Witness Name: George Galea
Statement No.: WITN6931001
Exhibits: WITN6931002-003
Dated: 23 November 2021

**INFECTED BLOOD INQUIRY**

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**WRITTEN STATEMENT OF DR GEORGE GALEA**

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I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 April 2021.

I, George Galea will say as follows:

## Section 1: Introduction

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

1. Name: Dr George Galea

Address:
C/o Scottish Central Legal Office
Anderson House
Breadalbane Street
Bonnington Road
Edinburgh EH6 5JR

DOB: GRO-C 1954

Qualifications: LRCP MRCS MD FRCP FRCPath.

2. ***Please set out your employment history with dates if possible, including the various roles and responsibilities that you have held throughout your career.***

2. Employment-
    - Lecturer in Haematology- University of Aberdeen 1980-1984
    - Senior Registrar Aberdeen and North East Scotland BTS 1984-1989
    - Consultant in Transfusion Medicine, Aberdeen and North East of Scotland BTS 1989-1993
    - Director, Inverness and North of Scotland BTS 1993-1996
    - Director, Dundee and East of Scotland BTS 1996-1999
    - Tissues and Cells Director, Edinburgh 1999-2013
    - Consultant to Maltese Government - Ministry of Health 2014- present

3. ***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 of your membership.***

3. Memberships-
    - Member of the Medical and Scientific Committee and Board of SNBTS (automatically selected once appointed as a Director).
    - Member of the UK/BTS Standing Advisory Committee on Donor Care and Selection, 1990-2000.
    - Member and later Chair of the UK NIBSC/BTS Standing Advisory Committee on Tissues and Stem Cells 2001-2010.
    - President (2003-2005) of the British Association for Tissue Banking.
    - Chair of British Association for Tissue Banking, Medical Special Interest Group, for the previous 4 years and Vice President (2001-2003).
    - Member (2007-2014) of SaBTO. (Safety of Blood Tissues and Organs)- a UK committee advising UK Ministers on safety matters on Blood Tissues and Cells. My role on the committee was as a Tissue Banker/Expert.

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

4. I kept abreast of developments through various ways including, medical and scientific reading of relevant articles, writing scientific articles (I have written 60 publications in scientific/medical journals), attending meetings and attending and speaking at conferences. I always maintained a satisfactory number of CPD points as requested by the relevant college (RCPath in my case).

5. ***Please confirm whether you have provided evidence or have been involved in any other inquiries, investigations, criminal or civil litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement.***

5. I have never given evidence or been involved in any inquiry or official investigation/litigation.

**Section 2: Your role in the Blood Services**

6. ***Please describe the roles, functions and responsibilities you had within the SNBTS, including at Inverness, Aberdeen and Dundee Blood Transfusion Centres ("BTCs") and the Blood Services during your period as:***

    ***a. Consultant haematologist; and***

    ***b. Director***

    ***and explain how these changed over time. Please answer any of the following questions in relation to BTCs with reference to your tenure at these and any other SNBTS BTCs.***

6. My first appointment as a Consultant was in Aberdeen, under the Regional Director, Dr S. Urbaniak, in 1989/90. I had a number of roles within the

Aberdeen Centre, but I focussed mostly on donor matters. After approx. 3 years, I was appointed Director in Inverness. This was my first appointment in charge of a Centre and an entirely new role for me. It was my first managerial post and I spent a lot of time getting used to managing people and establishing myself. It was the time when a new centre in Inverness was being built and I was quite deeply involved in ensuring it was fit for purpose etc. Besides getting to know the staff at the centre I also got to know many clinicians at Raigmore hospital, particularly haematologists, who were the main users of SNBTS products. In my short time in Inverness, I re-structured the department and conducted a few studies on the economic assessment of blood collection in remote areas.

7. In 1996 I was offered a post as Director of the Dundee Centre. It was a transitional time for SNBTS, when the processing of blood was centralised in Edinburgh and Glasgow. Prior to that time, each of the transfusion centres had their own processing and testing facilities. It was therefore a time when I oversaw this change, which was quite stressful for the staff and an important change to the function of the Dundee Centre (as it was for Aberdeen and Inverness). Managing this change was my main role during the period 1996 to 1999.

8. In both the Inverness and Dundee centres, I had to ensure that business as usual took place in a smooth manner. I ensured that we collected enough blood for patients - this changed from mostly satisfying the local needs to a more central/national approach. I ensured that the centres operated to Good Manufacturing Practice (GMP) quality standards in all their transfusion functions, within the budgets that were allocated to me.

9. In 1999/2000 I took over as Tissue and Cells Director, a role based in Edinburgh. This was a national role and a new directorate within SNBTS, whereby its remit expanded into the field of tissues and cells, with full Scottish Government approval. I developed this service significantly over the 15 years I led it, with a significant increase in the numbers and range of tissues and a concomitant increase in staff (up to 35 people from 7).

10. My role involved the National co-ordination of all SNBTS Tissue services activities in the 5 Scottish regions– professional, managerial, training whilst meeting increasing demands for tissues for patients in Scotland (and sometimes supplying the rest of the UK as requested).

11. The programme was expanded over the years to include bone, heart valves, tendons, skin and vessels to support Scottish patient needs. A major programme was introduced in 2009 -pancreatic islet cell banking as part of a major Scottish initiative in an attempt to cure a subgroup of severely diabetic patients.

12. Expansion of the mortuary programme in Edinburgh and Glasgow involved the creation of a national bone storage site in Aberdeen and the establishment of 2 dedicated mortuaries for tissue retrieval in Gartnavel General Hospital and the Western General Hospital in Edinburgh. All this effort significantly increased the referral of potential tissue donors from less than 10 to over 70 in 7 years (to put this in context- the number of organ donors in Scotland in 2014 was 76).

13. My team maintained a close relationship with the Scottish Transplant coordinators. This was particularly important at a time of significant change whilst introducing a programme of designated requesters for tissue donation.

14. Throughout my time as Tissue Services Director, I maintained a close relationship with the Cell therapy R&D group led by Professor Marc Turner to support their research programmes. We were involved in peripheral blood stem cell processing and later in clinical trials involving a variety of cellular therapies.

7. ***Please describe the organisation of the BTCs and SNBTS during the time you worked there, including:***

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

15. The organisation of the Blood Centres in Inverness and Dundee was very similar. I had a closely knit management team consisting of an Operations Manager, who was mostly responsible for laboratory matters, a Donor Services Manager, who looked after donor affairs (non-medical) and donor publicity and a Business Services Manager. Working with them, there were nurses, scientific laboratory staff and admin staff. I also had a Personal Secretary.

16. I was accountable to the National Medical and Scientific Director for professional and medical matters and to the National Director for managerial matters. Finances were very tightly controlled and although I was nominally in charge of a budget, any spend had to be approved centrally by the National Finance Director. Also, saving targets were imposed centrally and they had to be adhered to wherever possible.

***b. how the BTC was funded and how this changed;***

17. The BTC was funded centrally throughout my employment with SNBTS. When funding became very tight for service improvements, some services were cross-charged to hospitals - always with approval centrally, not just to create a service level agreement, but also on the level of charges concerned.

***c. its remit, including the geographical area it covered and the hospitals within its area;***

18. The area covered in Inverness was the Highland and Islands of Scotland (excluding Orkney and Shetland, which were covered by the Aberdeen Centre.) The hospitals were:
    - Raigmore - the main hospital in Inverness
    - Fort William
    - Stornoway in Lewis

19. The area covered in Dundee was Tayside and Fife. The hospitals were:
    - Ninewells Hospital – the main hospital in Dundee
    - Stracathro Hospital - in Stracathro

- Queen Margaret Hospital - in Dunfermline
- Victoria Hospital - in Kirkcaldy

20. On the collection side, SNBTS was responsible for blood collection from the region it was situated in. Collection targets were largely based on historical experience.

21. On the supply side, our main remit was to provide all the transfusion needs to the hospitals we served. We provided all the blood components/products on a regular basis to ensure that their blood banks were adequately stocked and routinely replenished. We also served as a blood bank for the main hospital we were located in- Raigmore in Inverness and Ninewells, in Dundee. We crossmatched all the blood for patients requiring transfusions at these hospitals. We also served as a reference centre to cross match blood for difficult patients with multiple antibodies and we provided medical/transfusion advice on a regular basis involving being on call on a 24/7 basis.

***d. its place in the NBTS together with information as to whom the centre was answerable to at the NBTS, if anyone. When answering this question, please refer to paragraphs 4-16 of Dr Harold Gunson's statement in A and Others v National Blood Authority and another [2001] 3 All E.R. 289 (A & Others) and explain whether you agree with what is said there (NHBT0000025_001; NHBT0000026_009);***

22. I have already stated my accountability at Question 7a above. Ultimately, the National Director was accountable to the Common Services Agency, which was responsible to the Scottish Government Health Department. SNBTS was always autonomous from NHSBT. Therefore I do not feel competent to answer this question since it relates solely to the management structure of the Blood Services in England.

***e. whether the BTC was associated or linked with other Blood Transfusion Centres ("BTCs") and, if so, how and for what purpose;***

23. In terms of transfusion medical and professional advice, the role of the clinical staff was always autonomous and had remained so throughout my employment at SNBTS. Managerially, the role was less autonomous, and any changes to staffing or their roles had to be discussed and approved by SNBTS HQ, since finances were controlled centrally.

24. Regarding blood collection, the BTC was responsible for collecting enough to satisfy local patient needs, in terms of blood components, platelets and FFP. However, the BTC had also to collect enough plasma to meet SNBTS National plasma targets. This meant that if not enough plasma was collected through the whole blood collection process, plasma was procured through plasmapheresis. Following the establishment of the 2 processing and testing sites in the central belt (in Edinburgh and Glasgow), each BTC became linked by sending all the blood collected to these sites for processing and testing. Although most activities in the BTCs were incorporated in local SOPs to reflect the circumstances of each BTC, policies were in general SNBTS wide.

***f. whether the BTC was subject to any form of regulation and if so, what;***

25. The Blood Centres had to be licenced by the MHRA on a biannual basis. I cannot remember when this started but it was early in my professional career, probably around 1990.

***g. the BTCs relationship with the Plasma Fractionation Centre ("PFC")] and any other laboratory involved in the production of blood products or processing of blood; and***

26. There was a close relationship with the Plasma Fractionation Centre. All the plasma that was collected and not required clinically and locally was sent to PFC for fractionation to produce Factor VIII, Immunoglobulin, Albumin etc. Each Centre was provided with targets specifying how much plasma to collect for this purpose.

***h. the approximate number of donations collected each year.***

27. I cannot remember the exact figures; however, Inverness was the smallest collecting centre in Scotland, with around 20,000 collections annually, and Dundee was the next one with around 38,000 donations annually.

**Section 3: Blood Collection**

8. ***Please explain the system for blood collection at the BTCs during your employment there and how it changed over time.***

28. The system for blood collection was quite similar in both Centres I was in charge of. Blood was collected from either a fixed donation centre (part of the BTC) or at 'mobile' sessions held either in halls in villages or at workplaces. A mobile donation unit was also in use to obtain blood donations where a suitable fixed location could not be found.

29. Sessions were initially staffed by nurses, medical staff and session clerks. The donor was registered and had his/her haemoglobin checked. Following this, donors underwent a medical screening process whereby questioning about their health and behavioural history was undertaken. If this was satisfactory, the blood was collected and then the donor rested for some time and was given some form of refreshment.

30. The process varied over time in a number of ways -

    From around 1995/96 onwards - First time donors (who were considered 'riskier' since they had not been screened beforehand) and lapsed donors (donors who had not donated in the 2 years previously) began to undergo a personal interview in private, conducted by one of the medical/nursing staff at the session. These members of staff had been trained on how to conduct these interviews. Also, all other donors had to tick an answer to specific (medical and high risk) questions prior to donating.

31. At around the same time, most of the sessions began to be run solely by nursing staff, and medical staff were not present at sessions (although always available for advice). This was done for a number of reasons, including lack of availability of suitable medical staff and following an audit, which showed that the quality of decision making in the context of deferring donors was of an equally high standard, independent of the status of the deferrer being a doctor or a nurse. Sometime following this audit the sessions began to be led solely by nurses. This programme was rolled out throughout SNBTS.

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

32. Publicity to blood donors was the remit of the Donor Services Manager and their team of publicity officers. I do not remember the details, but there were frequent meetings with local organisers who would publicise the fact that a donation would take place at a particular time at a particular hall. They liaised very closely with the local organisers - usually volunteers from various civic groups.

33. Occasionally there were features in newspapers or sometimes a radio campaign would take place to highlight the utility of donating blood.

34. These steps were successful in that, very rarely (if ever) did we have to cancel operations due to lack of blood. In fact, I am not sure I can remember a single occasion when this happened. Also, during my time in charge of Inverness and Dundee, we never asked for relatives to donate - we never needed to and it was not considered a safe practice.

**10.** ***To what extent did each BTC collect blood from prisons, borstals and similar institutions?***

35. During my time in charge in Inverness and Dundee during the period 1993 to 1999 we did not collect blood from prisons and borstals. I cannot recall what

happened in Aberdeen, but I do not think blood was collected in prisons there either during the period 1989 to 1993.

11. ***Please identify and set out the number of institutions from which blood was collected and the frequency of sessions. In particular:***
    a. ***When did this practice cease?***
    b. ***What role, if any, did you have in this practice?***
    c. ***What were the relative costs of collecting blood from prisons as compared to collecting blood at the BTCs?***
    d. ***Were prisoners in Scotland provided with any form of incentive to donate blood? If so, what?***
    e. ***Were hepatitis and HIV considered risks in this specific population? If so, how were these risks managed?***
    f. ***What information, if any, was presented to donors before they gave blood?***

36. Please refer to my answer to Question 10.

12. ***Please describe the way in which donations were collected at the BTCs during your time there. In particular:***
    a. ***What were the staffing arrangements during blood donation sessions? Were the staff medically trained?***

37. Please refer to my answer to Question 8.

    b. ***Where did these sessions take place?***

38. Please refer to my answer to Question 8.

    c. ***How frequently could a person donate blood?***

39. Males could donate 4 times a year and females 3 times a year. This was the maximum and usually they donated with less frequency than this. This was

important since females had lower haemoglobins due to menstrual losses and pregnancies and we therefore did not wish to make them iron depleted.

