Witness Name: David Bainbridge McIntosh

Statement No.: WITN3523001

Exhibits: WITN3523002 - 3

Dated: 24.11.2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DAVID BAINBRIDGE MCINTOSH

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

I, David Bainbridge McIntosh, will say as follows:

Section 1:

Introduction

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

1. David Bainbridge McIntosh

   GRO-C, Hampshire, England. GRO-C

   Dob. GRO-C 1946

   M.A. (Oxon). Chartered Fellow of the Chartered Institute of Personnel and Development.

   Member of the Institute of Health and Social Care Management.

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

- 2016 – Present: non-executive director of Surrey University spin-out company, artificial intelligence specialists, Sensus Futuris Limited.
- 2016 – 2021: Chairman of the EPSRC funded artificial intelligence research programme - Face Matching for Automatic Identity Retrieval, Recognition, Verification and Management (FACER2VM)
- 2008 – 2016: Chairman and Chief Executive Officer of specialist Law Enforcement and Security software supplier - 3rd Forensic Limited.
- 2002 – 2008: Chief Executive Officer of computer vision specialists OmniPerception Limited.
- 1996 – 2002: Employed by broadcast electronics company Snell & Wilcox, latterly as Chief Executive Officer of modular products division.
- 1990 – 1996: General Manager and Management Board Chairman at the Scottish National Blood Transfusion Service.
- 1987 – 1990: Director of the NHS in Scotland Management Development Group.
- 1968 - 1987: International management career with Coats Patons plc. Latterly as General Manager of manufacturing facilities in Colombia, South America.

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.

- Fellow of the Chartered Institute of Personnel and Development since 1973
- Member of the Institute of Health and Social Care Management since 1990

- Founder and Chair of United Kingdom Plasma Action: 2019 - Present
- Blood donor: 1968 – Present

4 The inquiry understands that you gave evidence to the Penrose inquiry. The Inquiry has the following statements/transcripts of that evidence. Please confirm whether these statements and the oral evidence you gave are, to the best of your knowledge and belief, true and accurate. If there are any matters within your evidence to the Penrose Inquiry that you do not consider to be true and accurate, please explain what they are and how the inaccuracy occurred.

2. To the best of my knowledge and belief, all the statements I made to the Penrose Inquiry, both in writing and verbally, were and are true and accurate.

5 Are there any statements you made to the Penrose Inquiry missing?

3. No. I don't believe that any of my statements to the Penrose Inquiry are missing.

If so, please provide them. In particular, were you involved in preparing any of the SNBTS submission to the Penrose Inquiry?

4. No, I do not recall being involved in the preparation of any SNBTS submissions to the Penrose Inquiry. I believe that I prepared and submitted my own statements only.

If so, please list them and describe your involvement in them. In particular please explain who proposed and organised the papers, who assisted in their preparation, and who, if anyone, approved final. Please also confirm whether the submissions are, to the best of your knowledge and belief, true and accurate. If there are any matters within those submissions to the Penrose Inquiry that you do not consider to be true and accurate, please explain what they are and how the inaccuracy occurred.

5. I am not aware of any errors, omissions or inaccuracies in the SNBTS submissions to the Penrose Inquiry; but cannot vouch for the absence of such as I was not involved in their preparation, nor did I study them all in detail. (Note: I had been retired from the SNBTS for many years at the time of the Penrose Inquiry).

6 The Inquiry is aware of the following documents which suggest you may have provided evidence or were otherwise involved in litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis C virus ("HCV") infections in blood and/or blood products: PRSE0001657. Please provide details of your involvement.

6. I believe that what is referred to here is my involvement as a witness in the Penrose Inquiry. That is a matter of record. I do not recall ever being involved in any other matters of this kind, whether in litigation or otherwise.

7 In addition to the evidence given to the Penrose Inquiry or to the litigation addressed in question 6, please confirm whether you have provided evidence or have been involved in any other inquiries, investigations, criminal or civil litigation in relation to HIV, HCV and/or hepatitis B virus (HBV) infection and/or Creutzfeldt-Jakob disease (vCJD) in blood and/or blood products. Please provide details of your involvement.

7. As above, in response to question 6, I do not recall ever being involved in any other inquiries or investigations, nor in any criminal or civil litigation in relation to HIV, HCV and/or hepatitis B virus (HBV) infection. I have however been deeply involved in the recent investigations into Variant Creutzfeldt Jakob disease (vCJD) in blood and/or blood products. The Inquiry team may find the attached UKPA Memorandum on the subject of interest [WITN3523002] (UKPA.Memorandum.906/D, submitted in evidence to the MHRA in connection with the UK Plasma Policy Review.) I appreciate that as

the Infected Blood Inquiry's investigations only started in 2018, they may be out with the scope of this Inquiry, but I mention them in case of interest.

Section 2: Your role at the Scottish National Blood Transfusion Service

8 Please describe the roles, functions and responsibilities you had at the Scottish National Blood Transfusion Service ("SNBTS") during your period as:

a. General Manager; and

b. Chairman of the Board

and explain how these changed over time.

8. My official appointment within the NHS in Scotland Common Services Agency was as General Manager of the SNBTS. This involved the overall leadership of the service, its strategic direction and the management of my direct reports – the National Medical Director, the Director of the Protein Fractionation Centre, the National Donor Manager, the National Finance Manager, the SNBTS Personnel Manager, the National Quality Manager and the Regional Centre Directors. I was the budget holder for the SNBTS and responsible for the organisation's performance and achievement of objectives, within the financial and other resources made available to it by Government. The role of Chairman of the Management Board was an internal SNBTS appointment, created when the Management Board was created. It was a traditional chairmanship role – leading, stimulating and coordinating Board discussion and promoting team solidarity and collective responsibility.

9 Please describe the organisation of the SNBTS during the time you worked there, including:

a. Its structure and staffing and in particular to whom you were accountable (PRSE0003892; NHBT0010968);

9. The structure and staffing of the SNBTS from 1990 to 1996 is a matter of record, to which I don't feel able to add further useful information after this interval of time. As SNBTS General Manager I was directly responsible to the Management Board of the NHS in Scotland Common Services Agency, through the General Manager of the Agency and also had a dotted line relationship with the (then) Minister of State for Health, through the relevant civil servants in the (then) Scottish Office Home and Health Department, who took a close interest in SNBTS matters.

b. What influence you had in your role over staffing structure and recruitment within the SNBTS and individual RTCs (SBTS0000411_142);

10. My first role in relation to the staffing structure at the SNBTS was as the author and instigator of a major reorganisation of the Service, of which my appointment as General Manager was a part. This involved a number of key changes to the structure of the SNBTS that were implemented in 1990 and consolidated in the coming years. Thereafter, my role in staffing and recruitment within the SNBTS (which included the five RTCs) was mainly a strategic one. I hope that I set the scene with appropriate policies and practices, but once the original reorganisation was complete, I would not have been involved personally in any but the most senior appointments, nor in any but the most critical structural matters.

c. What influence you had in your role over the formation and maintenance of various committees (SBTS0000456_009);

11. A major task for me in my early days in post was a root and branch reorganisation of the Service, which involved the creation and maintenance of two new committees in particular - The Management Board and the Medical and Scientific Committee (MSC). These were essentially my creations, but were of course established with the consent and active participation of my senior colleagues. As evidenced by the content of SBTS0000456_009, I also took a personal interest in the overall committee structure at levels below Board and MSC level. With apologies, I have to admit that my memory is not sharp

on the details of that. However, I believe that it's true to say that while I had influence in the maintenance of those lower level committees, and would certainly have taken an interest in their performance and output, I did not influence their formation.

12. It is probably relevant to also note here that the new organisational structure that I introduced in the SNBTS was formally approved by the Management Board of the NHS in Scotland Common Services Agency, with the approval also of the (then) Scottish Office Home and Health Department.

d. how the SNBTS was funded and how this changed;

13. As the record shows, I was involved in a number of other committees and regular meetings, including those involving liaison with the English Blood Transfusion Services, the Northern Ireland BTS, the Scottish Haemophilia Directors and others. This also included attendance at meetings of the European Plasma Fractionation Association, where I was a founder member and Chairman of the Publications Committee.

14. The funding of the SNBTS is a matter of record. As I recall, the rules, policies and procedures in this area did not change significantly during my time in post. The amount of funding increased year-on-year, in response to well-argued cases submitted to the (then) Scottish Office Home and Health Department; but I don't believe that the funding changed at all in terms of its source, application or other significant strategic aspect.

e. how the SNBTS allocated funding to individual RTCs.

15. The allocation of funding to individual RTCs, as also to the Plasma Fractionation Centre, the R&D laboratory and the other central national roles and functions was decided upon by the SNBTS Management Board and also approved annually by the Management Board of the NHS in Scotland Common Services Agency, and by the (then) Scottish Office Home and Health Department.

16. The details of how and how much were always worked out very carefully, with input from all the key people involved, resulting in funding allocation decisions that normally had the support of all concerned. It is not therefore strictly accurate to describe the process as being an allocation of funding by the SNBTS to individual RTCs. The SNBTS budget each year was arrived at by internal SNBTS arrangements involving all concerned in a collective process. In this context, it should also be noted that the Directors of the Scottish Regional Transfusion Services (the RTC Directors) were all members of both the SNBTS MSC and of the SNBTS Management Board, so that their involvement in the funding allocation process and decisions arising from it was a very close and comprehensive one.

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

17. These are matters of record. In summary, in my time, the SNBTS was a National Service charged with collecting, processing and distributing sufficient blood and fresh blood components to fully provide for all the relevant needs of patients throughout Scotland; and also provide all the necessary Plasma Derived Medicinal Products (PDMPs) required to treat patients, also Scotland-wide. In my time, it served the Nation through seven main centres of effort:

- The five Regional Transfusion Centres in Glasgow, Edinburgh, Dundee, Aberdeen and Inverness – serving all hospitals all over Scotland, each in its own region – both NHS and private;
- The Protein Fractionation Centre in Edinburgh, using the collected plasma to produce a wide range of PDMPs, also to provide for the needs of patients throughout Scotland; and
- The Headquarters and central National Services, including R&D, reagent production, donor services, finance, personnel, etc

g. its place in the NHS/NBA together with information as to whom the Service

was answerable to at the NHS/NBA, if anyone.

18. The SNBTS had no place in the NHS/NBA and was not answerable to anyone there. The SNBTS was a national body within the NHS in Scotland and was answerable ultimately to the Secretary of State for Scotland, through the (then) NHS in Scotland Common Services Agency and the Scottish Office Home and Health Department.
19. As the Inquiry may be aware, even in the years before Devolution and the establishment of the Scottish Parliament, the NHS in Scotland was always an independent organisation answerable to Scottish authorities, not to Whitehall departments.

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 (NHBT0000026_009; NHBT0000026_009);

20. I remember having great sympathy for Dr Gunson, given the organisational difficulties he faced in England and Wales. There is no doubt in my mind that he was broadly correct in his diagnosis of the problems and in the tenor of his proposed solution(s), but given what he was up against, with hindsight, his was probably simply an impossible job.

h. To what extent did the "profitability of the SNBTS" impact decision making (SBTS0000057_031);

21. In the letter referenced, Professor Cash used the expression "profitability" in parenthesis advisedly. There was of course in fact no such thing as SNBTS profitability. The SNBTS, in common with other central NHS services, in Scotland and elsewhere, exists to serve. It is a public body dedicated to patient care, not to profit.

22. However, the Service is of course charged with achieving cost effectiveness, living sustainably within the budget allocated to it and achieving the best value for money for the tax-payer, as well as the best possible husbandry of the donor's gifts and the best possible provision of medicines and services for patients. Therefore the SNBTS, given finite resources, was and is required to have due regard to this aspect in all of its decision making.

23. I don't recall the word "profitability" ever being used in the SNBTS, other than in the reference letter from Professor Cash to Dr Stewart. However, I think it does, idiomatically, sum up the value-for-money aspect of the Service's responsibilities quite well. The context in which Professor Cash was writing was the need for the SNBTS to have to hand clear information comparing the levels of value-for-money being achieved by the Service with those offered in the private sector. This was something that we did diligently – benchmarking ourselves against the best of the rest - to ensure that our effective monopoly over the supply of PDMPs in Scotland did not lead to complacency nor to waste of resources.

24. However, if it were to be suggested that somehow the SNBTS may ever have sought to optimise cost-efficiency at the expense of patient care or safety, this would be untrue. I can state quite confidently that such a thing never happened on my watch; and I would very much doubt that it ever did at any time.

i. whether the SNBTS was associated or linked with other NBTS's and, if so, how and for what purpose;

25. The SNBTS was not officially linked with any other UK blood services (ref for instance my response to question 9 (g) above). It was however part of the wider professional transfusion, haematology and other relevant clinical communities. Many SNBTS staff kept quite closely in touch with their opposite numbers in England and Wales and also, especially, in neighbouring Northern Ireland. As one may imagine, these professional links were maintained for a great many

purposes, mostly in the realm of peer group interaction, professional training, information exchange and note-swapping on best practice.

j. whether the SNBTS was subject to any form of regulation and if so, what (you may find SBTS0000030_122 of assistance);

26. The regulatory position with respect to the SNBNTS changed very significantly during my time in post. In 1990 the organisation was covered by the long standing tradition of "Crown Immunity". Shortly after however, it became subject to the same regulatory controls, inspections, etc as similar organisations in the private sector. Under Crown Immunity, the Protein Fractionation Centre for instance was not subject to regulatory control by the Medicines Control Agency (now the MHRA), whereas thereafter it was. This meant very significant changes to standard operating procedure setting and recording in order that all relevant areas of the SNBTS were able fully to comply with the regulations, submit to formal inspections by the regulatory authorities and - I'm glad to be able to say - to pass with flying colours.

k. the SNBTS relationship with the Blood Products Laboratory ("BPL") and the Plasma Fractionation Centre ("PFC") and any other laboratory involved in the production of blood products or processing of blood (SBTS0000030_122); and

27. As explained above in response to questions 9 (f) and 9 (g), the PFC was part of the SNBTS. The Director of the PFC reported direct to the SNBTS General Manager and was himself a member of the Management Board of the SNBTS and also of the SNBTS MSC. The other UK fractionator, BPL, was the PFC's opposite number at that time, serving England and Wales. It was not part of the SNBTS nor did it have any organisational ties to or links with it.

28. The SNBTS relationship with BPL was cordial but not close. I can only think of one significant example of our having direct dealings with BPL, when the NHS

in England was having trouble with shortages of hyper-immune anti-Cytomegalovirus immunoglobulin. The BPL team asked us to help them by sending supplies, processed for them at our PFC plant in Edinburgh. There would in that case have been a cost-recovery charge involved – as with all "exports" to other UK nations and regions. [Note: For some years we in the SNBTS supplied polyclonal immunoglobulin products to the NHS in England and Wales, because of shortages in the commercial marketplace and because BPL's output was not sufficient to meet the needs of patients in England and Wales (England and Wales were not self-sufficient in Immunoglobulin at that time). However, this was done by direct supply to hospitals and health authorities and did not involve SNBTS dealings with BPL.]

l. the approximate number of donations collected each year (you may find NHBT0027512 of assistance).

29. Please note that the document referenced is a letter from one of the English Directors to Dr Gunson at the National Directorate of the National Blood Transfusion Service. It has no relevance to donation numbers or collection volumes in Scotland. Scottish collections are a matter of separate record. From memory, I would say that during my time at the SNBTS we collected approximately 900 donations a day, but I feel sure that the records on this will be more accurate than my memory 25 years on.

10 Please explain how you kept abreast of medical and scientific developments and research in your field in the course of your career, and to what extent this was a requirement of your role.

30. As my organisation's chief executive officer, my main roles were essentially strategic and non-specialised. I certainly never regarded myself as a scientist or a medic. However, I did of course always try to understand enough and stay up-to-date enough to be able to make informed judgments on managerial matters that impacted on all or any area(s) of my organisation, including

medical and pharmaceutical matters. This was essentially a life-long learning journey, but always with thoroughly well qualified professional clinicians and scientists at my right hand to ensure that where deep medical, biochemical or pharmaceutical knowledge was required it was readily available. My first degree was in Psychology and Philosophy and my post-graduate and professional qualifications are in Personnel and Development, a field in which I kept up to date mainly by attending conferences, reading my professional journal and by peer-to-peer contacts, both inside the NHS and beyond.

11 Please explain your role in regards to decision making in technical or clinical matters (PRSE0003403). Who advised you in these decisions?

31. The document referenced relates to a set of important decisions that my organisation had to take during 1990 and 1991 in relation to Factor VIII – at a time when a number of issues, both internal and external, were making it necessary for us to make simultaneous changes in both product type and production volume, alongside the addition of extra viral safety steps to confront the then relatively newly arrived threats of two only recently identified pathogens (HIV and HCV.) Because these were highly important matters involving almost all parts of my organisation, I made it my business to get very closely involved. In addition, one of the key features of the appropriate way forward was the obtention from the Lille Blood Transfusion Service in France of new FVIII purification and viral inactivation technologies; a task that I led personally, negotiating with my opposite number there. However, as I remember it, this was an unusually close involvement on my part in areas where I would normally have expected to stand back and leave most decisions most of the time to my professional team.

32. Day to day technical and clinical matters were of course the subject of on the spot decision making by the qualified staff responsible. Clinical and technical policy matters were always discussed fully among the senior team and with other relevant parties before any decisions were made. On most matters of that kind the MSC had the authority (delegated to it by the Management Board)

to make its own decisions – subject of course to their being consistent with generally accepted professional practice.

33. Major technical decisions would usually also be debated at the MSC before referral to the Management Board, but might, for instance in the case of Protein Fractionation matters, be dealt with by the Director responsible, either on his own or in consultation with the General Manager.

34. Professional advice on medical and technical matters came to me from three principal sources (available to me as General Manager, but also – and more importantly – to all of us collectively) – namely –

- The members of the MSC (Chaired by the SNBTS Medical and Scientific Director), both individually and collectively;
- Other scientific and medical staff within the SNBTS itself;
- The medical team at the (then) Scottish Home and Health Department
- The transfusion community peer group throughout the UK, Europe and beyond

To what extent were you, at any time, a final decision maker on technical or clinical matters?

35. My job was to ensure that the right issues were properly considered and the right decisions were made at the end of the day. I did that (I hope) by leadership, sapiential authority and persuasion, endeavouring to take my team with me at all times. On medical and scientific matters, I would only ever have been the final decision maker under one of two sets of circumstances –

either

(a) when I was simply endorsing/confirming a decision recommended by the relevant adviser(s) (for instance, the National Medical Director, the Director of the PFC, the SNBTS Quality Manager or another relevant expert); or

(b) when I was faced with conflicting scientific and medical advice, proposing different courses of action.

36. As General Manager, though I certainly had a duty to see to it that the right questions were asked and the right decisions were made; and I did have the ultimate responsibility for those decisions within the SNBTS; I don't believe that I would ever have imposed a managerial decision on any technical or clinical matter against the consensus view of the professionally qualified colleagues involved. In the second situation mentioned above at (b), I would certainly not have taken a decision on a technical or medical matter that did not have the clear support of at least some of my expert advisers, with good clear reasons why.

12 In evidence to the Penrose Inquiry, Dr Ruthven Mitchell indicated the necessity for a General Manager to assist with the increasing administration work. Is this an accurate description of the General Manager role, as you understood it to be?

37. No, I don't believe that it is an accurate description, but neither do I believe that Dr Mitchell thought so either. Both he and I knew very well that management and leadership are rather more than simply administration. I feel sure that Dr Mitchell never really meant to assert anything to the contrary.

13 How would you describe your relationship with the RTC Directors and people in technical positions during your tenure (PRSE0006084 p. 74, 76-80, 91-92; SBTS0000661_063)?

38. The brief answer to this question is that I remember my relationships with my team as having been cordial and highly productive throughout my time at the SNBTS. I believe that they (those who are still alive at this time) would in fact endorse that view if asked.

39. There's no doubt that tensions arose, more often with some colleagues than others, most notably with the swashbuckling and sometimes overly assertive

Professor John Cash (an example of which is well illustrated in SBTS0000661_063). However, I do not recall my relationship with my RTC team members as having been anything but friendly and purposeful; as it was also with John Cash for most purposes, most of the time.

