Witness Name: Professor Ian Franklin
Statement No.: WITN4032030
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INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR IAN FRANKLIN

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 23 August 2021.

I, Ian Franklin, will say as follows:

Section 1: Introduction

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

Name: Dr Ian Maxwell Franklin
Address: GRO-C Bristol

Professional qualifications are listed in WITN4032001.

Section 2: Your role at the Glasgow and West of Scotland Blood Transfusion Service

I remain unclear in many of the questions as to whether the Inquiry wishes me to answer from the perspective of my position as head of GBTS, which I held for 8 months, or the 13 year period when I was NMSD for the whole SNBTS. I have tried to be clear about

which perspective I am responding from when answering, in order to be most helpful to the Inquiry.

2. **Please describe the roles, functions and responsibilities you had at the Glasgow and West of Scotland Blood Transfusion Service ("GBTS") during your period as Director.**

   As director of GBTS I was de facto head of service. The roles, functions and responsibilities of the service were those of a blood establishment as defined in the EU Blood directive, although my period there pre-dated the EU directive. This consisted of recruiting blood donors, collecting blood donations, processing and testing the blood. Blood would be prepared for clinical use in the centre and distributed to hospitals in the region. This was from May 1996 to January 1997, as I recall.

3. **Please describe the organisation of the GBTS during the time you worked there, including:**

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

      I was accountable to the general manager of SNBTS. The holder of this post changed a few days before I took up my job. The general manager in the first few months was Francis Gibb CBE before the appointment of Angus Macmillan Douglas. I don't recall specifically but my appointment as NMSD was in January 1997 and I started very soon afterwards.

      The structure of the Glasgow service consisted of blood donation and collection team[s], testing laboratories, processing laboratories and facilities for issuing blood. I recall we had our own vehicles.

   b. **how the GBTS was funded;**

      Funding was allocated downwards from the Scottish Health Department [which had many guises during my time] to the Common Services Agency [CSA]. At some point the CSA became known as National Services

Scotland [NSS]. I cannot recall the details of how the funding was divided up between parts of the agency and also within SNBTS itself.

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

The role of the service was to meet the transfusion needs of the hospitals and patients in the region. This was substantial and included areas to the north and south of the River Clyde, south down to the border with England and along the middle of south of Scotland approximately following the route of the M74 motorway. The health service in Scotland at that time was divided into something like 13 health boards and this included for Glasgow the Forth Valley area covering Stirling which was about as far north as we covered.

d. its place in the Scottish National Blood Transfusion Service ("SNBTS") together with information as to whom the centre was answerable at the SNBTS, if anyone;

The Glasgow service was an important and the largest component of SNBTS. The service was answerable to the general manager of SNBTS and then upward to CSA and thereafter the Scottish Health Department. The GBTS was quasi autonomous as were the other components of the SNBTS.

e. whether the GBTS was associated or linked with other Scottish Blood Transfusion Services ("BTSs") and, if so, how and for what purpose;

Despite the view outside Scotland that this was an integrated National blood service this was in fact not the case and at that time the service was highly regionally administered. Each of the 5 regions collected, tested and processed blood independently. There was only modest movement of finished blood components between regions as I recall.

f. **whether the GBTS was subject to any form of regulation and if so, what (you may find SBTS0000360_003 of assistance);**

During my time in the Glasgow Centre the sites and services were inspected and regulated by the Medicines Control Agency [MCA, later the MHRA]. Prior to my appointment there had been a range of different arrangements including Crown Immunity, but during my time it was the MCA and its later successors.

g. **the GBTS' relationship with the Plasma Fractionation Centre ("PFC") and any other laboratory involved in the production of blood products or processing of blood; and the approximate number of donations collected each year**

The relationship with PFC involved supplying plasma to PFC for manufacture into plasma products. There were targets for the volumes of plasma to be provided to PFC and these were reflected in the amount of processed plasma medicinal products returned to the Glasgow region.

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

I don't recall the number of donations collected each year but imagine there are figures available for this. It was likely to be approximately 50% of the Scottish total. From memory we transfused between 80,000 and 100,0000 people annually in Scotland so Glasgow would have collected at least 50,000 donations.

4. **Please set out any information you hold in relation to the matters addressed in question 3 above prior to your directorship of the GBTS.**

I hold no information in regard to the matters above at all other than academic publications prior to c.2004.

<u>Section 3: Your role as National Medical and Scientific Director of the SNBTS</u>

5. **Please outline the roles, functions and responsibilities you had at the SNBTS**

during your period as National Medical and Scientific Director.

I provided medical advice, support to all medical and scientific functions, and gave direction and some management. The lead scientist, Dr C V Prowse, reported to me. The clinical directors in Glasgow, Aberdeen, Edinburgh, Dundee and Inverness reported to me. I was de facto deputy to the SNBTS Director, and was de jure acting Director for one month between Mr Macmillan Douglas leaving and Mr Thompson joining the service. I acted as the medical lead for PFC during most of my time. For a period this role of PFC Medical Advisor was undertaken by the late Dr Peter Clark, but in this role he reported ultimately to me.

6. **Please outline the main issues of relevance to the Inquiry's terms of reference that you had oversight of during your period as National Medical and Scientific Director.**

I was the professional lead of the SNBTS reporting to the general manager. As such I had overall responsibility for blood safety policy - but this was not executive authority and I did not hold a budget. I also advised the general manager regarding issues such as blood collection but I was not directly responsible for that area. During the early period of my tenure the regional directors reported to the general manager, not to me. However, following a reorganisation in the first year of my appointment as NMSD the clinical directors were accountable to me. The operations director, whose remit included all donor services and laboratory testing, reported to the general manager.

7. **Please describe the following in respect to the SNBTS during your period as National Medical and Scientific Director:**

My answers below are from my memory and may not be a complete record of all activities or functions.

a. **its structure, staffing and hierarchy;** SNBTS was a division of a statutory body and part of NHS Scotland, known as the Common Services Agency [CSA], latterly National Services Scotland [NSS]. The CEO of CSA reported to the CE of NHS Scotland. SNBTS was led by a National Director

supported by other Directors - National Medical & Scientific Director, Operations Director, Tissue Services Director, Quality Director, HR and Finance. We also had a Research & Development Director and Regional Clinical Directors. The latter senior consultant doctors provided clinical transfusion medicine services in their regions. The Protein Fractionation Centre was a separate division reporting to the National Director. There was a diagnostics division - ultimately called Diagnostics Scotland - that supplied tests or reagents for tests to the NHS in Scotland and also sold these tests to private companies. These roles all met on a monthly basis at a Management Board meeting. Medical and Scientific issues were addressed at monthly or two monthly meetings of a Medical & Scientific Committee [MSC]. Fairly late during my time Diagnostics Scotland became a fully private company.

b. **its remit;** Meeting the transfusion needs of patients in Scotland.

c. **its aims and objectives**; To provide transfusion components and products from volunteer non-remunerated donors for the health services in Scotland. Also to provide transfusion advice and services such as clinical transfusion medicine, hospital blood banking and therapeutic apheresis [cell separator services]. Diagnostic tests and reagents were provided to the NHS. This was predominantly for the NHS but a small number of private sector hospitals were also supported. The quality of the components and products were to be of world class and to do this there was an active research and development programme, divided into 5 theme groups to address the needs of the service.

d. **how it was funded;** Finance came from the Scottish Government as an allocation via the CSA. This was tax payers' money. SNBTS also attempted to generate income from sales of excess plasma fractionated products or from contract fractionation for others. The diagnostics division sold their tests to England and to private companies. I do not recall how much income ever was generated, and concerns about the safety of UK plasma after the

vCJD discovery greatly reduced such opportunities in relation to therapeutics - less so for diagnostics.

e. **the level of interaction with the various BTSs**; Links between the four UK transfusion services were always good. SNBTS had a special relationship with the Northern Ireland (NI) BTS that pre-dated my arrival. Plasma collected in NI was sent to PFC for fractionation and the Medical Director / CEO of the NI BTS would attend Medical and Scientific Committee meetings of SNBTS. Until the founding of the UK Forum, links with England and Wales tended to be through the JELC/JPAC committee system. This worked well at a professional level but contact with senior managers in the other services for myself was minimal. Once the UK Forum started there were quarterly meetings between the CEO [& equivalent] of each UK service and the medical directors.

   Another major advance was the founding of the European Blood Alliance [EBA] in the late years of the 20th Century. Initially to prepare blood services for the impending EU Blood Directive, it continued after that as a most useful forum for problem sharing and solving between European blood services. SNBTS was a full member from the outset.

f. **how decisions were made;** The National Director had executive authority within SNBTS and would take decisions after discussion at board and MSC meetings. Individual Directors had considerable scope to act within pre-agreed outcome requirements. These were the operational decisions, like which machinery to buy for testing, and how best to deploy donor teams to collect sufficient blood. These in the main could be done easily and within reasonable time scales. The big decisions, such as which transfusion transmissible infections [TTI] to test for was for MSBT[O] and its successor SaBTO to determine. I don't think there was ever the awareness of what a public health issue blood transfusion was by these bodies, particularly by earlier bodies like MSBT. Huge numbers like a million UK-wide donations processed into 2 million transfusion components annually - less now I believe - needed prompt decision making and clear advice. What we got were delays in HIV testing in 1985 and Hepatitis C testing, which should

have started well before late 1991, and an absence of surrogate testing for NANB hepatitis. This didn't improve much later when I and colleagues had to prepare a pilot study to show that HTLV could be tested for economically.

g. to whom the SNBTS was answerable.

Direct accountability was to CSA and up to the Scottish Health Department and the First Minister ultimately. But we also had accountability to the Scottish public - to treat donors fairly and to use their donations wisely and to patients - to provide blood components, products and services as safely and effectively as possible. We also had some accountability to other UK blood services to keep them informed as to what plans we had that could impact their own decisions. This worked both ways.

8. Please describe your relationship and level of interaction with the following senior personnel:

a. the SNBTS General Manager;

There was always a high level of interaction between me as NMSD and the SNBTS general manager. I worked with Mr Macmillan Douglas and Mr Thompson in my time. I think relationships were good, sound working ones. Professional relationships not social ones. Contact was at least three times a week, sometimes more. This would usually be face to face. E-mails obviously daily, including weekends often.

b. the Common Services Agency General Manager; and

Personally, I think I had good working relationships with the first 2 CSA general managers. Mr Gibb was affable, but I would only meet him every few weeks perhaps. There were professional tensions between Mr Gibb and Mr Macmillan Douglas over budgets. I recall CSA wished to take £1,000,000 out of the SNBTS budget. Neither Mr Macmillan Douglas nor I agreed or could accept that and I think the issue was dropped or a much smaller number agreed. Also CSA arbitrarily removed one floor of the new blood centre at Gartnavel during the planning stage. This reduced the

functionality of the building and possibly prevented its use later as a single site processing and testing unit for SNBTS. When Stuart Bain was head of CSA, after Mr Gibb retired, things were much easier. It was not just personal qualities but Mr Bain was an experienced NHS senior manager and seemed happy to allow his senior subordinates to manage without obsessive oversight. The final CSA/NSS head during my time was Ian Crichton, and things became very tedious during his tenure. Whether he was instructed from the Scottish Government I do not know, but there was an obsession with horizontal integration within NSS and the explosion in the number of meetings held on site at NSS in Edinburgh became a substantial overhead to the work of myself, the general manager, Keith Thompson, and other senior SNBTS managers. Overall, I felt the CSA in general added to SNBTS work and did not facilitate it, although I felt Mr Bain did try to mitigate this. I thought then that there was an inherent jealousy within CSA/NSS that SNBTS had a clear public image and role, which other divisions - although of course important in themselves - did not have. We didn't need CSA to help us collaborate with SCIEH [Scottish Centre for Infection & Environmental Health], another CSA division. We would have done so anyway. At some point there was a 'consultation' about whether SNBTS should leave CSA and become an independent body within NHS Scotland. When this consultation recommended no change Mr Macmillan Douglas decided to retire. I believe these tensions continued and ultimately lead to the departure of Mr Thompson, Mr Macmillan Douglas's successor, although this was after I had moved to Ireland. I think Mr Thompson's success in his next role at NHS Catapult speaks for itself, he was made a CBE, in that the oversight from NSS was unnecessary.

c. the Director of the PFC.

As NMSD my relationship with the PFC Director was as a colleague on the SNBTS Management Board. I had a good personal relationship with Dr Perry, whom I liked. Meetings were more structured, usually within committee or more formal briefings, rather than regular casual meetings. My relationship with his successor was personally less close, although we had worked closely together during the 'Taiwan Project' and got along OK.

[The Taiwan project was a plan to transfer intellectual property and expertise into Taiwan to enable them to set up their own plasma fractionation facility. It was derailed by the vCJD problems in the UK]. However due to issues relating to the delivery of the quality management system in PFC and revelations about reports that had not been shared with the SNBTS Management Board, I did have to suspend the PFC director from their position when Keith Thompson was on annual leave. This followed the adverse MHRA inspection of January 2006, which led ultimately to the closure of PFC.

9. What was the relationship between the SNBTS and the SHHD?

There were clear political aspects to the work of SNBTS, particularly in relation to blood safety and supply. Because of this, and despite the line of managerial command being from the head of the NHS in Scotland through the CSA/NSS to SNBTS, the Scottish health department did hold regular meetings with senior members of the SNBTS to discuss 'general issues.' During my time, Dr Aileen Keel attended whenever available as deputy Chief Medical Officer [CMO]. CMO did not attend but if meetings with CMO were needed these would occur through Dr Keel. Civil servants of varying seniority also attended, and notes were taken. In the main, relationships were good with Dr Keel and the various CMOs. Dr Mac Armstrong [CMO 2000-2005] was particularly supportive of the Effective Use of Blood initiative and assisted greatly in achieving funding for this. Meetings with ministers were very rare, and I recall only one which related to the closure of PFC. I think Mr Macmillan Douglas may have met ministers more often relating to the Taiwan project.

Section 4: Blood collection at the GBTS

10. Please explain the system for blood collection at the GBTS during your employment there and how it changed over time.

Blood collection was organised in donor teams, all of which were based in Glasgow. The teams would assemble in the centre of the city each morning and then head off

to the donor collection sites, returning that evening. Occasional visits to more rural areas such as the West Coast or islands might involve an overnight stay for the staff. The donor teams were managed by Mrs Moira Eadie, who was accountable to me during the period in 1996/97 that I was Director of GBTS. I do not believe there was any change in the donor system during the six months or so that I was the head of the Glasgow service. In later years we did introduce more locally based donor teams and one of these was in Dumfries & Galloway.

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

I don't fully recall the publicity used at that time. We advertised on billboards: in the main we did not use television but since the English blood service did use television advertising we benefited from these when they were included in programmes shown in Scotland. I'm unable to comment about how successful the advertising process was.

12. **Please describe the way in which donations were collected at the GBTS during your time there. In particular:**

    a. **What were the staffing arrangements during blood donation sessions?**

    I do not recall. There were some nurses and some 'donor attendant' grades. There would have been a driver[s] for the donor truck.

    b. **Were the staff involved medically trained?**

    In the early stages each donor team was led by a registered medical practitioner. Some years later these were phased out in favour of nurse-led teams. I agreed with this change.

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

The sessions took place largely in community venues such as town halls or community centres. There was a city centre donor site initially in St Vincent Street and latterly on Nelson Mandela Place in the centre of Glasgow. I recall we had a small number of mobile units - in effect lorries fitted out as donation areas.

d. How frequently could a person donate blood?

The frequency with which a person could donate blood would have been dependent upon the guidelines for the UK blood transfusion services known as the "Red Book." Whole blood donors would be three or four times a year, but plasma donors and platelet donors more often, but the intervals were carefully regulated, records inspected and rules adhered to.

e. How were blood donors recruited?

Donors were recruited by poster campaigns, leafletting near open sessions, and local radio. We would use 'below the line' tactics to get donor awareness issues into newspapers and onto local radio. Below the line is a way to use a human interest story related to blood that is newsworthy. Perhaps a survivor of a major bleed in pregnancy, or someone who survived an accident against the odds due to blood transfusion. All subjects of such stories gave their permission and indeed would give an interview or even speak to camera.

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

I do not think these systems changed during my tenure but when I moved to become NMSD there was a major reorganisation which did lead to significant change. In particular, donor services became nationally organised and co-ordinated, as did advertising.

13. **Did the GBTS have donation collection targets that it was required to meet? If so, did the GBTS meet its donation collection targets during your tenure? If not, why not?**

The local donation targets would have been dependent on how stocks were running with regards the red cells and platelets components. We had more forward-looking targets with regard to plasma that was required to be sent to PFC to be processed into pharmacological products. As far as I recall there were no sustained shortages of blood components during this period. It was sometimes operationally difficult to meet the requirements of PFC for the highest quality plasma due to the need to freeze plasma within a few hours of collection, particularly from donations collected a long distance from the main centre in Lanarkshire.

14. **Please set out any information you hold in relation to the matters addressed in questions 10 to 13 above prior to your directorship of the GBTS.**

I have no information held regarding these matters other than that in my memory.

15. **In your evidence to this Inquiry, given 28 October 2020 (INQY1000068, page 17), you stated that "In fact, the collection of blood from prisons in the UK was encouraged by the Home Office as part of a social inclusion process of -- for people in prison." Can you explain what you meant by this?**

At the relevant time I do recall seeing a document from the Home Office stating that blood donation by prisoners should be encouraged. This was intended to engage them with society and assist in their rehabilitation. I do not know where this document is now. Beyond that I would have thought my statement to the enquiry of 28 October 2020 was quite clear.

Effective use of blood

16. **In June 1988 you wrote to the Chief Medical Officer of the Scottish Office to make suggestions in regards to the effective use of blood, including providing funding for nurse practitioners who would be responsible for the development of transfusion policies, and the improved education of patients (SCGV0000099_089).**

a. **Please describe the extent to which policies on the effective use of blood were utilised as a measure to reduce the risk of transfusion transmitted infection during your tenure at the SNBTS.**

The date of this letter is 1998, not 1988.

This was against the background of concerns about variant[v] CJD contaminating donated blood. There was no likely test for vCJD expected. There was also evidence at that time of major differences in transfusion practice between hospitals with regard to, for example, total hip replacement surgery. Shortly after this letter there was a paper published which suggested that using a lower threshold for transfusion was not only safe but probably better than using a higher transfusion threshold [WITN4032031 Hebert et al., 1999]. It seemed probable to many of us in the field that should CJD be transmitted by blood there would be a major review in terms of whether transfusions were indeed necessary. Indeed, over ensuing years the use of blood component therapy in many areas of surgery has been dramatically reduced such that it would now be normal for blood transfusion not to be required in primary joint replacements such as knee or hip. The next CMO did support funding for this effective use of blood project. Also, the SHOT organisation was established in 1996 to monitor adverse events of transfusion. This showed that there were fundamental failures in hospital transfusion practice leading to incorrect blood given. In the present day 'patient blood management' is a central part of transfusion practice in hospitals.

b. **As far as you are aware, were policies on the effective use of blood utilised to the same extent prior to your tenure, particularly prior to the introduction of screening tests for HIV and Hepatitis C?**

I am fairly confident that there was no particular attempt made to manage or reduce the use of transfusion around the time of the introduction of screening tests for HIV or hepatitis C. Regarding HIV I do recall there was a degree of transfusion refusal by patients in Birmingham, and also some thought given to reducing exposure of individuals to blood transfusion but

as I recall this was not sustained thereafter. I recall discussions with surgeons about reducing blood use and the response was always "why, can't you collect enough blood?"