***d. How were blood donors recruited?***

40. Please refer to my answer to Question 9.

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

41. Please refer to my answer to Question 8.

**13.** ***Did the BTCs have donation collection targets that it was required to meet? If so, did the BTS meet its donation collection targets during your tenure? If not, why not? What was done to improve blood collection? What more could or should have been done? What were the barriers?***

42. Yes, both Inverness and Dundee (as all the other Scottish Centres) had blood collection targets to meet. They did not change much, if at all, during my tenure and as I recall they were always met or very nearly met. They were historically based on the catchment population and the blood collected satisfied all the clinical and surgical requirements. The routine publicity that was done was nearly always satisfactory. I cannot remember an emergency appeal for blood donors during my stay in both Inverness and Dundee.

**14.** ***The Inquiry understands that the autologous transfusion occurred within the SNBTS in the course of your employment (PRSE0000233, page 2).***

***a. Were any steps taken to develop an autologous transfusion programme at the BTCs you worked within?***

***b. What was your opinion of autologous transfusion?***

43. In the context of autologous transfusion, SNBTS was involved in pre-deposit autologous transfusion. This involved the collection of the patient's own blood on a weekly basis for 2-3 weeks prior to an elective operation, so they could be transfused back post operatively. This would avoid or lessen the exposure to

blood from other donors. We had a policy that this would be offered in each Centre and we had SOPs for this to be made available. It is my recollection that the uptake of this service was very small in both Inverness and Dundee.

44. Although one would have thought that having your own blood back is the safest option, there are a number of issues that need to be taken into account. Such a procedure is only suitable for elective surgery. If for any reason the operation was cancelled (bed shortage or the patient is unwell) then all the blood would be wasted, since very often, it could not be transfused to others. Also, since autologous transfusion collections remained a low frequency procedure, the chances of failing quality standards (e.g. storage and labelling) would become quite high and blood collected may therefore not be available for transfusion.

45. Clinicians understood these issues and the pick up of this service was therefore not high at all, and it remained a very low volume procedure.

**Section 4: Plasma procurement and production of fresh frozen plasma at BTCs**

15. ***The Inquiry understands that BTC procured plasma from blood donor sessions to produce fresh frozen plasma ("FFP") to provide to the Plasma Fractionation Centre ("PFC"). Please explain:***

    ***a. where the production of FFP took place;***

46. The production of FFP took place at the Transfusion Centres.

    ***b. broadly, the process that was undertaken, the capacity of the BTCs to manufacture FFP and whether this changed during your tenure and why;***

47. The capacity of the BTC to collect FFP from whole blood did not change much during my tenure. The majority of blood units were processed anyway into their components at the BTCs. Very little blood was transfused as whole blood. Red cells and platelets were separated and used clinically. The plasma was either

used clinically as FFP (Fresh Frozen Plasma) or separated and sent to PFC for fractionation. After the establishment of the 2 processing sites in the Central Belt all FFP was then produced at these sites and appropriate quantities based on clinical demand were sent back to the BTCs.

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

48. The proportion that was processed as FFP was determined clinically, dependent on patient needs. Practically all the blood collected was separated into its components and the plasma was quickly frozen to preserve its quality and levels of Factor VIII in particular. The volume of plasma derived from blood collection that was not required clinically, was sent to PFC (determined by PFC according to agreed targets). From my recollection, the majority of blood units were processed and these targets were always met. Please also see my response to question 15d below.

***d. And, how quickly the BTCs could have increased its manufacture of FFP, had they wished to.***

49. The number of units of plasma was determined ultimately by the number of donations collected. Therefore, if more plasma was required the only option available was to get it through plasmapheresis- a process whereby a donor is attached to a machine and only plasma is removed, whilst the red cells are returned to the donor. By this method, suitable donors could donate plasma more frequently. However, there was a lead time that was needed to recruit these donors and assess their suitability as plasma donors. I would say this lead time would be measured in months, depending of course on the numbers that needed to be recruited.

**16.** ***As far as you are aware, how was plasma procurement at the BTCs funded throughout the 1980s?***

50. The plasma procurement was all funded centrally.

17. ***Please describe the arrangements for supplying FFP to hospitals and haemophilia centres within the region covered by the BTC.***

51. In the case of Inverness and Dundee, (where we also ran the blood bank for the major hospitals) clinicians phoned up the blood bank and asked for FFP for patients with specific clinical conditions. Other peripheral hospitals were supplied with small stocks of FFP and were replenished as needed.

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

52. Yes we had targets for plasma collection. They were set centrally after an assessment of the projected need of their products following discussions with the key stakeholders particularly haemophilia directors. These targets were then agreed by the BTC directors, since we had to ensure that the agreed targets were collected and that we had the capacity to do so. I cannot remember what the targets were, but they were always met in Inverness and Dundee. The amount of plasma was determined by the need to meet all clinical demand and to obtain enough plasma from Scottish donors to meet the demands for Scottish patients for plasma products- e.g. Factor VIII and Immunoglobulin. The volumes of plasma required by the latter were the main driver. Initially it was factor VIII and later intravenous immunoglobulin.

19. ***What impact did the setting of targets for the collection of plasma have on decision-making at the BTC?***

53. As I recall, in both Inverness and Dundee the plasma targets were in excess of what could be collected via processing whole blood. The main question in this context was therefore the number of plasmapheresis procedures we had to do to achieve our set target. Once this was decided we had to recruit the requisite number of donors that would be suitable for this programme and we also had

to negotiate with the National Finance Director to get enough funding for the kits for these procedures. Once the plasma targets were agreed, the funding was usually forthcoming.

**20.** ***What were the consequences if the targets were not met? Were there any benefits to the BTC if the targets were exceeded?***

54. Targets were always met or exceeded in Dundee and Inverness. There was no specific benefit for the BTC when targets were exceeded. They were seen as a national target for Scotland.

**21.** ***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 each BTCs you worked with gave to implementing plasmapheresis, including:***

***a. whether manual or machine plasmapheresis was preferred;***

55. Both in Inverness and in Dundee, machine plasmapheresis was used.

***b. the relative cost differences between each method;***

56. I cannot provide figures, but machine apheresis was more expensive than manual.

***c. the infrastructure, expertise and capacity of each BTC to introduce plasmapheresis during your tenure; and***

57. Clearly to introduce a machine apheresis programme, required a number of building blocks:
    - capacity of the donor pool – they provide the source material
    - capacity in space - this was not an issue since there was spare space in the donation centres in both Inverness and Dundee

- expertise - nurses had to be trained in handling complicated equipment and new kits. Training was provided by the companies that provided the machinery.

58. Therefore, in both centres we had the capacity and expertise to perform plasmapheresis in a safe and competent manner. In fact, the systems were in place by the time I was in charge of both centres. Recruiting the appropriate donors took effort and resource, but in both centres, I believe we had enough donors to meet all needs.

***a. whether, in your view, plasmapheresis would increase the amount of available plasma.***

59. Yes. Plasmapheresis had the capacity to increase the amount of available plasma. More plasma could be obtained from a donor on every occasion and donors could be called to give plasma much more frequently than if they gave whole blood. Whilst a donor could only give blood and therefore provide about 250 mls of plasma, once every 3-4 months at the most, a plasma donor could donate approximately every month and provide up to 600 mls of plasma, provided a number of tests that were done to ensure that the donor could undertake the procedure.

**22. *Please set out the extent of the plasmapheresis programme at each BTC during your tenure. As far as you are aware, did this programme differ from other BTCs? If so, why?***

60. I cannot remember numbers, but both centres had a plasmapheresis programme running. I cannot remember the proportion of plasma that was derived from the programme, but it was a significant proportion. I do not think this programme differed from any other centre.

*Use of plasma reduced blood and red cell concentrates*

23. ***What steps, if any, did each BTC 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?***

61. At the time I was Director, clinical practice had shown that there is no point using whole blood when in the majority of instances, the patient needed red cell concentrate. In fact, giving whole blood could be seen as detrimental by overloading the patients' circulation. Therefore, there was no need to persuade clinicians to use less whole blood to release plasma for fractionation. In fact, the requested product was for red cell concentrates in 95% of cases or more, rather than for whole blood.

## Section 5: Arrangements for obtaining and allocating blood products at BTCs

24. ***Please describe the arrangements in place in the SNBTS regions where you worked for the purchase and holding of, and the allocation to haemophilia centres within the region, 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").***

62. Historically, PFC products e.g. Factor VIII, DefIX, Albumin, Immunoglobulin, Hyperimmune plasma were kept by the BTC. We received stocks from PFC that were replenished on a regular basis as they were used.

63. We also kept stacks of FEIBA (a commercial product for haemophiliacs with inhibitors). I am not sure what the arrangements were to procure the non-PFC products. However, as far as I know the BTCs where I worked did not have any funding for these products. So, I am pretty sure they were centrally procured. As far as I can remember, there was never an issue with supply or shortages, although I believe there were occasions when we had some BPL products as well.

64. As far as I remember we never stocked in Inverness and Dundee US imported products during the time I worked there.

***In particular:***

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

65. While I worked there, (1993-99) the only haemophilia centres supplied by the BTCs were in Raigmore and Ninewells Hospitals.

***b. Please outline the respective responsibilities of each BTC, the PFC, the Common Service Agency (CSA), Scottish Home and Health Department (SHHD) and successors, and haemophilia centre directors, and how these responsibilities changed over time.***

66. The BTCs (5 in number) and PFC were managed by SNBTS- which in turn was under the management of CSA (Common Services Agency) which in turn reported to SHHD. CSA was a support agency for the whole of the NHS in Scotland. There were many branches within it, of which SNBTS was one. There was also the Scottish Ambulance Service (which later separated from it); National Statistics Division; Central Legal Office, Information and Statistics Division; Anti-Fraud office and others. These arrangements did not change during my tenure at both BTCs.

**25.** ***Please explain whether any forums were established between BTC, the PFC, the Common Service Agency (CSA), Scottish Home and Health Department (SHHD) and successors, 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?***

67. The 5 Regional Transfusion Directors and PFC Directors met regularly at SNBTS MSC (Medical and Scientific Committee) and Board Meetings, held approximately at 2 monthly intervals. The former were chaired by the medical

and Scientific Director and the latter by the National Director. Sometimes, the Acting Chief Medical Officer of Scotland attended the MSC meetings. I believe that the Medical and Scientific Director and the National Director attended CSA meetings and I am sure that CSA had meetings with SHHD, but the frequency with which they were held and what was discussed, I was never privy to.

68. The meetings I attended were all minuted. As a broad generalisation, at MSCs medical and professional matters were discussed, whilst at Board meetings, management and financial matters were discussed. However, the membership of both was very similar but not the same, so many agenda items at both meetings overlapped to some extent.

69. I believe there were discussions at CSA about the possibility of SNBTS becoming an independent entity. I was not party to these discussions and during my employment with SNBTS, it remained under the management of CSA (which changed its name to National Services Scotland -NSS).

**26.** ***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 in other regions, or was there a degree of regional differentiation (and if so what)?***

70. As far as I am aware, the arrangements for purchase, storage and distribution of all blood products were centrally funded and controlled and it was similar in all regions.

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

- ***a. how and by whom the decision was made to contract with the particular pharmaceutical company;***
- ***b. the broad terms of the contractual agreements made; and***
- ***c. the factors taken into account when determining whether to contract with one pharmaceutical company over another.***

71. I never contracted directly or indirectly with any pharmaceutical company in connection with the importation of blood products.

**28.** ***What was the impact on the BTC of shortfalls in NHS products coming from the PFC? How frequently did this occur?***

72. I cannot remember shortages of NHS products coming from PFC during my tenure in Dundee and Inverness BTCs. There may have been occasions when we got BPL products instead.

**29.** ***Were the BTCs 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? If haemophilia centre directors were responsible for these decisions, did the BTCs have any influence over their product choices?***

73. During my stay in Inverness and Dundee I had no say or influence in the choice of product to treat haemophiliacs. My recollection is that mostly PFC products were used. Decisions on which products to use and what quantities were manufactured were generally taken at Haemophilia Directors meetings with key PFC and Scientific staff. I did not attend those meetings.

**30.** ***What, in your view, were the key factors influencing the choice between NHS blood products and imported blood products?***

74. I am not in a position to answer this question. These were clinical decisions based on agreements made between the haemophilia directors and PFC. I did not attend these meetings.

**31.** ***Please explain, in your view, the impact of clinical freedom on the relative use of NHS blood products and imported blood products in the UK.***

75. Please refer to my answer to Question 30

32. ***As far as you are aware, what influence did pharmaceutical companies have in the way that the imported blood products they supplied to the BTCs/Regions were used? For example, can you recall whether pharmaceutical companies provided advice on the use of the products?***

76. See my answer to question 30. I was not involved in any instance where pharmaceutical companies provided me with any advice on the use of any product.

**Section 6: Production of cryoprecipitate**

33. ***Did the BTC produce cryoprecipitate? If not, where was this produced for the BTC region and what were the arrangements in place?***

77. Yes, both Inverness and Dundee BTCs produced cryoprecipitate. The number produced was based on clinical demand.

34. ***If the BTC did produce cryoprecipitate, please describe:***
    a. ***where the production of cryoprecipitate took place;***

78. The production took place at both Inverness and Dundee BTCs Once the processing and testing sites were transferred to Edinburgh and Glasgow around 1998, cryoprecipitate was produced in the SNBTS laboratories at these sites.

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

79. The process was a relatively simple one and included the thawing of frozen plasma followed by centrifugation and resuspension. The product was then refrozen. It did not require specialised equipment but the process was longer than the production of FFP and required more staff time to manufacture it.

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

80. I cannot remember how many units of cryoprecipitate were produced in Inverness or Dundee, but it was led by clinical demand. As far as I know no cryoprecipitate was sent to BPL from Inverness or Dundee BTCs. Whether the processing sites (Edinburgh and Glasgow) - once established - did, I do not know.