40. The relationship between a leader and his team being a complex one, there are bound to be ups and downs, especially in the early days of getting to know one another. This is especially so when a new leader is imposed on an established organisation with long-standing traditions, values and working habits. In the case of the SNBTS, when I joined as General Manager, the organisation had been in existence for 50 years and had never had a General Manager before. It had been run for half a century by a loose-knit relationship between medical professionals and administrators. The arrival of a professional manager must undoubtedly have been rather a shock for many – especially the medical directors who had, until then, been highly independent – and most especially the National Medical Director (the late Professor John Cash) who had in recent years seen himself as the key executive force in almost all aspects of the Service, without the need to defer to any line manager.

Did your position as General Manager come into conflict with the role of the RTC Directors? If so, why? What were the consequences of this conflict for the organisation?

41. No. I would not describe any of the discussions and debates that we had over the years as examples of my coming into conflict with the RTC Directors. In fact, on the contrary, I remember my relationships with all of them as being very positive. I had a great respect for them and I believe that the feeling was mutual. It is very sad to read the testimony of my old friend and colleague Dr Ruthven Mitchell in MDDU0000022_003. I do not believe that it represents the true position, either in respect of his relationship with me, nor the relationship overall between me and my team of Regional Directors. Of course at times there were tensions. General management isn't a love-in, but on the whole I don't believe that I could have wished for a better team. The specific occasion

that Dr Mitchell's testimony refers to, in which we as a full senior team met under the guidance of a Kings Fund consultant was, as I remember it, arranged at my instigation, not the Regional Directors'. It was a wide-ranging two day team building and discussion session and I recall it as having been a useful event.

14 On 9 April 1990 you wrote to the SHHD. In that letter you expressed views about the clinical desirability of treatment for patients. When discussing matters of a clinical nature, did you seek advice as required or was this knowledge you gained through the general course of performing your role (PRSE0003146)?

42. Yes, on both counts. I always sought specific advice on clinical matters when required and I also gained extensive knowledge in the course of my 6 years in charge of the Service. (Please see also my answers above to questions 10 and 11.)

15 Dr Mitchell described you as abruptly leaving office in 1996 (MDDU0000022_003 p.2). Is this an accurate description of your departure? Please explain the details and nature of your departure from the SNBTS (HSOC0027095; DHSC0004351_014).

43. I'm not sure that Dr Mitchell was in a position to comment on this. He retired from the Service in 1995 and was no longer with us at the time of my leaving in 1996. I think that Mr Gibb's letter of May 28TH 1996 explains the position well.

Section 3: Blood Collection at the SNBTS

16 Please explain the system for blood collection at the SNBTS during your employment there and how it changed over time. You may find NHBT0071589_001 of assistance.

44. As a long retired SNBTS General Manager I don't believe that I can give any information here that would enlighten the Inquiry team further than that which is already on record. I believe that the contents of NHBT0071589_001 record a typical example of the kinds of issues that any competent blood transfusion service is examining and reviewing on a more or less constant basis. However, I don't believe that these or any other matters that I can recall to mind constitute a significant change in the system of blood collection. As I recall, in all strategically significant aspects, blood collection in Scotland before, during and after my time, has been and still is much the same.

17 What if any steps did the SNBTS take to publicise itself to potential donor populations in order to increase donations? How successful were these steps? You may find NHBT0118157_012 p.1 and SBTS0000281_017 of assistance.

45. The public relations, advertising and general awareness raising campaigns and activities undertaken by all of the UK blood transfusion services are a vital part of essential NHS work, without which hospital operating theatres simply could not function and without which patient mortality would be horrendous.

46. In the specific case of the SNBTS between 1990 and 1996, I can confidently report that our efforts in that area were gratifyingly successful. Generous Scottish donors provided us with ample supplies and we were able to provide the NHS in Scotland with all the blood, components and plasma derived medicines that were needed for patients throughout Scotland.

18 To what extent did the SNBTS collect blood from prisons, borstals and similar institutions? 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 information, if any, was presented to prison donors before they gave blood?

d. Were hepatitis and HIV considered risks in this specific population? If so, how were these risks managed?

e. What were the relative costs of collecting blood from prisons as compared to collecting blood at an RTC by the SNBTS?

f. Were prisoners in Scotland provided with any form of incentive to donate blood? If so, what?

47. Reference all of the above, I don't believe that I can help with these matters as they pre-date my time in post. We had ceased collecting from such places by the time I came to the SNBTS.

19 Please describe the way in which donations were collected at the SNBTS during your time there. In particular:

a. What were the staffing arrangements during blood donation sessions? Were they medically trained staff?

48. The details of this are matters of record, to which I'm afraid that my memory will be unable to add further value. As I recall, donations were collected according to time-honoured principles – with trained non-medical staff as well as nurses and always at least one doctor in attendance. Donor sessions were typically held in one of three ways –
    - In the RTCs
    - In local premises (places of employment, church halls, etc)
    - Travelling donation centres (purpose-built bus-like vehicles kitted out specifically for the purpose)
49. When I was first appointed (and, as a donor, for many years before) I was aware that the actual needle insertion for each donation had to be performed by a doctor. That was changed during my time. Then and up to the present day that job is done by specially trained phlebotomists.

b. Where did these sessions take place?

50. As at (a) above – various locations.

c. What influence did the SNBTS have over RTCs in relation to blood donation sessions?

51. The RTCs were part of the SNBTS. They reported to the General Manager of the SNBTS and operated at all times in close cooperation with the headquarters team; and under their guidance as and when necessary. The planning of the overall national collection volume required, the share-out of volume between the regions and other strategic matters were determined centrally, but of course with extensive RTC involvement, including the presence of the RTC Directors at all strategically significant meetings. Session policies and practices were mostly determined by the National Donor Services Manager (DSM), in close consultation with her regional donor services manager colleagues. (To be clear, the regional DSMs reported directly to their own RTC Director but had a strong dotted line professional relationship with the National DSM.)

d. How frequently could a person donate blood?

52. As I recall, the norm in Scotland in my day was once every 16 weeks, apart from the Glasgow and West of Scotland region where the minimum gap allowed between donations was 12 weeks. Both come within internationally accepted norms. The higher frequency in Glasgow and the West was, as I remember it, a reflection of the greater difficulty that had historically been experienced there in raising and maintaining donation volume when taking donations less frequently. [Note: Collection performance in this region had been problematic historically, but became much better after 1990 in response to a series of measures taken under Headquarters guidance and a splendid effort by the donor services team in Glasgow.]

e. How were blood donors recruited? You may find SCGV0000057_022 of

assistance.

53. As I recall, donors were recruited by a multiplicity of means including television advertising, radio coverage, printed media campaigns, articles and stories and by word of mouth. I myself appeared on television and in radio interviews from time to time to help stimulate interest and support, but the main effort was put in by regional donor services management and staff in cooperation with and support from the National Donor Services Manager and her team at SNBTS H.Q.

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

54. No, if my memory serves me, none of these matters changed significantly during my time in post. Collection performance improved somewhat and I believe that the donor experience improved also. However, these are routine matters for any transfusion service and I don't believe that the alterations we made were far above the normal.

20 Did the SNBTS have donation collection targets that it was required to meet? If so, did the SNBTS 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? You may find SCGV0000057_022 of assistance.

55. These are points on which my memory is quite clear and on which I believe it to be accurate.

- Yes, the SNBTS had annual (and proportionate monthly and weekly) collection targets that it committed itself to meet and which were closely monitored;
- Yes, the SNBTS did indeed meet its collection targets. I do not believe that we ever fell short of our collection targets to any significant extent during my time in post. We achieved and maintained national self-

sufficiency in blood and all relevant blood derived medicines – for all patients in Scotland.

[Note: In relation to what more might have been done, it is worth noting that more did not need to be done. Quite the contrary. In fact, over the period of my time in post we deliberately reduced whole blood collections in favour of a slightly lower initial collection volume but better management of that, less wastage and also the encouragement of clinicians to actually use less - saving cost of course, but also improving safety and the overall quality of patient care. This tendency to use less blood (red cell concentrate) is a common theme in the developed World. As I understand it, red cell usage in Scotland has dropped by roughly 50% since my time.

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

Production of fresh frozen plasma

21 The Inquiry understands that RTCs under the umbrella of the SNBTS procured plasma from blood donor sessions to produce fresh frozen plasma ("FFP") to provide to the Protein Fractionation Centre ("PFC")].

56. With respect, the Inquiry's understanding of this is incorrect.

    i. The RTCs did not procure plasma under the umbrella of the SNBTS. The SNBTS, as the national organisation responsible, procured blood and plasma through the coordinated efforts of a national team. The RTCs were an integral part of that team.

    ii. The sense of the question as worded seems to imply that the SNBTS was somehow an arm's length supplier of plasma to the PFC. For the avoidance of doubt, the PFC, like the RTCs was an integral part of the SNBTS.

57. It may therefore be helpful to the Inquiry team to explain that in this regard the Scottish arrangements were very different from those in England and Wales, where there was much less integration. The NBA had a role to play in collection

of course but not as the direct line manager of the English collection centres. Each one of those was part of their own local NHS authority structure, not an integral part of the NBA. Similarly, the Bio Products Laboratory (BPL) was a different body altogether, neither part of nor directly associated with either the NBA or the blood transfusion centres. I believe that this may be why the Inquiry team has gained the impression that they have of the Scottish set-up. It was not in fact at all similar to the English system in these respects. We operated as an integrated whole, designed to achieve national self-sufficiency in blood and all blood derived products for patients in Scotland – as a common goal for all parts of a united organisation.

Please explain:

a. where the production of FFP took place;

58. Unfortunately, helpful responses to these questions must necessarily be prefaced by some further explanation.

(i) Human plasma is a natural fluid that comprises a little over 50% of the blood that circulates in the human body. Strictly speaking therefore it is not and cannot be "produced" in an industrial or pharmaceutical sense of the word. It is produced naturally by the human body.

(ii) In the current context – the therapeutic use of plasma and/or its components/ingredients) – there are two main ways in which plasma is obtained :

- by separation/extraction from donated whole blood (from which the cellular components, including red cells, are also extracted and are also used therapeutically). This is normally referred to as "Recovered Plasma" (because it is "recovered" or extracted from whole blood);
- alternatively, plasma can be obtained by using special equipment to allow only the plasma to be taken at the donation session, with all the donor's other blood components (red cells, platelets, etc) being automatically returned to their body. This is normally known as "Source Plasma".

(iii) The plasma that is obtained by these two methods is essentially exactly the same fluid. The different names used only distinguish the way in which they were extracted from the donor's blood. They are both often referred to as "harvested".

(iv) Once harvested, human plasma is normally used in one or other of two different ways:

- for direct clinical use, mainly in hospital settings. This plasma, which is not pooled into large batches but is administered to patients one bag at a time, is normally referred to as FFP (Fresh Frozen Plasma). The term is not normally used to refer to plasma that is destined for fractionation.

- for use as the raw material for the production of PDMPs. In this use case, the individual bags of harvested plasma are pooled into large batches before being pharmaceutically processed into clotting factors, albumin, immunoglobulin and other PDMPs needed for patients. Plasma destined for use in this way was most commonly referred to in my day as "Recovered Plasma" because almost all plasma for fractionation at that time was plasma that had been obtained by extraction from whole blood donations. Nowadays it is most commonly referred to as PFF (Plasma For Fractionation) because both Recovered Plasma and Source Plasma are used for PDMP production.

(v) The questions the Inquiry team poses here refer, I think, to what would normally be termed "Recovered Plasma" or "Plasma for Fractionation"– that plasma that is extracted from whole blood, sent to a fractionation plant, frozen, stored and in due course used as the raw material for the production of PDMPs.

(vi) Since the Inquiry's main focus in the present context is on medicines derived from recovered plasma by fractionation, I assume that what is of interest here is not in fact what is normally called FFP, but is in fact Plasma for Fractionation (PFF). This is therefore the term that I use here in my responses.

b. broadly, the process that was undertaken,

59. Classically, whole blood is taken from the donor, normally into one large bag with a number of smaller bags attached by various tubes (collectively known as a "giving set"). These are then used to partition the donation into its component parts, usually involving settling and centrifugation. The part of the process most relevant here is the separation of the plasma (protein) content from the cellular (live) component (mainly red cells) by centrifugation and the subsequent freeze-down of the plasma for satisfactory preservation of its important therapeutic potential.

c. the capacity of the SNBTS to manufacture FFP and whether this changed during your tenure and why;

60. As explained above (21 (a)) I assume here that the question refers to PFF and that this question (c) is intended as an enquiry about the SNBTS's capacity to harvest PFF in sufficient quantity. It is important to explain here that the most important rate limiting steps in this context were not to do with PFF harvesting, as such. The key determinant was whole blood collection volume. Plasma volume in my time at the SNBTS was entirely determined by whole blood volume. The SNBTS team therefore took great care to balance whole blood collection targets to the known requirement for recovered plasma for fractionation (PFF) to meet the anticipated needs of patients' for the PDMPs that would be produced in this way. During my time there, as I remember it, the SNBTS was always successful in meeting those collection targets.

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

61. From memory, I would say that the direct answer to this question is – approximately 94%. However, it may perhaps be helpful to add some

background explanation to the bald figure. In the modern context, whole blood collections are destined, broadly, for two main ends-

(i) a very tiny amount of clinical use in the natural form, as whole blood transfusions. (Now vanishingly rare. I'm guessing about 1%, but cannot be certain about that from memory); and

(ii) separation into its component parts (hence the term "component therapy"). This accounts for approximately 99% of all blood collected and involves principally the preparation of red cell concentrate, concentrated platelet preparations and plasma extraction. (There are other components, but these are by far the most important.)

62. Once the plasma portion of the donated whole blood has been extracted, that in turn is then destined for one or the other of two main applications –

a) for clinical use as FFP - fresh frozen plasma for direct clinical use, in its raw state – but of course at body temperature after thawing. This I believe would have accounted for approximately 5% of total plasma volume in my time.

b) for bulk pharmaceutical processing (fractionation) into the vital PDMPs so badly needed by so many patients (albumin, immunoglobulin, etc – and including in my day Factor VIII and other clotting factors.) As I recall, when I was at the SNBTS, this accounted for approximately 95% of all plasma.

63. Therefore, the net effect is that approximately 94% of all blood collected was made available for the extraction of PFF and so to the onward production of PDMP's for patients in Scotland.

64. In my time at the SNBTS, there was never any question of increasing or reducing that proportion. We always harvested as much plasma for fractionation as we could (of course without prejudicing the clinical availability of the fresh components needed for patients). This was not really a decision for us to take at all. It was dictated to us by the clinical needs identified by and

in Scottish hospitals and Health Boards. Essentially, we always needed as much plasma as we could get, to meet those needs.

e. how quickly the SNBTS could have increased its manufacture of FFP, had it wished to.

65. Again here, I am assuming that the question refers to PFF (not FFP as written). Increasing the availability of recovered plasma for fractionation would have meant collecting more blood. This was not necessary.

66. Had it been necessary, the speed with which we achieved it would have depended on the urgency of the situation. However, to give some idea of our capacity to react quickly to such an emergency, we did once more or less double our blood stocks in only seven days at the time of the First Gulf War (by going on television and radio and in the newspapers, setting up a special telephone help line and arranging special extra donor sessions.)

22 As far as you are aware, how was plasma procurement funded by the SNBTS throughout the 1980s and 1990s?

67. Throughout my time at the SNBTS our funding came to us as part of the overall national budget for the NHS in Scotland, through an appropriate allocation to the NHS in Scotland Common Services Agency, earmarked and ring-fenced for the SNBTS by the (then) Scottish Office Home and Health Department. As I understand it, that was the funding arrangement throughout the '80s and '90s.

68. However, to describe this as funding for plasma procurement is a misnomer. The SNBTS was funded with the overall strategic goal of providing a fully sufficient service to the healthcare system in Scotland, both public and private, with respect to the full range of products and services that it was our responsibility to provide. The extent and depth of these is a matter of record

the detail of which probably has no place here. However, if I can assist the Inquiry with any further information on this I will of course be happy to do so.

69. For the avoidance of doubt, the various budget heads under which the various parts of the SNBTS were funded to do their work did of course include funding for blood collection and also, separately, for the processing of both blood and plasma, including the transformation of plasma into PDMPs. However these were matters for decision within the SNBTS, subject only to our fulfilment of our overall mission and were not pre-ordained in detail by any outside body.

23 Please describe the arrangements for supplying FFP to hospitals and haemophilia centres within the regions covered by the SNBTS.

70. As explained above in my answer to question 21 (a), I believe that this question is intended to refer to PFF (not FFP).

71. For the purposes of the Inquiry it's probably important also to explain that plasma for fractionation (PFF) isn't normally supplied either to haemophilia centres or to hospitals. If supply arrangements are felt to be an important matter for inquiry, then I would suggest that the relevant arrangements to be considered are

- the supply of whole blood, red cell concentrate and other fresh components to hospital blood banks; and also directly to hospital wards and operating theatres and to A&E departments by the SNBTS's own blood banks; and
- quite separately – and very differently – the supply of all the various PDMPs from the PFC to the various customer units involved, including the haemophilia centres.

72. I believe that these are matters of record. However, if the Inquiry team requires further details of these supply systems, I would suggest that my medical colleagues and others more directly involved in such arrangements will be better able than I am to assist in these matters.

Plasma targets

24 Did the SNBTS set targets for the amount of plasma that had to be collected by each centre? If so, who set these targets and what were they? If not, why not? What was the purpose of the targets?

73. The SNBTS team set themselves collection targets appropriate to the anticipated need for blood and blood products to meet Scottish needs. These targets were not normally expressed in terms of plasma volume. Everything flowed from the collection of units of whole blood (of which plasma formed a part – circa 52%). Within the overall targets agreed for the Service, there were specific local targets appropriate to each region's particular situation. The detailed breakdown of targets as between regions was a matter decided upon by consensus after wide-ranging discussion and analysis of the situation on the ground. The purpose of the targets was to define clear goals for each individual team and for the organisation as a whole, so that we all knew what we were aiming for and had the best chance of delivering successfully on our mission – the maintenance of full Scottish national self-sufficiency, for the sake of the patients in need of our products and services.

25 What was your role in both establishing and meeting plasma targets?

74. My role as General Manager was to ensure that my team worked efficiently, harmoniously and cost-effectively in the accurate calculation of the target volumes required and in the achievement of those targets – to ensure that my organisation fulfilled its overall strategic responsibility to deliver national self-sufficiency in all blood, blood components and derivatives - with safe and efficacious medicinal products and services. Oversight of the establishment of appropriate targets and the management of performance in meeting those targets was part of that job.

26 In January 1990 you attended a meeting in which it was agreed to create 9 months stock of finished Factor VIII product by the end of 1991/1992, which was noted as a substantial increase (PRSE0000759). As far as you are aware, what were the standard stock requirements? Was this new target considered the standard moving forward?

75. As I recall, there was a constantly rising demand for Factor VIII throughout my period in post, so that both production volume targets and appropriate target stock levels tended to be revised upward accordingly. Any agreed standard stock levels would therefore have been unlikely to have applied for long. However, I don't believe that stock levels were ever a particularly controversial or difficult issue – just often a fair old struggle – particularly during the complex and often hectic period of transition between earlier versions of the SNBTS FVIII product and its higher purity successor.

76. I'm afraid I don't remember whether or not the 9 month level set in early 1990 was ever changed, but I can safely say that by the time I left the SNBTS in 1996, a 9 month stock would certainly have represented a much larger amount of Factor VIII than it had in 1990.

27 In October 1990 you raised concerns that Factor VIII stocks were "dangerously thin and that PFC would need to be alerted". What did you do to counteract this? (PRSE0001184) You also refer to a "phase III/IV building programme". Please explain the connection between the "building programme" and stock levels. How successful was the "building programme" in increasing stock levels?

77. I do recall times in my early days at the SNBTS when it was somewhat of an uphill struggle to ensure fully sufficient FVIII stock levels everywhere at all times. However, I do not recall that we ever actually fell short of our supply

commitments. This particular point (PRSE0001184) is in reference to a period when three major factors were impacting on the SNBTS at once:

(i) a rapidly increasing demand for FVIII generally;

(ii) an increasing concern among clinicians that traditional FVIII products were not of sufficiently high purity, that new pathogen threats required new solutions and that new methods should be found/used to provide next-generation versions to replace the old products.;

(iii) the realisation that these two factors added up to an urgent need for the SNBTS/PFC to re-think both production volume capacity and processing methods to respond in an appropriate way.