Section 5: Plasma procurement and production of fresh frozen plasma at the GBTS

Production of fresh frozen plasma

17. The Inquiry understands that the GBTS procured plasma from blood donor sessions to produce fresh frozen plasma ("FFP") to provide to the PFC.

I don't have much concrete information to provide to the Inquiry in this area. It was a function of the Glasgow service to provide plasma to PFC for fractionation. Plasma will have been separated from the whole blood donation and frozen as quickly as possible. The earlier the plasma was separated and frozen, the higher the recovery, or yield, of clotting factors such as Factor VIII that were to be produced as concentrates. I recall plasma supplied to PFC was given letters relating to the speed with which they were frozen. "A" would be best. There was also a modest programme of collecting plasma only by machine, known as plasmapheresis.

Please explain:

a. where the production of FFP took place;

If blood was collected at the city centre site we had freezing equipment available to rapidly freeze down the fresh plasma. For more remote donation sites the separation of the plasma had to wait until the whole blood donations were returned to the main transfusion centre in Carluke.

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

FFP was separated by centrifugation of the red cells and platelets, and the bag squeezed in a controlled manner to push the plasma into a second

bag. This second bag was detached in a sterile manner and the plasma frozen. I do not recall any useful information about capacity.

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

I have no recollection as to what proportion of blood collections were allocated to this process with regard to the removal of plasma. However, at that time blood component therapy rather than whole blood transfusion was preferred and so most blood donations would have had plasma removed prior to transfusion. It was necessary to provide as much plasma as possible to PFC to achieve or maintain self-sufficiency.

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

I don't remember the arrangements for supplying FFP. I imagine that each hospital would identify its own preferred stock level and then re-order FFP according to which plasma blood groups they required to be replaced. This would then have been delivered in SNBTS vans. This distribution process was regulated and inspected by the MCA [now MHRA].

19. **Please set out any information you hold in relation to the matters addressed in questions 17 and 18 above prior to your directorship of the GBTS.**

I don't hold any information other than in my memory with regard to these issues.

20. **In 2005, you gave an interview to the BBC in which you stated that "Oh the facilities were small, they were cramped, and the staff that worked in them did a fantastic job to keep the plasma supplies coming through" (SBTS0000362_041, page 9). Did the facilities limit the GBTS's ability to meet plasma demand?**

Even 2005 was 16 years ago. The interview I suspect was triggered by the release

of MCA inspection reports under the Freedom of Information Act [FOI] of the facilities at the GBTS facility in Carluke, Lanarkshire. These reports were adverse and suggested strongly that a new centre was needed to replace the outdated facilities. This eventually happened on the site of Gartnavel General Hospital in Glasgow, although the building was reduced in size, as mentioned above at 8.b. The FOI requests were part of the campaign in Scotland for a public inquiry into the transmission of HIV and hepatitis C by blood components and products. This eventually took place under Lord Penrose. The physical nature of the facilities in which FFP was prepared were wooden buildings, perhaps re-utilised from hospital buildings. The blood centre was regulated by the MCA and for some time they had criticised the facilities at Carluke but had agreed that plasma preparation could continue pending the development of a new blood centre which eventually was built in Glasgow. I don't think there was any significant safety concern with regard to virus or other contamination other than that the old facilities made it more difficult to maintain full GMP compliance.

Plasma targets

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

There were targets for the amount of plasma to be collected. I think the targets were probably set by the blood service management board bearing in mind the current and anticipated demand for fractionated plasma medicinal products. The purpose of any targets was to ensure that the needs of patients who required fractionated plasma products could be met.

22. What impact did the setting of targets for the collection of plasma have on decision-making at the GBTS?

I don't recall any specific impact of the targets other than that we obviously had to develop the collection and freezing systems to ensure that the targets could be achieved. Targets had no impact on the quality of the products or on the selection of donors during my time.

23. Please set out any information you hold in relation to the matters addressed in questions 21 and 22 above prior to your directorship of the GBTS.

I do not hold any specific information other than in my memory with regard to these issues.

Plasmapheresis

24. Please set out the extent of the plasmapheresis programme at the GBTS during your tenure. As far as you are aware, did this programme differ from other BTSs? If so, why?

Other than that I remember that there was a plasmapheresis program in Glasgow at the time I don't recall how well developed this was or how great a proportion of plasma was provided in this way.

25. Please set out any information you hold in relation to the matters addressed in question 24 above prior to your directorship of the GBTS.

Again I am relying solely on memory with regard to these issues.

Use of plasma reduced blood and red cell concentrates

26. What steps, if any, did the GBTS 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?

The issues around persuading hospital clinicians to use less whole blood had really been dealt with before my arrival I think. Blood components therapy was well established by the mid-1990s I would have thought. It was something I was strongly in favour of as many of my hospital patients endured adverse reactions to stored blood components. I considered residual white cells contained in red cell and platelet transfusions as contaminants and was very much in favour of universal leukocyte

depletion of blood components. This was eventually implemented as a safety measure against the possible transmission of vCJD by blood transfusion in c.1999.

27. **Please set out any information you hold in relation to the matters addressed in question 26 above prior to your directorship of the GBTS.**

I do not hold any specific information other than in my memory with regard to these issues.

Section 6: Arrangements for obtaining and allocating blood products

28. **Please describe the arrangements in place in the Glasgow and West of Scotland region for the purchase and holding of, and the allocation to haemophilia centres within the region, of factor concentrates and/or other blood products produced by the PFC ("PFC blood products") during your tenure. In particular:**

    a. **Please identify which haemophilia centres were supplied with such products by the GBTS.**

    I don't remember any of this. I recall that the quantities of fractionated plasma products were distributed back to the SNBTS regions on a pro-rata basis dependent on the amount of FFP sent to PFC. I'm sure there must be papers that describe the arrangements then that are still in existence. I believe the main haemophilia centre for adults was at Glasgow Royal Infirmary. Children were mainly treated at Yorkhill Hospital in Glasgow. I don't recall whether there were any smaller centres in our region although it is likely, given geography, that places such as Dumfries may have treated patients locally.

    b. **Please outline the respective responsibilities of the GBTS, PFC, the Scottish Home and Health Department ("SHHD"), and haemophilia centre directors.**

    I think the responsibilities of these groups were discharged mainly through

the operation of the coagulation factor working party, which met on a regular basis to discuss all issues with regard to those medicinal products related to controlling haemostasis.

29. **Please explain whether any forums were established between the GBTS, PFC, the SHHD, 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?**

I think this refers to the Coagulation Factor Working Party[CFWP]. Minutes were certainly taken and circulated and I think a senior member of PFC used to take the minutes and act as secretary to the group. In my time it was mainly Professor Christopher Ludlam who chaired it. I could spend a lot of time explaining what was discussed at meetings but it would probably be better to refer to the minutes, which cover in considerable detail issues around the quality, supply and future projections of the requirement for products. The issue around developing the clinical trials of new and emerging products will also have been an important part of the agenda.

30. **In a statement prepared for the Archer Inquiry in 2007, you wrote: "From the reading of the relevant papers, and discussion with colleagues, I believe it is likely that Scotland was the first country in the world to have become self-sufficient in home-grown, unpaid donor Factor VIII concentrates. This occurred some time in 1983. There was certainly sufficient Scottish derived Factor VIII available for the treatment of bleeding episodes using the regimes of treatment then current" (ARCH0000443, page 7). It is presumed in light of this statement that imported factor concentrates and/or other blood products ("imported blood products") were not used in the Glasgow and West of Scotland region during your tenure at the GBTS. Please confirm whether this is the case.**

I do still believe that it is likely that Scotland was the first country in the world to become self-sufficient in these products. The issue of self-sufficiency in plasma products is a complex one because usage was tending to rise, and I believe is still rising, so it was always a matter of increasing production to ensure that SNBTS was indeed providing sufficient products at each time point. One of the important

functions of the CFWP was for the clinicians to advise SNBTS on the volume of each product needed. Since I worked for a considerable time at Glasgow Royal Infirmary, although not in the haemophilia unit, I was aware that some supplies of commercial imported factor concentrates were indeed used at the centre and I believe this is a matter of record elsewhere. I was not a member of the Haemophilia Centre at that hospital and so I am not in a position to advise what the reasons were for their choice of products.

31. **You also stated "my assessment of the performance of SNBTS and PFC in developing safe, sufficient Factor VIII concentrates at a time of immense difficulty is that they did an outstanding job - as good as any other blood service or company and quite likely the best overall performance of any in the world." (ARCH0000443, page 11). Why did you feel this way? Have your views changed over time?**

I think the ability of SNBTS to provide HIV safe factor VIII concentrates as quickly as it did was indeed an outstanding piece of work and was achieved ahead of most other countries. So, my views have not changed over time with regard to this particular issue.

32. **Please set out any information you hold in relation to the use of imported blood products in the Glasgow and West of Scotland region prior to your directorship of the GBTS, including but not limited to:**
    a. **the arrangements in place for the purchase and holding of, and the allocation to haemophilia centres within the region, of these imported blood products;**
    b. **the respective responsibilities of the GBTS, PFC, the SHHD, and haemophilia centre directors with respect to (a) above;**
    c. **whether anyone at the GBTS contracted directly with any pharmaceutical company involved in the manufacture and/or importation and/or sale of imported blood products;**
    d. **whether the GBTS was 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; and

e. **when, if at all, the Glasgow and West of Scotland region ceased to use imported blood products.**

I do not believe any imported products went through the Glasgow Transfusion Centre, not to my knowledge anyway. It was my belief at the time and I still believe that there was some direct relationship between hospitals such as Yorkhill and Glasgow Royal Infirmary and manufacturers to acquire commercial products. I do not know how these were managed within the budgetary system extant at that time. I'm fairly sure that the GBTS was not involved in decisions about the choice of product used to treat patients with haemophilia and certainly I personally was not involved in such decisions that I can recall. Such decisions would have been made through the CFWP.

Section 7: Production of cryoprecipitate at the GBTS

33. **Did the GBTS produce cryoprecipitate during your directorship? If yes, please describe:**

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

Cryoprecipitate was indeed prepared in the Glasgow Centre in a laboratory at the main Carluke Centre as I recall.

b. **broadly, the process that was undertaken and the capacity of the GBTS to manufacture cryoprecipitate;**

The process that was undertaken would have been compliant with the UK guidelines contained within the red book. I have no recollection of the capacity of the centre to manufacture cryoprecipitate.

c. **what proportion of blood collections were allocated to this process and what sent to the PFC and and how this decision was made; and**

I do not recall what proportion of blood collections were allocated to this. I was there after 1991 and by this time all blood donations were being tested for HIV and Hepatitis C by antibody tests

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d. **how much funding was provided by the SHHD for the production of cryoprecipitate.**

I would be fairly confident that the funding from SHHD would not have been specified with regard to the production of cryoprecipitate but would have been included within the general provision of funding to SNBTS via CSA.

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

I suspect this was the same as for plasma and that once hospitals had fallen below the stock levels that they wished to maintain they would order more cryoprecipitate obtained from the service.

35. **Please set out any information you hold in relation to the matters addressed in questions 33 and 34 above prior to your directorship of the GBTS. The Inquiry would be particularly interested in the following information:**
    a. **what consideration the GBTS gave to increasing the production and use of cryoprecipitate in response to the growing awareness of the risks associated with Factor VIII concentrate products in the 1980s; and**
    b. **the steps taken by the GBTS to increase the production of cryoprecipitate during this time.**

I hold no information with regard to these matters. I was a consultant haematologist in Birmingham at that time.

36. **On the 28 October 2020 you gave oral evidence to the Infected Blood Inquiry in which you stated "to switch from factor concentrate to cryo would have**

really needed some sort of national push to say that that's what's needs to be done because otherwise, you're just going to be creating holes in supply elsewhere" (INQY1000068, page 2). In your opinion, who would this national push have had to come from?

This aspect has been covered elsewhere in some detail although I am not sure where to access the information any longer. I think at the time when there were major concerns about HIV in plasma products the switch from imported plasma products to local cryoprecipitate would have been unpopular with clinicians and patients, hence my comment about requiring a national decision, probably including the Department of Health. The reason for mentioning the creation of 'holes' would be that in Scotland for example if we had begun to produce more cryoprecipitate this would have led to a reduction in our ability to provide factor VIII concentrate. My colleague Peter Foster and I have reported elsewhere, as I recall, that switching from factor VIII concentrate to cryoprecipitate in Scotland would not significantly have reduced the risk of hepatitis C in men being treated for haemophilia WITN6666007 WITN6666007, although had ALT tested plasma been used to produce the cryo this may have reduced HCV somewhat. However, it is probable that the risk of HIV would have been reduced substantially throughout the UK by switching to cryo. But if hospitals in Scotland were using some commercial products in preference to the SNBTS products it is not clear to me that this would ever have occurred other than by edict, such as the MCA rescinding licences for concentrates. What I can be clear about is that when I was a haemophilia doctor in Birmingham I would always have preferred to treat my patients with UK derived products from BPL - that is, with NHS products. In England we did not have access to SNBTS factor VIII. But there was never sufficient product from BPL to enable that there, but I believe there was in Scotland.

The other important issue about reverting back to cryoprecipitate is timing. I believe, from the evidence given last year, that most of the men with haemophilia were infected by 1982. So the switch would have to have been made almost as soon as AIDS was identified in gay men and perhaps when the first person died from transfusion associated AIDS. Perhaps only stopping using concentrates in the mid-1970s when they were causing jaundice and NANB hepatitis would have made a big difference.

Section 8: Self-sufficiency

37. As referenced in question 29 above, the Inquiry understands that you believe Scotland attained self-sufficiency in Factor VIII at some point during 1983 (ARCH0000443, page 7). At the time of making this statement to the Archer Inquiry, what did you understand the term 'self-sufficiency' to mean?

I suspect there never was a well-defined meaning of the term self-sufficiency. At the time of making the statement to Archer I would have considered it to mean producing sufficient quantities of safe and effective coagulation factor products to meet the needs of all patients in Scotland. The difficulty being of course, as I mentioned earlier, that the demand was continuing to rise, so I think there were occasional tensions between the haemophilia centre doctors and the Scottish blood service providers in what precise quantities would represent self-sufficiency. However, I do think that a time of crisis with concerns about HIV, and when there was the strong possibility that UK derived products were safer, then 'self-sufficiency' might have been achieved through modest controls over usage.

I would comment at this point by saying that at no time did the transfusion services in England get anywhere near close to self-sufficiency, however defined, and this includes the period of time when the BPL Centre had hepatitis C safe factor VIII concentrate [8Y], which was not available in Scotland. This English-based product was available in very short supply and as a haemophilia doctor at the time I received very limited amounts of it for my adult patients and still had to rely on commercial products, which although by then HIV safe they were not yet hepatitis C safe.

38. As far as you are aware, did Scotland remain self-sufficient throughout your directorship of the GBTS?

My directorship of the GBTS lasted only little over six months and I can't recall whether Scotland was self-sufficient in that time. During my tenure as NMSD there were definitely periods when we did not maintain self-sufficiency. These would be noted in the minutes of the CFWP.

39. Was 'self-sufficiency' a concept that influenced decision-making at the GBTS during your directorship?

Again I think my short period at GBTS is perhaps less helpful. Self-sufficiency was definitely a very strong concept that did influence decision-making within the whole of SNBTS until the withdrawal of plasma derived coagulation factors and their replacement with recombinant factors.

40. In a draft letter to The Scotsman in December 2000, you compared England's approach to self-sufficiency against that of Scotland's, noting that Scotland achieved self-sufficiency some time before the mid-1980s, while England never achieved it (SBTS0000354_082). From your experience working in both England and Scotland, in your view why was it that Scotland was able to achieve self-sufficiency while England was not?

There was a strong push to achieve self-sufficiency led by Professor Cash, my predecessor in SNBTS, and supported by the then haemophilia centre doctors. Professor Cash obtained funding from the Scottish Health Department to collect enough plasma to move towards and then achieve self-sufficiency. Money was invested in PFC. The relatively small population of Scotland could be supplied by the single PFC plant. England is a much larger country and I think there were major differences in how the Regional Health Authorities [RHA] supported their transfusion services. At that time blood transfusion was a regional activity, and there were 14 RHAs. One production plant at BPL would have had to be very much larger and needed much more investment. In Scotland the levers of government were much shorter than in England. I do recall comments from that time when researching my previous evidence that there was perhaps a degree of impatience from some larger haemophilia centres in England who wished to import the US derived products because they provided improved haemostatic cover for patients.

41. On 28 October 2020 you gave oral evidence to the Infected Blood Inquiry. During this evidence, you stated "And I think that really describes the reasons why the whole self-sufficiency project failed, because there was no central management. It was all left to individual Regional Transfusion Directors, admirable in their own rights, but they would have different priorities."

(INQY1000068, page 2). Please expand on this statement. Was this problem specific to England or was it also experienced in Scotland? In your opinion, should central management have been introduced earlier in England?

This really moves on from the previous answer. The transfusion service in England at that time [1982 until the founding of the NBA in about 1992] was very much regionally based. It could be argued that so was the Scottish one, but at least in Scotland there was a centralised coordinating body in SNBTS. In England each RHA, as was, funded its own regional transfusion centre and service and therefore it would be quite normal to see different priorities in different regions. Regional directors would have different skills and priorities. Unfortunately my RHA [not the Transfusion Centre] in the West Midlands never seemed to consider support or care for haemophilia very highly and this was the reason for some of the comments that I made during my evidence, in particular citing the failure to provide support for the men with haemophilia suffering with HIV. Now we have central management of the transfusion service in England things might be better but the issue of what would have happened over time with regard to plasma products has been obscured by the introduction of recombinant products. Also the banning of the use of UK plasma due to vCJD concerns, only very recently re-instated for immunoglobulin production, clearly prevented any possibility of self-sufficiency, even if that were something that was still desired.

