responsible Person of the NIBTS in June 2008 (DHSC0042431 and DHSC0007444). Can you please confirm whether this is the case? If so, did you appeal the decision made by the MHRA? Please provide details.**

It will be noted these were draft letters which were never received by me. I was not relieved of the duties as Responsible Person under the legislation.

As noted in 199 above, during post inspection discussions with MHRA it was clarified that this role involved having responsibility for the quality management system. It was furthermore agreed between MHRA and NIBTS that this role would most appropriately be undertaken by the acting Quality Manager (from October 2008 the Regulatory Affairs and Compliance Manager) since this was the person with direct day to day responsibility for the QMS. I was party to this agreement which I was happy to support. It did not affect my role as Chief Executive in which I had responsibility for the overall management of the service or my role as Medical Director.

General

203. Please comment on whether you believe there to have been systemic institutional hurdles within the NIBTS preventing it from achieving adequate quality control standards. If such hurdles existed, what impact did they have on the ability of the NIBTS to provide a quality service? What steps did you take, as Director of the NIBTS, to remove such hurdles?

I have endeavoured to explain in paras 196, 197 and 198 what I believe to have been the most important issues. I consider that these and the fact that we were able to turn things around to achieve a position of compliance with the new standards in a relatively short space of time indicates that this adverse inspection was in the nature of a temporary setback albeit a significant one. I have tried to explain the context, including the serious staff resource issues in the run up to the inspection.

I accept there was insufficient "buy-in" to quality control by staff at various levels but that this improved greatly as a result of input from various sources of external assistance/consultancy, training etc. While staff at all levels played their part I would particularly wish to acknowledge the outstanding

work and direction provided by the acting Quality Manager. This was key to enabling a successful outcome.

Section 17: Variant Creutzfeldt-Jakob disease (vCJD)

204. How did your knowledge of vCJD develop over time? What if any involvement did you have in addressing or responding to these risks?

In the mid-1990s there was a widespread outbreak of BSE in cattle and the subsequent appearance of vCJD in humans in the UK. This led to alarm within the UK Blood 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 the plasma components. I then became aware of the first case reports of vCJD in a patient who had received blood from a donor who subsequently developed vCJD (unsure of date). 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.

205. You were present at a meeting of the NIBTS agency in 1999 during which it was noted that the uptake of "plasma derived factor VIII has decreased substantially" in the context of vCJD (page 2 NIBS0000433). Please provide details about this comment, as far as you are able.

I have not been provided with a breakdown of annual usage figures but I assume this decrease would have been linked to purchases of recombinant Factor 8. The latter would have been used for selected patients at this time and gradually phased in to replace plasma derived Factor 8 completely.

206. On 18 December 2003, you wrote an internal memo for a staff briefing regarding vCJD in which you stated that "several precautions have been taken in recent years to reduce the possible risk of vCJD being transmitted by blood transfusion, including universal leukodepletion" (NIBS0000612). Please confirm what precautions you were referring to and when leucodepletion was implemented within NIBTS. To what extent did this method render blood donations safer?

As noted above the two major precautions were (i) universal leucodepletion of blood components and (ii) all plasma products in use being derived from non-UK donor plasma (by November 1999). Leuco-depletion of red cells and platelets was fully implemented by November 1999 and for FFP and cryo by December 1999.

As far as I am aware no cases of vCJD have ever been shown to be caused by transmission from leuco-depleted components.

I am not aware that any cases of vCJD have been shown to be caused by a plasma product.

207. Was the NIBTS involved in a look back programme for vCJD? If so, please provide details. You may wish to refer to NHBT0009036.

Policies relating to this were closely coordinated between the four UK services and implemented simultaneously.

My colleague Dr C Bharucha and later Dr K Morris and Dr J Murdock were the Consultants responsible for donor issues around this period and as such would have been responsible for implementing these policies.

208. In order to reduce the risk of vCJD transmission via blood products, was the NIBTS informed by the CJD Surveillance Unit/Specialists/GPs about donations from individuals suspected of carrying the variant CJD? If so, what measures, if any, were taken to trace the individuals and recall their donations? In answering this question, you may wish to refer to NHBT0009036.

In keeping with Dr Metters letter, NIBTS would have been informed of any such donations. As far as I remember there were no such instances during my tenure.