78. To deal with the situation, it was necessary to take a series of urgent actions that may be summarised as follows –

- The building programme undertaken at PFC was designed to deal satisfactorily with item (iii) above – addressing the other two factors very well as soon as it was finished (which, after approximately 12 months it was, fully satisfactorily).
- However, the building programme was too major an exercise to be completed in time to do the job fast enough on its own. Production of the new high purity FVIII product could not have been ramped up fast enough and stock levels would not have been sufficient to meet the needs of patients. An interim "stop-gap" solution was required.
- Therefore, the Service made appropriate arrangements to have SNBTS plasma processed, temporarily, elsewhere (in the fractionation plant of the Lille Blood Transfusion Service, in France) – to cover the relevant period until PFC production could take over again and locally produced stock could be built up again sufficiently to maintain continuity of supply for patients.

79. It may also be helpful to the Inquiry if I add a summary of other steps that were successfully taken to improve FVIII production during my time at the SNBTS -

- better plasma recovery volumes, due to the full adoption of optimal additive solution at the initial whole blood collection points;
- more effective and efficient use of the PFC estate and plant - including fundamental changes to working terms and conditions and the introduction of shift working;
- investment in enlarging the PFC estate and plant to increase capacity overall (including, but not limited to, the building programme mentioned above); and
- improvements in the fractionation and associated processes at the PFC.

80. The sum total effect of these improvements was to successfully transition the PFC from its pre-1990 condition, under Crown Immunity and with capacity limiting constraints arising from day-time working (without shift work) into the new condition planned for it, in readiness to face the future with greater confidence. As a result, FVIII production levels and stock holding both became routine matters and not at all problematic, despite the inexorable rise in demand.

28 Please explain what you were referring to in your letter to Dr Panton on 9 December 1991 (SBTS0000030_122) in which you said "it would not be appropriate to try to take advantage of this new opportunity immediately because of the upheavals of Phase III/IV to allow the essential "good manufacturing practice" improvements required by the Medicines Inspectorate to be built in to our improved PFC facilities". What were the "good manufacturing practice" improvements which were required? Were they implemented correctly and efficiently? Please provide details.

81. As mentioned in answer to Question 9 (j) on regulation, the SNBTS, in common with all other NHS organisations, entered the 1990s still classified in the age-old category of having "Crown Immunity" – effectively self-regulated – not under the purview of the independent regulatory bodies that looked after the private

sector. This situation changed very early in the 1990s and as a consequence my PFC colleagues and I had to plan and undertake a very extensive review of all practices and procedures at the plant, where we were running a complex pharmaceutical processing facility that was suddenly faced with having to comply with a whole new set of rules and regulations, alongside other pressures. This is not to say that anyone believed that previous PFC methods were sub-standard, just that a whole new set of standards and operating procedures had been suddenly imposed on it by the change in its legal status and these would now have to be complied with.

82. I am happy to be able to report that all the necessary regulatory requirements were successfully implemented and the PFC passed its first ever Medicines Inspectorate inspection with flying colours.

29 In April 1990 Lothian Health Board complained about the increase in cost of purchasing commercial Factor VIII and that they believed the SNBTS was building up stock as a reserve and therefore supplying them with reduced quantities (PRSE0004486,). Were complaints of this nature from Health Boards a common occurrence? If so, please provide details. As far as you are aware, was this an accurate assessment? You may find your response, "It is untrue that we are building any stock beyond that which is absolutely essential to safeguard regular reliable supplies to all our customers including Lothian Health Board" (PRSE0003146) of assistance.

83. No. I cannot recall any other Health Board or hospital making such a complaint. As I remember it, this particular issue over Lothian Health Board stock levels was not at all long-lived. As I recall, it was quickly sorted out (if I remember rightly, by internal stock transfers between SNBTS units). My recollection is of generally very well satisfied customer doctors and hospitals throughout Scotland for most of my years at the SNBTS.

30 What impact did the setting of targets for the collection of plasma have on decision-making at the SNBTS?

84. As explained in response to Question 20, the collection targets were a central driving factor in our work at the SNBTS. They were the result of a whole series of analyses and decision-making steps. After they had been set each year they then became a key guiding light in much of our activity.

31 What were the consequences if the targets were not met?

85. They would have been dire – for patient care throughout Scotland. Happily this never came to pass.

32 Were there any benefits to the SNBTS if the targets were exceeded?

86. No, far from it. Collecting more blood and/or plasma than was actually needed for patients would have been highly inappropriate – wasteful both of the public money used to do such a thing and of the precious gifts so generously given to us by Scottish donors. The targets were there to be met as exactly as possible, unless deliberately adjusted in line with the demands of customer hospitals, clinics and surgeries. Exceeding them would have brought benefit to no one.

33 Were targets set by the SNBTS for individual RTCs or for Scotland as a whole?

87. Both, as explained above in my answers to questions 24 and 25.

Plasmapheresis

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

a. whether manual or machine plasmapheresis was preferred;

b. the relative cost differences between each method;

c. the infrastructure, expertise and capacity of the SNBTS to introduce plasmapheresis; and

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

88. The discussions in 1981 predate my involvement with the SNBTS. In my time as General Manager, the only plasmapheresis applications I remember us using were

- therapeutic apheresis (plasma exchange therapy for individual patients); and
- hyper-immune (or "specific") plasma harvesting for the manufacture of special immunoglobulin products

89. There may also have been a small amount of pheresis used for platelet harvesting, but I'm afraid I don't recall that detail.

90. The main point here though is that in my time we were in the happy position of having red cell requirements and Factor VIII demand in pretty close synchronicity - in other words, if we collected enough whole blood to meet all the Scottish needs for red cell concentrate and harvested the plasma from that whole blood efficiently, we found ourselves with the right volume of plasma to deliver customers' needs for FVIII also. This is a slight over-simplification, but I think it makes the point that from 1990 – 1996 there was never any need to contemplate large scale investment in volume plasma collection by pheresis ("source plasma"). We had enough recovered plasma to do the job. [Note: In the present day this is absolutely no longer the case, but it was then.]

35 Please set out the extent of the plasmapheresis programme at the SNBTS during your tenure. As far as you are aware, did this programme differ from other NBTS's? If so, why?

91. As in my answer to question 35, I do not recall large scale pheresis as being an issue in my day – neither for us in Scotland, nor as far as I know for the other UK Services.

36 To what extent were decisions made within the SNBTS influenced by larger European policies and trends?

92. Greatly. Any organisation engaged in clinical, therapeutic and/or pharmaceutical work has to stay fully abreast of developments globally if it is to do its job properly. My professional colleagues in particular were very active in this way and I of course encouraged it. I was myself a founder member of the European Plasma Fractionation Association, very much with this in mind.

Were meetings between Plasma Fractionation Associations across Europe a common occurrence (SBTS0000684_063)?

93. Yes they were a common occurrence, though not very frequent. From memory, I would say that we met perhaps four times a year.

37 During a meeting of the SNBTS Board in April 1991 it was noted that the Finnish BTS were closing plasmapheresis centres apparently due to attaining higher factor VIII yields from recovered plasma using the Baxter immunopurification process (SBTS0000108_079). Do you recall the extent to which BTS activity from outside of the UK influenced SNBTS decisions? Were these decisions ever at odds with UK-wide guidelines?

94. My memory is of frequent collegiate contacts with fellow practitioners and a healthy exchange of views on an almost constant basis. Our Finnish colleagues in particular were valued friends and collaborators, as were our counterparts in Lille in France. These will often have influenced our ideas and also at times our practices and procedures. I do not recall that any of this ever

put us at odds with UK-wide guidelines, recommendations or accepted professional practices.

Was the SNBTS able to make decisions outside of the UK framework if it saw a clinical advantage to doing so? Was there an approval process the SNBTS would need to follow? If so, please provide details.

95. The answer to this question is a complex one. It is dealt with at more length elsewhere in this testimony (ref Question 150 below). In brief summary here, yes, the SNBTS was free to make a wide range of decisions as it felt appropriate, provided always that we abided by

- the rules and regulations laid down by the (then) Scottish Office Home and Health Department
- the legal obligations on us prescribed for instance in the Regulatory controls on us post the removal of Crown Immunity; and
- an extensive set of medical and pharmaceutical regulations governing the activities of all similar organisations

[Note: It is also true that to some extent there was a "UK Framework" consisting of a loose informal alliance of the various UK transfusion services, the various Health Departments and a concatenation of advisory bodies of various kinds. However, as noted elsewhere in this testimony (eg in answer to Question 150), none of this was clearly stated and whether one was inside or outside of the "UK Framework" was often hard to tell.]

38 During a meeting of the Factor VIII Working Party in April 1990 it was suggested that maximum stock levels be imposed on certain RTCs to prevent uneven distribution (SBTS0000299_020 p.2). Do you recall uneven distribution being a persistent issue? Were the caps implemented? If so, were they successful? Were there options, other than maximum stock level caps, available to improve supply?

96. This reference relates to the same period and the same matters covered above in my responses to questions 26 to 28. This was a period that I remember as characterised by collaborative efforts by the SNBTS team, especially the R&D people and the PFC team, with the haemophilia directors' community, to deal with an often stressful time, which, as I remember it, they did very well indeed. As set out above in my response to question 27, the complex programme of measures taken, including, but by no means limited to, the stock management measures mentioned in SBTS0000299_020, combined to achieve all that we had hoped to achieve; in terms of FVIII volume, stock availability and also in enhanced product quality and safety - as a result of the new production methods adopted to deliver what the clinical community had specified as desirable. I do not recall that uneven FVIII stock distribution was ever a serious problem. It was certainly not a persistent issue.

Use of plasma reduced blood and red cell concentrates

39 What steps, if any, did the SNBTS 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? If no steps were taken, please explain why.

97. This question does not relate to my time at the SNBTS. Component therapy was well established by the time I came into post. Persuading clinicians not to use whole blood was never on my agenda.

(Note: Helping to persuade them to use less red cell concentrate was another matter. As an indicator of this aspect it may be relevant to note that red cell use in the NHS has fallen by approximately 50% since I left the Service in 1996. There are of course many reasons for this, including a great increase in "key hole" surgery, but there is also a significant element that can be attributed to greater clinical awareness of the desirability of limiting the prescribing of blood transfusions to those most genuinely in urgent need of them, rather than just as a routine well-being booster. We must regard this as a positive step in

absolutely the right direction. However, it may be of interest also to note that it has greatly reduced the volume of recovered plasma available today from whole blood collections. This now means that the only way to achieve national self-sufficiency in PDMPs is to invest in apheresis – as HMG is in fact now doing.)

Supply to blood and blood products outside the NHS in Scotland

40 In 1989, cross-charging was introduced in England and Wales to act as an incentive for RTCs to increase the amount of plasma being sent to BPL (see SBTS0000648_154). As far as you are aware, what effect (if any) did cross-charging have on the plasma supply of blood and blood products from Scotland to England? To what extent would cross-charging benefits affect the choice of laboratory? You may find SBTS0000708_071 and SBTS0000708_070 of assistance in answering this question.

98. The mission of the SNBTS was to serve patients in Scotland. We had no remit South of the Border. Cross-charging was (thankfully) not an issue for us in Scotland. If, as we occasionally did to help out in times of need, we sent medicines to the NHS in England, in such cases charges were of course levied – because the (then) Scottish Home and Health Department was not funded to generate supplies for English patients and was duty bound to recover any costs it incurred in doing so. However, we did not regard this as cross charging in the conventional sense. The amount of medicine we were able to send to England depended on only two things – whether or not they had a need for it and whether or not we had a genuine surplus we could spare without endangering the reliable sufficiency of supply to Scottish patients. Cross-charging or other payment methods had nothing to do with it.

99. By "laboratory" I take it that what is meant is the English Bio Products Laboratory (BPL) and the Scottish PFC, as appropriate. If so, I should explain

that there was no choice of laboratory. English and Welsh plasma was fractionated at BPL. Scottish plasma was fractionated at the PFC.

41 As far as you are aware, what effect (if any) did cross-charging have on the plasma supply chains connecting Scotland, England, Wales, and Northern Ireland SCGV0000056_044)?

100. I do not believe that there were any plasma supply chains that connected Scotland, England, Wales, and Northern Ireland. We in Scotland certainly did fractionate plasma for Northern Ireland during my time at the SNBTS and we very occasionally made products, on special request, for England; but we would certainly never have thought of ourselves as part of a UK-wide plasma supply chain.

101. That having been said, in relation to cross-charging, I do not believe that this had any effect on such occasional supply arrangements as did arise between ourselves and other parts of the UK. We supplied to need, if possible, as explained above in my answer to question 40, not as an income generation exercise.

42 In November 1990, The Haemophilia Directors (via Christopher Ludlum) advised you in terms of factor VIII concentrate "the ideal product should be licensed and manufactured from U.K. volunteer plasma donations. It should be of high purity (>100 i.u./mg protein), high potency (>25 i.u./ml in the syringe) and readily soluble and stable in solution at room temperature for at least 12 hours. Our top priority is that the product must be safe particularly from virus transmission" (SBTS0000706_223). In February 1991, the Haemophilia Directors for Scotland and Northern Ireland (again via Christopher Ludlam) advised you that they were "keen to use a licensed factor VIII concentrate manufactured from locally collected plasma" with a preference towards "a product of higher specific activity than the current Z8" (PRSE0003536). Do you recall the extent to which these opinions drove decision making regarding the production of Factor VIII and the various trials commissioned by the SNBTS?

102. Indeed I do remember it well. That whole period of rapid development and the intensely cooperative work that was done by the SNBTS team, the haemophilia directors and others at that time is still very fresh in my memory. We in the SNBTS did not see the haemophilia directors' recommendations as "opinions". They were the target specification to which our efforts were addressed. As I remember it, they were met partly due to the great work done in Scotland, but also with the invaluable help of our transfusion service colleagues in Lille in France (co-founder members of the European Plasma Fractionation Association).

43 When requests from countries for Scottish blood products were received, who would be involved in the decision making process regarding allocation and supply (ARCH0003321_017)?

103. The document referenced relates mainly to the possibility of the Scottish PFC undertaking contract fractionation for the Republic of Ireland. It is not focussed on the export of Scottish blood products. It was not a common practice for the SNBTS to export blood or plasma products. I only recall three examples – the emergency supply of red cell concentrates to war-torn Bosnia at the request of the WHO (8,000 pints); the supply of polyclonal Immunoglobulin to the NHS in England to help meet demand that BPL was unable to satisfy at a time of shortages in the marketplace for commercial products; and a small supply of specialist hyper-immune immunoglobulin (anti-Cytomegalovirus) also requested by BPL. The supply of polyclonal immunoglobulin grew into a routine supply arrangement that lasted for some years, but remained the exception not the rule. I would have been closely involved in any such cases that arose. In the cases mentioned here (the only ones I can recall) I gave them my strong support.

44 Under Section 54 of the NHS (Scotland) Act 1978, the SNBTS was legally bound to only supply blood and/or blood products for patients outside the NHSiS if this could be done without detriment to the NHSiS or to NHSiS

patients. As far as you are aware, who would decide whether blood product supply to private hospitals was detrimental to the NHSiS or its patients (SCGV0000160_098)? How often did this occur?

104. The supply of blood and blood related products for administration to private patients in Scotland was always planned in at the start of each year. It was planned for and delivered, without detriment to the NHSiS or to any NHSiS patients. Had there ever been a question of detriment, and a need therefore to decide whether or not to supply, this would have been considered first by the MSC and, if necessary, referred upwards to the SNBTS Management Board for final decision. However, I don't recall this ever having been necessary.

45 The Inquiry understands that you established a system for RTCs outside of Scotland to receive blood products from Scottish RTCs (NHBT0010669). Please explain what this system entailed? What was the process before this system was implemented?

105. The system referred to in the document referenced was set up to avoid ad hoc proliferation of transfers from Scottish to English centres and/or hospitals. I don't recall the details of this, but I would imagine that previously individual English centres might just have telephoned their friends in Scotland and made ad hoc on the spot arrangements. It was of course perfectly legitimate for us to help out fellow NHS centres in all parts of the UK in times of need. We were committed to do that whenever necessary. However, this had to be managed and controlled, to ensure that we did not in so doing prejudice our ability to fulfil our core obligations to the NHS in Scotland. As I recall, however, this never became a major issue.

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

46 Please describe the arrangements in place in Scotland 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")

106. My memory of the detail of these arrangements is not sharp. However, I do recall that every regional centre held stocks of FVIII in order to assure the clinical haemophilia community of adequate availability. It may also be helpful to note that there was no question of our buying any NHS blood products. The SNBTS was funded centrally to provide for the needs of Scottish patients and all blood and plasma products were issued to hospitals free of charge.

(b) imported factor concentrates and/or other blood products ("imported blood products").

107. I don't believe that we in the SNBTS ever purchased, stocked or otherwise dealt with any imported blood products. In that category of medicines Scotland was self-sufficient on the basis of its own donors' plasma.

[Note: As I recall, in the early days of the transition from Human derived FVIII (a PDMP) to recombinant FVIII (a synthetically produced product) we did I think buy a small amount of the recombinant FVIII product in the course of a clinical trial collaboration between us and the haemophilia directors, but this was an isolated case and did not involve us in importing plasma products.]

In particular:

a. Please identify which haemophilia centres were supplied with such products by the SNBTS and over what period of time (PRSE0001484; PRSE0002327).

108. If the products referred to are imported blood products, the answer here must be that the SNBTS supplied no centres with these, at any time. If the question refers to SNBTS/PFC products, then the answer is that all centres were so supplied.

b. Please outline the respective responsibilities of the SNBTS, BPL/PFC, the relevant Regional Health Authority ("RHA"), and haemophilia centre directors, and how these responsibilities changed over time (PRSE0004409).

You may find PRSE0003083 of assistance.

109. In answering this question I should first make it clear that the SNBTS had very little contact with RHAs. These are and were English institutions and not within our area of responsibility. Also, our responsibilities for the PFC, its conduct, performance and output were unrelated to BPL, with which we also had very little to do. The references quoted in the question relate exclusively to Scotland and Northern Ireland.

110. In Scotland, the equivalent of the English regional health authorities are the Area Health Boards. These are responsible for the oversight and strategic direction of the NHS units and services within their area. Because they operate at the strategic level, we in the SNBTS only rarely had occasion to deal with them directly. We mostly dealt with their various units and services as and when appropriate.

111. The haemophilia centre directors on the other hand were close colleagues, friends and indeed, importantly, customers. They were of course responsible, as prescribing clinicians, for the type and quantity of medicinal product that was made available to patients in Scotland (and also Northern Ireland). They also advised the SNBTS on the specifications for clotting factor products being, or planned to be, manufactured in Scotland. They also cooperated closely with the SNBTS team over product supply arrangements, planned quantities, etc.

112. We in the SNBTS were responsible for the production of appropriate safe and efficacious products to meet the specified requirements and their safe and timely delivery in appropriate quantities.

113. I do not recall that the respective responsibilities of the various bodies involved changed at all significantly over time.

[Note: It may also be helpful to note here that the two documents referenced above (PRSE0004409 and PRSE0003083) relate to an atypical period in the life of the SNBTS, during the transitional phase between the previous SNBTS/PFC clotting factor products and the new range of higher purity equivalents (reference also 26-28 above). They did not involve the allocation of imported factor concentrates in the normal sense of that phrase. They related to special contract fractionation arrangements made to turn Scottish donors' plasma into clotting factors in alternative premises until the transitional phase was completed. As I recall, the temporary arrangements made to cover patients' needs during that period were carefully worked out in close collaboration with the clinical haemophilia community and were carried through to a successful conclusion, without the need to import any commercial plasma products at all.]

47 Please explain whether any forums were established between the SNBTS, BPL/PFC, the relevant RHA, 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? You may find PRSE0001484 and PRSE0002327of assistance.

114. With the caveat that the SNBTS had no such arrangements with either English Regional Health Authorities or BPL, the answer to this question (47) in respect of Scotland is that yes indeed, relevant forums were established and maintained to promote the best possible supply, availability and distribution of appropriate products for haemophilia patients throughout the country. The most relevant of these I believe would have been the Factor VIII Working Party for Scotland and Northern Ireland (ref Question 76 above). I recall that this met frequently (once monthly or more) and achieved excellent results as a collaborative development and organisational grouping. I believe that minutes were always taken and I would hope that these may be available from the

records.