Section 9: Services for donors at the GBTS

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

I do not believe, by any definition of counselling that I can find, that blood donors were given counselling prior to testing for HIV, HCV, or HBV. Information would have been provided by an information leaflet and the donor questionnaire. The fact that these tests would be done was clearly stated on the donor questionnaire that each donor is required to sign. A typical blood donor session might involve 150 people turning up at random intervals - appointments were not usual until the last 10 years or so - making personal counselling impossible. Donors are not patients but

volunteers and were required to complete a questionnaire prior to their donation. If they had any risk factors for the above conditions they were asked to withdraw from donation. I recall that there was also a box that they could tick if they were concerned that their donation should not be used for clinical use. This box was provided in case groups of friends appeared to donate together, and it was difficult for a particular person to self-exclude. Donors were informed through the questionnaire that these tests were going to be undertaken as well as other possible tests. They were also informed through the form that a sample of their donation would be kept for possible future use - this latter after 1985.

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

Donors who tested positive for any of the serious transfusion transmitted diseases were seen by one of the donor consultants or their colleagues in the service. They were seen after being sent a letter asking them to contact the service to make an appointment to be seen. At this point they were advised of the test result and a further sample was taken with their permission, to confirm the result. The staff conducting these interviews were trained and experienced in the role. Individuals who were confirmed as positive for any of the relevant markers were referred to specialist services.

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

Recipients who received infected donations and became positive for any of the relevant viruses would have been tested, had their diagnosis confirmed and advised by the clinicians caring for them. As far as I'm aware these services were not provided by the GBTS or any other parts of the SNBTS during my time working for them.

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

With regard to donors I believe these arrangements were sufficient, but it is highly likely that depending on the part of the country where the donor lived their access to further support might have varied. With regard to patients who acquired transfusion transmitted infections, I believe the same would have applied that there may have been differences depending on where the person was treated originally and where the diagnosis was confirmed. I think we all agree that the arrangements for persons infected through blood transfusions was not sufficient and in many respects it is the purpose of the Inquiry to identify where these failures occurred.

46. Please set out any information you hold in relation to the matters addressed in questions 42 to 45 above prior to your directorship of the GBTS.

I don't hold any concrete information relating to these matters other than from my own memory.

Section 10: Meetings of various committees

Coagulation Factor Working Party

47. The Inquiry understands that you attended meetings of the Coagulation Factor Working Party ("CFWP") for Scotland and Northern Ireland. Copies of the minutes of the meetings you attended that the Inquiry holds, and relevant annual reports, have been provided for your reference: GRAM0000005_002; GRAM0000006_001; GRAM0000007; GRAM0000008; SCGV0000078_005; LOTH0000024_007. What do you consider to have been the purpose(s) of the meetings of the CFWP? Do you consider that these meetings were conducive to fulfilling the purpose(s) for which they were established?

As far as I recall the CFWP was in existence when I joined the SNBTS. My understanding of the purpose of the meetings was to deliver sufficient and safe plasma products to patients with inherited bleeding disorders in Scotland and Northern Ireland. The meetings were crucial in attempting to deliver and maintain self-sufficiency in these products for patients in Scotland and Northern Ireland. I think for many years these meetings were effective in fulfilling their purpose but as in many

areas of medicine progress was made and changed arrangements became necessary. The obvious example was the introduction of recombinant human coagulation factors for the management of haemophilia. Subsequently, concerns about vCJD and its potential for transmission by blood transfusion led to the need to import plasma and indirectly to the closure of PFC.

48. Please explain, as far as you are able, the decision-making remit of the CFWP.

The decision-making remit of the committee was in relation to the quantity of plasma derived products required by the clinicians responsible for the patients with haemophilia and other similar conditions. It also considered the range of products and when product enhancements became necessary on the grounds of safety or improved quality of care.

49. In 2001, you stated to the Scottish Health and Community Care Committee that all doctors responsible for the direct care of people with haemophilia in Scotland and Northern Ireland attended what was now the CFWP, and that the safety of blood products and their specifications were discussed at these meetings (SBTS0000356_022, page 15). Are you able to provide any further information as to the arrangements in place for this discussion between haemophilia clinicians and the SNBTS prior to the establishment of the CFWP in 1991?

In 1991 I was still a hospital consultant in Birmingham. As far as I recall 1990 was when Crown Immunity was removed and what might be considered modern accountability procedures introduced. This would have included the formal inspection of facilities and the licensing of products by the MCA. Beyond that I don't know what happened in relation to the relevant discussions prior to the establishment of CFWP.

50. In November 1997, you attended the first meeting of the SNBTS Coagulation Factor Safety Committee ("CFSC"); a group which was established in response to a request from haemophilia directors that an independent committee consider the safety of future SNBTS clinical trials. During the meeting, you noted that there had been a "mutual loss of confidence" between

the SNBTS and Scottish haemophilia directors following the discovery of a precipitate in SNBTS High Purity Factor IX (BART0002132, page 3). Please further explain the problems leading to the establishment of the CFSC and the role the CFSC played in relation to clinical trials of SNBTS blood products.

I recall that there was a problem with the new version of the high purity factor nine [HIPFIX] and there was some disagreement between SNBTS and the haemophilia doctors with regard to whether the product was fit for use. I recall, either during this meeting or more likely an earlier meeting, that I asked for a break in the meeting and during this break advised the general manager of SNBTS that the new product should be withdrawn forthwith and that no further attempts to encourage the haemophilia doctors to use it should be made. This was on the basis that it was for haemophilia doctors - very senior doctors with extensive experience - to decide which products were suitable to give to their patients. It was for SNBTS as the provider to meet their needs and to focus on modifying the HIPFIX so that it met their requirements. The general manager accepted my advice and the product was withdrawn. I think this episode is what caused the mutual loss of confidence and the feeling that there should be an independent clinical trials management process for SNBTS products that went beyond the relationship between SNBTS and the haemophilia consultants in Scotland. My recollection is that after this we had independent safety and oversight committees to review data that involved senior clinicians in the UK who were neither haemophilia doctors in Scotland nor SNBTS employees.

Standing Advisory Committee on Transfusion Transmitted Infections

51. **The Inquiry understands that the UK Advisory Committee on Transfusion Transmitted Diseases ("ACTTD") was replaced by SACTTI in 1993 following the creation of the National Blood Authority ("NBA"). Please see the attached schedule for copies of the minutes the Inquiry holds of meetings you attended from 1998 to 2005. Please answer the following:**
    a. **What was the function and remit of SACTTI?**
    b. **As far as you are aware, how did SACTTI's remit differ from its predecessor ACTTD?**
    c. **How frequently did SACTTI meet?**

d. Who did SACTTI report to, how frequently and by what means?

e. Did SACTTI have any powers or was it purely advisory?

My understanding was that the loss of Crown immunity in 1991 led to the establishment of the guidelines for the transfusion services of the UK and that SACTTI was the committee tasked with writing the section on transfusion transmitted infection in the guidelines. [some of these changes are described in SBTS0000360_003]. The guidelines were published in a red cover and became known as the Red Book. There were a number of other standing committees that were responsible for writing the other sections of the Red Book and these committees continued over time to amend and revise the Red Book on an annual basis. Subsequently SACTTI developed a reputation for expertise in the field and was used by UK blood services and even occasionally MSBT to provide advice and background documents to brief these organisations. I don't know how the remit of the predecessor committee to SACTTI differed from it. My recollection is that SACTTI met about four times a year. SACTTI was one of a number of committees that reported to the joint professional advisory committee [JPAC] which had previous incarnations as joint executive committee or other such names. The reporting mechanism was by submitting the approved minutes to JPAC. The chair of SACTTI and perhaps the Secretary also sat on the JELC\JPAC group and so would be in a position to report orally.

I think the authority of SACTTI was as an advisory body and its reputation was of a sapiential nature. In other words, its authority came from the quality of its advice. Very occasionally, and the issue with SARS comes to mind in about 2002, SACTTI had a quasi-operational role in maintaining real-time communications with other international blood services in order to ensure that the UK blood services response to the SARS outbreak was appropriate and timely.

52. Please explain the relationship between the SACTTI and the SNBTS, including but not limited to:

a. whether SACTTI made decisions that the SNBTS was required to implement; and

b. whether, and how frequently, you provided feedback on the recommendations made by the SACTTI.

SNBTS was a full member of the JELC\JPAC groups and had members on all of the subsidiary committees including SACTTI. SACTTI made recommendations and did not take decisions and so SNBTS was and remained independent with regard to implementation issues. The SNBTS management board met on a monthly basis and I would have provided feedback on important issues from SACTTI to the board where they were relevant to the actions and requirements of SNBTS.

53. Please explain, to the best of your knowledge, the relationship between the SACTTI and the Scottish BTS.

From the time of the reorganisation of SNBTS there was only a single transfusion service in Scotland with respect to the collection, processing and distribution of blood components. In the few months prior to my becoming NMSD, while I was head of the GBTS, I don't remember what the relationship was between SNBTS and SACTTI. However my predecessor in Glasgow, Dr Mitchell, was an expert in hepatitis viruses and was a very prominent member of the relevant committees. At this distance in time I can't be sure whether he was a member of SACTTI or its predecessor.

UK Joint Professional Advisory Committee of the UK Blood Services

54. You wrote in your previous statement to the Inquiry that you were a member of the UK Joint Professional Advisory Committee ("JPAC") of the UK Blood Services from 1997 to 2010, which "worked to ensure that each UK blood service was aware of what each other was doing, and aimed to standardise activity as much as possible" (WITN4032001, page 4). Please further explain the role of the JPAC. In particular:

a. When was the JPAC established?

b. How often did the JPAC meet?

c. **How did the JPAC standardise policies and decision-making across the UK blood services?**
d. **How did the JPAC coordinate the advice received from the numerous standing advisory committees, such as SACTTI, that reported to the JPAC?**
e. **Was the JPAC the ultimate decision-making body in regards to the advice provided to Ministers on blood safety policy?**

I don't have papers to be definitive about when JPAC was established. There was a previous incarnation known as the joint executive liaison committee (JELC). I think with various changes in the English blood service there was perceived to be a need to change from JELC to JPAC. I think the issue may have been the word 'executive,' which it wasn't. I remember Dr Wallington, who I believe was deputy medical director in England for the blood service, being tasked with changing the arrangements to improve governance. Also at some point and as a parallel development, the four UK blood services in England and Wales, Northern Ireland and Scotland began to meet at a high level on a quarterly basis. This latter group became known as the UK Forum. The chief executive and medical director for each service would attend and other individuals relevant to the business in hand would be invited to the meeting. The JPAC reported to the UK Forum and the JPAC director / head would attend all or most of the UK Forum meetings. This provided a clear chain of command from the professional advice-giving bodies to the executive.

I think JPAC met only maybe twice a year. JPAC operated by consensus and agreement in producing the guidelines for the UK blood services. Certainly JPAC was never the body that provided any advice to ministers in Scotland on blood safety policy. The only body that I was aware of that advised ministers in this area was MSBT, and later SaBTO.

55. **In a letter to Dr Frank Boulton in March 2000, you queried whether a statement on HIV was meant to represent the views of the 'Joint Liaison Executive Committee of the UK blood services i.e. The Red Book group.' (NHBT0002656). Was the Joint Liaison Executive Committee/Red Book Group another name for the JPAC? If not, how did the committees differ?**

The JLEC (Red Book group) was an earlier incarnation of JPAC.

56. In the same letter, you requested that the Joint Liaison Committee discussed how important information should be disseminated due to the issues cropping up with other standing advisory committees. It was your view that management aspects of proposals or statements should be sent through the Red Book Executive system (NHBT0002656). To the extent not already covered by question 52(d) and (e) above, please explain the role and responsibilities of the Red Book Executive Committee in relation to blood safety policies.

I think my communication makes clear that I felt it was important that advice from any of the SACs should go through a formal route and not be disseminated through word-of-mouth or informal channels. I think the establishment of the JPAC arrangements did firm this up and made sure that all four UK blood services were operating, if not in identical ways, but using the same guidelines at all times.

Section 11: Information handling by and information sharing between BTSs

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

My recollection is that we had a computer system for blood donors. I do not recall physically where these were kept or on what computer system or who had access to them at the time.

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

From the start of HIV testing of blood donations in 1985 SNBTS retained samples from each and every donation, which were frozen. For my period of time in the organisation these samples were retained indefinitely. Therefore I would assume also that the donor records would also be kept indefinitely.

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

I do not recall any policies or practices relating to the destruction of our blood donation records.

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

I suspect that prior to the reorganisation and a national computer system being implemented that each region quite likely had different computer systems. I do not recall to what extent these could interact.

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

I think the record keeping measures would probably be adequate, and they were subject to inspection and approval by the MCA. The real issue is that blood donation is a voluntary act and depends on a very great degree of trust between the service, representing patients who are the recipients, and the donors themselves. With regard to preventing donors who were suspected of carrying blood borne infections from continuing to give blood, this would depend on the donor giving truthful information at the time they came forward to donate. If they chose to lie I'm not sure that any system could be effective since information such as passports or identity cards were not in use.

62. 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. Did the GBTS contribute data on HIV positive donors to the database

during your directorship? If not, why not? If so, what data?

b. **Are you aware of whether other BTSs contributed data on HIV positive donors to the database?**
c. **Did the GBTS maintain a separate, or additional, database to track HIV positive blood donors?**

I don't have any memory one way or the other on the contribution of GBTS data to a database. I would have thought that such a database would have required the specific consent of any donor to be included on it. I'm sure we kept a record or a database of HIV-positive blood donors but I don't know whether this would have been used to track them. In fact, I am not quite sure what is meant by tracking HIV positive people or blood donors. I do not know how other blood services might have behaved in this area.

63. **A 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. **What was the purpose of the system and what information was it intended to collect?**
    b. **Was the J donor system re-introduced? If so, when and how did it work?**
    c. **Was the J donor system widely used after the "re-introduction"? If no, why not? If yes, who was responsible for overseeing the system?**
    d. **As far as you are aware, does the system still exist?**

At this distance in time I have a vague recollection of the J donor system but I'm afraid I cannot assist the enquiry any further than that.

64. **In 1998, you wrote to Dr Angela Robinson with regards to a proposed national register of HCV infection with a known date of acquisition. In your letter, you also noted that there was discussion in Scotland about the Scottish Centre for Infection and Environmental Health ("SCIEH") coordinating a register that tracked HCV infection in all its manifestations (NHBT0035397). Please explain**

whether these registers were implemented, and if so, how they operated and interacted.

I do recall these issues regarding the hepatitis C database. There was clearly some value in knowing the natural history of a condition from the date of acquisition of hepatitis C. My recollection is that the register was coordinated by a Dr Harris, probably in CDSC. I also recall a register in Scotland which used a method of anonymisation called Soundex. Whether or not the final decisions came down in favour of obtaining the consent of individuals to go on a register, as I would personally have preferred and as I stated in the letter, I do not know.

65. **In addition to the database(s) mentioned above, did the GBTS share information with other BTSs 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 GBTS used to share this information, if any.**

The question refers here to GBTS. I think there would perhaps been sharing within the five SNBTS regions. Once we had a single blood service there would be only be one database and system. Sharing information with other transfusion services outside Scotland would have been complex with regard to issues of confidentiality and consent from individuals and I do not recall any attempts to do this. I do not recall evidence of donors who were a risk to blood safety going from blood service to service. Perhaps I do not understand this question. Donors who tested positive would be excluded. Donors who self-deferred as, for example, men who had sex with men (MSM) or had used intravenous drugs would presumably continue to self-exclude and not present to donate. Once the issue of vCJD came in however, where there was clearly a perceived risk but no ability to test, compounded by the concept of risk registers of people who did not know they were on a list. In this context the general view was that the maintenance of public health did override issues of confidentiality and my recollection is that some data was shared. These complexities led to the establishment of the CJD Incidents Panel.

66. **In your opinion, were the information sharing measures in place between BTSs**

in Scotland adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations?

I think the measures in place in Scotland would have been adequate to prevent donors who were coming forward and were telling the truth about their identities. However they would probably not be sufficient in the event of someone wishing to use deception to donate. This would be in the context of someone testing negative for a potential infection, who was at risk, yet continued to donate.

In the late 'noughties' occasionally MSM would claim to have given blood to create problems. This was in the context of the campaign to allow MSM to donate blood. Our response was to appeal to their conscience and better nature not to do such things.

Section 12: Knowledge of risk of infections while at the GBTS

HIV/AIDS

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

My tenure at GBTS was fairly brief. In 2006 and 2007, by which time HIV AIDS testing by antibody had been in place for over 10 years.

Subsequent to my becoming NMSD of SNBTS we did continue to be concerned about the risk of transmission of HIV from blood transfusion. The SNBTS Microbiology Reference Unit [MRU] was my responsibility and the lead scientist, Dr Brian Dow, and I met regularly to review the epidemiology of blood donors in Scotland. I think there is some later correspondence which reflects the increased number of HIV-positive donations we were detecting in Scotland. This led us to wish to introduce an additional test using an HIV nucleic acid test [NAT] that would substantially reduce the 'window period' in which a person might be infected with HIV and not test positive. This measure was contentious because other UK blood services were not using NAT at that time. There had been a long-standing view that

all UK blood services should use equivalent tests and that these should be introduced all together on the same day - not a view that I ever agreed with. Our argument was that we had evidence in Scotland of a higher risk than elsewhere and this needed to be reduced. We did introduce NAT using mini-pools of donor samples and within the first 6 months did intercept a HIV positive donation that would have been missed by the antibody test we were using at that time. [see discussion of this in NHBT0089655].

Hepatitis

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

Again during this period testing for hepatitis B and hepatitis C had been ongoing for some years. However my relationship with the MRU meant that we regularly reviewed the data and in particular were looking at any difficulties in detecting or confirming results in positive donations, and the management of these.

General

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

By the time I was working in this area the seriousness of these conditions was well-known and donor selection policies were in place. In the early period of my time there was concern that referring to gay men was likely to miss a number of men who engaged in homosexual acts and so the wording was changed, and the term 'men who have sex with men' [MSM] introduced. There were numerous other areas relevant here as to individuals who had travelled to Africa. Most of these issues would have been considered in detail at the SAC for the care and selection of donors and the deliberations from that group passed for approval to JPAC and then back to SNBTS for consideration and implementation. The seriousness of an HIV transmission by blood was the reason why I continued to oppose relaxation of the exclusion of MSM from donation. In fact, had I not already given notice of standing

down as a member of SaBTO in 2010, I would have had to resign from it as I disagreed with the advice that a relaxation in the deferral rules for MSM was appropriate.

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

I don't think there were any special measures in GBTS, other than the MRU was based there due to the special expertise of my predecessor, Dr Mitchell. These issues were discussed at the regular meetings of the SNBTS Medical & Scientific Committee [MSC: as I remember it was called].

71. What if any role did the GBTS 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.

With regard to the plasma products produced by PFC these all contained warnings about the potential for virus transmission from an early stage and these were included on the literature contained within the box. Also, discussions at CFWP would have included discussions about the risks of infection and certainly in my time, when vCJD was the big concern, these were considered in great detail. I recall that the wording on blood bags for platelet, red cell and FFP transfusion was changed to mention vCJD. I would acknowledge that although these changes to leaflets and labels was essential, it was far from sufficient and that some form of detailed information for patients would be required to be given by the treating clinicians.