***d. how much funding was provided by the CSA/health or other government or public agencies for the production of cryoprecipitate; and***

81. No separate funding was given for the production of cryoprecipitate. All BTC functions were centrally funded.

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

82. Whilst the process of producing cryoprecipitate is relatively simple, to increase production would need extra resources. The process does require more staff time and training. Therefore the speed of increased manufacture would very much depend on how big the increase in cryoprecipitate production would have had to be. A small increase would probably have been accommodated with the then current staffing complement, but a significant increase would need more staffing and clearly this would cause delays in terms of obtaining funding, training and possibly increased processing laboratory space.

**35.** ***Please explain what consideration the BTCs 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 1980s.***

83. These discussions were mainly held at Haemophilia Directors meetings, but I was not party to those discussions. I only joined SNBTS in 1985 and I was in training until 1989.

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

84. Please refer to my answer to question 37.

**37. *Please describe the arrangements for supplying cryoprecipitate to hospitals and haemophilia centres within the region covered by the BTCs.***

85. Questions 36 and 37. I cannot recollect if the level of cryoprecipitate was increased or not. I was in training until 1989. As far as I know the requests for cryoprecipitate or FFP or Factor VIII concentrate was clinically led and the BTC staff responded to these requests in a timely manner. Whether cryoprecipitate or Factor VIII was produced, was a decision taken by the haemophilia directors in discussion with SNBTS PFC and Scientific staff. Regular meetings were held.

## Section 7: Self-sufficiency

**38. *During your time at BTC, what did you understand the term 'self-sufficiency' to mean? Did this change over time?***

86. The term 'self-sufficiency' when the Inverness and Dundee Centres had their own processing and testing sites meant that there were enough red cells and platelets and FFP/cryoprecipitate to satisfy local demand and collection of enough plasma to meet clinical demand and PFC targets. My belief is that PFC targets were set to achieve self-sufficiency in Factor VIII and other fractionated products for Scottish patients- e.g. intravenous immunoglobulin. The latter became the main driver, once recombinant Factor VIII became available, I believe in the mid 1990s.

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

***a. plasma procurement;***

***b. decisions with regard to cryoprecipitate production;***

87. Please refer to my answer to Question 38.

***c. purchases of commercial blood products;***

88. I was not involved in any purchase of commercial products. The BTCs I worked in (Inverness and Dundee) were 'stockists' of all fractionated products, commercial or otherwise.

***d. funding received from the Common Services Agency or other government agencies or departments.***

89. Central funding was commensurate with the activities of the BTC and targets agreed with PFC.

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

90. It is my understanding that whilst Scotland had or nearly achieved self-sufficiency in all plasma products, the same was not the case in England.

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

91. Yes.

**Section 8: Services for donors at BTC**

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

92. HIV testing started around 1985. I was still in training at the time. I cannot comment or remember what counselling was offered specifically to HIV positive donors. However, I will describe below (in my answer to question 43) what I believe was the standard of care offered to all donors who had confirmed positive microbiological markers.

43. ***What counselling and psychological services were available for donors who tested positive for hepatitis or HIV? Were such services delivered by the BTCs or were referrals to other agencies made? Please describe the process.***

93. When I became a Consultant and later a Director from 1990 onwards, it was always felt that SNBTS had a duty of care to its donors, including those found positive for microbiological markers.

94. Donors who had a confirmed positive to one of the markers we tested for, were asked to come back to the Centre via a registered letter. Care was taken to send the letter at the beginning of the week, so that the donor would not receive 'bad' news at the end of a week and have to wait anxiously throughout the weekend. An urgent appointment would be given and the donor seen in private, where a blood sample would be taken to confirm the result of the positive marker. This would also confirm the identity of the donor. A full interview would be held by a senior medical member of staff with the donor to assess any risk factors he/she may have had and try to understand why such risk factors were missed during the donation interview. The donor was then given advice on how to minimise infecting others (household/sexual contacts) and referred to a specialist. This would have been an infectious disease specialist in the case of HIV/syphilis or a hepatologist in the case of hepatitis B/C. Arrangements would have been made before with these specialists to give referred donors an urgent appointment so that they could be assessed by them. The duty of care then was passed on to these clinicians. The donors would be advised that they could not remain as blood or organ/tissue donors. Donors were always asked to

contact SNBTS if they had any remaining concerns. Sometimes donors were seen on more than one occasion.

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

95. Recipients of infected donations were handled differently from donors and for good reason. Once a recipient was identified as having received an infected unit of blood, the Consultant who had ordered the blood would be notified and he would research the patient's circumstances. If the patient was still alive, the clinician would then contact the patient to let him/her know of the possibility of having been infected. When discussing the case with the clinician I asked that he/she always spoke to the patient in person (not by letter for example). The clinician would then agree to speak with the patient, take the appropriate blood samples for testing and refer to the appropriate specialist if required.

45. ***Were these arrangements sufficient in your view? If not, why not?***

96. This was the right way in my view, since the recipient had already built a rapport with the Consultant who ordered the transfusion and both of them would know each other. Therefore, it was much better if the news that the recipient received about having been infected, was delivered by someone he/she trusted, in contrast to staff at the BTC who would not know the recipient at all. Clearly, the clinician would also know if the recipient was still alive or not and could assess a future plan for his patient.

46. ***On 19 December 1990, Dr Cash wrote to you in relation to Guidelines, stating that 'we have done much to secure a position of strength' in relation to HCV (SBTS0000670_112, page 1) and suggesting an expansion of the program. Did you agree with Dr Cash's assessment of the SNBTS as being in a 'position of strength' in relation to HCV testing, and if so,***

***why? What 'professional guidelines' were in place (and from when) in respect of donor counselling (see the reference in SBTS0000670_112).***

97. The letter from Dr Cash is in relation to Donor Counselling- a process I described above in Section 8. I am not quite sure about the context of this letter. I suspect it may be in relation to a SOP that was drafted with other Consultants within SNBTS (including myself) on the procedures I described above. In that case, the context would be to establish common donor counselling SOPs on how to handle donors with positive microbiological markers – HIV HBV, HBC and syphilis. As Dr Cash said in his letter, this may have been done as part of the audit programme run by Dr McClelland. I cannot remember if that is the case.

98. If my interpretation is correct, I do believe that our donor counselling procedures were correct and robust and therefore I agree with Dr Cash's assessment.

99. I do not now have access to the SOPs that covered donor counselling and therefore cannot say when they started to be implemented.

47. ***What was your understanding of the status of these guidelines in relation to guiding donor counselling practice at Centres?***

100. When national guidelines were introduced, the general policy was that the principles were agreed at the Medical and Scientific Committee of SNBTS. Once agreed, each BTC would then implement them, having adapted the SOP to their local circumstances, while sticking to the agreed principles.

48. ***On 15 October 1993, Professor Cash wrote to you and other SNBTS Directors about HCV lookbacks and counselling (PRSE0000796). He stated that "One of the outcomes of the recent HCV Symposium at the RCPE was that there is a need to refer patients who have recently acquired HCV infection to specialists for consideration as to whether they should have early interferon therapy. I do believe this places an obligation on the BTS to use its best endeavours to advise clinical colleagues***

***accordingly when we have evidence that a recipient may have acquired HCV." Did you agree with this suggestion? What did the BTC do in response to this suggestion?***

101. I agree with Dr Cash's comment. At the time when Lookback commenced nationally, the BTC where I worked implemented it in full.

49. ***In a letter of 14 December 1990, Professor Cash wrote to Dr Calman, Chief Medical Officer, SHHD to discuss Blood Donor Self Exclusion Leaflet Policy in the UK (NHBT0000190_063, page 1), stating that "There has been a tradition in Scotland whereby the content of donor self-exclusion leaflets has been the responsibility of SNBTS Directors.... there has been no requirement of SHHD clearance... the significant advantage of this regime has been the speed at which the SNBTS can introduce change." In your experience as a Director, did you feel that you had the autonomy to make changes to leaflets? What was involved in making such decisions?***

102. No. I did not feel I had the autonomy to make important changes to leaflets, particularly in the context of donor self-exclusions. I feel that there was a clear direction that donor exclusion criteria and many other matters should be handled on an SNBTS wide basis. My recollection is that many such decisions were discussed initially by the Scottish Donor Consultants. Once agreed, these were discussed at MSC and, if approved, would then be implemented nationally (within Scotland), with SOPS written locally (as described above). There were also the Donor Services Managers who handled a lot of the donor publicity material. Their Head used to attend the Donor Consultants' group to ensure that any changes in the leaflets were medically correct. It is my understanding that changes in leaflets were also approved at MSC. As time went by, and with the withdrawal of crown immunity, there was a further desire to act in unison on a UK wide basis.

50. ***In the same letter (NHBT0000190_063, page 2), Dr Cash notes that you were part of a small group to ensure 'collective SNBTS input is put into***

***the UKBTS Standing Committee.' Please describe your work within this group. Who else was involved in the group? What was the decision making remit of this group? Did the group make recommendations, decisions or representations to any other SNBTS or other UKBTS group, body or organisation?***

103. I was part of the Scottish Donor Consultants Group, which I chaired for a period of time. I am not sure it had an official remit, but as I recall we used to discuss donor related material, mostly donor deferral or exclusion criteria and we reviewed donor publicity material. We then made recommendations to MSC for approval. There was a push (as I stressed before) that there was a Scottish approach versus a Regional approach in most of what we did.

104. There was also a push to have a UK approach to these matters, and in the early 1990s there was the formation of a Standing Advisory Committee (SAC) on Donor Care and Selection, on which I sat. I was the Scottish representative (along with Mairi Thornton - the Scottish National Donor Services Manager), ensuring that there was commonality north and south of the border. Therefore, relevant issues that arose at the Scottish Donor Consultants Group were also brought to this SAC.

105. This SAC made recommendations to the Joint Professional Advisory Committee of the UK Blood Services. If agreed at this forum then these recommendations were implemented. Actual implementation was the responsibility of the Blood Service of each UK country.

**51.** ***Dr Cash also described differences between the Scottish and English/Welsh systems, suggesting that the Scottish practice allowed for faster changes (NHBT0000190_063, page 1). Dr Cash mentioned this in the context of HIV haemophilia litigation and 'future legal tussles.' In your view, did awareness of or consideration of prospective litigation or legal liabilities inform the development of donor leaflet practice in Scotland or England/Wales?***

106. From my personal perspective, the important aspect of putting items on donor leaflets was that they were medically correct. I suspect litigation was always at the back of one's mind but I am not sure it was a major consideration in development of leaflets and donor exclusion criteria. The emphasis was on scientific evidence and getting the right information on which to make the recommendations. It was important to me that wherever possible the UK acted in unison. This was primarily for the sake of the donors' and recipient safety.

## Section 9: Meetings of various committees

*Meetings of SNBTS Directors / SNBTS Medical and Scientific Committee*

Please see the attached schedule for copies of the minutes the Inquiry holds of meetings you attended.

52. ***As far as you are aware, who established the regular meetings between regional directors of the SNBTS? What do you consider to have been the purpose(s) of those meetings?***

107. The Medical and Scientific Committee (MSC) and the SNBTS Board meetings were already in place when I became director, so I cannot be sure. However, I believe it was a decision of the then Medical and Scientific Director Prof J Cash and Mr David McIntosh to establish these meetings. I think that prior to that there were only the SNBTS Directors' meetings.

108. The purpose of the MSC was to discuss medical and professional matters and to garner expertise from invited experts on an ad-hoc basis. MSC also made sure that appropriate audits took place and that SNBTS was kept up to date with relevant matters. This was usually done by members of the committee reporting back on conferences or meetings attended. The professional contacts of MSC members were very good. Matters agreed at this committee were then brought to the Management Board of SNBTS particularly if they had management and financial implications.

53. ***Please explain the decision-making remit of the group. Did the directors meet in a decision-making capacity or otherwise? Were the directors empowered to make collective decisions that affected the policies and procedures of all BTCs? If yes, please describe the decision-making process.***

109. The best I can describe it is that the MSC made recommendations to the SNBTS board - particularly if the recommendations had financial implications. Decisions that were agreed that were of a professional nature eg a new exclusion criterion, would be implemented after agreement at MSC. In most instances I would say that most of the recommendations made at MSC went to the Board for approval. Even then, some decisions had to go to other fora - CSA, SaBTO, UK JPAC, SHHD etc, depending on the nature of the decision reached.

110. As I have said before, during my time as Director of Inverness and Dundee, there was an increasing effort to have national policies and agreement that was implemented at all 5 centres. The responsibility of implementing nationally agreed policies was that of the local Director.

54. ***The minutes of a meeting of SNBTS directors held on 23 June 1981 record that Dr Cash and Dr Mitchell had been invited to attend meetings of English and Welsh directors. In return, SNBTS directors agreed to invite Dr Wagstaff and Dr Tovey to the meetings of SNBTS directors as "observers" (PRSE0003924). Please explain the purpose(s) of attending meetings in an observational capacity and how this worked in practice. In your view, was this development successful in aiding cooperation between the NBTS and SNBTS?***

111. The decision to have observers at SNBTS MSC meetings was done well before my time. I do recollect NBTS directors/medical staff attending SNBTS meetings but their presence was rare.

112. Therefore, I cannot say whether the earlier attendance of NBTS observers to SNBTS meetings helped with cooperation between the 2 services.

113. During my time as Director, increasingly cooperation on a UK wide basis was sought through the various SACs (Standing Advisory Committees) and JPAC (Joint Professional Advisory Committee of the UK BTS).

**55.** ***It appears that a representative of the Northern Ireland Blood Transfusion Service ("NIBTS") was also sometimes present at meetings of SNBTS directors (PRSE0002617). Was the NIBTS similarly represented in an observational capacity? Please explain the level of cooperation between SNBTS Directors and the NIBTS and whether this differed in any way to the SNBTS' cooperation with the NBTS.***

114. Yes, the NI Director attended as an observer on a regular basis. I believe it was important for the NI Director to keep abreast of developments in Scotland. As I recall (though cannot be 100% sure) SNBTS fractionated plasma for NI Blood service. As I stated in answer to question 54, an NBTS director was invited to join the MSC, this was in 1990 - before I began attending regularly. I believe that when I was present the NBTS medical director rarely attended.