48 Did you, or anyone else at the SNBTS, 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.

You may find PRSE0003083 of assistance.

115. No, neither I nor, as far as I know, anyone else at the SNBTS contracted with any such company. For the avoidance of doubt, we did contract with the Lille Blood Transfusion Service in France for some key short-term contract fractionation assistance; but Lille at that time was a publicly funded not-for-profit body, not a pharmaceutical company.

49 What was the impact on the SNBTS of shortfalls in NHS product coming from PFC? How frequently did this occur?

116. It may be helpful here to clarify that there is no sense in which the SNBTS could experience shortfalls coming from the PFC. The PFC was a fully integrated part of the SNBTS. Had there been any shortfalls we would have faced them as a unified organisation (unlike the situation as between BPL and the NBA). Happily however, the situation did not arise.

50 Was the SNBTS 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

SNBTS have any influence over their product choices? You may find PRSE0001254 of assistance.

117. No. I don't believe that we at the SNBTS would have had any right to try to influence the Haemophilia directors in this way. I certainly have no recollection of any attempts having been made in that direction. We always tried to manufacture plasma-derived medicines that met the requirements of the clinicians we were supplying. In so doing, we hoped to avoid any need for them to make decisions as between one imported product or another. If we did our job properly, there should be no imported products. As I recall, the question of "importation" (in fact, contract fractionation overseas) only ever arose once in my time at the SNBTS – in the context of the temporary arrangements made with Lille to help Scotland out. The product in that case though was not an "imported product" as such. It was made to an SNBTS specification agreed with clinicians and just happened, for a short time, to be made in France (from Scottish plasma).

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

118. Such decisions, if any, would be a matter for clinicians to decide, but as I understand it clinicians have two prime concerns in all such matters –

- can I be confident that the product under consideration is as safe and efficacious as it possibly can be? And

- is the safe and efficacious product under consideration the right one for my patient at this time under their current medical circumstances? [Even the very best medicine will sometimes be unsuitable for a particular patient and this must always be taken carefully into account.]

119. As mentioned above, however, haemophilia clinicians in Scotland typically had more confidence in the products produced by the NHS in Scotland (the SNBTS)

for the NHS in Scotland (Scottish clinicians, hospitals and clinics) rather than imports of any kind. They therefore very rarely had to make choices between other plasma derived medicinal products and the locally available equivalents that were specifically produced to their specification and provided as part of the national commitment to self-sufficiency.

52 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.

120. I would hope that clinical freedom appropriately applied would have been the sole determinant of this matter, but, again, this is a matter for the clinicians, not for me as a former supplier. In Scotland during my time at the SNBTS, we were fortunate in being able to provide clinicians with the medicines they required. In our case, the salient elements of clinical freedom were exercised in helping the SNBTS to specify and to achieve the type and quality of products they required for best patient care. There was therefore only very rarely any need for them to exercise their clinical freedom any more widely than that, in this particular clinical area.

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

121. I feel sure that there were imported blood products used in Scotland, before, during and after my time at the SNBTS. There would always have been specific cases – rare but not vanishingly so – where a patient and the clinician responsible would decide that an imported product was more appropriate in their particular circumstances. However, as I recall my time at the SNBTS we were consistently producing enough Scottish NHS product (in volume and in specification) to meet all the patient needs in the country and almost all the clinicians involved were favouring our SNBTS products over the imported

alternatives that were or might be available. Effectively, Scotland was self-sufficient in all blood and plasma products. These questions therefore don't really apply to Scotland (in the way that they do to England).

122. I'm afraid therefore that I'm unable to be of further help to the Inquiry on this point. There was only a very limited amount of commercial product imported into Scotland in those days, because of the extent of Scottish national self-sufficiency in PDMPs. I am aware however that pharmaceutical companies do provide advice on the use of their products and that this is tightly regulated by the relevant authorities.

Section 6: Production of cryoprecipitate within the SNBTS

54 Did RTCs within the SNBTS produce cryoprecipitate during your tenure as General Manager? If not, where was this produced for Scotland and what were the arrangements in place?

123. My recollection is that by the time I came into post, the therapeutic use of cryoprecipitate had already greatly diminished. Fractionated clotting factors were the preferred clinical solution. Among the many reasons why this is so that the viral inactivation and purification steps incorporated into modern fractionation processes confer a much higher level of safety confidence than can be achieved with cryoprecipitate.

[Note: It is sometimes said that the smaller number of donors involved in a given dose of cryoprecipitate – as compared to the number needed to provide a dose of concentrated FVIII – is a risk mitigation factor worth considering. However, as I understand it, this is not borne out by experience, nor by the scientific literature. The viral inactivation effects of modern fractionation have been shown to provide a significantly greater level of risk reduction than is achievable by reduction of donor-per-dose numbers.]

124. It may be helpful to go into this in a little more detail. The Plasma Protein Therapeutics Industry typically guards against pathogens (both known and unknown) in three main ways:

- Selection of donors: known to reduce risk by a factor of between 100 and 1000
- Donation testing (for known pathogens): this is also thought to reduce risk circa 100 fold
- The plasma processing itself: This is by far the biggest risk-reduction element of the three. It includes pooling (contaminant dilution), purification and process steps specifically aimed at pathogen inactivation/removal. These elements of the production process have been shown to reduce risk by approximately 1,000,000 fold per inactivation step.

125. The literature on these matters is extensive but a good summary can be found in Thomas R. Kreil, Building blocks of the viral safety margins of industrial plasma products doi: 10.21037/aob. 2018.02.01: http://dx.doi.org/10.21037/aob.2018.02.01 [WITN3523003]

55 If RTCs within the SNBTS did produce cryoprecipitate, please describe:

a. where the production of cryoprecipitate took place;

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

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

d. how much funding was provided by the SNBTS for the production of cryoprecipitate; and

126. All of the above questions would seem to have been framed with the English services in mind, not the SNBTS. For instance, the SNBTS never sent

cryoprecipitate to BPL. In the Scottish context, I do not recall there being any need to make any special arrangements for the supply of cryoprecipitate during my time in post.

56 Please describe, as far as you are aware, the steps taken by the SNBTS to increase the production of cryoprecipitate during this time. If no steps were taken, please explain why.

127. As above (54 and 55) cryoprecipitate was never an issue for my colleagues and me during my time at the SNBTS, as far as I can recall. It was almost completely superseded by the much more effective – and much safer - factor concentrate therapies now available.

57 Please describe the arrangements for supplying cryoprecipitate to hospitals and haemophilia centres within Scotland.

128. As above (54, 55 & 56), I'm afraid I do not recall that cryoprecipitate was ever an issue for my colleagues and me during my time at the SNBTS.

Section 7: Self-sufficiency

58 During your time at the SNBTS, what did you understand the term 'self-sufficiency' to mean? Did this change over time? You may find PRSE0002051 of assistance.

129. The phrase "self-sufficiency" was – and is - used in various ways, but my preferred definition has always been the following –

"The provision, in Scotland, from Scottish donor sources, of a sufficient supply of safe and efficacious blood, blood components and blood/plasma derived medicinal products to meet all the clinical needs of patients."

130. This contrasts with the definition that, as I remember it, seemed most prevalent when I first arrived at the SNBTS, which looked upon the demands of prescribing clinicians as the key factor – in other words allowing for "self-sufficiency" to include situations where imported products were being used due to the preferences of prescribing clinicians. Under this latter definition, self-sufficiency would be deemed to apply so long as it were true to say that "The clinicians are getting as much locally sourced medicine as they want". In contrast, under the definition that I prefer, it would only be correct to assert self-sufficiency if it were true to say that "The patients are being supplied exclusively with locally sourced medicines."

131. Of course, it is always preferable if both conditions can be met – ie when sufficient local national products are available to meet all patient needs and prescribing clinicians are in agreement that these are the most appropriate products to prescribe. I am happy to be able to report that this was in fact almost completely the position in Scotland during my time in the Service.

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

a. plasma procurement;

132. Utterly central to all decisions in that area.

b. decisions with regard to cryoprecipitate production;

133. Please see my answers above, in response to questions in Section 6.

c. purchases of commercial blood products;

134. It was never part of the SNBTS brief to purchase commercial blood products and I don't believe that we ever did so. I do seem to remember that we may have purchased a certain amount of commercial recombinant Factor VIII (not

produced by any transfusion service) in the early days of the growth of that alternative medical product. However, that is not strictly speaking a blood product. The purchase of it would not have been to do with self-sufficiency, but as part of a cooperative effort in support of clinicians serving patients in need, under special circumstances.

d. funding provided to RTCs by the SNBTS.

135. I think it will be more helpful here not to think in terms of funding provided to RTCs by the SNBTS, but rather to note that the organisation as a whole planned the annual collection programme – driven principally by the commitment to national self-sufficiency – and that each RTC willingly signed up to that programme and to the portion of it for which they were to be responsible and were funded accordingly.

60 What was your view on the prospect of Scotland achieving self-sufficiency? You might find PRSE0003113 of assistance.

136. As I recall – and I believe that my memory is clear on this point – I joined the SNBTS with a clear brief that Scottish national self-sufficiency was to be achieved and maintained as a top priority. My view of that was

    a) that it most certainly should be achievable (we were almost there already); and that

    b) my team and I would see to it that it was achieved.

137. After an initial somewhat touch-and-go period of transition from old to new ways of working, I believe that we achieved full self-sufficiency early in my second year in post and maintained it thereafter until I left in 1996.

    [Note: In relation to PRSE0003113, that is a good example of the work done during the transition period. My comment to Dr Stewart about "just for the joy of self-sufficiency" reflects the fact that patient care always came first, self-sufficiency second. However, thanks to the splendid efforts of the SNBTS

team, working in close cooperation with the haemophilia directors, it was possible for us to provide clinicians with the safe and efficacious medicines they needed and to thereby maintain self-sufficiency throughout.]

61 As far as you are aware, did your views on self-sufficiency accord with the views of your peers and the Blood Transfusion Services? You might find SBTS0000656_051 of assistance.

138. I recall much discussion of this point – most heatedly with colleagues in England, where self-sufficiency was also a goal, but never one that actually came within reach. The often acute shortages of blood products in England gave self-sufficiency debates a different slant there. However, I do not recall anyone on my team at the SNBTS disagreeing with my definition. I believe that the features of self-sufficiency mapped out by Professor Cash in SBTS0000656_051 constitute an excellent summary of a matter over which he and I were in full agreement.

[Note: The concept of national self-sufficiency is often thought of as conflicting with the principle of clinical freedom, but as explained above in my responses to questions 51 and 52, this need not be the case. If there ever is a genuine conflict there, it's likely to be either

(i) because a specific patient needs a specific rare product not available from the preferred national supplier – which is perfectly normal and acceptable. It only covers a small minority of cases and is not considered to breach self-sufficiency policy; or

(ii) the other, more theoretical/hypothetical case is where a country's chosen national products are simply not good enough – requiring them to be made good enough with all speed.

Happily, the second of these alternative scenarios never came to pass during my time at the SNBTS.]

62 During a meeting of the SNBTS Management Board on 11 January 1990 it

was agreed that Glasgow would be given a one year "break" from its progress towards regional self-sufficiency (PRSE0004676 p.2). Were you concerned that this decision came into conflict with UK and European directives for self-sufficiency? What was your view on this regional "break" being agreed to?

139. No, I was not concerned at all. Glasgow and the West of Scotland is well known to be very different from the rest of Scotland, socially, economically and epidemiologically. It was perfectly understandable that the hospitals there would from time to time need blood and/or blood/plasma products from other parts of Scotland with a more stable donor base and a greater level of donation per head of population. Also, Glasgow was a centre of excellence for a number of clinical areas that used a lot of SNBTS products and services and looked after many patients transferred there from other parts of the country. It would therefore have been totally inappropriate to think of the region as somehow sealed off from the rest of the country – to be left alone to sink or swim on the strength of its own donation/collection rate.

140. Solidarity and mutual support between regions within a given country is fully consistent with UK, European and WHO recommendations (not directives) on self-sufficiency.

63 During your time at the SNBTS, what was your view on Health Care International (an American firm related to the Clydebank Hospital Project in Glasgow) importing autologous units for transfusion, outside of the UK's policy of self-sufficiency (SCGV0000198_008)?

141. As far as I am aware nothing that was done at HCI was in contravention of any UK policy. For instance, when members of the Royal Family are holidaying at Balmoral, precautionary units of autologous blood are kept at a hospital in Aberdeen, to guard against any possible emergency. Many private patients choose to use autologous blood rather than standard stock. If a patient has journeyed to Scotland for treatment, they may very well wish to bring their own (autologous) blood with them. This does not, in my view, constitute "the

importation of blood", nor any weakening of Scottish self-sufficiency. As can be seen from Mr Panton's letter (referenced document SCGV0000198_008) there had obviously been some concerns at the time over the possible establishment by HCI of their own mini internal blood transfusion service, but I don't recall this ever having been a real problem. I recall establishing a cordial working relationship with the management at HCI and also arranging for SNBTS clinical expertise to be shared with them, to ensure a smooth start-up to their haematology services for their patients. I do not recall any difficulties arising from any of this.

64 Did the private sector demand for NHS product have an impact on the SNBTS' ability to achieve full self-sufficiency in blood and blood products (SCGV0000136_026)?

142. No, I don't believe that it ever had the slightest impact. For it to have done, we would need to have been already perilously close to a nation-wide shortage already. Private sector demand was always only a tiny proportion of the total national demand and was always easy to accommodate.

65 During your time at the SNBTS, did you understand self-sufficiency to mean self-sufficiency within Scotland or within the whole of the UK? You may find DHSC0004014_183 of assistance.

143. My actual responsibility for any kind of self-sufficiency ended at the Border. However, as set out in the referenced document (DHSC0004014_183) we in Scotland were keen not to waste any of our donors' gifts and developed a policy of "full fractionation" – that is to say, the production, from Scottish plasma, of as many PDMPs as possible and at as great a volume as was available from that plasma. Once this policy was put into effect, we were then in a position to send supplies of some medicines (most notably Immunoglobulin) to our friends in the NHS in England and Wales, to help them meet their patients' needs. We were not obliged to do this. It was not our responsibility to contribute to English self-sufficiency. We did however feel it our duty to do so if we could.

66 During a meeting of the SNBTS Management Board in October 1994 it was noted that Scottish stocks were lower than usual for the time of year and it was agreed that efforts should be made to build up the Scottish programme to capitalise on "recent publicity re shortages in England" (SBTS0000121_043 p.6). Do you recall whether the intention to capitalise on publicity was reputational or operational? As far as you are aware, did Scotland compete with England and Wales to be the main provider of blood products in the North of England?

144. The desire to capitalise on good publicity launched on widely broadcast UK TV channels in favour of more blood donation was both a natural one and very much part of a good job well done by any competent transfusion service. This was an operational matter, not a reputational one.

145. There was certainly never any question of our competing with England and Wales in any sphere. We generally operated independently and separately, but when we came together it was to cooperate, not to compete.

146. In relation to the NHS in the North of England, we most certainly never had any intention of trying to be the supplier of choice of blood products in that region. If the Inquiry team have any reason to believe that that might have been the case, I imagine that it must have been in relation to the Immunoglobulin supplies mentioned above in my response to question 65. From memory, I think it safe to say that NHS hospitals and clinics in the North of England probably did benefit from Scottish Immunoglobulin supplies during my time at the SNBTS. However, those would have been sent in response to need, at a time when England was greatly reliant on imported Immunoglobulin (mainly from Sandoz in Switzerland).

Section 8: Services for donors at the SNBTS

67 What counselling was offered to donors prior to (i) HIV testing (ii) HCV

testing and (iii) HBV testing taking place? Please describe the process.

147. As I recall, there was no – and no need for – counselling of donors unless and until a positive test result was recorded. All donations were tested on each occasion, so that counselling for all before testing would have been both practically impossible and certainly unnecessary. I should confirm that all donors were (and are) notified about all the testing that is done and were/are informed in advance that they will be contacted in the event that any test of their blood generates a positive result.

68 What counselling and psychological services were available for donors who tested positive for hepatitis or HIV? Were such services delivered by the RTC impacted, the SNBTS, or were referrals to other agencies made? Please describe the process. You may find PRSE0002954 of assistance in answering this question.

148. Unfortunately, my memory of these matters does not stretch to the detail. For this, my former professional colleagues will be able to be much more helpful. However, I certainly can confirm from memory that the NHS in Scotland was very conscientious about counselling and appropriate medical support, including psychological services where appropriate. If a donation tested positive, the most strenuous efforts would always be made to trace the donor, inform them and offer advice and support.

149. The follow-up from any positive test result was a team effort, involving the SNBTS, the relevant NHS units in the relevant area(s) and other experts as appropriate.

150. I'm afraid that my memory of the detail is not likely to be able to add much, if any further assistance above what is already available on the records of these matters.

69 What counselling and psychological services were available for recipients

of infected donations? Were such services delivered by the SNBTS or were referrals to other agencies made? Please describe the process.

151. Whereas the process of identifying, tracing and contacting infected donors always started with SNBTS efforts and developed to involve others as appropriate; the care of patients was (and is) primarily a matter for front-line clinicians. I do not recall that treatment, care, counselling and psychological services in this context normally involved SNBTS staff.

Section 9: Meetings of various committees

Meetings of the NBTS/SNBTS Liaison Committee

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

70 The Inquiry understands that you attended the first meeting of the NBTS/SNBTS Liaison Committee (NHBT0000189_173). What do you consider to be the purpose of these meetings?

152. As I recall these meetings, they were instituted and conducted for the purpose of peer-group liaison and note-swapping – exchanges of views on matters of mutual interest and concern.

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

153. In relation to the decision-making remit of the Liaison Committee mentioned in question 70, I would say that, as far as I remember, the committee did not involve RTC directors from either England or Scotland, at least not officially. It was a mechanism for the leadership of the SNBTS (Scotland) and the NBTS (England and Wales) to liaise with one another and swop notes on matters of

mutual interest. As I recall it, that is as far as it went. I don't recall that the group had any formal decision-making remit at all.

154. However, I do believe that discussions and deliberations at these liaison meetings often led to a consensus on the best way to approach a particular issue within the decision-making remit of each individual manager or director present. In such cases a decision to recommend a particular course of action would often result in widespread, often universal, voluntary compliance with that recommendation.

155. In the event that a matter was raised that required a significant strategic decision to be made, that would normally I believe have been referred back to senior line management, in Scotland, England and Wales respectively, for a definitive decision to be taken, or, if necessary, a decision to be sought from relevant authorities at a higher level.

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

156. I am unclear as to whether this question is intended to relate to the Scottish RTC Directors' meetings pre-1990 or to the English/Scottish Liaison Committee (above). If to the former, I'm afraid I have nothing further to add. If to the latter, then I should say that I have always felt that these informal groupings have a place in the scheme of things – as peer-groups for the exchange of information and ideas. The value of that aspect should not be underestimated. In that context, yes, I believe that this forum did achieve its legitimate goals. However, it is I think important to stress here that this was not a formal decision-making body with any authority over the conduct of any directorial or managerial entities. These were all part of their own formal line management structure and were subject to the decision-making powers allocated within that structure.

73 What was your understanding of why the meetings were abolished?

157. As above, I am unclear as to which meetings this question refers. If to the Scottish RTC Directors' meetings, I should refer to my answers above to question 8. The old RTC Directors' meetings were discontinued when we established the new SNBTS Board and MSC structure.

158. If the question concerns the English/Scottish Liaison Committee meetings, then I'd have to say that I don't recall them being abolished during my time.

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

159. I feel that the best I can do in answer to this question is to refer the Inquiry team to my answers above (especially, though not exclusively, to question 73).

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

160. As above (73) I'm afraid I'm unable to assist further with this matter.

Meetings of the Factor VIII Working Party for Scotland and Northern Ireland

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

76 The Inquiry understands that you attended your first meeting of the Factor VIII Working Party for Scotland and Northern Ireland in April 1990 and continued to regularly attend them during your tenure as General Manager. What do you consider to be the purpose of these meetings?

161. The background to this matter is extremely important to understand. The SNBTS in my day was primarily driven by the needs of Scottish patients for clotting factors, most particular FVIII. This created two primary imperatives for my organisation-

(i) The recovery of enough plasma to make sufficient quantities of FVIII to supply the needs of all patients in Scotland; and

(ii) The design, development and delivery of a safe and efficacious FVIII product that met the required specifications expected by prescribing clinicians.