What information was given to hospitals about the potential risk of blood component therapy I don't know from prior to my joining the service in 1996.

In the main the operational delivery of blood transfusion components - that is red cells, platelets, and FFP - in hospitals was not conducive to giving advice to recipients and this was one reason why I felt it was important that consent to receive a transfusion

should be implemented. This certainly never occurred during my time despite lobbying and arguing and as far as I'm aware probably still doesn't. Having read the recent version of the SaBTO independent document on consent I would still consider that this provides so many opportunities for consent not to be obtained, or not to be genuinely obtained as to make it hardly worthwhile.

Section 13: Reduction of risk of infections

Donor selection

72. What donor selection policies and processes were in place during your tenure at the GBTS?

Selection policies would have been in place as defined in the 'Red Book' guidelines and would have been clarified by the form that donors had to sign. These forms changed over time and included more and more information for donors. The necessary criteria were developed and defined by the SAC for the Care & Selection of Donors and recorded in the Red Book guidelines. This in turn would be converted into a donor identification form. I assume that these forms are still available to be seen by the IBI and it would be easier to work from a direct copy rather than my memory.

The selection policies were uniform across the UK based on the Red Book guidelines and inspected for compliance by the MHRA. When the EU blood directive was implemented this would also have informed selection criteria.

SaBTO also had a role in donor selection and as I was leaving the UK in 2010 advised Ministers that MSM should be allowed to donate after a period of 12 months from last risk.

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

I think the high risk categories were well established by the time I joined the service, which included intravenous drug use at any point preceding, any homosexual act, and a whole range of travel exclusions, previous illnesses et cetera. These guidelines and requirements were reviewed on an annual basis by the Red Book group and the SNBTS would have implemented these in full.

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

I don't recall during the eight months or so I was at GBTS. With regard to the exclusion of donors subsequently there was a long-running issue around the ability of men who had had or were having sex with men to donate blood. This was a contentious issue publicly and required a lot of attention, both to ensure the exclusion policy was fair and was clearly explained. My view was that it was the responsibility of SNBTS and myself as NMSD to ensure as far as possible that the blood supply was safe. If there was a requirement for government to extend the opportunity for blood donation to other groups on the basis of equality, then that was a matter for ministers to accept the risk not myself, and preferably not the patient recipients. It wasn't difficult implementing, rather it was the perception that needed to be managed.

75. 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 BTS in Scotland produce its own leaflet?

There was certainly an agreed leaflet in my time throughout the whole SNBTS. I think there were variations earlier in the early 80s and I think the production of a leaflet that related to the risk of AIDS by the Edinburgh group was considered to be quite important and trailblazing. However by the time I joined the service all these issues were well established. On further recollection the donor form was highly regulated by the MCA then MHRA, particularly after the EU Blood Directive came into force since aspects of donor selection and exclusion were legal requirements.

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

The donor selection leaflet and questionnaire was regularly reviewed UK wide through the Red Book organisation, on an annual basis. The form would have to be compliant with the EU Blood Directive. Had there been any requirement for more rapid implementation of change this would have been done, and was done. Travel rules changed regularly and the West Nile Virus outbreak in the USA caused numerous changes to the travel rules that had to be implemented promptly. These would have been approved on an emergency basis and implemented via change control procedures in the Quality Management System. It wasn't necessary to wait for a new version of the Red Book. As far as I can recall this also occurred with relation to SARS in or about 2001-2002, when travel from areas that had seen a lot of SARS, such as Canada and Hong Kong, would have led to donor exclusion on an immediate basis.

77. **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?**

Not sure I can add to this. I think the important issue is what written information was given to donors. I'm not sure what other mechanism, perhaps advertising, would have been effective. On reflection, and remembering when I was a blood donor, reminders would be sent out to encourage the next donation. This would have been an opportunity to provide more information. I do not recall if that happened.

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

When hepatitis C testing was introduced in Scotland in late 1991 the incidence in blood donors coming forward was about 10% of the numbers seen in the general population in Scotland at that time. This is from memory. This suggests that donor selection criteria did have some considerable impact and that some of this was due to self-deferral of at risk donors. Clearly one would have liked the reduction in HCV positive donors to have been down at perhaps 1% level or lower.

79. Please set out any information you hold in relation to the matters addressed in questions 78 to 84 above prior to your tenure at the GBTS.

I don't have any concrete information other than having just answered this from memory and from some of the information the Inquiry has provided and reviewing the SaBTO advice on patient consent.

Introduction of virally inactivated products

80. In a draft letter to The Scotsman in December 2000, you compared Scotland's approach to the introduction of HIV-safe and Hepatitis-safe products in the 1980s to that of England's, noting that Scotland were able to produce their HIV-safe product "in sufficient quantity to meet the needs of all patients in Scotland, avoiding the need for unsafe products to be imported for any patient" while the majority of your patients in England continued to be dependent on imported plasma products (SBTS0000354_082). Please further explain your understanding of the development of heat-treated products in Scotland and England in respect of both HIV and Hepatitis. You may also find HSOC0009717, your comments in your statement to the Archer Inquiry (ARCH0000443), and your comments in your previous statement to the Inquiry (WITN4032001) of assistance in answering this question.

In order to further explain my understanding of the development of heat-treated products in Scotland and England in respect of both HIV and Hepatitis, I refer to two documents prepared by the Scottish Government Health Department in October 2000. I think this exercise was known as the 'Deacon' report after the then health minister in Scotland. The main report is entitled "Hepatitis C and heat treatment of blood products for haemophiliacs in the mid 1980s" It is accompanied by a timeline document as Annex A. Haemophiliacs and Hepatitis C Timeline. Although both relate to hepatitis C specifically they also cover HIV. The timeline [20001001-SEHD-report-HCV-timeline] states on page 5 that after hearing in November 1984 of the efficacy of 68°C heat in destroying HIV, the PFC staff successfully treated a year's worth of FVIII stock in December of that year and all stocks issued after that were HIV safe.

In the main report "Hepatitis C and heat treatment of blood products for haemophiliacs in the mid 1980s" the conclusion states on the second page [unnumbered - the first three pages of this report are unnumbered and numbering begins with '3' on the fourth page] that the SNBTS "were around 18 months behind the Bio Products Laboratory in England in producing a heat-treated product which was subsequently found to have eliminated the hepatitis C virus:' The report acknowledges that there was no way of knowing that heating at 80°C for 72 hours would prevent hepatitis C transmission because the virus was then unidentified and indeed has never been cultured. Knowledge of the efficacy of this degree of heating had to await trials in patients. What it does not state is that no other pharmaceutical company or country was able to produce an HCV safe product before BPL and then SNBTS did so. Further, although the English product was excellent and safe, I speak from personal experience that it was in short supply and, not unreasonably, mainly directed to children and previously untreated patients. The Deacon report states in the chronology of the main report [third unnumbered page] for September 1985 that "BPL heat treating all of its Factor VIII at 80°C for 72 hours. This accounted for 25% of the requirement in England and Wales." Scottish haemophilia units therefore received sufficient HCV safe product for most of their patients - if not all - before this occurred in England. And in England this was still a mixed economy of imported products and UK plasma derived products.

81. In the evidence you gave to the Archer Inquiry, you stated that "it is a misrepresentation to imply that Scotland did not introduce Hepatitis C-safe products quickly enough when this was achieved some years before for example in other countries like Australia, France and the United States" (ARCH0000443, page 7). Do you still hold this view? If so, why?

Yes.

The 'Deacon' report quoted above in my response to question 80 states that a "preliminary clinical report issued in September 1986 suggested that 80-C dry heat treatment was indeed effective against NANBH." [para.27]. This was the first evidence that this degree of heat treatment might prevent NANBH transmission.

82. Please explain the extent of your involvement in the development of virally inactivated plasma in the late 1990s/early 2000s. You may find HCDO0000133_086 and page 9 of PRSE0002021 of assistance.

During this period attempts were made to develop fresh frozen plasma [FFP] treated to reduce the risk of virus transmission. My recollection is that neither the methylene blue treated [MB-FFP] product nor the UV-light product were ever introduced to the clinic. I am not sure if either ever completed - or perhaps even began - clinical trials but perhaps the IBI or SNBTS can provide evidence of what progress was made. There were issues with the MB-FFP having a blue caste to it that made clinicians have doubts about its likely acceptance by patients. Either the MB product or the UV product was withdrawn when one - probably the first - patient to receive it had a reaction[s]. I do observe that the internal briefing note from Dr Keel regarding the MSBT meeting held on 16 February 1999 [SCGV0000210_031] states that "SNBTS are now producing small quantities of methylene blue (MB) inactivated plasma to supply current demand, which apparently is low." This suggests that we were issuing such a product. My involvement would have been, with the general manager, to approve the R&D to develop the product, monitor progress as it moved forward and to then discuss with potential user colleagues, probably through the CFWP, how to begin clinical trials. MCA or MHRA approval would have been necessary before it could be used, either in a trial or for non-trial use.

83. Please refer to SBTS0000379_018, a transcript of an interview you gave with BBC Radio Scotland in 1999. At page 2, you state that "dealing with the HIV threat was the priority," such that hepatitis-safe blood products heated to 80 degrees Celsius were gradually phased in, while those heated less intensely (and which therefore may have transmitted hepatitis) remained in use.

I was not working in Scotland in the 1980s [this period]. So my views are an interpretation of information made available to me at that time and subsequently.

Please explain:

a. The rationale behind the decision to prioritise HIV over HCV/NANB in respect of such products;

In the late 1970s and 1980s it was well known that coagulation factor concentrates transmitted hepatitis, that became known as NANB hepatitis. The consensus at the time was that this was not a very serious issue, or at least not serious enough to justify ceasing to use the plasma products. Clearly this consensus proved to be incorrect and NANB hepatitis represented a serious disease with a long latent period. At that time most patients were continuing in good health. When HIV/AIDS was a risk of using these products, it was immediately recognised as a highly dangerous condition, leading to death in most cases within 2 years of diagnosis of AIDS. That was the rationale for prioritising prevention of HIV, which seems reasonable given the circumstances and understanding then present.

b. How demand for blood products influenced the decision to phase in products heated to 80 degrees; and

Since I was not there at the time but working in hospital haematology in Birmingham, I don't think I can answer this question directly. The alternative to 'phasing' in would have been to withdraw the 68°C heated produce while building stocks of the 80°C for 72 hours product. This would have left patients in Scotland with no local product, having to be switched to commercial products that were not HCV safe, when there was no certainty that the 80°C for 72 hours was going to prevent HCV transmission. Having worked through the period when BPL withdrew their product when I was in England, it is not a scenario I would recommend, attempting to care for patients with life-threatening bleeding disorders with insufficient product.

c. What other factors, if any, prevented the SNBTS from heating all blood products more intensively (and specifically to deal with hepatitis) prior to 1987?

I think the reasons are well spelled out in the Deacon report of October 2000 referred to in my response to question 80. I don't think I can add to

that since I was not there at the time.

Provision of diagnostic screening kits

84. Please describe the arrangements in place at the GBTS in regards to the provision of diagnostic testing kits for donation screening ("screening kits").

My only recollection from 1996/97 is that the 5 regions in SNBTS had different testing systems. In Glasgow we had "Abbott Commander" but were planning a move to "Abbott Prism", and I recall we had one "Prism" machine being evaluated. Some of this divergence was based on differing volumes of tests to be done. Our smallest Centre in Inverness used a system geared to small volume testing, that had been developed in Inverness to deal with the needs of the centre. These variations were swept away when SNBTS re-organised into a single service with then two processing and testing sites with a common system [Abbott PRISM as I recall].

In the GBTS when I joined the service we were running on a "Commander" system for testing donations for hepatitis B, C and HIV. This was also an "Abbott" system. I do not know what the procurement process was prior to me joining.

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

I do not believe there were any personal contractual arrangements, and certainly not with me. Procurement was done through CSA / NSS as I recall, and was highly formalised. We did receive many gifts of small numbers of new tests and kit systems to test in the MRU, to compare with the tests we were using.

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

There would have been tendering documents which I suspect still exist. Important criteria would have been specificity of the test, sensitivity of the test, throughput of the machines, ease of use [walk away systems], cost and experience with the

supplier. It was not an area at which I professed expertise, but we had able individuals in SNBTS who could do all this. It would have been led by the Operations Director. The tendering and decision process was carried out independently to ensure transparency within CSA.

87. **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?**

I don't recall any special influence. Clearly once a service committed to a particular company's platform this was not something that could be changed quickly or easily. It was more likely there was interaction with engineers regarding equipment than with sales or marketing persons. There would certainly be advice about the operational introduction of machines - it would have been very foolish not to have been taking such advice.

Surrogate testing

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

Both of these issues were germane well before I joined SNBTS.

a. **HIV; and**

I was aware that in the USA surrogate tests were used for HIV including an antigen test and anti-HBc. At that time, in the 1980s, I was not competent to judge their merits - I was a hospital consultant not working in blood transfusion services - and I am not sure I am now. I was more concerned with what I considered to be delays in the introduction of testing of blood donations for HIV in the UK. I was aware that trials or studies of testing for HIV in pregnant women were being done locally in Birmingham and that it must be possible to test blood donors. I discussed this with my local transfusion centre director. I was worried about all my patients, but from

the blood transfusion point of view it was the sickle cell patients and bone marrow transplant recipients who gave me most concern. We knew already that many of the men with haemophilia were testing HIV positive and they were not in the main receiving blood component therapy, only plasma products. I knew other countries were testing blood donations and that the UK was not, and came to know that testing was to begin in autumn 1985 on a specific date. In effect, this date was to accommodate the blood centres least competent to introduce the tests. I could not understand, and still neither understand nor accept, why testing of the UK blood supply did not begin earlier, and why tests were not introduced as soon as possible rather than waiting for the slowest to catch up. We now know that some of this delay was due to 'testing nationalism', waiting for the Wellcome test to come through. I dread to think of how many people were infected by blood transfusions during this period. I would say that my local centre director in Birmingham was also most uncomfortable with this delay and I suspect may have been testing prior to the agreed date, perhaps under the guise of a 'pilot' programme. In which case, well done to him. This delay, and the similar delays around introducing hepatitis C tests around 1990 were what stimulated my career move into blood transfusion.

b. NANB/HCV.

I think surrogate testing for NANB using ALT should have been introduced in the UK. All the arguments I have seen relate to the issues of what to tell donors in the event of a high ALT being discovered. While I would expect consultants with responsibility for donor care to raise these issues as a problem, I believe they should have been overruled and ALT brought in. There may have been issues of supply but this did not seem to be a problem in Germany, which I think at that time may have used more blood per capita than in the UK. Some of these operational 'difficulties' were the sort of thing that could have been considered had the European Blood Alliance been operating. Sadly, the UK ploughed on in isolation to not implement. Any improvement in safety of transfusions would have been worthwhile and have saved lives. Even donors with high ALT may have benefitted by being informed, by subsequent monitoring, early intervention of liver disease and

advice about alcohol use. I am sure we will return to this issue later.

89. Please explain whether anti-HBc or ALT testing was carried out at the GBTS during your directorship.

I am fairly sure neither was used for screening. ALT probably not used at all either in GBTS or SNBTS generally. On reflection, perhaps ALT was tested on some donors to ascertain what the outcome of screening might be. But this would be speculation. I do not think anti-HBc was used for screening but would have been used in investigating donors who tested positive or perhaps were indeterminate for HBsAg. It was certainly one of many tests used in the MRU for investigating potential transfusion transmissions.

90. Please set out any information you hold in relation to the use of anti-HBc and/or ALT testing at the GBTS prior to your directorship.

I do not have any information on this.

91. In March 2001, you stated to the Scottish Health and Community Care Committee that the safety of Factor VIII products for haemophilia was not affected by whether the SNBTS undertook ALT testing (SBTS0000356_022, page 8).

a. Please further explain this view and confirm whether your view has changed since making this statement.

Briefly, this relates to the high prevalence of hepatitis C in Scotland at that time and that the reduction in ALT positive donations would not have made a huge impact on the large pools used to make Factor VIII. Even reducing the number of infectious donations by half would still have left enough infected donations to make the whole batch transmit Hepatitis C. There may have been a small impact for the risk of cryoprecipitate, especially for low use patients - that is, mild haemophiliacs, but not for concentrate. 91b below expands on this point. It isn't the same thing as saying it wouldn't have been better to take out as much infectivity as possible, it's just that

the outcome in terms of numbers of patients infected would have been the same. So in this regard my view hasn't changed.

b. **You later stated that "we can provide calculations to show that all our pools would have been infected by donations--even with ALT testing" (SBTS0000356_022, page 10). Please provide these calculations and any associated documents relating to this point.**

Between 1 and 2% of Scots are believed to have been HCV positive at the beginning of the 1990s. In blood donors it was reduced to about 0.1-0.3%. ALT testing was only, as I recall, about 50% effective so 0.05-0.15% of donations. Once we get to a plasma pool of between 5,000 and 7,000 for making coagulation factors the probability is that 5 to 21 HCV positive donors will be in any one pool. So reducing this by half will still leave all batches infectious. US plasma was ALT tested and yet all batches of US coagulation factors would transmit HCV prior to effective heat treatment. My colleague Dr Peter Foster provided a more precise calculation based on risk from cryo in WITN6666007, which would be a better source.

92. **During the same session, Angus Macmillan Douglas of the SNBTS stated that the SNBTS' decision not to introduce ALT testing was "clinically driven" and "was not a resource issue" (SBTS0000356_022, page 8). Please explain whether you agreed with Mr Douglas' statement at this time. Has your view changed since? What did you understand the clinical reasons for not introducing ALT testing to have been?**

As I mentioned above at 88b there was reluctance to upset donors with a complex issue like a high level of ALT. But Germany managed it, as did the USA and many other countries. In the main the UK has tested for fewer transfusion transmitted diseases with fewer tests than other equivalent countries. But I think it was true for Mr Macmillan Douglas to state that blood transfusion clinicians in the UK were not in favour of ALT testing, so perhaps that is clinically driven. But perhaps not driven by the right clinicians. Perhaps those treating patients at risk of transfusion transmitted infections - patients like those with thalassaemia or sickle cell disease, or leukaemia patients - might have been consulted.

Whether resources were ever sought or even estimated I do not know.

HIV testing

93. The Inquiry understands that screening for HIV ("anti-HIV screening") was introduced in Scotland prior to your tenure at the GBTS. However, the Inquiry would be interested in any information you hold in relation to the implementation of anti-HIV screening at the GBTS, including but not limited to:

a. whether anti-HIV screening commenced on or before 14 October 1985;

My recollection is that the date of 14 October 1985 was when all labile blood components issued had been tested negative for anti-HIV. I recall that testing began sometime around the middle of September that year and that during the period when testing began until all components / donations had been tested, untested stocks continued to be used and were perhaps issued from blood centres. I was not a member of any blood service at that time and played no part in these decisions.