209. In 1998, the NBA produced a position statement on advice to be given to patients who had received plasma from a donor infected with vCJD (NIBS0000377). The NIBTS Deputy Director, Dr Chitra Bharucha, sent you a summary of this approach, highlighting two significant points of the statement:

a. **Item 3.2: "No attempt should be made to advise individual recipients that they may have been treated with product from an affected batch".**
b. **Item 5: "There is no basis for assuming that individuals in receipt of therapeutic material from an implicated batch of plasma product**

should be considered to be in an "at risk" category with respect to blood donation".

To the best of your knowledge:

a. Did the NIBTS' approach change in light of the NBA's statement? If so,how?

I do not recall any change in our approach as a result of this position statement. To the best of my knowledge, there were no instances of patients in Northern Ireland receiving plasma products from a donor infected with vCJD.

b. Was this reviewed as scientific understanding developed?

This would have been reviewed regularly by the Departments of Health with their Advisory Committees. It is noted that by the following year (November 1999) all plasma products were derived from non-UK plasma.

210. On 27 September 2005 you wrote a letter to the Deputy Secretary of the DHSSPS, Mr Don Hill, in relation to vCJD and blood safety (NIBS0000663). With reference to this letter please answer the following questions:

a. Did the NIBTS undertake prion filtration on red blood cells? If so, please provide details. If not, why?

b. Why were pediatric patients going to be prioritised over other groups?

c. Did the service begin prion filtration of platelets and plasma before 2009?

d. **In your summary, on page 2, you stated that to implement a prion filtration programme would mean "substantial cost implications" and that the NIBTS would not be in a position to fund it. Given this position, did central government fund the programme and if not did this slow down the implementation of the programme?**

e. **Was a test for vCJD ever developed and if so was it implemented by the NIBTS?**

It was widely anticipated at this time that prion filtration of blood components might become mandatory in the fairly near future, and this letter was an alert to the Department to make financial provision for this potential high cost item. However as it transpired these developments did not happen during my tenure or indeed later as far as I know.

Accordingly, the questions at a- e above are not applicable.

Section 18: Other matters

211. **During Parliamentary questions on 10th December 1985, Mr Hayhoe stated that 'supplies of whole blood are not imported since the United Kingdom is self sufficient in its needs for blood for transfusions; it is only certain blood products which are imported' (HSOC0018830). To your knowledge, was the UK self-sufficient in its need for whole blood for transfusions?**

To my knowledge the UK generally and certainly NI specifically were self-sufficient in the need for whole blood.

212. **During your tenure at NIBTS and BTC, were you aware of patients being given blood transfusions with red blood cells imported from the USA? If so, was there any concern about its use at the time?**

During my tenure at NIBTS I was not aware of any patients being given a transfusion with red cells imported from the USA. This could only have arisen in the event of a patient with an extremely rare blood group problem for which a suitable blood donation could not be sourced anywhere in the UK. I cannot remember this happening.

213. **Please provide a list of any articles you have had published relevant to the terms of reference.**

I am unable to locate my CV where these details would be recorded.

The only three that come to mind were on:

Bacterial testing of platelets – NIBTS Experience (Comparative Study) – unsure of Journal.

Human Immunodeficiency Virus Infection in Northern Ireland 1980-1989 – already provided

Hepatitis B in Northern Ireland 1970-1987 – already provided.

214 **Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Infected Blood Inquiry. To assist, we have provided a list of issues (attached).**

I have nothing further to add at this stage.

Statement of Truth

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

Signed ..GRO-C.....

Dated ..21 Jan 2022.....

Table of exhibits:

Date	Notes/Description	Exhibit number
N/A	Penrose Report Chapter 26.41	WITN0892002
N/A	Donor records	NIBS0001871
16 October 1990	Letter from Dr Mayne to Dr Flett	WITN0892003
13 December 1988	Letter from J F Mckenna to Dr E Mayne	NIBS0001770
24 November 1983	A summary of present practices by Dr C Bharucha	WITN0892004
April 1986	Journal article by C Bharucha and D Crowley	WITN0892005
1 December 1977	NBTS Memorandum	PRSE0004358
1 December 1977	NBTS Memorandum	DHSC0003734_066
28 October 2021	Written statement of Dr Lorna Williamson	WITN0643001

25 October 2021	Written statement of Dr P Hewitt	WITN3101006