162. Against that background, it will be appreciated that a close collaboration was necessary between the SNBTS team and the relevant prescribing clinicians and their representative bodies. This was the principal reason for the existence of this Working Party. It was by no means the only such point of contact, but it did play a very useful and important part – in

- helping the SNBTS team to formulate the best forward plans for plasma recovery volume;
- achieving the right specification for the SNBTS/PFC FVIII product; and
- also, importantly, helping establish clinical confidence in and acceptance of that product as the most suitable for patients

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

163. The Factor VIII Working Party for Scotland and Northern Ireland did not (as I remember it) have a formal decision-making remit. It did however have considerable sapiential authority and its conclusions and recommendations were acted upon more often than not. As SNBTS General Manager, I certainly paid close attention to the views expressed by that particular "customer" group.

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

164. Emphatically, yes. As above, this group was not the only influential factor in SNBTS FVIII design and manufacture, but it played a very significant part. I remember it with fondness and gratitude.

Meetings of the SNBTS Management Board

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

79 The Inquiry understands that you would regularly attend meetings of the SNBTS Management Board. What do you consider to be the purpose of these meetings?

165. The SNBTS Management Board was the formal decision making body for all important matters not routinely delegated by it to other parts of the organisation. That being so, as with most company boards, it dealt mainly with significant strategic and policy matters, but also with any important issues that subordinate individuals or bodies within the organisation either felt unable to decide upon.

166. Within the scope delegated to the SNBTS by the Secretary of State, through Ministers and through the Management Board of the NHS in Scotland Common Services Agency, the SNBTS Management Board was the top relevant decision-making body.

80 Please explain, as far as you are able, the decision-making remit of the group (SBTS0000112_051).

167. Please see my response to question 79.

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

168. Yes I do.

Meetings of the Coagulation Factor Working Party for Scotland and Northern Ireland

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

82 The Inquiry understands that you would regularly attend meetings of the Coagulation Factor Working Party for Scotland and Northern Ireland. What do you consider to be the purpose of these meetings?

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

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

169. In respect to questions 82 – 84, I would refer the Inquiry team to my answers to questions 76 – 78 above. Either these two working parties, as described, are one and the same, or possibly (my memory is not clear on this) the "FVIII" one may have been a sub-group of the "Clotting Factor" one. In either case, I believe that my answers to questions 76-78 are also fully pertinent to questions 82-84.

85 During a meeting of the Coagulation Factor Working Party in May 1992 you indicated that you were prepared to support a trial study comparing HPVIII and Monoclate in anti-HIV positive patients (SBTS0000260_016 p.4). To what extent did your support affect the implementation of trials? Was this trial implemented? Were you responsible for the allocation of funding towards trials?

170. As recorded in SBTS0000260_016 (Dr Ludlam's thanks to me for obtaining the necessary funds), I believe that my support assisted the implementation of the trials. They certainly went ahead as planned. Yes, I was responsible for the allocation of funding for these trials. Any monies allocated to any such activities in the SNBTS were my ultimate responsibility.

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

86 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?

171. I believe that it's important here to distinguish clearly between the SNBTS arrangements in this area pre-1990 and after-1990. As I understand it (though I was not there at the time) meetings pre-1990 were an informal mechanism set up by the Regional Directors themselves, in consort with the then SNBTS National Medical Director, Professor John Cash. I am unable to comment on their establishment or effectiveness.

87 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 RTCs? If yes, please describe the decision-making process.

172. As above in answer to question 86, I believe that this question relates to the period before my arrival at the SNBTS in 1990 and I am therefore unable to assist the Inquiry on these points. If the question refers to the period post-1990, then I should refer the Inquiry team to my answers to question 9 above.

88 The Inquiry understands that the final meeting of SNBTS Directors took place in 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;

173. As enlarged upon more fully above (in response to question 9 and elsewhere), this was done as part of a root and branch reorganisation of the SNBTS following the appointment of the organisation's first General Manager. The loose knit and mostly extremely informal arrangements that had subsisted between 1940 and 1989 were replaced by a more business-like structure, designed to clarify and facilitate decision-making, performance management and overall organisational effectiveness.

b. How the MSC meetings differed from the SNBTS Directors meetings in terms of remit, composition, and matters discussed (you may find SBTS0000672_158 of assistance); and

174. The MSC, that I set up precisely for this purpose, was a specifically professionally focussed body – dealing with Medical and Scientific matters only. (The detailed MSC remit is covered quite well I think in document PRSE0000171.)

175. The earlier Directors' meetings had tried to fulfil the roles of both a professional advisory committee and an operational management board – without any actual formal remit to do either; and without any actual authority to impose meeting decisions on the organisation as whole. The old forum had been set up and was conducted as a communication channel between the Regional Directors and the National Medical Director, on the basis of peer-to-peer dialogue. Decision-making, such as it was, was by consensus.

176. In contrast, the MSC had a focussed remit, within a clear organisational hierarchy within which it reported to the SNBTS Management Board, through the National Medical and Scientific Director (who reported directly to the SNBTS General Manager). The old Directors' meetings had no such focus and, as far as one can tell, reported to no one. [Note: It should be noted however, that though organisationally unconventional, the SNBTS pre-1990 had nevertheless

functioned very well for 50 years. It was indeed recognised globally as a centre of excellence in its field. I do not therefore claim that the reorganisation in 1990 was necessarily a huge improvement, but I do believe that it helped us all move forward more surely and more successfully during a challenging period for the Service; more effectively than might otherwise have been possible under the old regime.]

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

177. The SNBTS Management Board was the top level policy setting body on all SNBTS matters. It was chaired by and reported to the SNBTS General Manager. The MSC was essentially an advisory body. (These matters are dealt with at more length above, in the answers to questions 8, 9 & 11).

d. Your role on the MSC. You may find PRSE0000171 of assistance.

178. I set up the MSC, but I was not myself a member of it. I may well have attended some meetings, as an observer, but do not recall doing so. I tried hard not to interfere in medical and scientific matters unless absolutely necessary.

89 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?

179. I find it very difficult to compare the situation post-1990 with the earlier arrangements as I was not there to experience those. However, I can say that, as I remember it, SNBTS relationships with NBTS and NIBTS during my time

were extremely cordial. I don't believe that there was any serious discontinuity in those relationships caused by the SNBTS reorganisation of 1990.

Section 10: Information handling by and information sharing between Blood Transfusion Services

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

180. This is detail outside my field. I may have been aware of these matters at the time, but have no recollection of them now.

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

181. I am unable to assist the Inquiry with this matter.

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

182. These are matters of record and I'm afraid that my memory will not assist the Inquiry further. As I recall, we had some 400,000 donors on our register when I was at the SNBTS and of course we had to keep a record of every single donation made by every one of them – and, in the case of PDMPs, a record also of every batch of every product made from those donations; and of every vial of medicine produced from each batch. I remember record keeping – both day-to-day and archival – as a huge issue for us in my time; and one that we took very seriously. However, I have to confess that I do not retain any details in my memory after the 25 years that have elapsed since.

93 Please set out how long these records were kept for.

183. As above, in my response to question 92, I feel sure that this is a matter of record.

94 Please set out what policy or practice was adopted by the SNBTS in relation to the destruction of these records.

184. The archiving and eventual destruction of records was subject to strict rules and I feel sure that these are a matter of record. Beyond that, I'm afraid that my memory is unable to assist the Inquiry further.

95 As far as you are aware, did all RTCs within the SNBTS follow the same record keeping practices, or did each centre implement its own system? You may find PRSE0001520 of assistance.

185. It would be my understanding that, with possibly some minor divergences due to local circumstances, all SNBTS RTCs would have been conforming to a common standard.

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

186. I don't believe that we would have had donors who were suspected of carrying blood-borne infections. We tested all donors for the relevant infectious agents. If a test was positive, the case would be followed through until we were sure whether or not the donor was in fact infected. An infected donor would be counselled and referred to his or her GP for follow-up. They certainly wouldn't be accepted for any further donation sessions while infected. Donors with

negative test results would be deemed safe to donate, subject of course to the questionnaire and face-to-face checks at donor sessions. "Suspected" of being infected should not arise.

187. Having said that, I should also record my belief that yes, SNBTS measures were adequate to prevent known infected donors from giving any repeat donations.

97 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 so aware?

188. My memory does not serve me well on the specific subject of the Communicable Disease Surveillance Centre ("CDSC"). However, I was certainly aware, from a very early stage that the NHS in Scotland was making huge efforts to find and record all people who had or might have HIV/AIDS.

189. I also recall that we in the SNBTS kept a very close eye on the situation, particularly of course as it affected blood donors. It was something we kept under constant review –both operationally and at Management Board level.

b. Who proposed the creation of the database?

190. The creation of the database pre-dates my time, so I'm afraid I don't know the answer to that.

c. Did Scotland have its own database or did the SNBTS contribute data on HIV positive donors to the database? If they did not have their own database,

why not? If they did not contribute, why not?

191. I'm afraid that I do not have these details in my head after all these years.

Are you aware of whether RTCs within the SNBTS contributed data on HIV positive donors to the database? If they did, what data?

192. No, I'm afraid that I cannot recall this detail.

Did the SNBTS maintain a separate, or additional, database to track HIV positive blood donors?

193. Yes, I believe that it did.

98 An NBTS departmental memorandum dated 15 May 1989 notes that "it has been decided to re-introduce the original 'J' donor system" to identify donors involved in cases of post-transfusion hepatitis (NHBT0005388). Were you aware of the existence of this system? If so, please answer the following questions regarding this system, as far as you are able:

a. Was there a similar system in use within SNBTS? If not, did the SNBTS contribute to the NBTS system?

194. I'm afraid that I don't remember the detail of this. The memorandum referenced was written before my time.

b. The use of the word "re-introduce" implies that the J donor system had been operational at an earlier time. When was the J donor system first introduced, and why did it stop operating?

195. I am unable to help the Inquiry with this item. It was before my time.

c. Who proposed the re-introduction of the J donor system?

196. I am unable to help the Inquiry with this item. It was before my time.

d. What was the intended scope of the J donor system? Were all RTCs expected to contribute to it?

197. I am unable to help the Inquiry with this item. It was before my time.

e. Was the proposal for the re-introduction made to a committee or forum similar to the regional transfusion centre directors' meetings?

198. I don't believe that any such system would have been introduced without the knowledge and agreement of the MSC (or an equivalent predecessor group).

f. What was your view of the proposal for the re-introduction of the system? How was the proposal received by other RTC directors?

199. I cannot recall having a view on this.

g. What was the purpose of the system and what information was it intended to collect?

200. I am unable to help the Inquiry with this item. It was before my time.

h. Was the J donor system re-introduced? If so, when and how did it work?

201. I am unable to help the Inquiry with this item. It was before my time.

i. Was the J donor system widely used after the "re-introduction"? If no, why not? If yes, who was responsible for overseeing the system?

202. I am unable to help the Inquiry with this item. It was before my time.

j. As far as you are aware, does the system still exist?

203. I'm afraid that I do not know.

k. What data was contributed to it?

204. I am unable to help the Inquiry with this item. It was before my time.

99 In addition to the database(s) mentioned above, did the SNBTS share information with 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 the SNBTS used to share this information, if any.

205. I do not remember the details of this.

100 In his statement in *A and Others*, Dr Gunson expressed the view that "there was no central organisation to ensure that...all RTCs operated in a uniform manner" (NHBT0000026_009; NHBT0000026_009).

Do you believe this criticism could also apply to RTCs within the SNBTS?

206. I believe that up until the change of arrangements in 1990, Dr Gunson's (accurate) assessment of the situation in England and Wales could have been said to have partially applied to Scotland also, but not at all to the same extent. In Scotland, even before 1990, the SNBTS was a national organisation of which

the RTCs and the PFC were an integral part; whereas in England and Wales the transfusion services were dispersed and operationally independent. Before 1990, the Scottish RTCs and the PFC had enjoyed quite a significant amount of freedom to act in accordance with their own local judgement. They were not as well integrated as they subsequently became (after 1990). However, they were much more integrated nationally than their English and Welsh counterparts.

207. However, I feel it important to point out that a failure to act in a uniform manner is not at all the same thing as a failure to share vital information. Whatever independent mannerisms individual RTCs may have adopted in the years prior to 1990, I do not believe that this would have included failures in vital areas like the one under discussion here.

In your opinion, were the information sharing measures adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations?

(information sharing measures) between RTCs within the SNBTS

208. Emphatically yes. This was certainly not a matter that fell between the cracks during my time at the SNBTS and I don't believe that this important aspect of information sharing was in any way sub-standard in the years before my time either.

(information sharing measures) between the SNBTS and other BTS

209. I do not remember any details of this. I believe that communication between the UK nations and regions on this important point would have been a key item and that appropriate information sharing arrangements would have been in place, but I cannot assert this as fact; not from memory.

101 What role did the SNBTS play in facilitating effective information sharing

measures between individual RTCs? In your view, how well did the SNBTS perform this role?

210. As phrased, the question seems to imply that the SNBTS was an organisation somehow different and separate from the RTCs – which was the case in England, as between Dr Gunson's organisation(s) and the English RTCs. However, this was not so. The RTCs were (and are) an integral part of the SNBTS. The Regional Transfusion Service Directors (referred to here as "the RTC directors") reported directly to the General Manager of the SNBTS. They were members of the Board of the SNBTS and also of the MSC. Therefore, information sharing – among many other things – was a common cause for all concerned. As I remember my time at the SNBTS, inter-RTC communication and internal SNBTS communications generally were excellent.

211. As above, the whole SNBTS, including the RTCs, undertook this role together and it was performed well collectively.

Section 11 Knowledge of risk of infections while at SNBTS

HIV/AIDS

102 During your time at the SNBTS, 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?

212. I came to the SNBTS after my colleagues, their front line clinical colleagues and the patients and their families and carers so sadly affected had already been experiencing the horrendous consequences of HIV/AIDS for some years. It was not possible therefore for me to take up post as SNBTS General Manager without already having had a very clear understanding of the situation and of such of the science as was by then already understood. In relation to the development of my knowledge and understanding from that point on, there

were many technical matters, in relation in particular to testing (both antibody and antigen), window periods and viral inactivation (both by dry heat and by solvent detergent treatment) that I became aware of in much more detail as time went by.

103 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?

213. I was aware of this from my first day in post.

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

214. By the time I took up post in January 1990, there was already a substantial body of literature on this subject; and the SNBTS had been working closely with other relevant organisations in the NHS in Scotland on these matters for some time. I do not recall that I ever needed to get involved in this work, as it was well underway by the time I arrived and was not something to which I could add much if at all.

215. Certainly, in my time at the SNBTS, there was never any doubt about the huge risks and horrendous consequences of any HIV (HTLVIII) getting into the blood supply. We were involved in a great deal of specific PDMP related research and development in the area of viral removal and deactivation, of which I did have personal knowledge and which made a very significant contribution to product safety at that time.

Hepatitis

105 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 SNBTS? How did your knowledge and understanding develop over time?

216. Hepatitis B had been well known for some time before I came into the SNBTS. Steps had already been taken to exclude it from the blood supply by donor screening and testing. However, in common with my colleagues and indeed, as I understand it the whole medical and scientific community at the time, my knowledge of the virus then known as Non-A-Non-B Hepatitis (later Hepatitis C) was as yet vague and partial.

217. My knowledge and understanding of both viruses and their significant relevance to transfusion service work developed over time, in step with the gradual unfolding of these matters, This was thanks to the research work undertaken in various parts of the NHS and elsewhere, including of course valuable feedback from clinicians and from patients. I think it is fair to say that we all knew much more, particularly about Hepatitis C, by 1996 (when I left the Service) than we had done in January 1990 (when I joined.)

106 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?

218. As I remember it, an association of this kind was something that was known about before my appointment in 1990. I would have been made aware of it as part of my induction into the job in January or February of that year.

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

219. I believe that this is a question with which the Inquiry is more likely to receive helpful answers from my medical and scientific colleagues than from me. My

own answer, as General Manager, would have to be that I am aware that many such enquiries and investigations were carried out, but I am unable to fill in the detail of those.

108 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?

220. I believe that my understanding mirrored that of my medical and scientific colleagues and that it developed over time as a result of the generally developing understanding reached by experts in the field during my time at the SNBTS.

109 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% (PRSE0002161). 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? 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?

221. I do not remember this specific paper. I may well have been aware of it at the time, but I'm inclined to doubt it. I was fully aware that my medical and scientific colleagues and others in the same field in other organisations were doing a lot of work on these matters at the time and indeed throughout my years in post. However, Dr Gunson's paper is only one part of a large body of relevant literature and documentation and I doubt that it would necessarily have been drawn to my attention.

b. Were these figures regarding the prevalence of NANB post-transfusion

hepatitis ever discussed by the SNBTS Management Board? If yes, please describe the general response to these figures.

222. The first thing to say here is that until such a matter led to specific recommendations for managerial action, or a specific change in Service policy, this would not have normally have been a subject for Board discussion. It would have fallen squarely into the remit of the Medical and Scientific Committee. Nevertheless, I do remember well how seriously we all took hepatitis (more and more seriously as time went by and scientific understanding progressed).

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

223. As I remember it, it was not the detailed understanding of HCV prevalence that was the greatest problem. This was more related to other aspects of the matter, including

    (i) the effects of HCV on patients: and

    (ii) the extent to which knowledge of the presence of HCV in someone could be used to guide beneficial treatments, caring regimes and/or lifestyle advice for that patient.

224. I believe that these factors contributed more to the overall problem than did ignorance of, or inaccuracies in the assessment of, HCV prevalence. Had these matters been better understood earlier and had the scientific knowledge become available earlier, the NHS would have been clearer earlier about the right thing(s) to do – regardless of variations in the known or likely prevalence of HCV, whether among patients, donors or the general population. Once the scientific work had been done – and hard lessons learned by experience – it was clear that if there was any significant prevalence at all, there was a serious threat. However, as I understand it, none of this was at all clear early on and only became so gradually over time.

General

111 How did your understanding of the seriousness of HCV and HIV/AIDS impact the donor selection policies and practice in place at the SNBTS?

225. In relation to HIV, the matter pre-dates my arrival at the SNBTS. As I understand it, the SNBTS team was already very aware of the seriousness of the matter well before I arrived and had already adjusted donor screening and testing processes accordingly.

    (i) Non-A-Non-B Hepatitis (later HepC or HCV) is a different matter. It remained poorly understood, globally, for a long time after HIV/AIDS had become quite well understood. The SNBTS had taken early action (in terms for instance of collection points and donor selection) that helped to minimise HCV infection of the blood supply, but an effective test for the virus was not forthcoming for quite a long time. (The record on this and related matters is extensive, so I will not attempt to add anything further here.)

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

226. I believe that this is a question with which my medical and scientific colleagues will be better placed to be of assistance to the Inquiry. I believe that most if not all of a satisfactory answer will be available from the records in any event.

227. As a former Service General Manager I would only say that I believe the SNBTS to have had in place during my time extensive advisory, analytical, experimental and decision-making processes to confront and to deal with infection risk, as well as or better than any such service anywhere in the World.

228. The Service had been aware since its foundation in 1940 that as well as offering potentially life-saving treatments, blood and its components always constitute a potential risk to patients when used therapeutically. For instance, SNBTS

blood bags are always labelled with a warning to that effect. Every clinician handling blood, a blood component or a PDMP knows that it may constitute a risk to their patient(s). The assessment of those risks and the long struggle to pin them down and act to minimise them, has always been a central part of the duties and responsibilities of transfusion services teams worldwide.

229. I believe that all risk is unlikely ever to be eliminated. More risks are certain to loom up in front of us as time goes on – risks of which we as yet know nothing. The worst calamities that have befallen patients due to blood or plasma-borne disease have come, historically, from "unknown unknowns" – of which HIV and HCV are striking recent examples, but by no means the only ones. It seems vanishingly unlikely that they will be the last.

113 What if any role did the SNBTS 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.

230. As stated above, in my response to question 112, I am confident that the existence of risk as a constant factor to which to be alert was and is widely understood. I believe that the record will show that neither hospitals nor haemophilia centres in Scotland had or have any need for further guidance from the SNBTS on that subject. However, if this question is intended to refer to specific cases of medicines or batches of medicines that were supplied by the SNBTS and later found to be, or suspected of being, infected, then I can confirm that in those cases the SNBTS did of course make strenuous efforts to contact and to warn the relevant organisations and the professionals affected, so that appropriate steps could be taken, wherever possible, to withdraw such medicines from use; and to trace, contact and counsel any patients known to have been affected.