As I recall the test used was an early phase test developed by Wellcome laboratories. It was usual practice in the UK blood transfusion services to always have an additional test for confirmation purposes. I do not know if such a test was used in those early months, or what it was, or when such a confirmatory test was introduced.

b. the process for screening donors and/or blood donations;

I don't know what questions were used at that time in 1985 to identify donors who would have been at higher risk of HIV. I believe that my Edinburgh colleague, Dr Brian McClelland, was very early in producing a leaflet for use at sessions to explain which risk factors and behaviours should lead to self-deferral.

c. **what happened to the unscreened blood that had been collected prior to anti-HIV screening being implemented;**

As far as I can recall the unscreened blood that had been collected prior to the testing being introduced was placed at issue in transfusion centres and was available to be issued to hospitals. With plasma products it is possible to build stocks then withdraw old untested stock and replace it with new, tested batches. Labile blood products like red cells have a shelf-life of 35 days, so it is hard to build a stock and recall untested units. However, it would probably have been possible to take back untested hospital stock and replace it with tested stock, then test the returned units to enable them to be placed at issue as safe products. I was not a member of any blood service at that time and played no part in these decisions.

d. **what happened when a donation was found to be infected with HIV (please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor); and**

I don't know the answer to this from any personal experience. If it had been a first time donor my expectation would be that the donor would have been informed and referred on, perhaps following further testing, to an appropriate HIV management service. If the donor had given on previous occasions I presume that a look-back would have occurred in terms of identifying where previous donations had been sent and to whom they would have been transfused. In SNBTS, one purpose of keeping archive samples from previous donations is that these could be taken out and tested again to confirm whether they were indeed negative at that time.

e. **the impact the introduction of anti-HIV screening had on the GBTS, including but not limited to the financial impact of screening, the impact on those working at the GBTS, and the impact on the risk of transmission of HIV through blood donations.**

I am not sure I understand this question. I would have hoped that the introduction of anti-HIV screening would have been wholly beneficial and would have reassured staff, donors and recipients that the blood supply was being maintained as safely as possible. The impact on the risk of transmission of HIV through blood transfusion would have been very markedly reduced, but sadly it was not zero. There was one well known case affecting a recipient of a bone marrow transplant who was infected by a transfusion of platelets. This platelet donation had been tested negative for HIV antibodies, but it turned out to be a window period donation and the donor subsequently tested positive. I am sure the staff in the blood centre were very disappointed in this outcome.

I would assume that the budget for testing for anti-HIV would have been provided from the SHHD as was. But I wasn't there at the time.

94. **A draft position paper from November 2002 noted concern about the potential for HIV transmission via blood components following an increase in HIV prevalence in Scotland. It stated that considering its "vulnerable position," the SNBTS had taken the step of introducing a second test for HIV "to achieve a level of security which is currently offered in other blood services by way of HIV "combi" assays or HIV NAT" (NHBT0089655, page 1-2). Please explain which additional test was introduced by the SNBTS in 2002 and explain how this improved the safety of blood components with respect to HIV.**

I was personally involved in this issue. As the document states it became clear in 2002 that there was an increase in the number of people in Scotland being diagnosed with HIV. My colleague Dr Brian Dow biomedical [scientist at the MRU] and I were very concerned at an increase in the number of HIV-positive blood donors presenting as donors to the service. At that time as I recall the test being used in Scotland was a single antibody test rather than an HIV Combi test. We were concerned that the antibody test, although very effective, may have been insufficient to fully protect the blood supply. My recollection is that it would have taken too long a period of time, I don't recall how long at this distance in time, to change the regular HIV assay to a more sensitive Combi version. Neither do I know now whether the Combi assay itself would have been sufficient to protect the blood supply from this increase in numbers

of persons with HIV coming forward to donate. I therefore recommended, and the SNBTS management board agreed, that we should introduce a mini pool PCR assay for HIV nucleic acid test [NAT]. This was chosen because SNBTS had the expertise and equipment to introduce this test promptly and at reasonable cost [I no longer recall what the cost was]. This was done but I'm not entirely certain of the date. The second page of the document that you refer to suggests that this occurred on 2 November 2002. My recollection is that the funding for this was agreed by the then Scottish government health department. With regard to the improvement in the safety of blood components I do know that within the first six months of introducing the mini pool NAT we intercepted an HIV antibody negative donation which was positive only using the mini pool NAT assay. This prevented the transmission of HIV to at least 2 recipients of what would otherwise have been an infected platelet donation.

HCV testing

95. The Inquiry understands that screening for HCV ("anti-HCV screening") was introduced in Scotland prior to your tenure at the GBTS. However, the Inquiry would be interested in any information you hold in relation to the implementation of anti-HCV screening at the GBTS, including but not limited to:

a. when the GBTS commenced anti-HCV screening;

I assume this occurred at the same time as HCV screening began in the rest of the UK on 1st September 1991.

b. what funding and operational support was provided to the GBTS to aid in the implementation of testing;

I don't know the answer to this question. It was prior to my joining the service.

c. the process for screening donors and/or blood donations;

As far as I recall the test introduced was a second generation anti–HCV test and would have been applied to every donation. There was much debate and dithering over the introduction of a first generation test as I became aware later. This seemed an example of the best being the enemy

of the good, the good being to have introduced the first generation HCV test as soon as possible.

d. what happened to the unscreened blood that had been collected prior to anti-HCV screening being implemented;

I am sorry I don't have a definitive answer to this question, but I presume that for a period of a few weeks there would have been a mixture of unscreened and screened blood components issued by blood centres throughout the UK.

e. what happened when a donation was found to be infected with HCV (please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor); and

I think this would have been exactly the same as for HIV testing. Obviously the service to whom HCV positive donors would have been referred would not be the same as donors with HIV, but to a liver or GI medicine service, either directly or via a GP. I was not a member of any blood service at that time and played no part in these decisions.

f. the impact the introduction of anti-HCV screening had on the GBTS, including but not limited to the financial impact of screening, the impact on those working at the GBTS, and the impact on the risk of transmission of HCV through blood donations.

Since the anti-HCV screening in the UK had waited until the second generation test was available the results were very reliable from the beginning. The impact on the risk of transmission of HCV through blood donations would therefore have been very substantial.

Recall practice and procedure at the GBTS

96. Please give an overview of product recall practice at the GBTS during your directorship.

I'm afraid I don't remember the systems in use at that time some 25 years ago. Recall procedures would have been approved and inspected by the MCA.

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

I do believe that there were formal recall procedures in place and I suspect that these are described in the relevant editions of the Red Book from that era. Recall procedures were highly controlled procedures within the Quality Management System and would be reviewed and approved by the MCA.

98. 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?

I don't recall from that early. But in my experience subsequently there was good cooperation in terms of recall requests, although with regard to fresh blood components such as platelets and also red cells, it would be unusual for these products to have remained at issue due to the timescales between donations. This means that if a repeat donor came along and was found to be positive for one of the infectious markers it would be highly likely that previous donations would already have been transfused or become outdated and therefore be destroyed. The exception would be plasma, whether as FFP or sent to PFC for fractionation which has a longer 'shelf-life.' Therefore issues around recalling fresh frozen plasma would have been important and also of course the recall of any manufactured plasma products made from such previous donations. These were issues that Quality Managers and the SNBTS Qualified Person would deal with.

Recall of unheated blood products

99. In evidence to the Archer Inquiry (ARCH0000443, p. 5), you refer to the withdrawal of non-heated NHS product in England in May 1985. As far as the Inquiry is aware, there was no formal recall of non-heated Factor VIII in England, although this was phased out and replaced gradually by several heated products.

Despite your finding no record of a formal recall I do have a very strong memory of the withdrawal from use of non-heated BPL factor VIII in that period of time. I would accept if you have no evidence that there was no formal recall but that is not my own personal recollection. This was of course 36 years ago.

a. Please confirm whether you understand there to have been a recall of non-heated Factor VIII products;

I did understand that there had been a recall of non-heated NHS factor VIII products. Perhaps BPL withdrew the product from use and my colleague in Birmingham managed this as a formal recall, which seems wise. Either way, one day we were using BPL factor VIII and the next we weren't.

b. If such a recall was initiated, please outline the extent of this. How was such a recall initiated? What was the response to the recall?

The impact of the withdrawal from use of the BPL product was really quite marked. Although the product was responsible for a significant minority of the factor VIII used in the Birmingham Centre its removal from use did have a big impact. My recollection is that this took place over the weekend, at a time when I was on holiday leave. My colleague Dr Hill and the haemophilia nurse at the time spent a very considerable amount of time ensuring that the product was traced back to individual patients who were contacted and asked to quarantine and bring back the product. The other response to the shortage was that we now had insufficient material to

maintain patients on home therapy and indeed we had barely enough treatment to maintain emergency treatment as I recall. My colleague and I had to get in touch with a number of the other importers / suppliers of US product to see if we could obtain any further supplies. I would have to add the caveat that given the length of time that has passed since this happened I couldn't be certain as to the precise dates when this occurred.

Recombinant and synthetic products

100. Please describe the extent of your involvement in the development and use of recombinant and synthetic products in Scotland. In particular, please explain your role in the Recombinant Factor VIII Consortium Group (SCGV0000116_032; SCGV0000116_031).

I had no personal involvement in the development or the use of recombinant or synthetic and coagulation factor products in Scotland or indeed anywhere else. I think my role as part of the Recombinant Factor VIII Consortium Group was to provide information from the blood transfusion service as required and also to report back to the service the deliberations of the group. Until I read these papers I did not remember that SNBTS had been holding stocks of recombinant factors, but I don't believe we ever were involved in making these. I think it was simply that we were a convenient and MCA/MHRA licensed distribution site at that time. Some years before I joined SNBTS I believe there had been a project to scope whether SNBTS could develop and make recombinant products, but this never happened in my time.

101. Please explain how the development and use of recombinant and synthetic products impacted the production of plasma products at the PFC. You may find RLIT0001231 of assistance.

There are really two major issues that impacted the production of plasma products at PFC. One of these was the switch away from plasma derived coagulation factors to the recombinant factors. The second was the decision to cease using UK plasma because of the concerns about variant CJD. For a range of complex reasons, after the switch from plasma derived to recombinant coagulation factors, the decision was taken to continue making albumin and immunoglobulins and some other products.

In retrospect this was probably a mistake from an economic perspective. The fact that plasma derived coagulation factors were no longer required from PFC should probably have been sufficient to conclude the activities of the enterprise. But that would have cost a lot of lost jobs of skilled people, and the albumin and immunoglobulin products were good and fully licensed. It was a difficult call.

Even after the requirement to cease using UK plasma for these residual products it was decided to continue to make them using imported plasma. This added a lot of cost to PFC's business, so the cost base increased as the product range declined.

Before the ban on UK plasma there were some discussions about whether PFC could continue to make plasma derived coagulation factors and market these in jurisdictions which were unable to afford recombinant factors. It should be said that many developing countries at the time had people with haemophilia with no access to treatment. However I took the view that it would be unethical to do this on the basis that these products were no longer acceptable in our home market. After some discussion this view prevailed.

Autologous transfusion

102. In an SNBTS briefing note on "CJD and Blood Transfusion" (BART0002129_017), written in 1997, you advised that "the SNBTS will continue to assist and advise on the provision of autologous transfusion to patients for whom this is suitable" (p. 3). To the best of your knowledge, how extensive was the provision of autologous transfusion by the SNBTS by 1997?

I don't remember any significant activity in the field of autologous transfusion. These services would have been provided by my clinical director colleagues locally in Scotland at Glasgow, Edinburgh, Aberdeen, Dundee and Inverness, rather than by myself.

103. In a letter written to L Love in September 2000 (JPAC0000142_030), you stated that "autologous pre donation would only help for that small proportion (perhaps 5%) of individuals of which the patient is fit enough and has an

appropriate disorder suitable for autologous donation" (p. 2). In contrast, a 1989 report by the British Medical Association suggested that, based on figures from the US, "25% of all elective cases" may have been eligible for admission to an autologous transfusion programme (NHBT0010270_003, paragraph 34). The same report also referred to a retrospective study carried out in Glasgow, which concluded that "only about 3% of patients were suitable for autologous transfusion," a figure closer to your estimate of 5%.

a. **Please outline how you came to calculate your estimate of 5%.**

   I do not recall how I calculated the estimate of 5%.

b. **In your opinion, why was there such a difference in the percentage of patients thought suitable for autologous donation in the above three studies?**

   Of the three estimates two came to a very similar figure of between three and 5%. I don't think my figure was based on a study however. The United States data is not necessarily relevant to the UK. Nor is the date of 1989 necessarily relevant to hospital practice in 2000. At that period of time the US transfused a lot more blood components per capita than was the case in the UK as I remember. So if a lot of unnecessary transfusions were being given it's not surprising that a lot of these could have been accommodated using an autologous transfusion program. Also in the UK there was a significant drop in the proportion of elective operations needing blood during the perioperative period if at all - elective hip and knee replacements - due to improved techniques and awareness of how to manage pre-operative anaemia, amongst other things. I do not have data to hand now but the use of minimum blood order schedules in hospitals - hailed as an advance at the time - seemed to me a licence to transfuse unnecessarily. Furthermore, between 1989 and 2000 the use of minimally invasive surgery - keyhole techniques - were being used more and more and in skilled hands led to minimal blood requirements.

c. **In your view now, in what proportion of elective procedures could autologous transfusion have been used, if the facilities, training, and financial investment had been provided across the UK between 1986-**

2000?

On reflection I would still be comfortable with the figure of 5% or even less. One other feature that contributed to a reduction in enthusiasm for autologous transfusion is that the SHOT report was beginning to show most of the errors and problems with transfusion related to the wrong sample of blood in the tube and bedside errors, which would not be reduced or eliminated by autologous transfusion. Also with regard to the transmission of infection, bacterial infection would also not have been impacted by autologous transfusion and I recall that at that time bacterial contamination was a rare but also important cause of major morbidity. There was also evidence accruing that the pre-operative reduction in haemoglobin produced by the autologous donations made it more likely that these people would be transfused with usual donated [allogeneic] blood, rather defeating the objective.

d. **In JPAC0000142_030 you additionally said that "more cell salvage initiatives within the operating theatres should probably be promoted." Did this happen? If not, what was your view of this?**

I certainly thought then and agree now that cell salvage initiatives within operating theatres would be a good thing to do. I think there were several initiatives in this area. I recall that in England and possibly Wales there was a decision to provide cell salvage equipment from the blood transfusion budget. However in Scotland we had a complication in that there was no cross charging for blood components as I believe happened at that time in England, and so SNBTS had no budget to allocate for these purposes, that we could offset against reduced transfusion requirements.

Another issue regarding cell salvage was that you need to be using a significant amount of blood in a particular procedure before this can be operated efficiently, or even at all. During this time there was a major drive to reduce unnecessary blood transfusion and improve transfusion practice generally which tended to work in the opposite direction, making more surgical procedures less bloody than would be required to justify cell

salvage. In general, my view is that cell salvage initiatives are good but the best thing to do is to have optimal transfusion practice, and this does take out a lot of the opportunities to use cell salvage.

104. In a letter written to Professor Sir David Carter in January 1998 (NHBT0000596) you discussed autologous transfusions (pp. 2-3).

a. In particular, you mentioned the requirement for substantial investment for an autologous strategy to be fully developed. Was the sort of investment you envisaged ever provided? If not, why not?

I don't think there was ever a major initiative to deliver autologous transfusion in Scotland. I think the reasons are those I have outlined in 103 above.

b. You also suggested that "we will not make a major impact with regards to autologous transfusion until we have a system that required informed consent prior to transfusion which will enable each patient (other than emergencies) to be involved in the debate over the advisability or not of blood products."

Well I was a supporter and proponent of consent prior to transfusion for a considerable period of time, but unfortunately the prevailing view throughout the NHS was that this was really too difficult. Of course, it isn't too difficult if you state that you are Jehovah's Witness and have a religious objection to receiving a blood transfusion, in which case a very substantial panoply of services, advice on managing pre-operative anaemia and other measures such as cell salvage and other discussions take place. I think any of us who might require a transfusion in future would consider that the protocols that are available for Jehovah's Witness individuals would be exactly what they would like to receive for themselves.

My feeling is that autologous transfusion, other than in a very small number of defined areas, does not deliver a sufficient advantage in safety and with the evidence that it could lead to an additional requirement for

allogeneic transfusion due to the autologous procedure causing preoperative anaemia, its role diminishes further. Blood sparing methods such as cell salvage could have been utilised more, but there were cost and operational issues.

i. **Was this idea ever explored further, either by yourself or by any medical bodies?**

There were a lot of discussions but not a lot of action or outcome in these areas. Most of the efforts in Scotland went on improving the quality of transfusion care, which did lead to a reduction in red cell transfusion of 9% [as I remember] and concentrated on reducing risk through minimising errors and adherence to transfusion protocols, which became known as Patient Blood Management.

ii. **Do you believe that autologous transfusion and similar blood sparing methods could have been utilised more?** I think they have largely been superseded by Patient Blood Management initiatives, and that is the route we took in Scotland with the Better Blood Transfusion programme. I would be interested to know how much autologous transfusion is used today. If it is substantial I would have to acknowledge we might have done more. However, I think myself and colleagues took the right approach by concentrating on making blood transfusion safer by training, reducing errors and focussing on high standards of transfusion practice rather than eye catching initiatives. The English NHSBT recent annual report states that red cell issues have reduced by 30% over the past decade.

105. In May 1999, you attended a SACTII meeting (NHBT0017405_001). At this meeting, it was decided to "maximise the use of autologous transfusion" (p. 6).

a. What can you recall about discussions surrounding this decision?

b. What was the outcome of this decision? How did it impact, if at all, upon the use of autologous transfusion and similar blood sparing methods?

We have discussed earlier that SACTII was an advisory body and had no executive function. I don't actually remember any other discussions beyond those which I have outlined in my answer to the previous question. At an operational level in SNBTS we decided to go down the Better Blood Transfusion route.

General

106. Please describe all other steps or actions taken at the GBTS 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.

I think during the whole period of my time at SNBTS the drive was to improve and ensure the blood was safe and to reduce risk to recipients. Not only for those risks intrinsic to the blood component but also to improve safety at the bedside through education and training. Very careful monitoring of all of the donor epidemiology data was undertaken in the MRU which was led by Dr Brian Dow FRCPath. Dr Dow and I worked closely together in reviewing these and one of the examples I would cite is the introduction of the second test for HIV when we were concerned about a potential increase in risk. The other area was in terms of HTLV testing where Dr Dow and myself worked with others to develop a cost-effective test to reduce the risk of infection from this virus when there seemed reluctance to introduce the test throughout the UK.