**56.** ***The Inquiry understands that the final meeting of SNBTS Directors took place on 12 June 1990. This forum was replaced with a Medical and Scientific Committee ("MSC") to "consider medical and scientific matters presented by its proposed sub-groups and to reach decisions as to how to advise the Management Board" (PRSE0002954). Please explain:***

***a. Why the meetings of SNBTS Directors were replaced with meetings of the MSC;***

115. I was not party to that decision - so cannot answer this question.

***b. How the MSC meetings differed from the SNBTS Directors meetings in terms of remit, composition, and matters discussed; and***

***c. How responsibility for decision-making by the SNBTS was delegated between the MSC and SNBTS Board.***

***d. You may find SBTS0000456_027 and PRSE0000171 of assistance in answering these questions.***

116. **b and c.** Please refer to my answer to Question 53 above.

117. The composition varied in that the National Director did not attend the MSC but chaired the Board meetings. Otherwise, the directors of the 5 BTCs, the PFC Director and the Scientific Director (National Science Laboratory) attended both meetings. Unless I'm mistaken the NI Director did not attend the Board meetings nor did the Acting CMO of SHHD.

**57.** ***The Inquiry understands that you were initially listed in the constitution of the Medical and Scientific Committee as the Medical Advisor to the Blood Collection programme (SBTS0000456_027, page 4). Please describe the duties, responsibilities and reporting associated with the role. What decisions did you make in the course of this role?***

118. My role as Medical Advisor to the blood collection programme involved having meetings with other SNBTS Donor Consultants. Our main role was to recommend changes to update donor medical issues and to harmonise donor matters throughout SNBTS, e.g. ensuring common donor exclusion criteria, through updating the medical guidelines and common donor counselling practices. We also had input in consultation with the National Donor Services Manager to ensure that the donor questionnaires that donors filled in were common and appropriate. We also conducted a number of audits and studies on the blood collection programme under the auspices of CRAG (Clinical Research and Audit Group).

119. Prior to my membership of MSC whenever there were items to report, I attended MSC (only for the part where I presented my report - I did not become a member of MSC until 1993). Usually, a discussion followed and MSC decided on the next steps - e.g. implement the change, need more information on costs etc. If there were management or budgetary issues, they would be taken up to the Management Board by appropriate MSC members.

120. Most of what was discussed at MSC would also be brought up at the SAC on Donor Care and Selection. In fact, many items brought up at those meetings I would relay back to the SNBTS Donor Consultants and MSC. It was a 2 way process.

121. The major changes the Donor Consultants group proposed were to have nurse led sessions and to introduce personal donor interviews for first time blood donors. Over a period of time these were implemented on an SNBTS wide basis.

58. ***The document entitled 'Management of SNBTS Donor Sessions' (SBTS0000640_009), referred to in the minutes of the 15 August 1991 meeting of the MSC (PRSE0002910), sets out the staffing arrangements for donor sessions. Please outline your understanding of this document. Was it a set policy for the SNBTS? Were the staffing levels adopted by BTC?***

122. I cannot comment whether the document was a set policy since I was not involved in its formulation or implementation but I believe that the staffing arrangements as described in these documents reflected what was happening on the ground at least in the centres I was in charge of.

59. ***The document further provides that you, along with Dr Cash and Mairi Thornton, would review the staffing arrangements of donor sessions on an annual basis. Did the annual reviews proposed take place? If so, were changes made? Please give details.***

123. I do not recollect doing an annual review of donor staffing at sessions with Professor Cash and Ms Thornton.

**60.** ***The minutes of the 9 and 10 February 1995 MSC meeting record that you led a discussion on 'Some views on the MSC with proposals for change', based on views from consultants and scientists in each Scottish region (STHB0000677, p5). What issues, trends or other trends drove this discussion?***

124. I recollect that as a new member of MSC I was asked to consult with colleagues on how to improve the 'image' of the committee. I remember making some recommendations, and I believe that they related to better communication of decisions made by the committee with the rest of the SNBTS. There was a feeling that communication could be improved. There was also a discussion on the MSC membership and how wide it should be and the creation of expert subgroups that reported to the Committee.

**61.** ***At the final SNBTS Directors meeting, it was noted that Dr Lee would be invited to future meetings of the MSC to maintain the link with the Northern Division of the NBTS. Dr Maurice McClelland of the NIBTS was also invited to MSC meetings (PRSE0002954). In your view, was the same level of cooperation between the SNBTS, NBTS and NIBTS maintained following the conclusion of the SNBTS Directors' meetings?***

125. Please refer to my answer to Questions 54 and 55.

*SNBTS Working Party on Donor Counselling for HCV*

***The Inquiry understands that you were a part of this Working Party. Please outline the purposes of this group, its membership, and its relationship to other entities. You may find PRSE0002954 of assistance.***

62. ***In a letter to Dr Gillon of June 1990, Dr Cash suggested that Dr Gillon chair a group, including Drs Galea and Crawford, to draft guidelines for the SNBTS on Donor Counselling for HCV (PRSE0004689).***

126. No question to answer.

63. ***Dr Cash noted 'we would like to see as much harmonisation north and South of the border as possible.'***
    a. ***What was your view of this request for 'harmonisation'?***
    b. ***In your view, was this a relevant consideration for donor selection, including in relation to donor safety or safety of the blood supply?***

127. I believe that there was a real wish on behalf of SNBTS that wherever possible there should be harmonisation of all issues surrounding blood transfusion, North and South of the border. In fact, over the 1990s and beyond there was the establishment of various UK SAC's that reported to JPAC so that most decisions became UK wide. SNBTS senior medical staff actively participated in these meetings. Implementation of decisions made always remained the responsibility of the respective service (NBTS/SNBTS etc) and sometimes, due to the complexity of the issues and the different size of each organisation, the implementation dates did not always coincide, although as I recall, the differences narrowed over the years.

128. There were also meetings between the Medical Directors and National Directors of the respective services that took place regularly. I never attended any of these, but I believe that their main aim was to promote harmonisation of policy implementation and to keep abreast of developments by each service.

*Donor Consultants Group*

***The Inquiry understands you attended and chaired meetings of the Donor Consultants Group.***

64. ***As far as you are aware, what led to the establishment of this group? Who constituted the membership? What do you consider to have been the purpose(s) of those meetings?***

129. I believe that the Donor Consultants group was an extension of my appointment as Medical Advisor to the Blood collection programme. I always preferred working as a team player and wanted to make sure that any recommendations made to MSC etc would have the consensus of all other donor consultants. Its remit was exactly the same as described in my answer to Question 57.

65. ***Please explain the decision-making remit of the group. Did the members meet in a decision-making capacity or otherwise? Were the members empowered to make collective decisions that affected the policies and procedures of all BTCs? If yes, please describe the decision-making process.***

130. The group met to discuss areas of interest to the blood collection programme - mostly of a medical nature and sometimes also on operational/management issues. All the recommendations went to MSC for agreement or otherwise. If MSC approved the recommendations, they were either implemented or taken to the SNBTS Board if there were management or financial implications.

*Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI)*

66. ***The Inquiry understands that you were a member of the SACTTI Working Group on vCJD and vCJD Test Sub-Group. The meetings of minutes you attended are listed in the Schedule for your reference. Please outline your involvement in these and other SACTTI groups.***

131. I attended some of the meetings of the SACTTI Working Group on vCJD. I am not a transfusion infection expert and certainly not an expert on vCJD. These meetings began in or around 2004. By this time I had been the Tissue Services Director, in charge of the tissue and cells programme within SNBTS for over 4 years. My role in attending these meetings was to keep abreast of vCJD

developments and in particular, to assess, if, what was discussed in the blood arena was applicable to tissues. This ranged from donor selection criteria to processing and testing of tissues. I was never a member of SACTTI.

67. ***As far as you are aware, what led to the establishment of this group? Who constituted the membership? What do you consider to have been the purpose(s) of those meetings?***

132. I'm not sure exactly how the group originated or on whose recommendation. I suspect it was either JPAC or SACTTI, with a remit to look at the safety implications of the impact of vCJD on the blood (and tissue) supply. At the time vCJD was a very serious concern for the blood services in the UK.

68. ***Please explain the decision-making remit of the group. Did the members meet in a decision-making capacity or otherwise?***

133. I am not certain, but I believe the group reported to either SACTTI or JPAC. Some of the issues were very complex and costly. Many of the recommendations also went to MSBT (SaBTO) and from there to Ministers.

*United Kingdom BTS / NIBSC Standing Advisory Committee on the Care and Selection of Donors*

69. ***The Inquiry understands that you participated in this advisory committee, serving as a Member and Chair. The Inquiry holds minutes of meetings of this committee from 1991 to 2006. The meetings of minutes you attended are listed in the Schedule for your reference. What do you consider to have been the purpose(s) of those meetings?***

134. I was a member of the SAC on the Care and Selection of Donors as the SNBTS representative. I was never a chairman. The purpose of the Group from the beginning was to act as a focus for discussing donor selection guidelines and other donor related matters that were harmonised amongst the 4 UK blood services.

70. ***Please explain, as far as you are able, the decision-making remit of the group.***

135. The remit was to discuss donor issues amongst selected donor consultants from the 4 UK Blood Services. Issues arose either from the group or were brought up by people on the ground (working at donor sessions) who had met with situations that needed clarification or further advice. Items were brought up and if the group felt that extra expertise was needed, appropriate experts were specifically asked for their opinion prior to making a decision.

136. The item remained on the agenda until a satisfactory answer was obtained and the committee was satisfied.

137. Sometimes other committees were asked for their input (eg SACTTI). There was quite a lot of 2-way flow on many matters. Cognisance was also given to the Council of Europe exclusion criteria to assess whether specific criteria needed to change in the UK. Also, updates from AABB, FDA and EU were standing items on the agenda. This ensured that the committee was kept up to date.

138. Once a decision was reached it went to JPAC for approval. Once a decision was approved, it was made clear on numerous occasions that the remit of the group was to make medical recommendations not to implement any of the changes. That was the responsibility of the relevant Blood Service.

139. The SAC also concerned itself with the revision of donor material, e.g. the Blood Safety leaflet. A lot of thought went into formulating these exclusion criteria, with the rationale being provided on each exclusion criterion (eg **JPAC0000002_013**). During my time on the committee, there were two (maybe 3) revisions of the leaflet that took place. In view of the sensitivity of such exclusions, all the recommendations on both occasions went to EAGA (Expert Advisory group on AIDS - as far as I know a Government Body) for approval and also to SaBTO, particularly in the later revisions.

140. This SAC was also in charge of producing the MAD (Medical Assessment of Donors) guidelines. Again, the implementation was left to the individual BTCs. Whenever a change was recommended that was considered urgent (and therefore could not wait until the next update), a Concessionary Letter was issued by the chair.

71. ***Supplementary Question 1:***
***At paragraph 140 of your draft statement, you state that "This SAC was also in charge of producing the MAD (Medical Assessment of Donors) guidelines." Please outline the role of the SAC in producing these documents. What was the purpose of these guidelines? You may be assisted by the document WITN3530083.***

141. The SAC on the Care and Selection of Donors was tasked with producing and updating the Donor Selection Guidelines (also known as the Medical Assessment of Donors guidelines within SNBTS, and colloquially as "the A-Z"). See also my reply to Supplementary Question 4 below. Most of the discussions at the SAC revolved around donor selection and exclusion criteria and the members of the SAC were all senior medical staff involved in donor care. Therefore, the SAC was the right forum to produce and update these guidelines.

142. These criteria were sent to JPAC for approval, after which it was left to the individual Blood Services to implement. Most of the time , their implementation took place at the same time, throughout the UK (or in very close proximity in time).

143. Within SNBTS, these guidelines would have been approved by the Medical and Scientific Committee and then action taken (resources, training etc) to implement them. These were used constantly and consistently at donor sessions to provide advice to clinical staff to accept or defer a donor. In the majority of instances, nurses and medical staff at sessions adhered to them very closely.

144. However, it is also important to note that the decisions to accept or defer a donor rested with the clinical staff (nurses and doctors) at sessions. Therefore, these guidelines could be varied at their professional discretion, provided they adhered to the concepts within them. Very often in my experience, clinical staff took a precautionary approach and deferred donors when they had any doubt.

145. An annual meeting was held with all donor medical and nursing staff of all the UK Blood services. The main purpose of such a meeting was to ensure that all staff were up to date with all the changes that took place.

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

146. As explained in response to question 70, the meetings were very conducive in fulfilling their purpose.

73. ***The Inquiry understands that you were involved in several policy audits. Please describe the use of audits as a tool within the Committee.***

147. I was not involved in policy audits as part of my membership of this group. The policy audits I recall to have undertaken were in SNBTS - on the deferral of donors in 2 centres (SE and NE Scotland), and on the introduction of personal interviews at sessions in Dundee.

74. ***Please describe the role of the Committee in coordinating donor selection policies between jurisdictions. In your view, was the Committee effective in resolving differences or aligning common issues between different blood services and agencies?***

148. As explained above, the process of changing a donor criterion was very thorough and therefore the significant majority (if not all) exclusion or deferral criteria were referred to JPAC for their consideration. Efforts were made at that forum to agree common (or as common as possible) implementation dates.

75. ***How influential was the committee in setting national policy on donor selection?***

149. The SAC was influential in coordinating donor selection policies.

76. ***Did any conflicts of interest exist between the aims of the committee and those of the organisations it was answerable to? If yes, what effect, if any, did these have on the development of policy?***

150. To my knowledge there were no such conflicts of interest - all members of the committee were staff of blood services.

77. ***What other organisations, if any, had influence on the committee's advice?***

151. Whenever it was felt necessary, input was sought from other SACs to formulate a recommendation. As previously indicated most (if not all) the recommendations, were sent to the 4 blood services, once approved. Some were sent to EAGA and some to SaBTO depending on the recommendation in question. These committees could all accept or modify the committee's recommendations.

78. ***How were the committee's decisions communicated to the NBTS / SNBTS?***

152. Please refer to my answers to Questions 70 and 76.

79. ***It appears the committee developed recommendations on the deferral periods of donors in particular categories, in particular, for donors who may pose a risk of transmissible infections.***

153. No question to answer.

80. ***How frequently were the deferral periods for donors reviewed?***

    a. ***Please describe the process of reviewing whether a deferral period was appropriate, including the types and sources of evidence which were taken into account.***

    b. ***How were decisions ultimately taken on whether to revise an established deferral period?***

154. The deferral periods varied and depended on the clinical situation. Some were based on historical data (e.g. vaccines), some were based on similar situations, e.g. rheumatoid arthritis and other autoimmune disease, and some were new situations, where advice was sought from experts or committees, particularly SACTTI e.g. deferral post endoscopy. In the case of deferral for high-risk behaviour, in view of the sensitivity of the situation, advice and approval was sought at the highest level e.g. EAGA.