114 In 1991 the Sunday Mail ran a campaign designed to persuade the Government to offer compensation to non-haemophilia patients who were

believed to have acquired HIV as a result of blood transfusion (SBTS0000301_081). Did you agree with the implementation of this campaign?

231. I don't believe that it would have been for me to agree or disagree with such a campaign.

Section 12: Reduction of risk of infections while at SNBTS

Donor selection

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

232. The donor selection policies and processes in place in relation to HIV/AIDS, HCV and HBV pre-dated my arrival at SNBTS. They had been initiated in response to the emergence of these viruses and were developed and refined over time, in response to the gathering body of knowledge about them. I believe that the detail of these policies and processes and their development over time will be found in the SNBTS records, particularly in MSC minutes, SNBTS Board minutes and the minutes of the regular meetings of the SNBTS Donor Services Managers group.

116 How were decisions made as to which donors were high risk and should be excluded from donating with the SNBTS? What was your role in this process at SNBTS? Were these decisions reviewed and, if so, how often? (SBTS0000479_006)

You may find SCGV0000163_040 and SBTS0000656_057 of assistance.

233. I think that the details set out in SBTS0000479_006 describe the policies and procedures in place in 1993 very well and as far as I recall, the basic structure of those decision making processes did not change between 1993 and 1996 when I left the Service. The detailed rules, practices and procedures would have changed somewhat in that time, but not the framework for decision making. Donor selection criteria are matters kept under constant review in line with advancing scientific understanding and experience – nationally and globally. This is an area where international norms and guidelines had (and I believe still have) a profound influence on the policies and practices of all transfusion services, not least because they form part of the "go/no go" criteria for the licensing of blood derived medicines by all national regulatory authorities. I do not however recall ever having involved myself in the details of these matters. I would I think have limited my personal involvement in this area to satisfying myself that the arrangements for review were appropriate. I cannot imagine myself ever having interfered with the review process itself.

117 Were there any difficulties in implementing the exclusion of high-risk donors at SNBTS?

234. No, not as far as I know.

118 In February 1990, John Cash told Rab Panton that during an international meeting in Rome on Factor VIII it was agreed that the UK concentrates were in "an elite group which were in the safest in the world - with regard to the possibility of virus transmission" (SBTS0000434_108). Did you agree with this assessment at the time? Has your opinion changed over time?

235. I would not have regarded this as an assessment. It was a report of remarks made at an international conference. It would have been pleasing news, but not something with which I would have been called upon to agree or disagree at the time; nor would it have affected my own opinion of UK concentrates one way or the other. My own opinion of UK concentrates is limited to those made in Scotland, in respect of which I would say that they certainly were at that time

among the best and safest in the World. However, it should also be noted here that the steps taken at the SNBTS in the months and years beyond February 1990 greatly improved the safety margins we were able to vouchsafe in all our products, including the clotting factors.

119 What information (either written or oral) was given to donors about the risk of them transmitting infections via their blood? When was such information provided? In particular, was there a nationally agreed leaflet or did each RTC produce its own leaflet? You may find SCGV0000155_105, PRSE0001721, and PRSE0004478 of assistance.

236. In relation to the creation and distribution of appropriate leaflets during my time in post (1990-1996) I believe I can say with certainty that these would always have conformed to an agreed standard national (Scottish) format. Beyond that, with apologies, I don't believe that my memory of these matters can add anything of significance to what the Inquiry team already has from the records.

120 To what extent did the blood scandal in France affect SNBTS decision making, especially considering the contract the SNBTS held with a Fractionation Centre in Lille (SBTS0000339_091)? You may find SBTS0000376_068 and SBTS0000666_056 of assistance in answering this question.

237. The SNBTS relationship with Lille was a long-standing cooperative relationship that pre-dated the events often referred to as "blood scandals" in both countries, and also survived well beyond them. The significance of that relationship is hard to over-emphasise. It included the transfer (by gift) to the PFC in Edinburgh from the centre in Lille of their proprietary chromatographic method of FVIII purification – the scientific innovation that secured the safe and effective availability of the new high purity FVIII product subsequently produced at PFC and provided to clinicians and their patients all over Scotland. It was, effectively, the basis for Scotland's achievement of full self-sufficiency in Factor VIII then and for some years after.

121 How often were these leaflets updated, and how was their content decided? You may find SCGV0000155_105 of assistance in answering this question.

238. As I recall, leaflet design was something that we kept under constant review. Their design and content were very collaborative collective matters, involving us all, but with most of the hard work done by the Donor Services teams in HQ and the Regions.

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?

239. Information was provided at every donor session, in leaflet form, in questionnaires and in face-to-face conversations between donors and Service staff.

123 How effective, in your view, were leaflets and other communications at reducing the risk of donations from high-risk individuals? You may find SBTS0000023_072 and SCGV0000155_105 of assistance.

240. I would say very effective but - I feel it very important to add - that it is well known that the testing of donations and subsequent processing steps (such as leucodepletion and fractionation plant processing steps) are very much more significant factors in the safety chain. (Please see also my answer to Question 54 above.)

Provision of diagnostic screening kits

124 Please describe the arrangements in place at the SNBTS in regards to the

provision of diagnostic testing kits for donation screening ("screening kits").

241. My memory of the details of the exact arrangements is not extensive after all these years. What I am clear about however is that SNBTS policies and standard operating procedures (SOPs) in this area were in line with the best accepted global standards prevailing at the time. Obviously, donation testing is at the heart of the safety assurance scheme for red cell concentrate and other fresh blood components and is also of great significance in the chain of protections designed to assure the safety of PDMPs. Therefore, donation testing – the pathogens to be tested for, SOPs for the procurement, testing and deployment of test kits, etc – was and is a matter of supreme significance to the SNBTS, as it would be to any other mature transfusion service globally.

125 Did you, or anyone else at the SNBTS, contract directly with any pharmaceutical company involved in the manufacture and/or sale of screening kits, or were contracts negotiated on a national basis? You may find NHBT0000189_173 of assistance.

242. No, I certainly did not contract with any SNBTS suppliers, nor did any of my team. All procurement in the SNBTS was handled organisationally, not individually, and strictly in line with the procedures, standards and guidelines laid down by the NHS in Scotland.

243. As to whether or not test kit procurement was always done on a national (pan-Scottish) basis or whether some procurement was done at the RTC level, I'm afraid I cannot say for certain. However, if my memory serves me right, at least some procurement was done at the RTC level, certainly in the early 1990s (less so, I think, as time went on and we centralised more of such things in the course of our reorganisation. Blood bag purchasing for instance had been an RTC matter before 1990 but I arranged for that to be centralised soon after my arrival.)

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

244. Fitness for purpose is the one primary factor. The balance between sensitivity and specificity is key. The record on these matters is extensive and anything further needed will be best contributed by my medical and scientific colleagues, rather than by me.

127 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?

245. I have no detailed memories of this matter. However, I feel certain that Abbot and other suppliers, global experts in the field and with an acute interest in the accuracy and effectiveness of their test kits, will have taken a close interest in such things and would have been involved in frequent discussions with my professional colleagues about the use and performance of the test kits they provided to us. This would have been particularly so during the trialling of new test kits (as for instance in the case of Hepatitis C) but would I think have been a day-today feature of Service life.

Introduction of HIV testing

128 Please describe the implementation of HIV screening within SNBTS.

246. The implementation of HIV screening preceded my arrival at the SNBTS.

In particular:

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

247. I believe that this is a matter of record. As I remember it, the ongoing precautionary processes in respect of the AIDS virus, as for other pathogens, were/are composed of two main complementary components –

donor screening (mainly by pre-donation questionnaire and pre-donation Q&A, discussion and observation) and

the actual testing of each donation.

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

248. It is important to note here that all donations have always been screened and tested according to the rules and procedures current at any given time. Before the introduction of HIV testing, donations were screened and tested to prevent transmission of various pathogens that had been identified and included in the standard list of precautions that applied (compulsorily) to all donations at any given time. After the introduction of HIV testing, this was added to the list.

249. In the years and months before the introduction of HIV screening, all blood donations were subject to the precautions in place at that time, which included comprehensive testing for other pathogens, but not yet for HIV. Afterwards, of course, those precautions did include the routine testing of all donations for the HIV virus (or, in fact, strictly speaking for antibodies to the virus – with all the "window period" implications of that.)

250. For the avoidance of doubt - all donations were processed through a strict SOP to ensure that

    (i) no blood or fresh components were ever despatched to the blood bank(s) ready for therapeutic use until their test results had been fully processed and each donation had been given the green light to proceed;

(ii) no plasma was passed for use in fractionation until the relevant test results for that plasma had been processed; and

(iii) each bag (and/or sub-container) was kept under standard conditions of handling, storage and temperature between the donation session and its final destination.

c. What happened when a donation was found to be infected with HIV?

251. That donation was removed and safely disposed of, the donor was informed and was not of course allowed to donate again. In addition, a thorough search would be conducted for all or any blood or products that might still be available that had contained previous donations from that donor; so that these, if still available, could be removed from use and safely disposed of.

d. Please set out the steps that had to be taken, both with respect to the donor, the donation and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.

252. My memory of the importance that was of course placed on these matters by all concerned is clear. However, in relation to the detail of the processes involved I'm afraid that these do not remain in my own memory after all these years.

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

253. HIV screening was introduced at SNBTS before my arrival there. I believe that the introduction of HIV screening (including testing) had had a huge positive impact on the Service and on all the hospitals and other medical centres in

Scotland to whom the SNBTS provided products and services. Prior to specific targeted screening/testing- during the harrowing period when AIDS was a potentially rampant unknown unknown, global blood supplies were enormously vulnerable, indeed almost completely defenceless. Once an effective test had been identified and universal testing had been established, it was then immediately possible to be a great deal more confident about the safety of the blood supply and the PDMPs that were made from it.

254. The financial impact of the extra screening costs was of course covered by the funding supplied to the SNBTS by the (then) Scottish Office Home and Health Department, through the (then) NHS in Scotland Common Services Agency. The impact of the establishment of an effective test regime was a great relief to the SNBTS and to all the staff involved; though of course the impact of the virus itself – and the continued danger it posed because of the window period phenomenon – was a source of constant concern and stress to all concerned.

255. The impact of the establishment of an effective test regime for HIV on the safety of the blood supply was of course that it was greatly improved. The risk of transmission of HIV through blood donations and also through blood-derived medicinal products was greatly reduced.

Surrogate testing

129 Whilst you were employed at the SNBTS, what was your opinion of surrogate testing as a potential method of donor screening, and how did this change over time?

256. With apologies, I do not believe that my testimony on the subject, from memory, will be able to add significant value for the Inquiry.

Please comment on each infection with reference to specific surrogate tests:

a. HIV; and

b. NANB/HCV.

257. As above, I am unable to provide these details.

130 Please advise whether surrogate testing (namely ALT or anti-HBc testing) was introduced at the SNBTS during your tenure.

258. As above (129), I am unable to provide these details.

131 If surrogate testing was introduced at the SNBTS, please explain what impact this had on RTCs within the SNBTS.

259. As above (129), I am unable to provide these details.

Introduction of anti-HCV screening

132 When did the SNBTS begin anti-HCV screening?

260. This is a matter of record, extensively so. As a former SNBTS General Manager, in post at the time of the introduction of anti-HCV testing, I can only add (as I have stated before and as recorded in my testimony to the Penrose Inquiry) that it was introduced later than it could and should have been and this was most unfortunate.

133 Dr Gunson wrote a letter to all RTC directors suggesting a delay in commencing anti-HCV screening from July to September 1991 so that "'second-round' comparative evaluation" of the testing kits could take place (NHBT0000073_065). Did you agree or disagree with Dr Gunson's suggestion to delay testing to undertake this comparative evaluation? Please explain the basis for your answer.

261. On a point of preliminary detail, for clarification, Dr Gunson's letter was not written to all RTC directors, only to RTC directors in England and Wales. His organisation's brief did not extend to the NHS in Scotland.

262. As I feel sure the Inquiry team will appreciate, as SNBTS General Manager I relied greatly on my professional colleagues and in particular upon the MSC for advice on these matters. I would not have agreed or disagreed with such a recommendation until I had canvassed qualified opinion within my own organisation.

263. However, I do feel a duty to record here that my most vivid memory of this matter is of delay and obfuscation by the various expert committees and advisers involved, including Dr Gunson's team – under, I believe, the influence of cost-conscious civil servants in the (then) Department of Health in Whitehall.

264. Generally speaking, I was not in agreement with delay on these matters – certainly not any delay that was not demonstrably necessary or at least strongly arguable as being in the best interest of patients. [Note: On this point, my own position can I think be accurately summed up as identical to that of Dr Lloyd in Newcastle (see also my response to question 134 below).]

134 In response to Dr Gunson's letter, some RTC directors suggested a staggered start date for the implementation of testing (i.e. different start dates for different RTCs) while others supported a uniform start date. Which view did you take? Why?

265. As I recall it, during discussions of these matters in Scotland, the position that I argued can be summarised as follows

- anti-HCV testing of all donations should be implemented as soon as ever possible (this had long since been enunciated as a clear moral duty by relevant Ministers, including a statement made in Westminster by an English Minister

which is I think in the records of the Penrose Inquiry. The need for it was not in doubt, only the timing.)

- early doubts about the sensitivity and specificity of the test kits that first became available were a valid reason for some sensible precautionary delay while this matter was bottomed out; but the advocacy of perfection in relation to those tests should not be allowed to hold back their introduction beyond that sensible short precautionary delay. A less than perfect test was much better than no test at all – and should be introduced in all areas as soon as ever possible, without any deliberate "staggering".

266. I was never in favour of staggered start dates within Scotland – except in the extreme case (which is the one that did in the end transpire) where we were forced to choose between staggered start dates and a delayed start date for all RTCs. As is clear from the record, the Glasgow and West of Scotland Region was chosen as the site for the last stage of test kit testing. The rest of Scotland followed on as soon as possible thereafter (once the West had reported favourably on the tests.) My own view (well-known at the time and a matter of record) was – and remains – that the delays involved in the protracted "testing of tests" were unnecessary, undesirable and should have been avoided. In agreement with the position adopted by Dr Lloyd's organisation in Newcastle, I believed then and believe now that universal anti-HVC testing should have been introduced sooner.

135 Despite Dr Gunson's suggestion to delay the introduction of screening, the Northern RTC led by Dr Lloyd introduced routine testing in April 1991, becoming the first centre to do so. Dr Lloyd's view, in contrast to that of Dr Gunson's, was that, the "Second Generation HCV tests were acceptable tests for donor screening" by June 1991 (NHBT0000076_009), and that deciding not to implement testing despite having the capability "would be indefensible under the current Product Liability Legislation" (NHBT0000074_014). As to this

a. Did you agree or disagree with Dr Lloyd? Please explain the view you had at the time.

267. I agreed wholeheartedly with Dr Lloyd. I believe that with the benefit of hindsight, including the investigations carried out by the Penrose Inquiry, everyone with any knowledge of these matters must surely now agree that Newcastle chose the right course of action and that it would have been far better for all concerned if all RTCs in the UK had done the same thing at the same time.

b. Have your views changed since then? If so, why? You may find PRSE0001183 of assistance.

268. No, my views have not changed. If anything I have become even clearer and more confirmed in my views on this over time.

136 What funding and operational support did SNBTS provide RTCs with to aid in the implementation of testing?

269. Funding and operational support were never controversial or difficult issues in this context in Scotland. Once the relevant policy decisions had been taken, all the necessary funding and support that was provided. I do not remember the financial details but these will certainly be available from the SNBTS records.

Did this have an effect on an individual RTC's ability or willingness to commence testing earlier?

270. In Scotland, there was never any question of any of the five Regional Transfusion Services acting separately on any testing issues. These were always dealt with as national matters, agreed at MSC and/or Board level. As far as I remember it, none of my RTC directors ever argued for a delayed implementation date on funding grounds, nor because of worries about operational support. Indeed I vividly recall an SNBTS Management Board meeting in which it was unanimously agreed that all the RTCs were ready and

willing to implement anti-HCV testing just as soon as Ministers gave us the green light (months earlier than implementation was eventually authorised.) For the avoidance of doubt, at no time was funding ever a determining issue in relation to the implementation of HCV testing, nor the timing of it in Scotland.

Recall practice and procedure at SNBTS

137 Please give an overview of product recall practice at SNBTS, and how this changed during your tenure.

271. This was a subject on which I was not much involved in the detail, even at the time. It's certainly not a matter on which very much detail is retained in my memory.
272. All I feel I can usefully say is that product recall was a hugely important factor in doing one's best to limit infection risks and was taken very seriously indeed.

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

273. I do not remember any details of the procedures involved.

139 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?

274. I feel sure that had these not been fully effective I would have been closely involved in the repercussions of any failures and would remember these. I believe therefore that I can say with confidence that the appropriate practices and procedures were effective. I certainly do not recall any case of a clinician failing to comply with them.

Autologous Transfusion

140 Please provide an overview of the use of autologous transfusion, and other blood sparing techniques, within the SNBTS, and how this changed during your tenure.

275. As far as I can remember, autologous transfusion was not typically thought of as a blood sparing technique, certainly not in my time at the SNBTS. Of course, prior to my time – and prior to the establishment of universal testing for HIV – in some cases of elective surgery where autologous transfusion was possible and appropriate it would have been something of much greater interest than it had become by January 1990. However, I do not recall it as a matter of strategic significance after that time.

276. The blood sparing techniques that I recall most vividly are cell salvage in the operating theatre (returning filtered bled blood back to the patient) and key-hole surgery (to avoid the need for blood altogether). Of these, I believe that key-hole surgery had the biggest impact on blood sparing during my time at the SNBTS.

141 At a Directors' Meeting in February 1990 (PRSE0000205, paragraph O) a request was discussed from the private sector for an autologous transfusion. Following the discussion of this request, what was the agreed position for private sector autologous transfusion requests?

277. I do not recall the details of this particular request or discussion. Autologous transfusion was not a subject that cropped up very often. On the rare occasions when it did, it was likely to arise in a private hospital context in relation to elective surgery. In the specific case of the (then) new private hospital Health Care International (HCI) in Clydebank, there was some occasional discussion of the possible implications of autologous blood donations being taken in the USA and brought into Scotland with the patient when they arrived, or, alternatively, being taken from patients on the premises at HCI. However, it should be noted here that it was not up to the SNBTS or any other part of the

NHS in Scotland to tell any private hospital what to do. In so far as any agreed consensus view was required on this matter within the SNBTS it would have been a consensus on what we might advise hospitals to do, nothing more.

142 In a letter to you from Dr Cash in July 1994 (SBTS0000411_038), various proposals relating to autologous transfusion were submitted to the SNBTS for consideration and approval from the Medical and Scientific Committee (MSC). In an SNBTS meeting in October 1994 (SBTS0000121_043, page 5), this proposal was rejected with suggestions for clarification. What was the eventual outcome of the discussions between the SNBTS and MSC in relation to autologous transfusion?

278. On a point of clarification, I assume that the "SNBTS meeting" referred to was a meeting of the SNBTS Management Board and that "discussions between the SNBTS and MSC" is intended to mean discussions between the SNBTS Management Board and the MSC. I do not recall the detail of this particular subject, but feel sure that I can say with confidence that the outcome would have been that further discussions and, as necessary, investigations would have taken place to achieve a set of recommendations on autologous transfusion that were agreeable to all. For the avoidance of doubt however, as above, these could only have been recommendations. Clinical practices in hospitals, whether in the NHS or in the private sector, were not within our remit.

143 In an SNBTS Management Meeting in April 1995, the "likelihood of rising demand" for autologous transfusion was discussed, as well as the need for a "firm policy... to ensure consistency across SNBTS." What was the outcome of this?

279. Again here, I assume that the "SNBTS Management Meeting" referred to was a meeting of the SNBTS Management Board. I do not recall any details of this, but I feel sure that an appropriate policy would have been agreed in due course and implemented by all the RTCs.