Through Better Blood Transfusion SNBTS was a leader in education and training and succeeded in having training in transfusion practice made mandatory in Scottish hospitals. Colleagues such as Dr Brian McClelland and Mrs Sandra Gray OBE, among others, made very special contributions in these areas.

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

I did have operational responsibilities in this area and always felt able to take any steps necessary to improve safety, although obviously this couldn't always be done

immediately. In particular the examples above relating to HIV NAT and the HTLV testing there was a requirement to agree funding for these. They were introduced as quickly as possible in my view. Given that we worked closely with the other three UK based transfusion services I felt this was an efficient way of working and given that there are always some limitations within the NHS and I didn't feel that we were being constrained in any serious way.

I would have liked to have introduced universal leucodepletion [white cell removal] of red cells and platelets earlier, but this was a very expensive intervention that was eventually mandated as a vCJD risk reduction measure. It wasn't in my gift to spend that sort of money.

I also felt free to contact senior colleagues about my concerns. On 8 November 2005 I wrote to the then CMO for Scotland, Sir Harry Burns. [WITN4032033]. I had recently beforehand attended a meeting of MSBTO at which it was proposed to recommend to Ministers that the UK blood services cease testing for hepatitis C using nucleic acid testing [HCV NAT]. I disagreed with this decision and felt it would be detrimental to blood safety in Scotland and have a negative impact on the public perception of the service.

Although I did not receive a direct response to this letter the end result was that HCV NAT was retained.

108. How did the desire for consensus across the BTSs impact efforts to achieve blood safety at a local level?

I think this has been an important issue and as I have stated I did not hold and do not now consider it essential that all transfusion services in the UK should coordinate their activities precisely when that means holding back implementations of blood safety. Most of the big tests had been introduced before I joined the blood service and we never had a test for variant CJD. However, one area where myself and colleagues in Scotland were successful in changing the consensus date idea was with leukocyte depletion. Concern over the risk of vCJD from residual white cells [leucocytes] lead to a decision to introduce universal leucocyte depletion of all blood components. We decided early on and agreed with the Scottish Health Department that we should be

implementing universal leukocyte depletion as soon as we could and simply getting on with it and not waiting for a particular 'big-bang' date. This did mean that some components were issued leukocyte depleted in parallel with others that had not been done, but we took the view that we needed to get this safety measure implemented as quickly as we possibly could and that seemed the best route. We did advise the other UK services through the UK Forum and health departments that we would be doing this.

109. To what extent were you and other regional directors reliant on the decisions of other bodies (advisory committees, directorates, SNBTS, the Scottish Home and Health Department ("SHHD")) 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?

I think all of us were highly dependent on the decisions of other bodies with regard to delivering blood safety. An individual Regional Director of blood service simply does not have the manoeuvrability or money to immediately implement new tests. In my opinion developments like the UK Forum of the four UK blood service CEOs and Medical Directors was a good step. Just as useful was the development of the European Blood Alliance in the run up to the development of the EU Blood Directive. Meeting twice a year with leaders in transfusion across Europe was incredibly helpful and enabled problem sharing and perhaps even some problem solving. Removing 'group think' attitudes that can take hold when working in isolation is important to maintaining flexibility in operational areas.

Who or what was responsible for defining what constituted safe blood is a brilliant question. My overall answer to that would probably have to be MSBT, but that group was not very fleet of foot. It was hamstrung by the Official Secrets Act and for many years the most relevant people in the blood services were not actually sitting on the committee, and could not be told the outcome of its deliberations. My personal view was that Germany offered the best model for delivering blood safety in similar nations to the UK. The Paul-Ehrlich-Institut seemed to include features of the MCA/MHRA and MSBT and to be proactive in blood safety areas. Germany tended to be early in implementing blood safety measures.

If I did not agree with the outcome of a particular decision or procedure, then provided I felt my arguments had been listened to and appropriately considered, I would usually accept the view of the majority. If I could act I did. My colleague, Dr Brian Dow, and I worked to find an economical way to test donations for HTLV infection, which I was very keen to see introduced. However there were aspects which I felt particularly strongly about. Among those was the SaBTO decision to relax the rules on MSM donors giving blood in 2010. This happened at the time when I was leaving the UK to work in the Republic of Ireland and had already given my notice to SaBTO. However I would have resigned from that body had I been planning to continue as a member. I think had I been working in blood services when the delays to introducing hepatitis C testing were occurring in around 1990 for example, I think again I would have had to speak out or have resigned from committees, or even from my post.

110. In 2001, you stated to the Scottish Health and Community Care Committee: "In the late 1980s, there was a perception that the level of blood supply was as important as measures such as ALT testing. Sitting here now in 2001 we might say that safety is paramount, but at that time there was a debate that balanced concerns about blood supply - considering whether we would run out of blood for life saving surgery - against concerns about unnecessarily worrying donors who did not have hepatitis but who had an abnormal test, and against concerns about safety" (SBTS0000356_022, page 11). You also stated that blood usage was beginning to "plateau or reduce slightly" in most developed western countries. (see page 17).

a. In your view, why had blood usage started to "plateau or reduce" in most developed western countries by 2001?

There was a range of issues which led to the awareness that transfusing more blood is not simply the answer. The study from 1999 by Hebert et al. in the New England Journal showed that in the intensive care situation, transfusion to a lower threshold was actually superior in the outcome to a more generous transfusion approach. This meant that less blood transfusion was better than more blood. This study was highly influential and led many clinicians to begin to review their experience with transfusion and to use fewer red cells. Earlier studies in orthopaedic surgery had

shown that there were major differences in transfusion practice between hospitals, perhaps countries, for the same operation, with no evidence of an improved output and outcome for those using more blood. It is highly likely that the use of minimally invasive surgery - keyhole surgery - has had an impact in the relative reduction in blood usage per operation.

b. Was this due to a shift in understanding of the inherent risks of the use of blood?

The concerns about variant CJD, for which there was no test, certainly had an important impact in the UK but I suspect also elsewhere, since there was always the possibility that other countries might have developed their own variant CJD problem. Fortunately, with the exception of perhaps France, this did not happen. Also I think the understanding that there were a lot of mistakes made in the transfusion process and that education was important also led to an improved understanding of the overall risks of blood transfusion, not only the risks 'in the bag.' Obviously, the issue of the cost of blood may have been a factor. I think there was an improved understanding and the fact that over-transfusion of blood could be harmful.

c. Did policies on effective use of blood and the prevention of unnecessary transfusions play a part?

I would like to think so because in Scotland we certainly spent a lot of time developing this area of medical practice.

d. Please further explain the change of approach to balancing factors such as the sufficient supply of blood, donor discomfort, and safety when making policy decisions with respect to the use of blood and blood products.

Changes in society over the last 50 years have been so great that many of these issues are no longer contentious. I don't think anyone now would think that donors should not be informed about all their results relevant to their health and it is possible to have a mature discussion with individuals,

even if some of those results are not immediately easy to interpret. Some examples of that would be in donors who have no definitive evidence of a particular infection, but whose blood for some reason reacts in one or other of the tests in an indeterminate way. Many years ago these were simply parked to one side and the donor not informed and the donation not used. However donors will now be informed of things like that. There are clear ethical objections to taking blood donations from donors whose donation the blood service knows will not be used.

There is always a need to maintain a good donor base, but the need to collect so much blood has decreased since before and after I retired, and it has become easier to meet demand since blood use per capita has reduced. The annual report of the NHSBT ending 31 March 2020 [last pre-Covid-19] [WITN4032034] states that red cells issues had declined by 33% since 2009/2010. This is remarkable especially when my English colleagues in 2010 were predicting a major increase in the need for red cell transfusion based on epidemiology of the patient population - ageing in essence. However, this in my view neglected the impact of improved surgical techniques to minimise haemostasis, the effect of minimally invasive keyhole surgery that reduces tissue damage, and the patient blood management initiatives that have reduced unnecessary transfusions. I do note that the NHSBT did issue 1.376 million red cell units in the year to March 2019 so it is still a very major activity despite the declining trend.

In SNBTS we did learn a lot from the decision to cease taking blood from previously transfused donors. My recollection was that this led to a reduction of at least 10% in donors and there were grave concerns that this would lead to a blood shortage. This did not occur as it was managed very effectively with improved donor recruitment and also education within hospitals to ensure that usage was appropriate.

111. In your statement to the Archer Inquiry, you referred to a 'precautionary principle' that was used in the introduction of precautions against Variant Creutzfeldt-Jakob disease ("vCJD") but "was not in evidence" at the time of the response to AIDS (ARCH0000443, page 5). You also stated that the

precautionary principle "should apply to unknown, uncertain and emerging transfusion transmitted disease" (see page 11). Please elaborate further on what you meant by the 'precautionary principle' and how this principle is applied to decision-making with respect to blood safety.

Far greater minds than mine have applied themselves to this issue. Probably the most influential to me was the Krever Commission Report published in Canada in 1997 [Krever H. *Final report: Commission of Inquiry on the Blood System in Canada.* Ottawa: The Commission; 1997.]. Krever addressed many of the issues being covered by the IBI 24 years ago. In 2007, Wilson, writing in the Canadian Medical Association Journal [*Wilson K, 2007, The Krever Commission, CMAJ 177; 1387-1389*], stated that "*Perhaps the most significant contribution of the Krever report to public health was its clarification of how evidence should be used to formulate policy with respect to blood safety. Before the report was released, a prominent criticism of decision-making in this regard was the reliance on high-level evidence as a prerequisite for action to protect the public's health. Although it was highly effective in guiding clinical decision-making, Justice Krever identified this approach as clearly inappropriate for blood safety. In particular, Krever criticised the delays in implementing measures to protect the blood supply from HIV because of uncertainty about the magnitude of this threat and delaying the implementation of surrogate testing for hepatitis C until clear evidence of its efficacy was available from a randomised trial. Waiting for definitive evidence of risk resulted in the potentially avoidable exposure of thousands of individuals to tainted blood products. Krever stated that this approach was inconsistent with the public health ethos:…*"

Wilson goes on to cite the measures introduced to prevent vCJD in the blood supply prior to strong evidence of their efficacy as being the correct way to proceed. Finally, Wilson [2011] [WITN4032032] reviews the field and proposes a framework for the application of the Precautionary Principle to transfusion safety.

A current [bad] example would be the UK government's initial reluctance to recommend, let alone mandate, the wearing of masks in public to prevent COVID-19 transmission. Once again issues like the lack of evidence for the efficacy of masks was cited as a reason for not adopting masks. If a respiratory disease like COVID-19 was highly likely to be spread by respiratory droplets or aerosols, masks

might help. Let's wear them until there is evidence they are unnecessary.

Section 14: Look back programmes at the GBTS

HIV

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

Not as I recall. HIV testing began 10 years before I joined SNBTS. Lookback on new cases would have been undertaken according to then current protocols by donor services medical staff. Positive HIV results in repeat donors were very unusual.

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

I don't recall being, no.

HCV

114. Were you involved in setting up any HCV look back programmes during your time at the GBTS? If so, please describe this process and your role in it and how it was funded. You may find NIBS0001284 and page 79 of WITN4032001 of assistance.

The main HCV lookback in Scotland began in Edinburgh and was well established by the time I joined the service. I don't have any recollection of the indeterminate cases look-back mentioned in Dr Dow's letter. The letter mentions discussions at the MSC meeting previous - probably in September that year. If the minutes from that meeting and the subsequent one on 14th November were available that might be helpful.

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

Not as far as I recall. HCV lookback was already under way. The only involvement I recall was trying to encourage some hospitals to keep going to try to identify all recipients. Unfortunately I cannot remember which hospitals were being less helpful than some others.

116. In April 1998, you wrote to Dr Aileen Keel at the Scottish Office and stated "progress with this [HCV lookback] has been virtually static" and that "we still have a number of patients whom we have been unable to trace and conclude that without additional resources from SOHD, doing so is not going to be possible" (PRSE0003277). Why was progress static? Did you obtain additional resources from the SOHD? You may find PRSE0004337 of assistance.

I can't be specific about why things were static at this distance in time. However, the lookback involved donors coming to SNBTS and being found HCV positive, who had last donated in the period before HCV testing began. So by 1998 that would be donors who had allowed 7 years or more to elapse since their last donation. Such donors would have been a very small number by then. Also, previous donations would have had to be traceable to a recipient. As time went by this would become more difficult. Case notes for some patients may have been legitimately destroyed according to then existing practices. Computer systems may have changed, with legacy systems less easily interrogated. Also, the issue had been referred to MSBT, who agreed that the formal programme could close, with caveats. I do not recall if there was a final report to ministers. Clearly if there were it would be useful. I don't recall whether more resources were provided, or what they would have been (possibly more staff in hospitals).

I would emphasise that should any donor have subsequently attended and been found to be HCV positive, previous donations would have been checked in case a window period donation had got through.

General

117. Please confirm whether you were involved in a look back process relating to any other infection during your time at the GBTS. If so, please provide an

overview of the relevant programmes and detail your involvement.

We did identify some donors when we were developing the HTLV assay using mini-pools and would have excluded these donors and attempted to trace the donations back to recipients, but I do not recall the outcome of this. This was when I was NMSD for SNBTS and not director of GBTS.

There were look-backs for vCJD which I was not involved in developing, as that fell to Dr Patricia Hewitt in England and Dr [now Prof] Marc Turner in SNBTS. I would have been kept up to date with the outcome but don't recall anything specific.

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

Yes.

119. To what extent could an BTS implement its own local look back programme? Did the GBTS do this? If so please give details. If not, why not?

In the early period after HCV testing was introduced there was a debate in the UK about look-back. It was before my time in the service, but the events are well covered in the 1995 BBC Panorama programme on the issue ['Bad Blood'?] that was shown to the IBI last year. Again, this is before my time, but colleagues in Scotland felt it should be done and the English service did not. Edinburgh colleagues undertook a feasibility exercise that showed it was entirely possible to identify many, if not all, recipients of potentially infected donations. So the answer would appear to be yes, but probably not without the agreement of the host blood service, in this case SNBTS. As far as I am aware the Glasgow & West of Scotland BTS did not do this independently, but as part of the Scotland wide lookback.

120. In June 1997, you were copied into a letter from Dr Brian McClelland in which he discussed an urgent need to reach a policy decision with the Scottish Office regarding the destruction of a large stock of blood donor samples (SCGV0000112_070). Can you recall what eventuated from this discussion? Were the samples retained to assist with look back programmes and/or other

epidemiological studies?

I don't recall this letter or the issue to which it relates. As far as I was aware, from September 1985 until I retired a small aliquot of every donation taken in Scotland was stored and held in an archive. Perhaps Dr McClelland had additional specimens? At some point, and bearing in mind the deliberations emerging from the Alder Hey retained parts and sample issue, the fact of the sample being kept was included in the donor session record and information leaflet, which the donor was required to read and sign.

Look back and record keeping

121. **To the best of your knowledge and with regard to the information you have already provided in response to [questions 118-126], please provide an outline of how donations were recorded by GBTS and who was responsible for managing that information over time (you may find NHBT0000088_030 of assistance).**

I am sure this information must be held somewhere in SNBTS records. I do not have this information.

a. **How were high risk donors identified and were they successfully prohibited from donating?**

High risk donors were identified at donor sessions by the answers they gave to the donor questionnaire. I don't recall any physical examination being undertaken. They would be prevented from donating dependent upon the answers and then subsequently by the results of the mandatory screening tests undertaken on the donation blood sample.

b. **Please set out the circumstances as to why the SNBTS would not be able to trace an original blood donor. If there were systemic issues in recording donations, please set these out in detail (you may find SCGV0000098_152 of assistance).**

I suppose a donor may have wilfully provided an incorrect address or contact number. I don't think there were systematic problems recording blood donations. I did not find anything in SCGV0000098_152 helpful in this regard. Tracing recipients in hospital could be more difficult, if records were not well maintained. But the lookback for HCV showed that most recipients were traceable.

c. **What was your opinion of this practice?**

I think it was important to have a system for tracing donors, particularly in cases where any of the donor tests returns a positive result. However, since blood donation is a voluntary practice it remains a matter of trusting the donor to be telling the truth regarding their life style and also where they live so they might be contacted. I am afraid I don't know the proportion of donors who could not be traced when required - perhaps a donor services consultant would be more likely to know or to remember.

122. **Minutes from the January 2003 SACTTI meeting, at which you were in attendance, reference the prospect of a donor register as part of a discussion on HTLV Look Back (JPAC0000029_079). Please set out all of**

the information that you recall on this subject, including but not limited to:

The minutes suggest such a register was likely to be agreed. I don't recall anything further in this regard, as to whether it was set up or what information came from it.

a. **if it was established,**
   I do not know.

b. **whether donor samples were held, and who were they held by,**

   Unlikely, beyond the sample archive retained from each donation in Scotland. However, if look-back was required this sample would be used for that purpose, and might eventually be used completely, meaning there was no further sample related to that donation.

c. **the potential ethical and legal implications of such a register.**

   It would be quite problematic to maintain a register unless consent was obtained from subjects in the register. I recall the HCV register referred to in the minutes was set up with anonymised data. The other relevant issue that developed over time is that it would be impossible to publish results from a register if consent of the subjects to be included in the register had not been obtained.

123. If registers or archives for different infections were ever discussed or created, please answer question 127 in relation to HBV, HCV, and HIV respectively.

I don't recall any disease specific sample archives beyond the donation sample archive stored on each donation. I do not recall any HIV register, or HBV register. The HCV registries have been considered in earlier questions.

There was a plan to establish a testing assessment facility [TAF] in the event of a

test for vCJD becoming available. I know the plans for this were well developed and included storing whole blood donations separated into components - red cell, plasma, platelets, and presumably white cells too. I do not recall whether it ever did become established. I recall strongly arguing that donations included in the archive should be included only with the specific consent of the donor. The intention was that donations were to be included from around the UK, including Scotland. So the requirement for consent was specifically relevant to me as Medical Director in Scotland. Apart from obvious ethical issues, I felt again that if results of studies using the TAF were to be published, reputable journals would want confirmation that consent had been obtained.

Section 15: Relationship between the SNBTS and NBTS

Relationship between the SNBTS and NBTS

124. 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.

During the earlier years of my time with SNBTS the main cooperation channels were through the JPAC committees and the various standing advisory committees. These committees have representation from the four home blood transfusion services. A little later, I am unsure when this initiative began but when Mr Macmillan Douglas was National Director and Martin Gorham was CEO in England, meetings began on a quarterly basis between the chief executives and medical directors of the four territorial blood services. Known as the UK Forum, this represented an advance and significant improvement in the understanding between the blood services.

125. 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?

I would say that policies tended to develop initially from local requirements and from a local perspective. However after the establishment of the UK blood services Forum that I referred to in answer 124 above, I would say that policy development was better coordinated. With regard to variant CJD I would say that the policies were developed on a UK wide basis throughout.

126. 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.