81. ***A fax from yourself to Dr Boulton in December 1998 describes the questioning of blood donors by the blood services in the Netherlands, Germany, Ireland and America (JPAC0000021_006).***

    a. ***How frequently, if at all, were international approaches to donor selection and donor questionnaires analysed? Who instigated this research?***

155. In this case, the information was requested by the chair of the SAC, Dr F Boulton (as the document states). I suspect it was one of the many sources collected in preparation of the Safety leaflet update/revision. Information on international practices was sought when deemed relevant, on an ad hoc basis.

    b. ***What impact, if any, did the practices in other countries have on the development of donor selection policies?***

156. Clearly deferral criteria in other countries were taken into account as part of the decision making process. However, ultimately the decision was based on local advice and input from UK experts and UK epidemiology.

82. ***Please consider the Committee's role in respect of donor leaflets and blood safety leaflets aimed at excluding high-risk groups. In particular:***

***a. What role, if any, did the Committee play in determining the content of such leaflets?***

157. Please refer to my answer to Question 70.

***b. How often did the Committee consider the effectiveness of such leaflets? How often were they updated, and what did the review process entail?***

158. I believe the Blood Safety Leaflet was updated at least once time during the time I served on this committee (approx. 1991-2000) and I believe there were subsequent changes thereafter. Each review took into account information and issues raised through the application of the previous criteria; an update of the epidemiology and an improvement in the wording and understanding of the leaflet, to make it clearer and simpler for the donors.

***c. In your view as a committee member, what role did donor leaflets and blood safety leaflets play when mandatory exclusion and selection criteria existed? How did both strategies work together to reduce the risk of infection?***

159. Donor leaflets and the Blood Safety leaflet played very important roles in donor deferrals. They were freely available at sessions, and many of the questions/ exclusions formed part of the personal interview questions or the health check questionnaires asked of each and every donor or every occasion they donated.

***d. In 1995, the scope of the Blood Safety Leaflet was expanded to cover HBV and HCV. Why were these viruses not included earlier? In your view, what impact did their addition to the Leaflet have? You may wish to refer to JPAC0000001_014, page 2.***

160. It is my understanding that the first version of the Blood Safety Leaflet was specifically for HIV, which was a very serious issue at that time. The exclusion criteria on this leaflet should also have excluded a number of donors with Hepatitis B and particularly C since some modes of transmission of these viruses can be quite similar. It was felt that specifically including Hepatitis B and C would increase the effectiveness of the leaflet and make it simpler to manage for the staff and the donors to understand.

*The Joint UKBTS/NIBSC Professional Advisory Committee*

83. ***The Inquiry understands that you participated in this advisory committee. The meetings of minutes you attended are listed in the Schedule for your reference. What do you consider to have been the purpose(s) of those meetings?***

161. The purpose of JPAC was to review all the decisions made by all the SACs and to approve them, or otherwise, for implementation by the 4 UK Blood services. My role on this committee was as Chair of the SAC on Tissue Banking. I believe it played an important role in increasing harmonisation of implementation by the 4 UK Blood Services.

84. ***Please explain, as far as you are able, the decision-making remit of the group.***

162. The chairs of the SACs presented the issues to JPAC. Each item was discussed and action taken - eg approved, further information requested etc. The decisions that were approved were then 'handed over' to the 4 Blood services to implement. Wherever possible, the implementation date was as close as possible in the 4 services.

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

163. I do believe that these meetings were conducive to fulfilling their purpose.

## Section 10: Information handling by and information sharing between BTCs

86. ***Please describe the record keeping system in place for blood donations and blood donors at the time of your directorship of the BTCs. In particular, please explain what records were kept, in what form, where and who had access to them.***

164. Initially the system was a manual one, each donor having his own card with the date of each donation. In Scotland around the mid 1980s the system for Donor Records became an electronic one. As far as I know, the system was the same in all regions. However, each BTC had access to the donors that donated in that region. The system was called DOBBIN. When this electronic transfer was done, the paper records, as far as I know, were kept in storage (I cannot be sure of that). Access to electronic donor records was very tightly controlled and strictly on a need to know basis, even within the BTC. Confidentiality was a very important aspect of our relationship with the donors.

87. ***Please set out how long these records were kept for.***

165. It is my understanding that the electronic records were kept indefinitely. An IT opinion would be useful to clarify this.

88. ***Please set out what policy or practice was adopted by BTCs in relation to the destruction of these records.***

166. I am not sure whether any records were ever destroyed. In general, SNBTS used to keep records for a very long time.

89. ***As far as you are aware, did all BTCs follow the same record keeping practices, or did each centre implement its own system?***

167. DOBBIN was a SNBTS wide system, but there was no link between the Scottish BTCs. After DOBBIN, (around 1995) the records from DOBBIN were transferred to a new electronic system called PROGESA by MAK systems. This was a SNBTS wide system.

**90.** ***Do you consider that the record keeping measures in place at BTCs were adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations at that centre?***

168. Yes. I consider the record keeping of our donors was more than adequate to prevent donors suspected as high risk, or who had a positive microbiological marker, from donating, not only at the centre but throughout all regions covered by SNBTS.

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

169. In those BTCs which acted as blood banks for hospitals, the BTC had records of the units that were crossmatched to particular patients. Initially they were paper records, but later became incorporated in the Progesa patient module. The return of data from the hospitals, as to whether the blood was transfused or not, initially was patchy. There were assumptions made that if a unit of blood was not returned to the BTC, it was assumed to have been transfused. This was not wholly satisfactory. However, I understand that many efforts were made to improve the flow of information from the hospitals back to the BTC regarding this and the situation became much better. However, in 2000, I became Tissue Services Director and therefore was no longer in touch with the details of transfusion transactions between hospitals and the BTC.

92. ***What information did BTC provide to SNBTS? For example, were monthly returns submitted? If so, what information was contained within these documents?***

170. As far as I know, details needed to be given as to whether the units provided for patients had been transfused. Paperwork was provided by BTC for the hospitals to fill in and return. SNBTS was provided with regular returns but I am not sure of the frequency, (I was Tissue Services Director after 2000 and therefore no longer in touch with transfusion practices.

93. ***The Inquiry understands that in or around February 1992, you co-authored a document with Mairi Thornton titled 'Purpose of National Medical Register Policy' (SBTS0000449_008) and that this paper was discussed at a meeting of the Medical and Scientific Committee (SBTS0000446_007). What was your view of a National Medical Register policy for donors? What led to the creation of this document and policy? To the best of your knowledge, what were the challenges and limitations associated with implementing this policy?***

171. The National Medical Register (NMR) was an SNBTS electronic system introduced before all the donor IT records became amalgamated into one. Since donor records were kept by each BTC, the NMR was a way of linking all regions, with data of donors who had been discovered as high risk or positive for a microbiological marker. That way a donor from one region could not donate in another region. To maintain confidentiality, the list of donors was 'diluted' by a few other donors who were not high risk, but were also ineligible to donate blood on a permanent basis. The NMR was updated weekly, by a specified consultant in each BTC. There were strict rules on the type of donors that could be placed on it.

94. ***The Inquiry is aware that the Communicable Disease Surveillance Centre ("CDSC") maintained a database to keep track of reporting of blood donors who tested positive for HIV (NHBT0004742_001). The Inquiry understands that this database was in existence in 1989, although it is***

***unclear for how long the CDSC operated it. Please answer the following questions regarding this database, as far as you are able:***

***a. Were you aware of the database, if so, when did you become aware?***

172. I have no knowledge of this database.

***b. Who proposed the creation of the database?***

***c. Did the BTC contribute data on HIV positive donors to the database? If not, why not?***

***d. Are you aware of whether other BTCs contributed data on HIV positive donors to the database?***

173. **b, c and d.** I have no knowledge.

***e. Did the BTC maintain a separate, or additional, database to track HIV positive blood donors?***

174. Yes - please refer to my answer on the NMR to Question 92.

**95.** ***Was viral hepatitis, NANB hepatitis or hepatitis C a notifiable disease during your tenure? If so, what obligations did this place on the BTCs? Did BTCs comply with these obligations? If not, why not?***

175. Confidentiality between the donor and the medical staff of SNBTS was critical. It is therefore my understanding that once a donor was counselled by SNBTS medical staff and referred to a specialist, at that point their duty of care was transferred to the clinician. The clinician/specialist would then notify the appropriate public health authority of the hepatitis in question.

**96.** ***Did the requirement to notify change during your tenure? If so, how and when?***

176. No. Please refer to my answer to Question 94.

**97.** ***In addition to the database(s) mentioned above, did BTCs share information with other BTCs about excluded donors, donors that posed a risk to the safety of the blood supply, or infected blood donations? If yes, was this on a formal or informal basis? Please describe the mechanisms each BTC used to share this information, if any.***

177. Please refer to my answer to Question 92. I provided details of how these donors were handled. It was a formal requirement to input data on NMR covered by detailed SOPs.

**98.** ***In your opinion, were the information sharing measures in place between BTCs adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations?***

178. Yes. The sharing measures in place between the BTCs were robust and adequate. I cannot remember an instance where the system failed.

**99.** ***Was viral hepatitis, NANB hepatitis or hepatitis C a notifiable disease during your tenure? If so, what obligations did this place on the BTC/Service? Did the BTC comply with these obligations? If not, why not?***

179. Please refer to my answer to Question 94.

**100.** ***Did the requirement to notify change during your tenure? If so, how and when?***

180. Please refer to my answer to Question 95.

**Section 11: Knowledge of risk of infections**

*HIV/AIDS*

**101.** ***During your time at the BTCs, 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?***

181. In the 80s it was clear very early on to me that HIV could be transmitted via blood and blood products (Factor VIII etc). Specific groups of people (eg gay men and intravenous drug users) were at high risk of transmitting the virus. At that time I was still in training but many conferences I attended discussed the topic and identified the high risk groups of donors. Also much work and research was done by the BTCs and through the SAC on care and selection of donors, to exclude people in these categories and others too eg donors who had heterosexual sex with people in sub-Saharan Africa, where the disease prevalence was very high. These categories were reviewed on a regular basis and refined/changed depending on the epidemiology data etc. Behavioural questions were asked to each donor on each and every occasion they attended to donate blood. Therefore through my attendance of the SAC and other scientific conferences, I kept myself up to date on the risk of transmission of the different donor groups and different blood products and components

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

182. Around 1983/4. I had started training in transfusion at the time and it was a very topical issue, discussed at the scientific conferences I attended.

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

183. Please refer to my answer to question 100. I was in my early transfusion training at the time and cannot comment in any detail and I had no direct involvement. However, I believe that as soon as the high risk groups were being identified,

questions were being asked of donors, so that the donors could not donate blood.

*Hepatitis*

**104. *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 the BTCs? How did your knowledge and understanding develop over time?***

184. The risk of transmission of Hepatitis B has long been known and I believe testing in the context of blood donation started in 1972 or thereabouts.

185. It was known for some time that there was another type of hepatitis (non A non B) that was being discovered more frequently in patients where the markers for hepatitis A and B were negative. I believe that it was often asymptomatic and subclinical but like hepatitis B, could give rise to liver failure. In the 1990's a test was manufactured and the disease became known as Hepatitis C. Initially there was no known cure for both types of hepatitis, but in the early 1990's antiviral agents became available that could ameliorate the disease in many patients.

186. I am not a virologist, but my understanding is that Hepatitis C was less infectious than Hepatitis B and the tests available for screening blood donors for the disease were initially quite non-specific. There was also a debate about the use of surrogate markers for this disease- ALT and anti-core tests. To my knowledge they were not deemed suitable for routine donor screening of blood donors in the UK, partly because of the impact on the blood supply. I believe some estimates stated that 3-5% of blood donors would be excluded from donation if these tests were to be implemented. This would be a very significant loss of donors that had to be taken into account.

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

187. Please refer to my answer to Question 103.

106. ***What, if any, further enquiries and/or investigations were carried out at the BTCs in respect of the risks of the transmission of hepatitis? What was your involvement? What information was obtained as a result?***

188. The risk factors for Hepatitis were similar to HIV so, over time, they became incorporated in the Blood Safety Leaflet, e.g. transmission via intravenous drug abuse (though the transmissibility risk varied). So, all the behavioural questions became a standard to ask to all donors on each and every occasion they presented to donate blood. The Blood safety leaflet was all encompassing and tried to capture all potential risks. Anything raised at that point by the donor, was further delved into by the nursing staff at sessions, to assess whether the donor could in fact donate blood or indeed why he/she presented to give blood in the first place.

107. ***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?***

189. Please refer to my answer to Question 103.

108. ***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 U.K 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 yes, when and in what circumstances did you become aware of the findings of this paper? If no, when did you become aware of it and/or the conclusions set out within it?***

190. I was still in training in 1986. I was not aware of this paper.

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

191. I cannot remember if these specific figures were discussed, though I am sure they would have been. Data were kept under review even after the introduction of testing, e.g. I can remember residual risk being discussed (even after the introduction of HCV PCR testing) on a number of occasions. Data was presented by the experts at MSC meetings and decisions about testing etc were made at committees I did not attend – e.g. SHHD. Detailed discussion also took place at SaBTO and recommendations were made to ministers as required via that group.

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

192. Please refer to my answer to Question 107.

*General*

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

193. As part of the SAC on the Care and Selection of Donors, it was clear that HIV and Hepatitis B and C were a serious threat to the safety of blood. The main exclusion criteria were contained in the Blood Safety Leaflet and on the donor

health check questionnaires and were under constant review. The criteria were updated in the 10 years I was on that Committee. All the updates were based on UK epidemiology and other scientific evidence of transmission.

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

194. Decisions on the Donor Selection Criteria were part of the remit of SAC on Donor care. SACTTI had a major role in the testing protocols and clearly the BTCs had a major role to play in the implementation of the decisions reached.