Viral Inactivation:

144 Please refer to SBTS0000066_009, a letter from Dr Cash to yourself regarding an update on HPVIII. Dr Cash stated "We have, in the time scales now set, no option but to abandon dry heat treatment and rely on in-process solvent detergent (SD) virus inactivation." To the best of your knowledge, please explain why this was the case and the rationale behind switching from dry-heat treatment to a solvent detergent method. You may also wish to refer to SBTS0000386_094.

280. The timely introduction of dry heat treatment, in which Professor Cash played an important and valuable role, was a key safety improvement for all PDMPs (most notably the clotting factors) and undoubtedly saved many lives. Equally however, the solvent detergent viral inactivation steps that were invented, validated and then implemented soon after brought an even greater improvement in safety. The period during which these measures were identified, refined and implemented was exciting and eventful, but by no means a smooth nor always easy transition. New ground was being broken repeatedly. The quotation here is obviously from one of the moments early on in this transitional period - when lessons were being learned and assimilated and appropriate next steps were being contemplated.

281. The detailed rationale for solvent detergent viral inactivation is a matter of record – extensively so. I do not believe that my memory can usefully add anything further.

145 Please refer to SBTS0000411_188. As far as you are aware, what factors may have persuaded Dr Cash of the need to return to the terminal dry heat treatment of SNBTS factor VIII and IX concentrates? Please outline the "fundamental issues" and how the payment of royalties had an impact.

282. As explained above (144) the introduction of dry heat and solvent detergent treatments was not quick or simple. We were racing against the clock and the viruses to achieve the best and safest outcome for patients. As I recall this period, at various stages each form of viral inactivation was relevant, sometimes both.

283. Professor Cash's reference to the possible implications of royalty payments may have been relevant at that particular moment. Various companies were offering viral reduction/deactivation technologies for use under licence at that time. However, in the end we at the SNBTS did not need to buy in any of that technology. The solutions that we introduced were either developed in-house or obtained, free of charge, from another not-for-profit organisation (in this case, the Lille Blood Transfusion Service in France.)

146 Please refer to LOTH0000051_032 (p. 4). The document outlines Haemophilia Directors' concerns that not all routes to enhancing the viral safety of H8 had been fully investigated due to a lack of resources. Such concerns were to be addressed to yourself. What was your response to these concerns? To the best of your knowledge, were these concerns well founded?

284. I do not recall the specific details of this reference to the clinicians' concerns, but as I remember the Haemophilia Directors, I do not believe that they would have expressed concern without due cause. As I recall that period, it was characterized by ground-breaking development work undertaken very rapidly – as required, in the face of the viral threats that we faced at that time. It was also characterized by the closest possible collaborative relationship between the SNBTS team and the relevant clinicians. The work was, necessarily, done primarily by my SNBTS medical and scientific colleagues. However, as General Manager, on such an important matter I took a close personal interest also. I feel confident in answering here that my response, in follow-up to LOTH0000051_032 was positive and that all the support, financial and otherwise, that was needed was in fact supplied, in response to the Haemophilia Directors' concerns and for the good of patients.

General

147 Please describe all other steps or actions taken at the SNBTS 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.

285. I must beg leave to decline to answer this question, instead referring to the extensive records on this subject that exist and are readily available. I do not believe that I will be able to assist the Inquiry further on this matter from memory.

148 Was blood safety ever subject to cost, time, staffing or any other constraints?

286. No, I do not believe that blood safety was ever subject to such constraints during my time at the SNBTS (nor, for the avoidance of doubt, do I believe that it ever was.)

If you felt a particular course of action needed to be taken to ensure blood safety, were you free to take it?

287. Yes, almost always. However, as explained in answer to earlier questions, in the cases both of HCV testing and look-back I was not free to act as I would have wished. This was not as a result of cost, time or staffing constraints but because of medico-scientific indecision and prevarication and civil service reticence (as expanded upon also in my answers to other questions here below).

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

288. I do not believe that the desire for consensus and consistency as between the Scottish RTCs had a negative impact on the achievement of the best possible blood safety at local level (nor at national Scottish level, for instance vis-a-vis PDMPs). What caused the worst adverse effect was the desire (not universal, but strongly advocated by Professor Cash and others at the time) to maintain "solidarity" with the English RTCs. As I remember it, and in my now well considered opinion, that misplaced desire for Anglo-Scottish solidarity was the clear cause of the unnecessary delays in the universal implementation of HCV testing in Scotland. I believed then, and remain convinced, that it was utterly inappropriate and resulted in a sub-optimal outcome in terms of blood and plasma product safety, to the detriment of patients in Scotland.

150 To what extent were you and other members of the SNBTS Management Board reliant on the decisions of other bodies (advisory committees, directorates, NBTS, DoH) 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?

289. In my view, these are absolutely the key questions most relevant to the subject matter of this Inquiry. My testimony to the Penrose Inquiry attempted to clarify at least a partial answer. In summary, I believe that the myriad of advisory committees, directorates, authorities, experts, Government Departments and other sources of advice and opinion formed a complex web of points of undoubted influence but most usually very little actual clear responsibility. I described them in my testimony to the Penrose Inquiry as a "cat's cradle" of decision making. That description still seems to me to be apt.

290. At the time and also now, with hindsight, I believed and believe that the following points are clear –

    (i) None of the advisory bodies and none of the organisations or Government Departments outside of Scotland had any actual formal authority over matters of blood safety in Scotland. As later clarified in a letter that Lord Fraser wrote to his English counterpart, the Secretary of

State for Scotland had a clear duty and responsibility in respect of these matters, from which he could not resile.

(ii) We in the SNBTS reported ultimately to the Secretary of State for Scotland and had no formal duty to obey instructions from anyone else if we did not feel that their advice or opinion was in the best interest of Scottish patients.

(iii) We were nevertheless duty bound to listen carefully to authoritative advice from competent professional sources and at least give it serious consideration. My medical colleagues in particular would quite understandably feel very uncomfortable if they thought that anything we did in the SNBTS flew in the face of established norms accepted elsewhere as de rigeure. This being so, they tended to regard professional advices of various kinds that they would receive from time to time as mandatory when in fact they were not. Also, other ingredients in the Scottish decision-making mix, such as the (then) Common Services Agency and the (then) Scottish Office Home and Health Department would sometimes form views of their own and these would often be influenced, directly or indirectly by attitudes coming from South of the Border. This did not always make for clear prompt decision making nor decisive action.

(iv) My Scottish Office Home and Health Department civil service colleagues had a web of "influencers" to whom they were obliged to pay attention – particularly their counterparts in the much larger and in many ways more powerful English Department of Health. They were not officially subordinate to the DoH but they were certainly so strongly influenced by it that one might at times be excused for thinking that they were.

(v) In my view, at the time and after considerable further thought, the combination of these points (i-iv above) added up to a fundamental flaw in the whole system. Most of the time – almost always – we could navigate successfully through the subtleties of "professionally desirable" –v- "mandatory" and "in the best interests of Scottish patients" –v-

"consistent with English (often thought of as UK) policy" etc. There are a thousand small complexities of policy and practice detail involved – and many advisory bodies with varying levels of relevance and importance.

291. Very rarely did the inherent deficiencies in such a decision-making structure actually show up as cracks. One could usually identify the right course of action on an issue and arrange for it to happen without too much trouble. However from time to time insurmountable obstacles would arise. The two most salient examples in the present context are

    (i) the unnecessary delay caused to the introduction of HCV testing in Scotland, to the detriment of Scottish patients; and

    (ii) similarly, the unnecessary delay in HCV look-back.

What happened if your own opinion conflicted with the decision or advice of that person or body?

292. As above, in such cases cracks appeared in the system and various battles had to be fought. (A sub-optimal state of affairs in my view.)

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). As far as you can recall, was this also the attitude of SNBTS at the time?

293. Yes, this was indeed the attitude of the SNBTS. I believe that any transfusion service would take the view that a procedure shown to be effective in preventing TTI should be deployed as soon as possible.

If so, was there a shift in policy to reflect this attitude? Please explain the reasons for your answer, including any relevant references to discussions with colleagues and official policy within the SNBTS.

294. It did not require any shift in policy for the SNBTS to adopt the stance to which it had always been committed – to act in the best interests of patients at all times.

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?

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

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

295. In respect of all of the above, I should emphasise that as far as I remember – and my memory is very clear on this – no shift in policy in this area occurred in Scotland during my time there. Nor was cost ever an obstacle that stood in the way of any safety developments that we ever had in mind.

Section 13: Look back programmes at SNBTS

HCV

153 During the first meeting of the NBTS/SNBTS Liaison Committee on 27 June 1994 it was agreed that "whilst tests and policies are evolving it would not be appropriate to establish a look back policy and that ACSVB should take a view in due course" (NHBT0000189_173 p.2). Did you agree with this

approach? Has your opinion changed over time

296. I believe that the meeting referenced (NHBT0000189_173) took place on June 27th 1990 (not 1994). I believe that at that time reliable proven test kits had not yet become available and that therefore no testing had yet been introduced. The reference to the advisability or otherwise of establishing a look-back programme would therefore seem to have been somewhat premature. I certainly would not have disagreed with the proposed approach at that time. My opinion on that has not changed since then. My criticism of the overly slow introduction of look-back came much later.

154 The Inquiry understands that you were advised in December 1994 to "take forward as expeditiously as possible the look-back exercise for all areas in Scotland" (PRSE0000661). Did you agree with this decision?

297. I was not advised so to do. It was a clear instruction. It was in fact the "green light" that I had been waiting for and advocating for some months (since May 1994). I agreed with it wholeheartedly, but was also clear in my mind that it had arrived some months later than it could and should have done.

155 What was your role in implementing the HCV look back programme during your time at SNBTS? Please describe what this involved. You may find PRSE0001657 p.4, SBTS0000377_145 and PRSE0000783 of assistance.

298. I believe that the most helpful thing I can do here is to refer the Inquiry team to my testimony to the Penrose Inquiry (PRSE0001657). I believe that my testimony then was as accurate and as comprehensive as I could make it after so long a passage of time. After a further lapse of years since then, I don't believe that my memory will be able to assist the present Inquiry further.

156 In evidence given to the Penrose Inquiry, you described your involvement with HCV look-back as "not great" and "hands off", and that you had been

pushing for look-back to begin 8 months before the official date (PRSE0001657 p.4). Looking back, what do you think you could have done differently to achieve this outcome? What were the major barriers to doing so?

299. I believe that the fundamental obstacles to good timely decision making in the relevant areas (both look-back and, earlier, HCV testing) are those that I highlighted in my testimony to the Penrose Inquiry, namely the opaque cumbersome complexities of the medico-scientific advisory structures involved and the indecisive behaviour of a number of key players, in the Department of Health, the Scottish Office Home and Health Department and the Transfusion Services throughout the UK.)

300. As I stated in my testimony to the Penrose Inquiry, I was then inclined to blame myself for not taking a firmer stance in favour of what I knew to be right and not raising a louder voice in support of it.

301. With further hindsight however, it does not seem to me to be helpful to reproach myself for not working harder to overturn and reform a broken decision-making system over which I had no control. The key thing now surely – with the full benefit of long hindsight – is to ensure that any enduring deficiencies in the relevant decision making systems are corrected for the benefit of posterity. (Please see also my answer to Question 150 above.)

157 In evidence given to the Penrose Inquiry, you said you did not recall the delay in implementing HCV look-back being influenced by cost considerations (PRSE0001657 p.11). Does this remain your view?

302. Emphatically yes, this does remain my clear memory of the facts. More importantly however, I believe it to be clearly borne out by the written record of these matters.

158 Why were there delays in implementing the look-back?

303. In answer to this question, I think it will be most helpful to refer the Inquiry team to my testimony to the Penrose Inquiry. I believe that I enunciated my view of the reasons for the delay as best I could then.

General

159 Did you consider there was an ethical obligation to inform patients who may have received transfusions from infected donations?

304. Yes, I did and I do.

If not, why not? You may find your evidence to the Penrose Inquiry helpful in which you spoke of a "moral/ethical requirement to inform those who may have been exposed to the risk of a transfusion transmitted disease and to inform also the doctors looking after them, so that the patients' condition can be checked and verified and that they may be made aware of it." You further said that "even in the absence of possible treatment, at least to allow counselling to take place on life-style choices (alcohol consumption, etc) that could affect their quality of life. Allow also counselling of those infected to enable them and their sexual partners to take appropriate precautions to guard against the possibility of onward transmission". (PRSE0001657 p.8).

305. I believe that all of those points accurately reflect my views as they were then. My views on these matters have not changed since.

160 Were the services offered by SNBTS to those who had received transfusions from infected donations sufficient in your view?

306. I believe that it is important to emphasise here that, as I understand it, the key support and services for patients affected by any treatment involving infected blood donations came and comes from staff in front-line clinical areas (hospitals, clinics, GP surgeries and other relevant sources of treatment, care

and support). I don't believe that it would have been a SNBTS responsibility to get directly involved in these matters – not after the first step of informing the relevant authorities of the originating infected product.

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

307. No, I don't believe I ever was.

162 To what extent could an RTC implement its own local look back programme? Did SNBTS facilitate this? If so please give details. If not, why not?

308. In relation to the Scottish RTCs I do not believe that it was SNBTS policy that any individual region should act differently from the others in this respect. However, there certainly was a good deal of freedom for centres to run their own tests and trials of things. In one highly relevant case, the Edinburgh and South East Scotland Blood Transfusion Service did in fact run an HCV look-back trial on ethical grounds. That trial was very influential in preparing the way for – and giving an important impulse to – the eventual adoption of lookback throughout Scotland. Sometimes the tail can – and should – wag the dog.

Section 14: Your relationship with commercial organisations

163 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?

309. Yes, I am currently employed as a consultant to Accord Healthcare Limited in support of their bid to win the contract to fractionate UK donors' plasma.

However, I believe it is important to point out that my work with Accord commenced in June 2021 and was/is the first ever such arrangement into which I have entered. I was never involved in anything of the kind at any time before or during my period in post at the SNBTS, nor for over 20 years afterwards.

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?

310. Yes, from Accord Healthcare Limited, as above (here at 163 (a)).

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?

311. No.

d. Received any funding to, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?

312. No.

If so, please provide details.

164 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?

313. I do not recall any such regulations, requirements or guidelines. I feel sure that

there were such things in place, but, as I never had occasion to get involved in anything of the kind, they would not have been relevant to me.

165 Please describe the nature of the relationship between the SNBTS/NHSiS and the private hospital industry? You may find SCGV0000137_023 of assistance.

314. Given that 99.5% of all the blood and blood products distributed by the SNBTS were destined for NHS use and only 0.5% went to patients in private care settings, this would hardly seem enough to constitute a "relationship" at all. However, provision to the private sector in Scotland was indeed part of our brief. This was/is because the fundamental duties and responsibilities of the SNBTS are to patients, not to the institutions that may from time to time be caring for them. I think the information in SCGV0000137_023 remains a good summary of the situation.

Section 15: Relationship between SNBTS and NBTS

Relationship between the SNBTS and NBTS

166 Please outline the arrangements in place to enable cooperation between the NBTS and SNBTS during your tenure at the SNBTS, including any forums or reporting lines established to aid this cooperation. You may find SBTS0000467_025, NHBT0027784, NHBT0028190_002 and NHBT0010669 of assistance in asking this question.

315. With respect, I believe that this question has already been dealt with above (Section 2, especially question 9).

167 Please explain the NBTS and SNBTS' approach to policy development and implementation. Was policy developed and implemented on a UK-wide basis unless otherwise agreed, or was the approach discussed on a case by case

basis?

316. With respect, again, I would suggest that this is also already dealt with above in response to other questions, mainly in Section 2. The SNBTS and its English counterpart were and are completely separate organisations, responsible ultimately to separate members of Her Majesty's Cabinet. As explained above, the two organisations had much in common. They shared information and they often tried to coordinate policy and practice along common lines; but each was separately responsible for its own policies and practices – each reporting up its own separate management hierarchy.

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.

317. As explained above in response to question 97, my memory does not serve me well on this point. I cannot imagine that we in the SNBTS would not have been party to a UK-wide system of reporting on these important issues, but I must ask the Inquiry team to consult the records on this matter, as I am unable to assist further from memory.

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" (NHBT0000026_009; NHBT0000026_009). What are your views on the success or otherwise of the National Directorate?

318. I do not believe that it would be appropriate for me to pass judgement on the National Directorate on the basis of the relatively slight acquaintance that I had with it. The impression I gained in the contact that I did have with Dr Gunson

and his colleagues was that they were on a valiant mission but were probably facing an impossible task. The sort of very soft-power persuasion that Dr Gunson had to deploy is not a recipe for effectiveness nor efficiency.

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? You may find SBTS0000466_019 of assistance.

319. Again, as a former SNBTS manager with a strictly Scottish brief, I don't believe that it's for me to comment on this. I felt much more fortunate in Scotland, in having a service that was already quite coherent and cohesive when I arrived and lent itself well to the further centralising ideas I had for it when I arrived.

171 Dr Rab Panton wrote to you in September 1991 after the proposal for the NBA and stated that he believed "The proposal for a National Co-ordinating Authority is a good one" (SBTS0000466_032). Did you agree with his assessment at the time? If so, why? If not, why not? Has your view changed over time?

320. I don't believe that I would have felt in a position to agree or disagree – any more, frankly, than Dr Panton was. It was none of our business. However, I feel sure that we both wished the NBA well, at the time.

172 What in your view were the strengths and weaknesses of the NBA?

321. Beyond my answers above (169 -171) I don't think I can assist the Inquiry team further on this matter.

173 In your evidence to the Penrose Inquiry, you were critical of decision

making during your time at SNBTS as being a "fog of consensus" and a "cats cradle of largely informal ties between Westminster and St. Andrew's House" (PRSE0000231).

322. My testimony to the Penrose Inquiry was not intended as criticism of decision making in my own organisation during my time there. My criticisms were specifically aimed at the decision-making structures in other areas; areas that lay behind and around the SNBTS and occasionally caused us great difficulty.

323. I hope that my testimony to the Penrose Inquiry was clear on this point and that my answers to some of the questions above may also help to further clarify my views. For instance, as I emphasised in my answer to question 150, the serious deficiencies in the advisory and decision-making systems related to fundamental safety issues were not apparent on a day-to-day basis, not even, often, year-to-year. They only became evident on the rare occasions when they were tasked with actually coming up with a timely decisive solution to a specific safety problem that our internal SNBTS decision-making was not authorised to deal with on its own. The two specific occasions of which I have personal experience were HVC testing and HCV look-back, on both of which, in my view, the system singularly failed.

In response to this criticism by you, Dr Ruthven Mitchell noted that "All of the members of the MSC and other committees could have provided any information to make it possible for him to communicate in a meaningful way with NBTS, DHSS, CSA, SHHD and even the Scottish Health Minister direct if he felt he was being excluded from National Policy Decisions" (MDDU0000001 p.2-3). Do you agree with Dr Mitchell's assessment as it pertains to your access to officials?

324. As above, this was not in fact the nature of my criticism. Had it been, yes, I would have agreed with Dr Mitchell. I had no complaints about my access to appropriate communication channels or to officials. My complaint, as enunciated to the Penrose Inquiry, was about the highly unsatisfactory decision-making hinterland that we all sometimes had to navigate.

Relationship between the Plasma Fractionation Centre and BioProducts Laboratory

174 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 RTCs in Scotland?

b. Do you consider there would have been merit in a joint UK approach to Factor VIII production and research?

325. As I recall, there was only very limited cooperation between PFC and BPL. There was a good deal of contact and, I know, mutual respect between the scientists at the two centres. There was certainly information sharing. However, actual active cooperation, joint R&D, etc was, as I remember it, slight-to-non-existent.

326. Yes, I do believe that there could have been great benefit in a joint UK approach to FVIII production and research; but this would have required a very different basic financial and governance structure of BPL. As things stood, they were simply not conducive to that sort of sort of joint activity across the North/South divide.

Relationship between SNBTS and Northern Ireland Blood Transfusion Service

175 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. You may find SBTS0000637_006 of assistance.

327. As I remember it, there was much close collaboration, including fractionation of

NI plasma at the PFC and the involvement of NI clinicians in SNBTS FVIII design.

176 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. You may find SBTS0000058_032 of assistance in answering this question.

328. I must defer to the record on these matters. My memory is unable to add to it.

177 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.

329. I have no recollection of these matters and can only hope that the Inquiry may be able to source the necessary information from the records.