I don't recall whether data on excluded donors or identifiable information about donors was shared between services, until the advent of variant CJD. The change in approach came about because there was no test for variant CJD and therefore donors who were flagged as being at risk from this condition could not be excluded using tests. Since some of these donors might be unaware that they were 'at risk for public health purposes,' as the term was, they could not self-defer themselves so data had to be shared between services. A donor with hepatitis C or HIV would be excluded by the testing regimes for those conditions. Subsequent to that they would be informed of the test results and be permanently deferred from further donation. With regard to the variant CJD information sharing, this would have been on a formal basis but do not recall whether any sharing of donor names was undertaken. I'm sure this information is available within SNBTS.

127. Please set out any information you hold in relation to the matters addressed in questions 130 to 132 above prior to your directorship of the GBTS.

I don't have any information on this aspect.

Relationship between the Plasma Fractionation Centre and Bio Products Laboratory

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

I think the relationships between PFC and BPL were cordial and professional, although I suspect there was a degree of intellectual rivalry between the bodies. During my time in the service I am not sure that we were collaborating over any shared products. The issues of heat treatment and virus inactivation had largely been resolved by that time, although there was still independent development of novel systems, such as the ultraviolet light treatment of plasma and also the use of methylene blue plasma. The potential for patenting of effective virus inactivation systems may have discouraged collaboration. At the time I was working in the service it seemed reasonable to have been continuing in the way that we did although I would have to say that looking from outside, and with the benefit of hindsight, it might have been better to have seen more cooperation over heat treatment. Perhaps there was more cooperation than I was aware of. If so it would have been particularly between our product development staff and the PFL scientists in Oxford. The difference in approach might be explained by the very strong drive within Scotland to achieve self-sufficiency and the fact that this could be achieved with a significantly smaller amount of finished product than would have been required in England.

Relationship between the SNBTS and Northern Ireland Blood Transfusion ***Service***

129. 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.

I do recall that the PFC was responsible for processing plasma from Northern

Ireland into products and that this was the route by which Northern Ireland received its plasma fractionated coagulation factors from PFC/SNBTS. I do not remember there being any significant movement of fresh blood components, such as red cell concentrates or platelets, but this may indeed have occurred from time to time.

130. 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.

I'm not sure I know a definitive answer to this. The blood donation process in Northern Ireland would have been equivalent to that in Scotland, using similar donor questionnaires, although there would have been local versions. Both services would have been following the Red Book guidelines. Almost certainly the plasma would have been separated from red-cell donations in Northern Ireland and frozen and then transported in this solid-state. The final products would have been returned on a pro rata basis, depending on the amount of plasma provided. I do not know whether Northern Ireland plasma was physically segregated within PFC for producing specific plasma products. It is unlikely to have been segregated.

131. 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.

The medical director of NIBTC was also the chief executive and he would attend the medical and scientific committee meetings of SNBTS during my time there. Beyond that NIBTC was fully represented on the standing advisory committees related to the JPAC system. When the UK forum was established, the chief executive of NIBTC would attend these meetings and meetings were held in Belfast annually, as well as in Cardiff, Edinburgh and London.

Outcomes in Scotland and England/Wales

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

I don't have any statistics or knowledge of studies that demonstrate these differences, other than would be obtainable from the offices of National statistics. It's well known that life expectancy in Scotland was lower, but I assume this question is intended to consider outcomes from blood transfusion. On reflection, the SHOT organisation did keep data based on the individual nations and these were made available to us. I do not remember whether the final reports did identify individual countries or not.

Section 16: Variant Creutzfeldt-Jakob disease (vCJD)

133. 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?

My recollection is that my first awareness was with the publication in the Lancet of the discovery of variant CJD by the Edinburgh group, although there had been earlier speculation about whether BSE could pass to humans. Although at that time it was not clear whether blood and blood products could transmit variant CJD, this was obviously a major concern from the beginning and even before. Over the next few years I was substantially involved in addressing and responding to the initial theoretical risk of variant CJD being transmitted by blood transfusion. My colleague Dr Marc Turner (now Professor and current NMSD of SNBTS) was the lead for SNBTS on issues relating to variant CJD and he liaised on a regular basis with the CJDSU based in Edinburgh.

134. In November 1997, the Inquiry understands that you authored a report entitled 'SNBTS Briefing Note on CJD and Blood Transfusion' (BART0002129_017). Please describe how information relating to the developing knowledge of risk of vCJD was disseminated to the blood services. How did the blood services communicate this risk to RTDs? As far as you are aware, were reporting systems similar in Scotland, England & Wales and Northern Ireland? If not, please specify what, if any, the differences were.

My recollection is that variant CJD became the major topic of concern from the publication of the paper from the CJDSU in the Lancet. A report was commissioned from a risk analysis company called DNV, probably by the English blood transfusion service, but possibly by the Department of Health in London. This report was discussed at a range of workshops as I recall but may have been a confidential document, at least initially. I do remember feeling uneasy that SNBTS was reliant on informal briefings about the DNV report in corridors outside other meetings from colleagues in England. An attempt was made to break down the issues which, from my recollection, were quite complex and difficult to understand. Discussions of the theoretical or other risks of variant CJD were discussed at all board meetings and medical scientific committee meetings in SNBTS thereafter. I was never comfortable with the term 'theoretical' risk, as it seemed to downplay the potential seriousness of the situation. There clearly was a risk, it was just difficult to quantitate it at that time - it was a known risk of unknown size - from zero to potentially a very great risk. Reporting systems would likely have come initially from SEAC [the Spongiform Encephalopathy Advisory Committee]. I recall a meeting in Edinburgh, probably in May 1998, between the chair of MSBT, Dr Jeremy Metters, and members of the CJDSU. Dr Robert Will of CJDSU was definitely present [NCRU0000109_062]. Some other SNBTS colleagues were present, but I do not recall if members of the other UK Blood Services were there. This was to discuss and confirm reporting arrangements from the CJDSU, when that body identified a person with definite or highly

suspected vCJD. It was at this meeting that I was insistent that all UK blood services were informed of new or highly suspected cases of vCJD, in case individuals had moved between countries of the UK. Reporting systems would have been UK wide, through JPAC, standing advisory committees and probably other forums. I don't know what the specific reporting systems were in England and Wales or Northern Ireland.

135. In December 2000, Dr Elizabeth Love wrote to you and proposed a workshop to discuss the issue of vCJD and the division of responsibility between various bodies and committees (JPAC0000007_095). Was this workshop held? If so, please can you comment on the outcome of these discussions. In particular:

a. Whether a framework document was prepared; and

b. What role, if any, the BTSs were to play in this regard.

I believe this workshop did take place and was a high-level event with very good attendance. Whether a framework document was produced I do not recall. I think that this was the event when Dr Paul Brown attended from the United States as an expert in Prion diseases generally and their transmission. In the absence of a copy of the notes I would not be able to comment on the details, although I believe Dr Brown opined that the UK was doing as much as it could at that time. I disagreed with that because although I am sure Dr Brown was correct in terms of blood component safety, there were still issues in reducing blood exposure and improved transfusion practice that might have been improved, and later were. If we look at the 33% fewer red cell issues since 2009/10 that is a one third risk reduction for vCJD, and any other unknown risks for that matter.

Risk reduction measures

136. Please provide details of your knowledge or involvement or knowledge in any discussions or proposals, whether accepted or not, that were made in an effort to protect the blood supply from the risk of vCJD. To assist you we have referenced below documents which indicate your presence at

meetings where particular risk reduction measures were discussed. In providing this outline, please state where possible:

a. **When and by whom any proposals were made;**
b. **The factors considered when deciding whether to implement these proposals;**
c. **Decisions made on such proposals, including the date on which they were made or rejected; and**
d. **How any such measures were implemented in practice, including efforts made to monitor their effectiveness.**

In the main, risk reduction measures were to encourage optimal transfusion practice and to avoid unnecessary transfusions. Subsequently the use of leukocyte depletion was discussed and following studies in sheep suggesting transmission of prion disease by white blood cell fractions, universal leukocyte depletion was subsequently introduced throughout the UK. I recall that there were specific CJD subcommittees set up, some of which I attended. These included a prion testing committee and a prion reduction committee - this latter was focussed on the development of a specific prion removal filter for blood. A very considerable amount of work went into developing tests to be applied to blood donations and there were many discussions about how such tests might be implemented. However, no such test ever reached the level of practicality or sensitivity required in order to be introduced for blood donors during my time working in Scotland or Ireland.

I seem also to recall that there were discussions about reducing the amount of residual plasma in blood components. There were also extensive discussions about whether labile blood components, such as red cells and platelets, should be imported, in particular for children born after 1996, at which point it was believed that the risk of variant CJD from eating beef had been substantially reduced. I don't recall whether these imports ever took place and I suspected they did not. I have subsequently been made aware that some such imports did occur, but I do not know when or where. Therefore, the only substantive measure that I can recall being introduced was leukocyte depletion. This is of

course in addition to the early decision to cease the use of UK derived plasma for making fractionated pooled plasma products. This was initially stated as being to avoid the large number of recalls that were already happening when a person with vCJD was found to have donated blood that contributed to a manufactured product batch. It was clearly a direct safety initiative as well.

Around this time we also stopped taking blood from previously transfused donors. I cannot remember whether this was considered to be a variant CJD risk reduction measure or whether it was simply in order to reduce the risk from other unknown viruses that might be transfusion transmissible.

With regard to monitoring measures as to their effectiveness against variant CJD, there were only ever four cases attributed to blood transfusion, all implicated in non-leukocyte depleted [LD] transfusions. It was difficult to determine if LD had been effective because there was never sufficient mathematical power in the data to feel confident about whether it had been effective. The lack of cases post-LD is most gratifying, of course. The subsequent decline in the number of cases of variant CJD since 2001 meant that there have been so few cases it is impossible to know which if any measures made a difference.

The risk reduction measures include but are not limited to:

a. **Donor selection and exclusion policies;**

Donor selection and exclusion policies would have included the exclusion of previously transfused donors and those donors who had been identified as being at risk for public health purposes, of whom we were notified.

b. **Development of screening diagnostic test (NHBT0062373, NHBT0064764, NIBS0000545, SCGV0000097_053);**

There was a very considerable amount of work went into this, but no test was ever implemented as I recall. There was a specific prion testing

working party established - I do not recall being a member but colleagues in SNBTS, such as Dr Turner and Dr Prowse, were. We were well represented in my view. SNBTS did indeed try to develop a test but although it showed promise, my recollection is it was never suitable as a donor screening test for use on a large scale in a short enough turn round time. In other words, it was more of a research test at best.

c. **Importation of plasma from the USA or elsewhere (NHBT0002114; SBTS0000359_015, NHBT0002580_002, SCGV0000096_005, JPAC0000007_095);**

   UK plasma was banned in order to minimise frequent recalls of products and also to reduce the risk of infection. Plasma was bought from the United States and the English Department of Health bought a plasma procurement company in the United States to provide plasma to BPL. SNBTS obtained plasma from unpaid donor sources in the US and also bought some plasma from German blood centres in Bavaria.

d. **Surveillance of donors and recipients of vCJD infected blood;**

   There was a CJD incidents panel which I seem to recall was involved in identifying individuals who were at risk of developing variant CJD from a public health perspective. This panel then took decisions as to what should be done on a case by case basis for each 'incident.' It was chaired by Dr Michael Banner, an academic theologian. These people were flagged on donor databases, even if they had never been blood donors before. As this was ethically quite a complex issue they were largely delegated to the CJD incidents panel, on which there was at least one member of the UK blood services [possibly Dr Patricia Hewitt].

e. **Product recall;**

   There were numerous recalls of batches of mainly plasma products made of many thousands of donations where an individual donor was identified as being at risk of variant CJD for public health purposes.

Most of the recalls were of products long past their 'use by' date, so whether there were any products that needed to be quarantined I do not remember [see below]. This was the main justification given for the ban on UK derived plasma.

Quarantine of batches; Batches of plasma products would have been identified as including a donation from a person known to have, or be highly suspected as having, vCJD. Such a batch would have been recalled from hospitals and placed in quarantine. I cannot remember to what extent recipients were traced or what they were told. Quarantined batches would have been managed by the Quality Director of PFC and probably destroyed by incineration following an agreed protocol.

f. **Filtration policy (JPAC0000118_003); and** In terms of fresh blood components like red cells and platelets, conventional blood filters for use in accredited blood centres were used. I do not know which filtration processes applied to fractionated plasma products. I do not think that specific prion removal filters were ever used, although some may have been CE marked. CE marking for medical devices was then, in my opinion, a flawed process as it did not require sufficient third party monitoring or clinical trials as was required for medicinal products. So, the presence of a CE mark was not necessarily evidence of sufficient efficacy and required further study.

g. **Recombinant blood products (SCGV0000116_031).**

Recombinant blood products were already being introduced due to long-running concerns about virus contamination. Concerns about vCJD hastened the wholesale switch to recombinant and the use of 'all-recombinant' products free of all human plasma.

137. Did you consider the risk of secondary transmission via blood and blood products to have been adequately mitigated at the time these measures were implemented? Has your view changed over time?

On balance, yes then and still yes now. The absolute risk of transmission of variant CJD by blood and blood products was never really adequately calculated, as there never was a test to determine how many donors might have been at risk of transmitting it. As far as I'm aware there were just the four cases implicated prior to the introduction of leukocyte filtration. It's probably a better outcome than could have been anticipated in 1997. Deferring all previously transfused persons as donors was implemented to address this possible secondary transmission.

138. With reference to question 131, please provide your opinion as to whether any decisions or actions could and/or should have been made earlier.

I think it would have helped to have a more open debate about the risks of vCJD from the earliest point. I made this point in a letter to Dr Banner in my response to the CJDIP in 2002 [NHBT0009503_002: section 1, p2]. I have been provided with a copy of the 2003 revised risk assessment from Det Norske Veritas, which includes additional papers from government department, EOR4, as a commentary on the risk assessment. I do not recall seeing these papers at the time, and indeed the headers to these documents state 'Restricted - Policy' or 'In strictest confidence.' I do not recall seeing the full 1999 DNV report either, although perhaps the SNBTS vCJD lead, Dr Turner, did. SEAC had recommended the need for a risk assessment in 1997 but it was 1999 before the report was produced. Clearly, these were complex issues, but more openness would have helped deal with uncertainties.

On the issue of whether anything could have been done before the identification of vCJD in 1997, there was a reassuring paper from the Edinburgh CJDSU, published in 1993 in the Lancet [Esmonde et al., Lancet 341: 205-207], that showed no evidence for blood transfusion being a major risk factor for [classic/sporadic] CJD. On the issue of whether it may have been a minor risk factor, a further paper in 1994 in the Lancet also found that no evidence for the transmission of CJD by blood transfusion could be found in a look back study of a donor who developed classic CJD after years of

donating 55 units. CJD experts were looking, but found nothing. In the mantra of the time, an absence of evidence is not evidence of absence. The main measures introduced after the recognition of vCJD were importing plasma and universal LD. The one initiative that could have been introduced before knowledge of vCJD would have been to reduce blood usage and increase cell salvage. We could argue about autologous transfusion, but despite some of my comments from the time I think that would not have been so helpful and might have been a distraction from improving transfusion practice generally. Ahead of the paper from Hebert et al. in 1999, there wasn't hard evidence on the safety of lower haemoglobin levels in patients, but perhaps a more holistic approach to what was then a theoretical risk of BSE causing a human TSE could have been adopted in a precautionary manner.

CJDIP Consultation

139. The Inquiry is aware of the CJDIP Consultation (NHBT0096710_001, NHBT0001954_001). As far as you are able:

a. What involvement, if any, did you have in this Consultation? If you did participate in the Consultation, what views did you share?

This was really quite a complex process and I certainly do remember the consultation and that the SNBTS and myself were involved. I did respond to this consultation in some detail in your ref. NHBT0009503_002.

b. How did this Consultation operate? In particular, how did Michael Banner, the chair of the CJD Incidents Panel, gather views?

My recollection is that the consultation began with an open/public meeting of the CJD incidents panel which was chaired by Michael Banner, a theologian and philosopher. It was facilitated by an experienced journalist, Michael Buerk [as I recall]. The meeting developed some proposals that lead to a document. This was then I think very widely distributed and views collected in this way. We were

then invited to respond and I did so [NHBT0009503_002].

Whether the findings of this consultation faced any opposition to its views and if so, by whom and what those opposing views were.

From reading my own detailed response to the consultation, it appears that I responded to an online consultation form. Unfortunately, I do not have a copy of the original form. However, I clearly outlined in my response those aspects with which I disagreed. I don't recall any systematic opposition to the work of the CJDIP.

140. To the extent not covered in [question 139], please set out how and when you first became aware of potential vCJD transmission within the SNBTS, when you drew these incidents to the CJD Panel's attention and how they responded. You may find NCRU0000111_078, HSOC0005222_002 and DHSC0004215_008 of assistance. In particular:

a. In relation to a vCJD incident in 1987-1989, it appears that there was a delay between you reporting it to the CJD Panel and patients being notified. As far as you are aware, how and why did this delay arise? You may find NIBS0000570_002 and SCGV0000098_152 of assistance.

NCRU0000111_078 appears to be a letter from the Deputy CMO England to the Director of the CJDSU, in response perhaps to my concerns over the notification system. This may have led to the meeting in Edinburgh of circa May 1998 to discuss this issue.

The press briefing of 27 November 2002 [NIBS0000570_002] does not imply any delay. It states clearly that a person who had recently been discovered to have vCJD had donated in their healthy past in 1987-1989. These donations expired in 1990. Variant CJD was described in 1996 by Will and colleagues. So the period relating to the time that passed between the person donating

blood and their developing vCJD was part of the incubation period of the disease in that previous donor. It wasn't a delay in communication.

The decision whether or not to inform the recipients I believe to have been made by the CJDIP, and from reading the press reports, this decision appears to have changed between 2002 and 2004, probably following the demonstration of transmission of vCJD by blood transfusion in man.

I do not remember any confirmed variant CJD transmissions within the SNBTS. That is, blood or plasma donations collected by SNBTS leading to vCJD in a recipient.

Notification of risk

The Inquiry is seeking to establish whether some or all recipients of blood that may have been exposed to vCJD through blood products and blood transfusion were informed of the potential risks of vCJD. The Inquiry is aware of further patient notification exercises between 2003 and 2009, in particular the large-scale notification exercises commencing from 2004 notifying patients they were 'at risk' of vCJD.