112. ***What if any role did each BTC 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.***

195. I was not involved in the decisions made regarding the advice on the risks of viral transmission via different blood products and components. I believe that the haemophilia directors were very knowledgeable about these risks. Moreover, I am aware that there were haemophilia directors' meetings with SNBTS where these issues were discussed. I did not attend these meetings but I believe that the choice of blood products to be given to haemophiliacs and other patients needing blood products was discussed at these meetings. Around 1995 (cannot be sure) recombinant factor 8 became available and this was seen as a major safety improvement in this context. Prior to this various treatments to human Factor 8 had also made these products safer (eg heat treatment and filtration).

113. ***Supplementary Question 2:***
***At paragraph 191 of your draft statement, you state that you were "aware that there were haemophilia directors' meetings with the SNBTS.... I did not attend these meetings." The Inquiry understands that the meetings for 21 July 1989 and 11 May 1990 record you as attending. Could you***

***please confirm your understanding of whether you attended the meetings, and if appropriate, amend your draft statement to reflect this? You may be assisted by the documents PRSE0004188 and PRSE0003783.***

196. I did not regularly attend the meetings between Haemophilia Directors and SNBTS Directors, although I did in fact attend the meetings held on 21 July 1989 and 11 May 1990. This was because the Director could not attend and I deputised for him.

**114.** ***Supplementary Question 3:***

***In a letter to Dr Gillon of June 1990, Dr Cash suggested that Dr Gillon chair a group, including Dr Crawford and yourself, to draft guidelines for the SNBTS on Donor Counselling for HCV (PRSE0004689). Did this group meet? If so, please outline the purposes of this group, its membership, and its relationship to other entities. What, if any, guidelines or other policies, procedures or documents did the group produce? Were you involved in any other working parties or groups relating to HCV counselling within the SNBTS? You may be assisted by PRSE0000515.***

197. The group did meet - I believe once in Edinburgh. Professor Cash had asked Dr Jack Gillon to form a small ad hoc group to formulate guidelines on donor counselling following the findings of a confirmed positive virological marker with particular reference to Hepatitis C. The group consisted of Dr Gillon (who chaired the group), Dr Robert Crawford (from Glasgow RTC), Dr Jan Davidson (Edinburgh BTC) and myself. We were all medical staff with a special interest in donor care. We drafted our thoughts on how to handle donors' donations in such circumstances and provide guidance on donor counselling. It is my understanding that whilst the report of our deliberations was for the attention of Professor Cash, Dr Gillon was asked to share it with Dr Harold Gunson at NHSBT, so that as much commonality as possible was achieved north and south of the border. As I recall, the report was the basis of the donor counselling SOPs within SNBTS and on donor re-entry criteria.

198. I was not involved in other working groups relating to HCV counselling.

## Section 12: Reduction of risk of infections

*Donor selection*

115. ***What donor selection policies and processes were in place during your tenure at the BTCs, and how did these change following the emergence of:***
    a. ***AIDS/HIV;***
    b. ***NANB/HCV; and***
    c. ***HBV?***

199. The deferral criteria following the emergence of HIV changed to include the permanent exclusion of donors discovered as HIV positive, Intravenous drug users, homosexual men engaged in high risk practices and prostitutes. A fixed exclusion on people who had sex with high risk people or with someone who lived in a high risk area- sub-saharan Africa. These criteria are very well described in **JPAC0000001_014**. The exclusion criteria included Hepatitis B and C and the donor selection policies over time became more standardised and were updated on a regular basis. The Blood Safety Leaflet (part of the donor selection process) was also regularly updated. SNBTS used these as a basis for their guidelines.

116. ***What national guidelines (if any) informed the donor selection policies and processes at the BTCs you worked with? In the event that the BTCs processes differed from any such guidelines, please explain how and why.***

200. The Medical Assessment of Donors (known colloquially as "the A-Z") was issued by JPAC and updated by the SAC on Donor Care and Selection. SNBTS adopted these guidelines in their entirety (or very close to them), but used their own SOP system to implement them. The implementation times were very close to those in the rest of the UK.

**117.** ***How were decisions made as to which donors were high risk and should be excluded from donating at each BTC? What was your role in this process at BTC? Were these decisions reviewed and, if so, how often?***

201. The decisions on high risk donors were made at the highest levels. The SAC on Donor Care proposed the changes and these were approved at a number of other committees including JPAC, SaBTO and EAGA.

**118.** ***How were decisions made at BTC as to which donors were high risk and should be excluded from donating? What was your role in this process?***

202. If donors were a first time donor or a lapsed donor (had not donated for over 2 years), they underwent a personal donor interview in private to elicit any high risk behaviour. Regular donors underwent a health check questionnaire. In Dundee (where I was Director) these changes occurred around 1997. This questionnaire was then checked by an SNBTS member of staff. Each donor signed that they understood the questions and that they agreed to be tested. The staff took a very precautionary approach and if there was a doubt in their mind that the donor fell into one of the high risk criteria, the donor was politely declined from donating. My role was to oversee that all procedures were in place, adequate training was given to the appropriate staff. Sometimes staff asked me if the right decision was taken, and I discussed their concerns with them individually.

**119.** ***Were there any difficulties in implementing the exclusion of high-risk donors at BTC?***

203. There were no difficulties in implementing exclusion of high-risk donors at BTCs where I worked. Staff were trained to handle potentially quite difficult and sensitive situations.

**120.** ***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 BTC produce its own leaflet?***

204. There were leaflets available at all sessions asking donors not to donate if they felt they were high risk and to speak to the clinical staff if they had any doubts. The leaflets were SNBTS wide leaflets.

**121.** ***How often were these leaflets updated, and how was their content decided?***

205. From my recollection, these leaflets were updated as necessary by the Donor Services Managers, but they were all based on the agreed donor selection criteria at the time of their publication.

**122.** ***What, if any, additional information was given to donors about the risk of them transmitting infection via their blood besides that contained in donor leaflets? When and how was such information provided?***

206. I believe there were media campaigns to explain to people about the issue of high-risk donors and blood donation - but I cannot remember the details.

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

207. I do believe that these leaflets and other communications were effective in reducing the risk of donations from high-risk individuals. Besides, there was a campaign, stressing that if people felt that they needed a test eg HIV, they should not give blood just to get a test, but that they should go to a STD clinic, where they could be tested anonymously.

**124.** ***On 16 November 1990, you wrote to Professor Cash to discuss AIDS leaflets from England, the UK and other countries, among other issues (MACK0001160). On page 3, you discussed excluding donors who were regularly using blood products, noting that "Although the risk from FFP***

***and Cryo are obviously much less in terms of donor exposure, FFP and Cryo are untreated in contrast to Factor VIII concentrates. Although epidemiologically the risks of exposure to FFP and Cryo are less than Factor VIII, I think that from a medico-legal point of view one should not accept such a risk, knowing that it exists." Did this view of risk inform donor policies? Did your view of the correct medico-legal approach to risk change over time?***

208. I suspect medico legal issues played a role in the decision making process. From my perspective, I was always of the view that the 4 UK blood Services should harmonise as much as possible in their policies and implementation dates. Some were relatively easy to achieve, e.g. implementing a new deferral criterion, others were much more complex and involved decisions at Governmental level - e.g. dependence on US plasma in the context of vCJD.

209. My view always remained that, wherever possible, there should be common approaches within all 4 UK Blood services. Probably, over time, my view became stronger. The withdrawal of Crown Immunity and the increasingly litigious behaviour of people in general probably strengthened my view that we should not have different policies amongst the 4 UK blood services. In general, my approach became more precautionary e.g. in the context of vCJD.

**125.** ***On 29 January 1991, Professor Cash wrote to Dr Crawford regarding the 'A-Z' of donor selection policies, noting that he had also provided Dr Crawford's comments to you (SBTS0000670_135). In that letter, he stated that, in relation to establishing 'harmony among the UK BTS': "This policy is closely associated with another parallel happening – the emerging propensity for citizens to resort to litigation against the NHS. The SNBTS Directors have decided to direct their attention to the concept of collective defence and because the CSA now foots all legal bills (including the medics medical defence payments), the strategy we have developed has much central support."***

***In your experience, did the knowledge of increased risk or incidence of litigation change or affect how the SNBTS or UKBTS developed its donor selection policies?***

210. All donor policies were based on medical and scientific knowledge. However, the increased risk of litigation probably made them more precautionary in nature. All Blood Services were very aware that donors were giving blood voluntarily, and besides ensuring that the blood they gave was safe, we wanted to ensure that the donors themselves came to no harm through the process of donation.

**126.** ***The SNBTS Medical and Scientific Committee minutes for the meeting of 27 November 1992 (PRSE0000874, page 7) recorded that you were leading an audit of donor deferral policies in North-East and South-East BTCs. Please explain what the audit involved, and any key findings. What led to the adoption of audit policies? Did you carry out other policy audits? Was the Scientific and Medical Committee able to make recommendations or binding policy on these recommendations or findings? You may find SBTS0000458_028 and SBTS0000479_048 of assistance.***

211. The audit was conducted between Aberdeen and Edinburgh BTCs over a 10-month period, looking retrospectively at the deferral patterns of donors. The study is explained very well in SBTS0000458_048. In summary, the key findings were:

*That most of the deferral processes were appropriate

* The SNBTS donor selection guidelines were fit for purpose

* The deferral rates were different between the 2 centres, and the potential reasons for this were thoroughly examined

212. However, a couple of key reasons were thought to be the most important (a) Edinburgh had a personal interview process for first time donors and (b) the quality of the decision making process in terms of deferrals was the same irrespective of the status of the person doing the deferral eg clerk, doctor or nurse.

213. The policies that were audited were decided upon by the SNBTS Medical Audit group and MSC.

214. I also carried out a separate audit on Personal Donor Interviews in Dundee, whilst I was Director there. SNBTS recommended that Personal Donor Interviews for first time donors should be introduced throughout Scotland. This had significant resource and training implications and they were introduced after the appropriate resources were found and training was done on all the necessary staff. Nurse led sessions were also introduced throughout Scotland, following further pilot studies in the West of Scotland (which I was not involved in) looked at nurse led sessions, and these were also implemented in the mid 1990s (around 1995, I believe).

*Introduction of virally inactivated products*

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

215. I cannot answer this question - I was in training in the late 1970's and mid 1980s.

216. Although I cannot recall specific details, since I did not attend Haemophilia Directors' meetings, I would be confident that safer products from PFC or the use of recombinant Factor VIII was discussed with the Haemophilia Directors. They would have made appropriate recommendations.

*Provision of diagnostic screening kits*

**128.** ***Please describe the arrangements in place at each BTC in regards to the provision of diagnostic testing kits for donation screening ("screening kits").***

217. Initially all of the 5 BTCs had their own processing and testing laboratories and therefore had their own stocks of screening kits. After the rationalisation of processing and testing in the mid to late 1990s, the kits were only available at the testing sites. The kits would have been approved for SNBTS use by microbiological experts (at National Microbiological Reference Unit) and laboratory managers.

**129.** ***Did you, or anyone else at BTC, contract directly with any pharmaceutical company involved in the manufacture and/or sale of screening kits, or were contracts negotiated on a national basis?***

218. I was never involved in any evaluation of the kits, but my understanding is that there was a kit evaluation team who assessed screening kits (see the answer to question 125) and the contracts were handled nationally.

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

219. I cannot answer this question as I was never involved.

**131.** ***What influence did pharmaceutical companies retain after supplying screening kits to the UK? For example, can you recall whether pharmaceutical companies provided advice on the implementation or use of the screening kits?***

220. I cannot answer this question as I was never involved.

*Introduction of HIV testing*

132. ***The Inquiry understands that HIV screening was to commence on 14 October 1985. Please confirm whether Aberdeen BTC were able to commence screening on this date. If yes, please explain the steps taken to ensure that Aberdeen BTC could begin screening on this date? If not, please explain when Aberdeen BTC commenced screening and how this was achieved.***

221. I cannot remember the exact day. I was not in charge of the Aberdeen centre and was not involved in any discussions on the start date.

133. ***Please describe the implementation of HIV screening at Aberdeen BTC. In particular:***

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

222. All donations were screened for HIV antibody. If reactive, the tests were repeated twice. If 2 out of the 3 tests were positive, then donors would be classified as repeat reactive and the sample sent to the Microbiological Reference Unit for further testing. There, a series of other tests were done to confirm the infection. The donation from a donor who was repeat reactive was discarded, as was any donation from a donor who tested positive. If a donor was found to be repeat reactive for HIV (but not confirmed) on 3 separate occasions he or she would be asked to stop being a donor, since we could not use their blood, and it was felt to be unethical to keep on bringing forward these donors and discarding their blood indefinitely.

223. Donors found to be positive on confirmatory testing were contacted and counselled as previously described and referred to a specialist.

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

224. I believe all the units in stock at all the SNBTS BTCs were tested.

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

225. See my response to question 130a. In addition, all donations from the donor would be withdrawn from the BTC stock and discarded. Moreover, any previous archived samples from that donor's previous donations would be tested. If any samples were found to be confirmed positive, the fate of those donations was established. Depending on their fate, appropriate action would be taken:-

- Blood not used - no further action would be indicated
- Plasma sent to PFC - PFC would be immediately notified
- Any component transfused - the recipients would be identified and the clinician responsible for the patient contacted and updated on the findings. The clinician would then be responsible to contact the donor (if applicable) and further action would then be taken as appropriate

***d. What impact did the introduction of HIV screening have on the BTC, including but not limited to the financial impact of screening, the impact on those working at BTC, and the impact on the risk of transmission of HIV through blood donations?***

226. All staff used normal precautions when handling routine untested blood from donors. This was standard practice. If a donation was found to be positive, staff handled the donation and any associated samples as 'high risk' material and the level of precautions increased significantly. Financially, all screening kits were funded centrally and the BTCs where I worked, extra staff were employed or deployed to cover the extra workload of testing.

227. The impact of screening was very significant in reducing the risks of transmission of HIV. It was an antibody test at the time, so there was risk of a 'window' transmission. Therefore, donor health check screening was still seen as a very important aspect of donation safety.

*Surrogate testing*

134. ***Whilst you were employed at the Aberdeen BTC, 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:***
    a. ***HIV; and***
    b. ***NANB/HCV.***

228. In 1987 I was still in training and learning, so I did not have a fixed opinion on surrogate testing, as on many other matters when one is gaining experience and still learning.