***178* 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.**

330. I recall the regular liaison meetings that we had as being very helpful and positive but I have no memory of the detailed arrangements that lay behind them.

Outcomes in Scotland and England/Wales

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

331. I do not recall these details, but I feel sure that they will be available from the record.

Section 16: Variant Creutzfeldt-Jakob disease (vCJD)

180 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? How did your knowledge develop over time? What if any involvement did you have in addressing or responding to these risks? You may find NIBS0000330_004 of assistance.

332. The document referenced does not relate to variant CJD but to the better known original CJD. As I remember it, the arrival of vCJD came just after I left the SNBTS. I did become heavily involved in the achievement of a better understanding of vCJD at a much later date (2019). This is documented in the United Kingdom Plasma Action Memorandum appended to this testimony, in case of interest to the Inquiry team. (UKPA.Memorandum.906/D/Draft.V.1.7_31.01.2020) [3523002].

Section 17: Other matters

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

333. The only document that I can offer as being of potential interest in this context is the UKPA Memorandum mentioned above (180) and attached as a reference WITN3532002. I have not published any other relevant articles.

182 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).

334. I hope that my testimony above covers all the matters within my personal experience that I believe to be relevant.

183 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?

335. In relation to Scotland, I can say with certainty that yes, we were always self-sufficient in terms of whole blood (and also red cell concentrate, which is the main form in which blood is used these days). In relation to the rest of the UK, I would have to caveat any remarks I make by emphasising that supplies in England were never my responsibility. However, I do believe that, though sometimes quite seriously tight for supplies (postponing operations, etc) the NHS in England was in my time (as I believe it is now) also broadly speaking self-sufficient in blood and red cells.

184 During your tenure at 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?

336. No, I don't believe that this ever happened in my time at the SNBTS and I find it very hard to believe that it would ever have happened anywhere in the UK at any time. [Note: It is important to note of course that there will almost certainly have been times when US citizens and other foreign nationals coming to the UK for treatment have brought their own (autologous) blood with them. However, for the avoidance of doubt, as mentioned in my answers to earlier questions on autologous transfusion, I would not regard those as cases of red blood cell importation within any sensible definition of the term.]

Statement of Truth

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

Signed GRO-C

Dated _24.11.2021___

Table of exhibits:

Date	Notes/ Description	Exhibit number
14/11/2011	C5 - Witness statement of David McIntosh regarding Hepatitis C look back including 2. Why was the look-back not commenced earlier given that a screening test for anti-HCV was available from 1991? including figure 1 forces at play influencing professional opinion and advice in favour of, and against, early HVC Look Back 1991-1992	PRSE0001657
31/01/2020	UKPA.Memorandum.906/D, submitted in evidence to the MHRA in connection with the UK Plasma Policy Review.	WITN3532002

07/05/1990	Report, 'Management of the SNBTS in the '90s - Part 1 - The Skeletal Structure' by David B McIntosh, General Manager, Scottish National Blood and Transfusion Service. Includes two related appendixes - a Medical and Scientific Committee (M.S.C.), outlining the groups membership and Sub-Committees and an organisational chart for the SNBTS management and committee structure	PRSE0003892
21/10/1994	Letter from David B. McIntosh, SNBTS, to Dr. W. Wagstaff, Trent Blood Transfusion Service, re: formal recognition for approved Guidelines; MCA involvement	NHBT0010968
08/06/1993	Letter from David B McIntosh, Scottish National Blood Transfusion Service, to Professor J. D. Cash, NMSD, re: comments on SNBTS leadership's role	SBTS0000411_142
02/09/1992	Letter from David B. McIntosh, Scottish National Blood Transfusion Service (SNBTS) to SNBTS management board, re: "review of sub committee/working groups", proposing annual slot in the agenda to deliberate on targeted reports from sub	SBTS0000456_009

	committees which standard format is said to follow enclosed	
03/01/2000	Hepatitis Litigation (A and Ors.), Witness Statement of Harold Hastings Gunson, re: the organisation of the NBTS (1946-1993), the hepatitis C virus and its discovery, surrogate testing for hepatitis NANB and the introduction of the anti-HCV tests.	NHBT0000026_009
15/05/1990	Letter from John D Cash (National Medical & Scientific Director) addressed to Dr R R C Stewart (Clinical Trials Manager) re PFC Plasma Products : Market Value	SBTS0000057_031
09/12/1991	Letter from David B. McIntosh, SNBTS, to R. Panton, SNBTS. CC to Dr. Perry, Prof. Cahs, and J. T. Donald. Doc title: SNBTS: Contract fractionation at PFC: Eire enquiry. Written confirmation of a telephone call on the same day. He says that following agreement with the unions they are switching to a shift structure. Says that the SNBTS strategy has extended to specialist contract fractionation for England & Wales (BPL, Elstree), and especially because of their high potency factor VIII product they are getting enquiries from other potential customers. Suggests	SBTS0000030_122

	criteria, including no paid donors and good screening and testing procedures.	
22/03/1989	Letter from Dr. E. Angela Robinson, Yorkshire Regional Health Authority, National Blood Transfusion Service, to Dr. H. H. Gunson, National Blood Transfusion Service, The National Directorate, re: strategy to achieve plasma targets	NHBT0027512
12/11/1990	Letter from Dr CV Prowse, Director National Science Laboratory, to Mr D McIntosh, General Manager, SNBTS HQ dated 12 November 1990 re: Factor VIII (HP) Project (draft).	PRSE0003403
13/01/2012	Evidence of Professor Vivienne Nathanson for the Penrose Inquiry	PRSE0006084
23/01/1992	Letter from David B McIntosh, General Manager of the Scottish National Blood Transfusion Service to Professor J. D. Cash, NMSD re a misunderstanding regarding his explanation of a "critical shortage of HP VIII" and criticism given	SBTS0000661_063
24/09/2014	Signed response by Dr Mitchell to criticism.	MDDU0000022_003
09/04/1990	Letter from David B McIntosh to Mr R Panton Factor VIII and Albumin	PRSE0003146

	Supplies regarding current stock of FVIII.	
27/04/1996	Press cuttings, The Scotsman, "Surprise as transfusion chief quits", Independent, "Girl, 15, could be youngest victims of CJD", and Sunday Times, "Blood money battle in court", April-May 1996.	HSOC0027095
28/05/1996	Letter from F F Gibb to the Director of Public Health (North Western Regional Health Authority) regarding the organisational restructure at SNBTS. David McIntosh would depart SNBTS in light of the restructure.	DHSC0004351_014
27/11/1992	Documents related to the Symposium on Donor Selection on 27 November 1992, from the Scottish National Blood Transfusion Service	NHBT0071589_001
25/07/1990	Minutes of Regional Donor Organisers and Donor Services Managers meeting on 1 June 1990 at SNBTS Headquarters.	NHBT0118157_012
15/05/1995	Letter from Mairi Thornton to Dr Gatea, Dr Yates, Dr Urbaniak, Dr Brookes, Dr McClelland, Mr J Francis re New Donor Day 15th July 1995	SBTS0000281_017

20/04/1993	Notes by David B. McIntosh, Scottish National Blood Transfusion Service for CSA Board, re: 'SNBTS 10 year strategic plan 1992-2002, some further notes on strategic issues'	SCGV0000057_022
16/01/1990	Notes by David B. McIntosh, Scottish National Blood Transfusion Service for CSA Board, re: 'SNBTS 10 year strategic plan 1992-2002, some further notes on strategic issues'	PRSE0000759
04/10/1990	Memo to Dr Bob Stewart to David B McIntosh re: Factor VIII Stocks	PRSE0001184
09/12/1991	Letter from David B. McIntosh, SNBTS, to R. Panton, SNBTS. CC to Dr. Perry, Prof. Cahs, and J. T. Donald. Doc title: SNBTS: Contract fractionation at PFC: Eire enquiry.	SBTS0000030_122
04/04/1990	Letter from R Panton to Mr David Mcintosh about the increase in the cost of purchasing commercial Factor VIII	PRSE0004486
09/04/1990	Letter from David B McIntosh to Mr R Panton Factor VIII and Albumin Supplies regarding current stock of FVIII.	PRSE0003146
01/03/1981	Minutes of the second meeting of the Advisory Committee on the National Blood Transfusion Service.	CBLA0001287

28/09/1990	Minutes of General Assembly of the European Plasma Fractionation Association, May 22 1990	SBTS0000684_063
09/04/1991	Minutes of Scottish National Blood Transfusion Service meeting on 9th and 10th April 1991	SBTS0000108_079
23/04/1990	Minutes of meeting of Factor V III Working Party for Scotland and Northern Ireland held at Haemophilia Centre, Royal Infirmary, Edinburgh 23 April 1990	SBTS0000299_020
27/05/1992	Letter from David B. McIntosh, General Manager, to Dr F. G. H. Hill, The Children's Hospital re: Supply of Factor VIII: Named patient basis.	SBTS0000648_154
04/09/1990	Letter from Dr. D. B. L. McClelland, Edinburgh & South East Scotland Blood Transfusion Service addressed to David B. McIntosh, (SNBTS) re Blood to England - shipping and cost of red cells	SBTS0000708_071
27/09/1990	Letter from David B McIntosh, Scottish National Blood Transfusion Service (SNBTS) addressed to Dr. D. B. L. McClelland re Blood to England	SBTS0000708_070
08/07/1991	Letter from G. W. Tucker, The Scottish Office to David McIntosh,	SCGV0000056_044

19/11/1990	Letter from C. A. Ludlum, Haemophilia Centre to Mr. D. McIntosh, SNBTS Headquarters Unit, regarding plans to manufacture a high level of Factor VIII concentrate and details of such manufacture	SBTS0000706_223
19/02/1991	Letter from C A Ludlam to Mr McIntosh re High Purity Factor VIII Concentrate. Follows a letter dated 19/11/1990 and 25/01/91 meeting of FVIII working party.	PRSE0003536
17/02/1993	Letter from David B. McIntosh, Scottish National blood Transfusion Service, to Mr. R. Paoton, re: Fractionation for EIRE.	ARCH0003321_017
27/06/1995	Fax from Karen Smythe, Scottish National Blood Transfusion Service, to Gary Wildridge, re: attached letter from David B. McIntosh,	SCGV0000160_098
07/10/1992	Letter from H. H. Gunson to G. R. Austin, South Western Regional Transfusion Centre	NHBT0010669
07/03/1991	Letter from C A Ludlam to David McIntosh re Factor VIII Allocation 1991-92	PRSE0001484
11/03/1990	Letter from C.A. Ludlam to Professor J.D. Cash Factor VIII Allocations for Financial Year	PRSE0002327

	1990-91	
26/07/1990	Distribution of Factor VIII regarding new arrangements bound to lead to an improved service	PRSE0004409
04/03/1992	Letter from R.J. Perry to D. McIntosh and J. Cash and R. Stewart regarding Supply of FVIII (8Y) and High Purity VWP	PRSE0003083
07/03/1991	Letter from C A Ludlam to David McIntosh re Factor VIII Allocation 1991-92	PRSE0001484
11/03/1990	Letter from C.A. Ludlam to Professor J.D. Cash Factor VIII Allocations for Financial Year 1990-91	PRSE0002327
02/04/1991	Letter from CA Ludlam, Consultant Haematologist at the Royal Infirmary of Edinburgh, to DR RJ Perry at the Protein Fractionation Centre in Edinburgh	PRSE0001254
01/02/2018	Thomas R. Kreil, Building blocks of the viral safety margins of industrial plasma products doi: 10.21037/aob. 2018.02.01: http://dx.doi.org/10.21037/aob.2018.02.01	WITN3523003
14/06/1990	Letter from DB McIntosh to Mr J T Donald re definition of self-sufficiency in blood and blood products	PRSE0002051

12/06/1990	Letter from David B McIntosh to Bob regarding FVIII - Meeting on Thursday, 14th June	PRSE0003113
17/08/1990	Letter from John D. Cash, to David McIntosh, General Manager, HQ Unit, re: Self-Sufficiency, High Purity Factor VIII Options,	SBTS0000656_051
11/01/1990	Scottish National Blood Transfusion Service; Minutes of a Meeting of the Management Board held in Headquarters on 11-12 October 1990	PRSE0004676
31/01/1994	Letter from R. Panton, Scottish Office, to D. McIntosh, Scottish National Blood Transfusion Service	SCGV0000198_008
11/03/1994	Letter from David B. McIntosh, Scottish National Blood Transfusion Service to all Trust Chief Executives and General Managers of DMUs	SCGV0000136_026
29/06/1994	Letter from David McIntosh, SNBTS, to Mrs Sandra Falconer	DHSC0004014_183
04/10/1994	Minutes of Scottish National Blood Transfusion Service Management Board meeting held 4th October 1994	SBTS0000121_043

12/06/1990	Minutes of a Directors' Meeting of the Scottish National Blood Transfusion Service Held on 12th June 1990	PRSE0002954
27/06/1990	Minutes of NBTS, NBTS/SNBTS Liason Committee 1st meeting at National Directorate, 27.6.1990.	NHBT0000189_173
23/04/1992	SNBTS Management Board Meeting re Constitution of Management Board	SBTS0000112_051
01/05/1992	Minutes of Meeting of Coagulation Factor Working Party, 1 May 1992, at the Haemophilia Centre, Royal Infirmary, Edinburgh,	SBTS0000260_016
12/06/1990	Minutes of a Directors' Meeting of the Scottish National Blood Transfusion Service Held on 12th June 1990.	PRSE0002954
18/06/1990	Letter from Dr. D. McClelland, Scottish National Blood Transfusion Service, to Prof. J. Cash	SBTS0000672_158
14/08/1990	Minutes of the Extra-Ordinary Meeting of the Medical and Scientific Committee Held on 14th August 1990	PRSE0000171
30/04/1993	5th Annual Report of The Coagulation Factor Working Party	PRSE0001520

	For Scotland and Northern Ireland, on 30 April 1993	
03/11/1989	Letter from Janet Mortimer, PHLS to Dr Gunson	NHBT0004742_001
15/05/1989	Internal Departmental Memorandum of the National Blood Transfusion Service (NBTS) from Mr Howell to Mrs Poole et al.	NHBT0005388
01/10/1986	"Alanine Amino-Transferase (ALT) and Anti-hepatitis B core (Anti-HBc) Screening of Blood Donations: Proposals for a Multi-Centre Study" by UK Working Party on Transfusion Associated Hepatitis	PRSE0002161
04/01/1991	Letter from Mr D. McIntosh to Professor J. D. Cash et al	SBTS0000301_081
01/03/1993	Appendix 1 to Procedure for Management and Update of SNBTS Donor Medical Selection Guidelines and Associated Literature.	SBTS0000479_006
20/08/1990	Memo from J. T. Donald, Scottish Health Service, to David B. McIntosh, re: routine screening for HIV-1.	SCGV0000163_040
07/08/1990	Letter from John D. Cash, to R. Panton, National Health Service in Scotland, re: HIV+1 Donors,	SBTS0000656_057

	actions taken when a donor is found to be HIV+ve.	
16/02/1990	Letter from John D Cash to R Panton SHHD regarding Safety of Current factor VIII Concentrates with regard to Virus Transmission.	SBTS0000434_108
28/08/1992	Letter from, Mairi Thornton, Scottish National Blood Transfusion Service, to Mr Rab Panton	SCGV0000155_105
07/01/1991	Minutes of the third NBTS/SNBTS Liaison Committee meeting on 7 January 1991	PRSE0001721
30/04/1991	Minutes of the SNBTS/NBTS Liaison Committee fourth meeting held on 30 April 1991	PRSE0004478
15/11/1990	Fax sent from R L Bruce addressed to David McIntosh	SBTS0000339_091
04/12/1992	From Dr R.J. Perry Table with supply figures Costs	SBTS0000376_068
11/06/1991	Fax/letter from David B. McIntosh, General Manager to SNBTS Management Board, re: French transfusion service Guardian article 7th June 1991	SBTS0000666_056
28/08/1992	Letter from, Mairi Thornton, Scottish National Blood Transfusion Service, to Mr Rab	SCGV0000155_105

	Panton	
29/08/1991	Letter from David B McIntosh to Mr D. M Hogg,	SBTS0000023_072
27/06/1990	Minutes of the first NBTS/SNBTS Liaison Committee meeting held on 27 June 1990	NHBT0000189_173
03/04/1991	Letter from H. H. Gunson, National Blood Transfusion Service, to All RTDs - England and Wales, re: Anti-HCV Tests on Blood Donations.	NHBT0000073_065
24/06/1991	Letter from H L Lloyd to Dr H HGunson re: Hepatitis C Testing. Concern that UK testing has not begun.	NHBT0000076_009
02/05/1991	Letter from Dr H L Lloyd to Dr H H Gunson, and Professor J D Cash	NHBT0000074_014
04/07/1991	Letter from H L Lloyd to Professor J D Cash regarding Hepatitis C Testing.	PRSE0001183
13/02/1990	Minutes of a Directors' Meeting held in the Headquarters Unit on 13 February 1990	PRSE0000205
19/07/1994	Letter from John D. Cash to David McIntosh Autologous Transfusion: MSC Meeting 18 May 1994	SBTS0000411_038

04/10/1994	Minutes of Scottish National Blood Transfusion Service Management Board meeting held 4th October 1994	SBTS0000121_043
26/09/1990	Letter from John Cash to David McIntosh re HP-VIII Update	SBTS0000066_009
06/01/1993	Letter from Christopher A. Ludlam, Royal Infirmary of Edinburgh, to David McIntosh	SBTS0000386_094
30/10/1992	Letter from John D Cash (National Medical & Scientific Director) addressed to Mr David B McIntosh	SBTS0000411_188
28/10/1993	Minutes of The Coagulation Factor Working Party meeting, Thursday 28th October 1993	LOTH0000051_032
23/01/1992	Preliminary Discussion Paper for ACTTD: Two topics related to transfusion safety by Dr Marcela Contreras and Dr John Barbara	NHBT0000044_095
27/06/1990	Minutes of the first NBTS/SNBTS Liaison Committee meeting held on 27 June 1990	NHBT0000189_173
22/12/1994	Letter from GW Tucker to Dr DB McIntosh re: Hepatitis C - Look Back. Cover letter referencing a letter from P Fraser to T Sackville.	PRSE0000661
14/11/2011	C5 - Witness statement of David McIntosh regarding Hepatitis C look back	PRSE0001657

23/11/1994	'Hepatitis C Lookback - Pilot and Preparations', A supplementary note for Scottish National Blood Transfusion Service (SNBTS) Senior Staff	SBTS0000377_145
19/03/1991	The Scotsman , "Blood Transfusion Service does not subsidise private sector in any way", March 1991	SCGV0000137_023
28/06/1991	Letter from H. H. Gunson, National Blood Transfusion Service (NBTS) to David. B. McIntosh	SBTS0000467_025
19/06/1991	Letter from David B McIntosh, General Manager to Dr W Whitrow, Dr S J Urbaniak, Dr E Brookes, Dr D B L McClelland and Dr R Mitchell.	NHBT0027784
01/07/1991	Notes of SNBTS/NBTS Liaison Committee on the following; Quality Assurance	NHBT0028190_002
07/10/1992	Letter from H. H. Gunson to G. R. Austin, South Western Regional Transfusion Centre.	NHBT0010669
25/10/1991	Letter from David. B. McIntosh, Scottish National Blood Transfusion Service Headquarters	SBTS0000466_019
26/09/1991	Letter from the Director at Glasgow and West of Scotland Blood Transfusion Service (GWSBTS) to David. B. McIntosh	SBTS0000466_032

11/10/2011	C4 - Witness statement of David McIntosh regarding screening of blood for Hepatitis C	PRSE0000231
11/11/2014	Signed Response from Dr Ruthven Mitchell to the Penrose Inquire regarding criticism received.	MDDU0000001
03/06/1991	Letter from John D Cash to Mr D McIntosh, Headquarters, re: UK Haemophilia Centre Directors	SBTS0000637_006
12/05/1992	Letter from Dr B Cuthbertson (Quality Manager) addressed to Dr R J Perry (Director)	SBTS0000058_032
02/09/1993	Letter from Mairi Thornton, Scottish National Blood Transfusion Service Headquarters, to Donor Consultants, Dr Brookes, Donor Services Managers, Dr S. Lumley	NIBS0000330_004
10/12/1985	Hansard Material from Parliamentary Monitoring Services re Aids HoC Discussions	HSOC0018830