141. Please set out how the policy of donor deferral of potential recipients exposed to the risk of vCJD influenced the policy of notifying those recipients of the risk that they posed. You may find NHBT0000088_030, NHBT0007217_001, NHBT0002156_001, GRAM0000127_002, HSOC0013717 and SCGV0000095_075 of assistance. My letter to Professor Ludlam [GRAM0000127_002] describes my position, which was one of considerable unease. Briefly, we knew of batches of plasma products that were made from a donation from a person who later developed vCJD. The implication is that we were advised not to notify clinicians about this until the CJDIP had provided advice. I would add the point that, although I say to Professor Ludlam that there was no need to notify prior to that date, I think the UK position was ***not*** to notify recipients until the CJDIP [Banner Committee] had provided advice, which from my letter would appear still to be awaited. My

own discomfort at this position is stated. SCGV0000095_075 makes clear this is the policy, not to notify, but to flag donors [or even potential donors] on the blood service computers, without the donors knowing this. I was most uncomfortable with this, as were my Donor Consultant colleagues, but SNBTS did follow the policy, given that we were aware that consideration was being given to this issue at a high level and that a solution was expected. Having said that, I cannot now remember what the ultimate view of the CJDIP was.

142. What was your perspective of the notification of risk? At the time, did you feel that this was necessary and if so, effective? Has your opinion changed over time? You may find JPAC0000029_079, SCGV0000210_031 and LOTH0000546 of assistance. These papers are interesting. I note that in JPAC0000029_079 MT [Dr Marc Turner] asked 'how to access the EOR assessment.' This suggests that the lead UK Blood Services expert on vCJD was not party to the DoH risk assessments at that time. Dr Turner mentions that there is a lack of uniformity on notification between UK services. This I do not recall but he does mention that advice was awaited from the Clinical Incidents Panel - which accords with my personal recollection. With regard to my perspective of the notification of risk, I suspect this was limited if neither myself nor Dr Turner had been given access to the EOR risk assessments. Keeping the risk assessments confidential, and not even releasing these to the leading vCJD expert in transfusion in the UK, made them useless from an operational perspective, certainly in Scotland.

143. Please provide a chronological overview of when and how the system of notification of risk was established between the devolved nations and organisations (NCRU0000109_062 and DHSC0038507_047), and if there were any differences between them (JPAC0000114_018).

As I have stated previously I was concerned that limiting notification of a person with vCJD only to the home BTS risked missing donations given when the person might have been travelling. NCRU0000109_062 confirms that a meeting took place between UK BTSs and the CJDSU in Edinburgh in May 1998, chaired by Dr Metters. Thereafter, and certainly after 7th August, all 4

UK BTS would be notified and the relatives of the vCJD patient advised of their inclusion in the donor database, but no consent for this sought. Had consent been sought and refused, this would have had considerable public health implications.

Regarding DHSC0038507_047, I do not have any recollection as to why we were not releasing these names to the CJDSU.

JPAC0000114_018 is a SACTTI minute from a working group on vCJD. This mentions foot-dragging by MSBT and also that in SNBTS we were deferring donors whose recipients had developed vCJD. I cannot be definite about whether these donors were told, but I think that Dr Turner did call them in and tell them.

I cannot give any more detail on the chronology with the papers at my disposal.

144. Were you aware of any circumstances where individuals were not informed of their risk status, or where the informing of the individual was delayed? If so, why?

I don't recall any such occasions.

145. What, if any, information or advice was provided to partners or family members of patients who were at risk of infection with vCJD?

For SNBTS, this would have applied to donors. Patient recipients would have been seen by their own physician. I do not remember the details of what donors were told, or what they may have been advised about the risk to partners etc. I do know I did not do this myself. It would have been either Donor Consultant staff or Dr Turner.

146. Please provide details of any psychological counselling or financial support offered by any organisation following those notification exercises between 2003 and 2009.

I do not recall any, which does not mean there were none. The UK government introduced a vCJD support package for those diagnosed with vCJD, which consisted of financial assistance and nursing and other medical and supportive care in 2001. This was managed through a vCJD Trust and delivered by the CJDSU.

147. To what extent, if at all, did you and/or your colleagues take into account the public health implications of vCJD when deciding what information or advice to provide to at-risk patients? You may find LOTH0000082_017 of assistance.

The public health implications were complex, due to there being no test to identify those people who were truly a risk for public health reasons, and those who were included solely due to being in receipt of blood components and / or plasma products.

It is clear from these minutes that there was no timely or definitive source of advice as to what to tell and when. In terms of at-risk patients, these would have been informed, advised and perhaps counselled by their physician or surgeon, not directly by the UK blood services staff. That said, I do recall being involved in discussions as to what to tell and what to include in briefing notes. I cannot remember what precisely these details were now. While I acknowledge that the task of the Clinical Incident Panel was great and complex, there was clear frustration recorded in these minutes about the delay in receiving advice, and clinicians were ready to go as soon as the advice was forthcoming. The protection of the public health was foremost in our thinking as shown by my own view recorded in section 8 of these minutes. [LOTH0000082_017].

148. Please set out, as far as you can recall, the policies and practices of patient de-notification that were implemented across the UK.

As I recall from memory, clinicians were informed about specific blood components or batches of plasma products and would then identify patients who had received these. The patients would then be informed. The implication in the LOTH0000082_017 meeting notes is that this notification would be done initially by letter. I do not remember whether this was the procedure throughout the whole of the UK.

Section 17: Your relationship with commercial organisations

149. Please answer the following questions with respect to your roles at the GBTS and SNBTS. Have you ever:

a. **Provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products?** No

b. **Received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture, sale and/or importation of blood products?** No.

c. **Sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture, importation or sale of blood products?** I have been a member of an advisory board for Glaxo-Smith-Kline, since I declared this in an academic paper. I am afraid I cannot recall what this was related to. Possibly the development of thrombopoietin. It was not in relation to blood products.

d. **Received any financial incentives from pharmaceutical companies to use certain blood products?** No

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

I was involved in a clinical trial of the prevention of cytomegalovirus infection in bone marrow transplant recipients when working as a Consultant Haematologist in Birmingham. I recall Alpha Therapeutic provided my hospital with high titre CMV immunoglobulin for this study at the same price as polyvalent immunoglobulin for use in the trial. This was at my request not at their request. I referred to this study in my earlier evidence to the IBI in 2020.

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

No.

150. **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?** I do not recall any specific requirements but I did provide paid advice to a pharmaceutical company called The Liposome Company which made an antifungal preparation of amphotericin B called Abelcet. This was when I was leading the bone marrow transplant unit at Glasgow Royal Infirmary. When I joined the SNBTS in 1996 I terminated this arrangement as I considered there could be a perception of conflict of interest and did not undertake any such work subsequently.

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

No. The CMV study referred to at 149.e was at my instigation and not on behalf of the company.

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

I do not recall providing the results of the CMV study to Alpha Therapeutic other than showing them the abstract that was submitted for presentation. This was prior to my involvement with SNBTS

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

I do not believe this was required in the 1980s. I did not receive funding directly, but my hospital received a specialist product - high titre anti-CMV immune globulin - at an advantageous price.

Section 18: Other matters

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

I attach a list with comments in the document 20210920-IMF_REFS-IBI. [WITN4032035].

155. 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).

Observations on past performance.

Underestimation of the risk of hepatitis, both in terms of number of adverse events [e.g. Contreras et al., 1991: Lancet 337; 753-757] and the severity of NANB / Hepatitis C [for example, Stevens et al. Brit J Haematol; 1983: 55; 649-655. Manchester haemophilia unit paper].

In the Lancet paper mentioned above, an incidence of 1 in 387 was interpreted as being very low, but when translated into hundreds of thousands of blood transfusion recipients over many years would have caused the infection with HCV of between 2 and 3 thousand annually, at transfusion rates then current in the UK. In minutes of a 12th February 1979 meeting of a Medical Research Council committee about Non-A, Non-B hepatitis, Dr Cleghorn, then director of the North London transfusion centre, stated that 'his impression was that PTH [post-transfusion hepatitis] must now be rare and that it would be difficult to find many cases.' Prof Sherlock concurred. However, Professor Zuckerman was concerned many cases could be non-icteric [that is, without jaundice and so would go unnoticed] - and so missed - and that 'the risk of progression to chronic liver disease remained, however mild the initial infection.' [I believe this issue was discussed at the IBI during Professor Christine Lee's evidence - reference is PRSE0001960 in my files]. As a junior hospital doctor in the 1970's I would say that this view as expressed by Dr Cleghorn was then prevalent and was taught to me. It is not clear to me now what systems were in place to assess the true risks of PTH in the UK at that time. What I have seen amounts to individual professional opinions, which represents a low level of evidence. [This aspect covers the list of issues 'knowledge of risk' generally].

Overanxiety with regard to supply

This was regularly in evidence over the period of interest [List of issues 24]. The CSM meeting of 13 July 1983 responded to the letter from Dr Galbraith of the PHLS [4 May 1983] who had suggested suspending the import of US coagulation factor concentrates [I do not have the IBI document references for these papers]. Although prescient, Dr Galbraith was already too late for his advice to prevent many of the HIV transmissions in men with haemophilia, which had already occurred. CSM minutes are redacted but mention 'grounds of supply' as a reason not to stop the imports of coagulation factors from the USA.

Another example of supply trumping safety would be ALT testing. Concerns over losing donors with raised ALT levels was a major reason given for not testing, as was not wishing to worry donors who might have a raised ALT that was hard to explain. This concern was repeated with the decision not to introduce first generation HCV antibody tests in c.1990 [see BBCO0000003]. More recently, on 1 November 1995, the CSM again considered that any withdrawal of blood products with respect to vCJD safety would 'create supply problems' and 'could also lead to a lack of public confidence in medicines containing blood derived ingredients' [MHRA0034568_004].

My response to this would be the subsequent success in implementing the deferral of previously transfused donors [PTD] in the UK, which lead to the loss of some 10% of donors without a blood shortage. Patient blood management initiatives [the Better Blood Transfusion project] in Scotland at that time reduced red cell use by 9% [separate from the PTD deferrals]. The reduction in red cell issues in England by 30% over the past ten years as cited by NHSBT suggests that, with not a great effort, supply issues could have been managed even in the 1980s to minimise unnecessary transfusion. Clearly managing without imports of coagulation factors for haemophilia care in the 1970s and 1980s would have been more challenging.

Failure to confront donors with uncertainty over results [Issue 297; perhaps also 143].

A lack of candour has coloured relations between the health system generally, and the blood services too, in their relationship with donors and recipients of blood transfusions. Not introducing ALT testing because, in part, it was not easy to explain a high ALT level seems now to be a weak excuse. Not wanting to disturb donors, even when a blood service has important information relevant to their health, such as a previous transfusion from a donor now known to have HCV, is also hard to defend in the current era. This was evidenced in the resistance to look-back for HCV. Usually when doctors don't want to tell patients or donors something, it reflects their own anxieties about giving bad or difficult news. Prior to my time as medical & scientific director of SNBTS, the

standard organisational response to a transfusion associated infection in the UK being made public was to emphasise the safety of blood. Mr Macmillan Douglas and I amended this response to state that "blood transfusion is safe by the standards of most medical and surgical treatments, but will never be zero risk."

Obsession with internal systems not being overwhelmed. A large number of indeterminate positive tests following ALT testing and first generation HCV tests [false positive donors with the first generation test] could 'clog up the system' [Panorama programme 1995 on 'Bad Blood.' IBI reference BBC00000003].

Reluctance to spend money on blood safety

Even after the HIV disaster there still persisted a reluctance to spend money on blood safety. In my time HTLV testing was a good example. Colleagues and I had to devise a cheap method of doing this before it was approved for implementation. There was a view in some parts of the UK transfusion services that cheap blood was a good thing. Perhaps this was the view passed down from the DoH. I never felt that pressure from the Scottish Health Department. From my perspective I believed in safe blood, and was concerned that making blood cheap would mean its use would be less controlled in hospitals. From my years working in hospitals it was always the expensive drugs that were scrutinised, not the cheap ones. I can't find this as a specific item in the list of issues, but mention it anyway.

Delays in decision making

Delays in decision making can occur when decisions are deferred to committees of busy people - however expert and keen to help - which may not meet sufficiently often. [List of Issues 1]. Even now we are beyond the Official Secrets Act controlling the flow of information, from my personal experience the

way in which SaBTO operated was not responsive enough to clinical needs. As a sometime member of SaBTO I can only commend the work put in by my colleagues, it is simply that I do not believe this is the best way to deliver blood safety. Using committees to decide matters of such great importance seems to hark back to the effortless amateurism of the British Empire.

There were delays in actually setting up committees when these had a political dimension - EAGA in the 80s for AIDS - the first meeting was on 29 January 1985, well into the AIDS crisis for those of us caring for HIV positive patients - and the CJDIP in the 90s.

Neglect of the infected individuals

Such neglect has been described in detail, both in respect of their medical care and support - HIV and HCV particularly - and in the provision of financial support, let alone 'compensation.' [List of issues 298 and 318 in particular but not exclusively].

These are problems of the past and perhaps the present.

Moving forward.

It will be important to move on from the current laborious system of developing blood safety which depends on government committees providing advice to ministers - not a very responsive way of making decisions. Working groups looking at costs per QALY is also a slow and laborious systems approach.

The cost of blood safety measures can appear very expensive compared to other interventions, even cancer treatment. This is predicated by the need to assign all the cost of an intervention to the few positive donations identified and so an infection prevented. No financial value is assigned to an HIV negative test, for example, even though such a test is a legal requirement. Although the NHSBT does not go into the costs of preventing HIV, HBV and HCV in their annual report, they do describe the risks as being one transmission every so

many years. Current [2019] figures for NHSBT [England regarding blood transfusion] show the risk of HIV from a blood transfusion as 1 in 12 years, for HCV 1 in 72 years and HBV 2 in a year [RLIT0000799].

Could this be a way of defining safe blood, identifying how infrequently such an event might occur, relevant to IBI question 109 above? Or will it be necessary to maintain and aim for >70 years between infections when red cell issues are some 1.3 million annually? One in 100 million transfusions. As blood transfusions of red cells fall it is possible that patients who receive these now may be more seriously ill than in the past and so fewer may survive to demonstrate TTI in later years. Continued surveillance and haemovigilance will be essential, and the data on survival of transfusion recipients revisited regularly. Immunoglobulin recipients are a concern, particularly those receiving anti-D to prevent Rh disease of the foetus and newborn. Improvements in the development of therapeutic monoclonal antibodies suggest re-visiting the use of monoclonals for anti-D to replace blood derived products.

It would be useful to calculate the current cost of a QALY for blood safety based on existing tests that it is considered could not be withdrawn - HIV antibody tests for example. This would give some idea of the real unavoidable costs of safe blood away from artificial costs per QALY, always subject to downward pressure, based on perceived affordability.

If there was a definition of what constituted 'safe' blood, then donor selection, testing and processing methods might respond to that. A consultation process would need to consider such a move. The [hopefully] very few who are affected by transfusion transmitted infections and perhaps other transfusion mishaps should be entitled to support, treatment and future care. Avoiding having to go through courts would be a high priority. There should be an appropriate support and reparation scheme, which would include financial support, compensation, medical care and other matters as required. Such a package, along the lines of that provided to vCJD patients, would provide some sense of restorative justice, rather than the prevailing utilitarian approach where the injured are left to their own devices to sue for compensation, and join a rationing queue for

treatment as happened to those infected with HCV in the past. The use of utilitarianism as a philosophy to underpin the delivery of healthcare has led us to this Inquiry. Also the administration of any support schemes would need to be more humane than some of the reports to the IBI of the current plethora of trusts.

History teaches us that there will be future pressures on cost in the blood transfusion services - this despite the one third reduction in transfused red cells in the past decade and the sorry history of past infection transmissions. One concern I have is that now the UK is out of the EU this will at some point be seen as an opportunity to diverge from the EU Blood directive and reduce the safety standards applied to blood transfusion. It would be preferable to continue to see the EU Directive as a useful template for minimum safety standards for blood transfusion in the UK but seek to amend the regulations to achieve higher standards wherever possible. An agreed level of blood safety - or what constitutes safe blood, as mentioned above and in q109 - might be identified using a consultation exercise between expert and patient groups. There should be consideration of developing a UK 'blood law' as exists in Germany that would ensure no back-sliding on safety.

Separating the responsibility for blood safety interventions from 'Ministers' and establishing a body with this responsibility would help, in my view. Rather like the Bank of England being given control of interest rates, an independent body could be given responsibility for ensuring safe blood. This would be similar to the current role of the Food and Drug Administration in the USA.

To summarise:

- Change the philosophy.
- Have a legally constituted body that is responsible for blood safety - not a committee.
- Determine a metric for what is safe blood.
- Put that into law.
- Obtain consent prior to, and provide information after, transfusion or exposure to blood derived products.

- Look after those [hopefully few] damaged despite all best efforts.

Many professionals in UK blood services, and indeed hospital staff, have not been involved in transfusion transmitted infection events. As the knowledge and memory of past disasters fades it will be important to ensure that safety systems remain rigorous to avoid history repeating itself and returning to the complacency of the mid-1970s.

Proper consent prior to transfusion wherever feasible and post-transfusion information will help to ensure that the safest blood transfusion remains the transfusion safely avoided.

156. 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?

As far as I am aware, there had never been imports of blood components until some platelets for paediatric use for children born after 1996 as a vCJD safety measure. Personally, I do not remember importing platelets but this issue is discussed in a SaBTO Paediatrics Components Working Group report from 2019 which recommends this may now cease. I do not know when these imports began or how many donations were imported or from where.

157. During your tenure, 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?

As far as I am aware, this never happened, and certainly not in my practice. The only scenario in which it may have occurred would have been using a donor from the Rare Donor Panel which would obtain exceptionally rare blood

group donations from around the world for life saving treatment. It is possible that the International Blood Group Reference Laboratory Red Cell Reference lead at NHSBT Filton would have access to such records.

Statement of Truth

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

Signed GRO-C

Dated 17th February 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
2 October 2020	Written statement of Professor Ian Maxwell Franklin.	WITN4032001
	A Multicenter, Randomised, Controlled Clinical Trial of Transfusion Requirements in Critical Care. Paul C. Hébert, M.D., & the Transfusion Requirements in Critical Care Investigators for the Canadian Critical Care Trials Group. N Engl J Med 1999; 340:409-417.	WITN4032031

	[https://www.nejm.org/doi/full/10.1056/NEJM199902113400601]	
8 November 2005	20051108-CMOBurns_HCV_NAT. Letter from IMF to CMO Scotland [draft]	WITN4032033
31 March 2020	NHS Blood and Transplant Annual Report and Accounts 2019/20 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/924960/30204_022nd_Annual_Report_and_Accounts_2019-2020_Accessible.pdf	WITN4032034
July 2011	Wilson K [2011] A Framework for Applying the Precautionary Principle to Transfusion Safety. Transfusion Medicine Reviews, Vol 25, No 3 (July), 2011: pp 177-183	WITN4032032
	20210920-IMF_REFS-IBI – List of articles published by Professor Ian Franklin.	WITN4032035
2019	Poster called 'Undetected HBV, HCV and HIV – the Risk in the UK Blood Supply, 2019' by NHS Blood and Transplant and Public Health England.	RLIT0000799