229. It is my understanding that surrogate testing (anti core and ALT) applies primarily to Hepatitis C.
230. Although not a test, a history of gonorrhoea or other sexually transmitted disease was used as a surrogate for a high risk sexual history in the context of HIV.

135. ***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. ***Whether surrogate testing (namely ALT or anti-HBc testing) was introduced at Aberdeen BTC during your tenure;***

231. To my knowledge surrogate testing was not performed in Aberdeen. Please note- I was not in charge in Aberdeen.

    b. ***If so, whether this had any impact on the BTC;***

c. ***How the surrogate testing was performed;***
d. ***What the process was for screening donors and/or blood donations;***
e. ***What, if anything, happened to the unscreened blood that had been collected prior to surrogate testing being implemented; and***
f. ***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.***

232. **b-f.** To my knowledge surrogate testing was not implemented in Aberdeen.

136. ***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). Did you agree with the reasoning provided in this article?***

233. This paper was written well before I became a director and I had no involvement in it at all. It is therefore very difficult to comment, without knowing the discussions that led the then directors to write their letter to the Lancet. The letter is in response to 3 other letters, also from SNBTS, arguing to the contrary. So I suppose one's view would depend on which side of the argument one is leaning to. It was a controversial issue. Since I had no involvement in either 'camp', I do not feel qualified to comment.

137. ***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.***

234. No question to answer.

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

235. The report was written in 1987, again well before I became a director. I was not aware of this report. The considerations seem sensible, and stress the importance of local epidemiological factors when it comes to deciding about the introduction of surrogate testing. Please see also my response to Question 130.

*Introduction of anti-HCV screening*

**139.** ***When did Inverness and Aberdeen BTCs begin anti-HCV screening?***

236. I cannot remember the exact date – probably around September/ October 1991. It is my understanding that all SNBTS BTCs started testing for HCV at the same time.

**140.** ***What impact did HCV testing have on Inverness and Aberdeen BTCs? In particular:***

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

237. The process was very similar to the processes described in my response to question 130. All donations were tested for HCV antibody, and if found to be repeat reactive were sent for confirmatory testing at the National Microbiology Reference Laboratory, where confirmatory tests were done to confirm the infection or otherwise.

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

238. It is my understanding that all the stock was screened at the start of testing.

***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.***

239. The donation was discarded (even if not confirmed positive). If the donor was found to be repeat reactive (but not confirmed) on 3 or more occasions, he/she was asked not to donate blood again and was counselled (as described before). Confirmatory testing was performed by the NMRU. If the donation was confirmed as HCV positive, then the donor was counselled by SNBTS medical staff, and referred to a specialist. This policy applied to all microbiological markers.

240. As part of the lookback programme, archive samples from any previous donations from the donor were also tested for HCV (by NMRU) and sequential testing was done until a negative sample was found. In BTCs which acted as blood banks for the main hospitals, (where I was - Inverness and Dundee) there were records of the fate of all these donations and those units that were transfused and patients who received the blood or plasma could be identified. In such cases, the clinician was contacted and given the details of the 'positive' donation and to whom it was given and when (this could have been years before). The clinician was then asked to contact the recipient and to refer as appropriate, after consultation. This was the correct procedure to follow, since these patients would have a rapport with their clinician and not with the SNBTS medical staff.

241. If plasma from any of the implicated units was sent to PFC for fractionation they were also informed.

***d. What impact did the introduction of testing have on the risk of transmission of HCV through blood donations?***

242. Clearly HCV testing made the blood supply significantly safer. Initially the test was an antibody test and therefore there was a risk of a 'window' period transmission. Therefore, donor health check screening was still seen as a very important aspect of donation safety

**141.** ***What funding and operational support were the BTCs provided with to aid in the implementation of testing? Did this have an effect on BTCs ability or willingness to commence testing earlier?***

243. All the screening tests were funded centrally. All the SOPs and procedures were based very much on nationally agreed protocols. Also all kit evaluations were performed by a national Kit Evaluation Group – a group of microbiological experts and laboratory managers. So I do not believe that this had an effect on the BTCs' (where I worked) ability to start HCV testing.

*Recall practice and procedures*

**142.** ***Please give an overview of product recall practice at the BTCs, and how this changed during your tenure.***

244. My understanding is that recall could stem from 2 sources
* information given to us post donation from the donor
*information about a product/ batch notified through outside sources eg MHRA or a centre outside SNBTS
I do not recall a change in procedures in cases of recalls.

**143.** ***What, if anything do you remember about any formal recall or notification procedures in place?***

245. Similar procedure was followed in both instances. If necessary, we recalled all the blood we had in stock and any untransfused blood/component in the hospital. If the unit/s had been transfused, the clinician was immediately informed and, through discussion, decided on the best course of action. This very much depended on the reason for the recall. If there were any components that were sent to PFC, they would be notified so that any appropriate action would be taken by them.

**144.** ***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?***

246. Yes, these procedures were effective and clinicians generally complied with them.

**145.** ***Please refer to SBTS0000007_021, a letter written by you regarding the procedure for recalling plasma from HCV-positive donors. As to this:***

***a. To whom was this letter sent?***

247. The letter was written to Professor John Cash.

***b. The letter states that recall of finished products from PFC "depends on the state of fractionation of the pools of plasma concerned." In what way did the state of fractionation determine which products would be recalled by PFC? Did PFC avoid recalling plasma which was further through the fractionation process? If so, what was the rationale for this policy?***

248. This question would be best answered by PFC. I was simply quoting their SOPs and informing Professor Cash about this. Since Dr Perry had told me that it was wise that all BTCs inform PFC about any potential reason for recall in the context of HCV. I believe that my letter to Professor Cash was sent so that he would let all the BTCs know to follow this protocol.

***c. The letter states that several donors at Aberdeen and North East Scotland RTC fell within paragraph 3.1(a) of SOP No 84 111 0001 05, in which case "a plasma recall should be initiated." Was a recall initiated in respect of these donors? If not, why not? If so, please give details.***

249. I cannot remember the specifics, but I am sure it would have followed the protocol.

***d. The letter states that RTCs should request recall from PFC in order "to be on medico legally solid ground." Please explain what you meant by this. What other outcomes, if any, were recall procedures intended to achieve?***

250. The rationale was that if all BTCs followed the same correct protocol, we would be on good medico-legal grounds. Recall procedures clearly made the blood supply safer in the case where blood/components were not transfused. In the case where blood was transfused, the clinician in question would be able to follow and if appropriate treat the patient at the earliest possible opportunity.

146. ***Please refer to NCRU0000111_067, which sets out the SNBTS standard operating procedure for responding to information supplied by the CJD surveillance unit. Were you at any stage involved in a response under this procedure? If so, please provide details, including whether recall, quarantine or withdrawal of blood or blood products was initiated as a result.***

251. I do not believe I was involved.

*General*

147. ***Please describe all other steps or actions taken at each BTC 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.***

252. I think I have already described all the processes SNBTS undertook to ensure blood safety and minimize transfusion risks. I followed them in both Inverness and Dundee, and in fact throughout my professional life with SNBTS. These ranged from information to the general public, detailed health check questionnaires and/or personal donor interviews; testing of donations and processing of donations to produce as safe a product as possible. Also any recall request was diligently followed.

148. ***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?***

253. Like everything else that needs coordination on a Scottish and UK wide scale, there will be constraints and delays to ensure that all BTCs work in harmony. Sometimes there was time that was needed for a number of reasons- training; financial issues that had to be tackled centrally e.g. new tests, more staffing requirements; implication for one BTC were more significant than in others etc. These issues may and probably did result in some delays to agreed 'start days'.

254. As I recall, some changes were strictly introduced on a specific day e.g. new microbiological testing; at other times changes were phased in (e.g. Personal Donor Interviews) over a specified time frame in different SNBTS BTCs. Harmonisation was considered very important, but phasing in some procedure in one BTC with short delays in others would help reduce unnecessary delays. To my knowledge all these procedures were agreed at MSC or SNBTS Board.

**149.** ***How did the desire for consensus across the BTCs impact efforts to achieve blood safety at a local level?***

255. Please refer to my answer to Question 146.

256. From my perspective, it was always my view that, as far as possible, there should be harmonisation. From the early years of my directorship I believed in this principle, ensuring that the Scottish BTCs I led acted in unison with the rest of SNBTS. As the years went by, I believed more and more that the UK Blood services should operate to the same standards and harmonise as much as possible.

257. Issues were always discussed at MSC and Board of SNBTS. So, local implementation of all measures was done after a decision was reached at these committees.

**150.** ***To what extent were you and other BTCs reliant on the decisions of other bodies (including advisory committees, SNBTS, government departments) 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?***

258. Issues were always discussed at MSC and Board of SNBTS. So local implementation of all measures was done after a decision was reached at these committees. There was a lot of consultation with numerous committees including the relevant SACs, JPAC and SaBTO etc.

259. My view has always been that any issues I had with a particular policy was discussed at these fora. Once a decision was reached, I believed in collective responsibility and followed the agreed procedure. Having said that, I do not recall having any fundamental disagreement with the decisions reached after it has been to these expert groups.

151. ***In January 1992, Dr Marcela Contreras wrote, ahead of an ACTTD meeting, that "the attitude towards transfusion safety has veered away from the concept of 'maximum benefit at minimal cost' towards the notion that if a procedure shown to prevent transfusion-transmitted infection and disease is available, it should be introduced" (NHBT0000044_095). Do you agree that this was a shift that the BTS made? Please explain the reasons for your answer, including any relevant references to discussions with colleagues and official policy within the BTS.***

260. In principle I agree, but I would add that a cost benefit analysis and a risk assessment is always a very important aspect of any decision made. Having said that, the withdrawal of crown immunity made a significant change in the Blood Services' thinking towards a more precautionary approach. This is best exemplified perhaps by the actions taken in the context of vCJD.

261. There were therefore always 2 conflicting pressures- one was to do all that is possible, irrespective of cost, to make the blood safer contrasting with introducing measures that were only cost effective. Both pathways were followed in different circumstances. Much depended on the level of knowledge available about the situation, and the risk to the patient (how severe the illness was). My impression is that the Blood Services became more precautionary over the time I worked.

152. ***If you do agree:***

    ***a. When, in your view, was this shift made?***

***b. Who was responsible for the original policy and who for the change in policy?***

***c. What caused the change to occur?***

262. **a-c**. Please refer to my answer to Question 148.

***d. What is your opinion of the merits of a cost-benefit approach to blood safety as against the latter approach?***

263. Cost benefit approaches are very useful in ensuring that funds (always limited) are spent in the most cost effective way. However, when new issues arise (e.g. a new virus, or disease transmission risk e.g. vCJD) and a measure is available, there is an increasing tendency to introduce it with urgency, to ensure that the blood remains as safe as is possible. Please refer to my answer to Question 148.

***e. Was the introduction of anti-HCV testing affected by this prior approach? What about other transfusion transmitted infections?***

264. I was not involved in the discussions about the introduction of HCV testing. However, I suspect that such issues must have played a very important role in the decisions made.

**Section 13: Look back programmes**

*HIV*

**153.** ***Were you involved in setting up any national or local HIV look back programmes during your time at Aberdeen, Inverness and Dundee BTCs? If so, please describe this process and your role in it and how it was funded.***

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

265. **Questions 150 and 151** - I cannot recall the details of any look back programme done in Aberdeen in the context of HIV. I believe I was still in training at the time (around 1985?). I believe that the policy for HIV confirmed positive donors was the same as for HCV, as described below.

*HCV*

**155.** ***Were you involved in setting up any HCV look back programmes during your time at Aberdeen, Inverness or Dundee BTCs? If so, please describe this process and your role in it and how it was funded.***

**156.** ***Were you involved in implementing any HCV look back programmes during your time at the BTCs? If so, please describe what this involved.***

266. **Questions 152 and 153 -** I was involved in the HVC lookback as an implementer of the agreed policy, in Inverness and Dundee. National SOPs and Policies were used. Previous donations from any donor who was confirmed positive for HCV were traced and tested by NMRU. This process went on sequentially until a negative donation was found. The positive donations were then traced to see if any components had been transfused or plasma sent to PFC This could be done because we acted as the blood bank for the major hospital within our area. Therefore we had access to all the transfusion records. Patients who were exposed to confirmed positive transfusions were then identified. Either another senior medical consultant or I would then contact the clinician who had ordered the transfusion, to establish whether the patient who had been transfused was still under his/her care and alive. Usually this involved a discussion with the clinician. The clinician was then asked to contact the patient, test him/her and to refer appropriately to a relevant specialist. There were some instances where the fate of the donation could not be confirmed and in such circumstances it was not possible to proceed further.

267. PFC were notified if any plasma from any implicated donations was sent to them, so that they could take any appropriate action.

268. The process was funded centrally. In both BTCs in which I worked, the workload was not very heavy and therefore no extra funds were asked for.

*General*

**157. *Please confirm whether you were involved in a look back process relating to any other infection during your time at the BTCs. If so, please provide an overview of the relevant programmes and detail your involvement.***

269. Please refer to my answer to Question 151.

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

270. There was an ethical reason and duty of care to inform patients who were exposed to positive microbiological donations.

**159. *To what extent could an BTC implement its own local look back programme? Did the BTCs do this? If so please give details. If not, why not?***

271. Yes the BTC was asked to implement its own lookback programme, following nationally agreed protocols. I followed the lookback programme after the SNBTS policy was agreed. Cannot answer for other BTCs although I believe that the BTC in Edinburgh had conducted a pilot before the rest of the SNBTS to assess the implications of performing a lookback if needed.

**160. *In a memorandum from Professor Cash to SNBTS Directors dated 21 June 1994, you are mentioned as agreeing that the SNBTS Consultants' Group would act "as a focus for an emerging draft national plan" (PRSE0003344,***

***page 3). Please outline the role of this group in the implementation of HCV and other lookbacks.***

272. From my recollection, the Donor Consultants Group which I attended, was tasked with establishing an operational plan (as described above). The plan had to be approved by MSC in the first instance and potentially the SHHD. Essentially this group made recommendations to MSC or SACs, as appropriate.

273. The implementation of the lookback programme was the responsibility of the individual director at the BTC.

## Section 14: Your relationship with commercial organisations

**161.** ***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?***

***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?***

***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?***

***d. Received any financial incentives from pharmaceutical companies to use certain blood products?***

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

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

274. **a-f.** My answer to all of the above sub questions is no.

**162.** ***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?***

275. I cannot answer this question as I was never involved.

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

276. No.

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

277. No.

**165.** ***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?***

278. No.

**Section 15: Organisational Relationships**

*Relationship between the SNBTS and NBTS*

**166.** ***Please outline the arrangements in place to enable cooperation between the SNBTS and NBTS during your tenure at the SNBTS, including any forums or reporting lines established to aid this cooperation.***

279. There were many joint professional Advisory Committees (SACs) - on donor care; transfusion transmitted infections; tissue banking etc. At these SACs experts from both organisations sat and discussed many professional matters. All the recommendations went to JPAC, where decisions were approved, or otherwise. This meant that most professional issues were agreed on a UK wide basis. Whilst implementation of the decisions reached was the responsibility of the individual blood service, increasingly over time, there was a clear wish to have very similar implementation dates.

**167.** ***Please explain the SNBTS and NBTS' 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?***

280. In most cases policy development and implementation was as described in my response to question 163. Policies on supply and demand and plasma fractionation etc were the individual BTC responsibility. Having said that, I do believe that there was a degree of cooperation between the 2 Blood Services in case of shortages. I was not involved in these matters and therefore I cannot be sure how frequently this happened, particularly post the rationalisation of processing and testing within SNBTS in the late 1990s.

**168.** ***Did the SNBTS share information with the NBTS about excluded donors, donors that posed a risk to the safety of the blood supply, or infected blood donations? If yes, was this on a formal or informal basis? Please describe the mechanisms in place to share this information, if any.***

281. I do not believe (or recall) that SNBTS shared such information.

169. ***In his witness statement for the A v Others litigation, Dr Gunson discussed the creation of the National Directorate to oversee the work of RTCs, although he noted that the Directorate "did not have executive authority and its successes came about by persuasion" (NHBT0000025_001; NHBT0000026_009). What are your views on the success or otherwise of the National Directorate?***

282. I do not have a view since I was never a part of NHSBT and therefore cannot comment on the success or otherwise of the National Directorate.

170. ***In the same statement, Dr Gunson commented that the work of the National Directorate became marginalised as a result of the devolution of health budgets to District level and eventually replaced by the creation of the National Blood Authority (NBA), which had responsibility for "both the central laboratories and the RTCs." What are your views on the need for centralised responsibility for RTCs?***

283. This seems to be an English proposal about how they should be managed. I do not feel competent to comment on such matters. As a principle I do believe there is merit in having a centralised 'governing' body to ensure that policies and SOPs etc throughout England are the same and harmonised, but cannot add anything else.

171. ***What in your view were the strengths and weaknesses of the NBA?***

284. I never worked within the NBA – so it is very difficult for me to comment. However, I had many interactions with a proportion of NBA staff through my interactions with SACs and other committees.

285. They are a large organisation and collected a very significant proportion of blood for the UK. They have a lot of expert staff and therefore their views mattered. Their arguments are usually strong and cogent.

286. However, they are a large organisation and as an SNBTS member I used to make sure that NBA colleagues took also our views into account, which they always did. Being large, they also had significant funds and their funding mechanisms were different from SNBTS.

287. Being large, understandably they are more difficult to manage and to respond as quickly as perhaps other smaller organisations could. This was taken into account when implementation dates were agreed, to ensure as much harmonisation as possible.

*Relationship between the Plasma Fractionation Centre and Bio Products Laboratory*

172. ***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 BTCs in Scotland?***

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

288. I am not competent to answer these questions - since I was not involved at all in that side of work. In principle, I believe there could have been merit in a joint UK approach, although I do believe that the 2 organisations had a different supply aim. PFC was aiming and I believe achieving self sufficiency in Factor VIII, and immunoglobulin whilst I believe BPL was not.

*Relationship between SNBTS and Northern Ireland Blood Transfusion Service*

173. ***Please explain the SNBTS's relationship with the Northern Ireland Blood Transfusion Service (NIBTS), in relation to the supply of blood and blood products to Northern Ireland.***

289. I cannot recall the details – I was not involved in any arrangement. I believe that PFC fractionated the plasma for NIBTS.

174. ***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.***

290. It believe that Northern Ireland plasma was sent to PFC for fractionation. If this was the case, I do not know whether the returned product to Northern Ireland was sourced from NI donors or whether the plasma was pooled for processing.

175. ***Prior to the arrangement between Northern Ireland and PFC there was an equivalent arrangement between Northern Ireland and BPL. Please explain the reasons for the change to PFC.***

291. I have no knowledge of any such arrangements.

176. ***Please outline the arrangements in place to enable cooperation between the NIBTC and SNBTS during your tenure at the SNBTS, including any forums or reporting lines established to aid this cooperation.***

292. The NI director used to attend MSC meetings on a regular basis. That way he kept abreast of developments and issues being discussed at SNBTS. I am not aware there was any other formal arrangement.

*Outcomes in Scotland and England/Wales*

177. ***Please outline any statistics or studies of which you are aware that demonstrate the difference in morbidities and fatalities between Scotland and England/Wales.***

293. I am not aware of any statistics and / or studies on this subject.

**Section 16: Variant Creutzfeldt-Jakob disease (vCJD)**

178. ***The Inquiry seeks to gain an understanding as to how knowledge of the risk of vCJD developed over time within the Blood Services, Haemophilia Centres and other NHS organisations. Secondly, the Inquiry seeks to understand what actions the Government and other organisations took in response to the risk of vCJD transmission via blood and blood products and the adequacy of these.***

    a. ***When and in what circumstances did you first become aware of the risks of transmission of vCJD associated with the use of blood and blood products?***

294. I cannot remember the exact date, but it must have been around 2002. 'Mad cow disease' was a major news item on the media and there was always a concern that the disease could be transmissible through body fluids, including blood.

    b. ***How did your knowledge of the risk develop over time?***

295. My knowledge of risk increased over time, since by 2004 there were clinical cases of transmission via blood and it became very clear that this disease could be transmitted via that route.

    c. ***What, if any, involvement did you have in addressing or responding to these risks?***

296. I was a member of the vCJD subgroup on SACTTI. I was not an expert on the subject, and my main role on that committee was to keep abreast of developments, to see what measures could be applied to bone, tissues and cells, since that was my area of speciality at that time. Many issues were discussed, including the use of prion filters, potential prion testing for donors, and exclusion criteria e.g. previously transfused donors. These were discussed in detail at this sub-committee and at SaBTO. The situation was very problematic and difficult, since the incubation period was very long (many years) and therefore asymptomatic individuals could come forward to donate blood. It was not known whether carrying the prion protein meant that you were necessarily infectious and there was no suitable test that could be used for screening purposes. Decisions reached at SaBTO, that were sent to ministers for approval, were very thoroughly thought through.

297. My involvement was in translating what was being agreed for blood donors and making recommendations for tissue and cell donors. These recommendations were discussed at the SAC on Tissue Banking and then at SaBTO for approval. Wherever possible the criteria that applied for blood were also applied to tissue donors.

179. ***On 22 June 1995, you wrote to Dr Cash to confirm that at the Medicine Control Agency's (MCA) request, both fractionation plants in Edinburgh and BPL would exclude donors with a family history of CJD, and requested that Dr Cash considered raising the "standing" of the Council of Europe recommendations at the next Red Book Executive Committee meeting (NHBT0002699_003).***
***Please explain your understanding of the 'standing' of these recommendations and their relationship to the Red Book guidelines.***

298. This letter refers to CJD (not vCJD). It is my understanding that Council of Europe recommendations at the time were just recommendations. At the SAC on Donor Care we discussed this on numerous occasions. However if the MCA adopted them, then their importance increased, since the MCA (and later

MHRA) issued the BTC with their licences to operate. Therefore, compliance with their requirements became mandatory.

180. ***Were the Red Book guidelines a relevant or significant police consideration for responding to concerns over:***

***i. CJD in the UK blood supply; or***

***ii. locally manufactured blood products; or***

***iii. both?***

299. Yes, the Red book guidelines were kept up to date with the discussions taking place on the subject of vCJD. However, major decisions on plasma importation and deferral of transfused donors and / or the assessment of testing etc, were taken at SaBTO. The Clinical Incidents Panel also made major decisions in the vCJD context, particularly in the notification process of potentially exposed donors - but I was not a member of that group.

181. ***Supplementary Question 4:***

***At paragraph 292 of your draft statement, you discuss the Guidelines on Blood Transfusion. The Inquiry understands these Guidelines were not legally binding. Could you please explain your view of this? What degree of influence did these guidelines have on the practise of blood transfusion medicine? You may be assisted by documents NHBT0000027_030 and NHBT0054484_003***

300. The Guidelines on Blood Transfusion in the UK were generally adopted as the benchmark for Transfusion Medicine and practice in the UK. They were produced by the UK Blood Services, which formed a liaison with the National Institute of Biological Standards and Control (NIBSC) to identify specifications of all materials produced by the UKBTSs for therapeutic and diagnostic use, and to provide guidelines for all procedures involved in the process. Various working groups (Standing Advisory Committees) were formed, and each SAC was responsible for writing and later updating a chapter relevant to their expertise.

301. My understanding is that although they were not legally binding (they were not part of UK legislation) they were used extensively and adhered to as much as possible. In fact, they were referred to in the inspection processes conducted by the MHRA.

**182.** ***What was the rationale for excluding individuals who had received donated blood, bone, or tissue from donating blood, bone, or tissue themselves? (NHBT0060871)***

302. It was known that prion protein could be transmitted via blood. Therefore, previously transfused donors were excluded from donating blood to stop the cycle of transmission. This was particularly important in the context of there being no available screening test and the very long incubation period of the disease. The same applied to tissues, and therefore it made sense that any recipient of blood or tissue would not be a donor himself or herself.

**183.** ***The Inquiry has heard evidence of the experiences of a number of infected and affected individuals who were notified of their 'at risk' status of vCJD. The Inquiry seeks to gain an understanding of the rationale behind policy decisions made in relation to notifying at-risk individuals and how this changed over time. (NIBS0000614)***

303. No question to answer.

***In so far as you are able, please provide the following:***

***a. A chronological summary of the knowledge held within the organisations and committees you belonged to in relation to the issues surrounding notification of risk to individuals deemed to be at risk of vCJD.***

304. Most of the vCJD notification issues were handled by the Clinical Incidents Panel - of which I was not a member. As a SNBTS MSC and Board member, I was made aware that this work was being done. I believe this was around

2002/2003. I cannot say which other committees were aware of this, though I am sure SaBTO would have been kept abreast and the issue discussed.

***b. A summary of the views, opinions and decisions regarding notification arising from the CJD Incidents Panel consultation process in 2000.***

305. The decisions to notify someone who was at risk of developing vCJD were very difficult to make. There was a real risk of providing information to people about a potential disease, that they may not have, or even if they did, they may never develop a clinical disease. I believe that the reasoning involved in patient notification was based on modelling of the potential number of infectious prions that they could have been exposed to. So, for example, it was deemed that patients who had received blood components (e.g. red cells, or platelets) should be notified, whilst for those who had received fractionated products (where the plasma would have been processed significantly and therefore was assumed to be safer) the calculations were much more complex. The decisions were also based on the pattern of plasma transfusions (frequency and volumes and therefore level of exposure) and the level of processing that was assumed to have cleared a significant proportion of the prion. I cannot comment in more detail than this.

***c. An outline of any policies and practices which were implemented across the U.K. in relation to patient notification and de-notification.***

***d. An account of the involvement of any organisations and committees you belonged to, if any, of those notification exercises between 2003 and 2009;***

***e. Details as to whether the organisations and committees you belonged to were aware of any circumstances where individuals were not informed of their risk status or at a later date and if so why;***

***f. An account of what, how, when and where patients were told that they might have been exposed to a greater risk of vCJD.***

***g. A summary of information or advice given to partners or family members of patients who were at risk of infection with vCJD.***

306. **c-g.** In 2003-2009 I was the Tissue Services director and therefore not involved in the notification exercises. Therefore, I cannot provide any more details. However, I had conducted an audit of potential transmission of vCJD via tissues and organs and there was no evidence of vCJD transmission via tissues and organs. Therefore, notification exercises were not relevant in my situation.

**Section 17: Other matters**

**184.** ***Please provide a list of any articles you have had published relevant to the terms of reference.***

307. Publications attached. (WITN6931002 and WITN6931003)

**185.** ***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?***

308. As far as I know the UK was self-sufficient in whole blood for transfusions.

**186.** ***During your tenure at the BTCs and within the SNBTS, 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?***

309. I was not aware that within my time at SNBTS patients were given blood transfusions imported from the USA.

187. ***Did you raise, or were these issues ever raised at meetings of the SACTTI working group on vCJD? Was there discussion of cadaveric screening for issues associated with imported red blood cells, and were any related screening programs implemented? You may find JPAC0000051_056 to be of assistance.***

310. Cadaveric donor screening relates to the potential testing of 'cadaveric' (i.e. donors who have died) tissue donors (not in the context of imported blood). Tissue can be stored for a significant period of time before it is used. Therefore, the potential existed to test such donors for vCJD prior to the tissue being used. A pilot study was conducted to test such donors, assessing the feasibility and operational issues associated with such testing. I am not sure what the outcome of this study was. I had left SNBTS by then.

188. ***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).***

311. I do not think I can provide any more relevant detail than that which I have already provided. It is important to note that from 1999/2000 I became the Director of Tissues and Cells within SNBTS and therefore my direct involvement in blood matters stopped by then.

**Statement of Truth**

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

Signed GRO-C

Dated 23/11/2021

**Table of exhibits:**

| Date | Notes/ Description | Exhibit number |
|---|---|---|
| 1996 | Study of medical donor deferrals 1994 | WITN6931002 |
| 1996 | The impact of the new tick-box questionnaire on donor deferrals in the East of Scotland | WITN6931003 |
| 22/09/1994 | Minutes of a meeting of the Committee on the Care and Selection of Donors. | JPAC0000002_013 |
| 1995 | The Blood Safety Leaflet - Background Information for Transfusion Service Staff by Dr Peter Flanagan. | JPAC0000001_014 |