Witness Name: Professor Stanislaw Urbaniak
Statement No.: WITN6960001
Exhibits: WITN6960002-017
Dated: 16 December 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR STANISLAW URBANIAK

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 3rd September 2021. .

I, Professor Stanislaw Urbaniak, will say as follows:

Section 1: Introduction

1. Name, address, date of birth and professional qualifications

1. Professor Stanislaw Joseph Urbaniak.

2. Date of birth: GRO-C 1945.

3. Address: GRO-C Scotland.

4. Professional qualifications: BSc (Hons), MBChB, PhD, FRCPEd, FRCP, FRCPath.

2. Employment history, dates, roles and responsibilities

5. I graduated from Edinburgh Medical School in June 1970 and my first appointment to the SNBTS Edinburgh was in 1974, as a Senior Registrar, and then I was appointed Consultant in 1977. I moved to the Aberdeen and North East Blood Transfusion Service (ANESBTS) in 1982 as Regional Director Designate and Consultant in Transfusion Medicine, and became Regional Director in March 1983 after the retiral of Dr Brodie Lewis.

6. I did all my pre-Consultant medical training in Edinburgh Hospitals, including working in the Medical Renal Unit as SHO looking after acute and chronic dialysis patients. This is where I first became aware of the issues surrounding HBV infected patients, and procedures required to avoid self-contamination from needle-stick and exposure to infectious blood, when at that time, the HBV positive dialysis patients were housed in a separate isolation ward. I also became familiar with the frozen/thawed red cell system developed in Edinburgh for renal patients to avoid viral transmission of disease. My first post in the SNBTS at the Edinburgh Centre was as Senior Registrar (1974-77). My interest was Immunohaematology, and being academically inclined, I undertook a part-time PhD at Edinburgh University during this time. I became familiar with all of the professional aspects of the Service from donor to patient as part of my training. After my appointment as Consultant in 1977, my responsibilities were as follows:

7. Consultant responsibilities at SEBTS (1977-82)

- Regional Antenatal Laboratory - testing blood of pregnant women for red cell management of such women in conjunction with Obstetricians including Intrauterine Transfusions; red cell exchange; and advice on use of anti-D immunoglobulin) to prevent immunization)
- Regional blood group reference service – diagnostic service for autoimmune Haemolytic Anaemia; investigation of haemolytic transfusion reactions; identification of complex antibodies in transfusion recipients.
- Regional Transplant and Tissue typing laboratory – HLA typing of dialysis and other renal patients awaiting transplant; HLA typing and matching of donor & recipients for renal transplants; identification of platelet and WBC antibodies in patients with Transfusion reactions.

- Regional therapeutic apheresis service for patients requiring plasma exchange, red cell and leukocyte apheresis (which I introduced to the service and developed from the beginning).
- I took over supervision of the Immunology Service from Dr. B Kay after he left to take up a post at Edinburgh University.
- Because of my expertise in HDN and anti-D immunoglobulin, Dr. Cash (the Director at that time) asked me to initiate a program to boost anti-D plasma production from RhD negative blood donors.
- I also took part in the 24-hr Medical on-call roster for the Blood Bank on an equal basis with the other 3 consultants (1in 4 nights/weekends)
- I participated in teaching and training, had a part-time Senior Lecturer position in the Department of Therapeutics and undertook research on grant-funded projects.

8. I had no Consultant responsibilities for care and selection of blood donors, the production of blood components, the collection of plasma for the Protein Fractionation Centre, the Hospital Blood Banks, the blood coagulation factor laboratory, or the microbiology/virus testing laboratory, which were the responsibility of the other Consultants and I was not involved in decision making in these functions involving donors. I therefore did not follow the literature in these areas particularly closely, but relied on information from my colleagues who did.

9. Because of my experience with the frozen/thawed red cell bank we elected to use blood from the same red cell donors, because this allowed quarantine of the donation for several months whilst donor health was followed, and repeat virology marker testing (to exclude window period infection) prior to release. This gave maximum available safety for the donor, and also the recipients of the products made from these donations. I therefore became familiar with the special circumstances surrounding selection for this particular group of donors. The WHO, and the Plasma Industry subsequently adopted my program for improving the safety of frozen red cell banks.

10. After taking Consultant responsibility for the Immunology Service in the late 1970s/early 1980s, I became aware of AIDS as an immunodeficiency disease. At that time there was greater concern that Hospital staff who came into contact with the blood of patients with AIDS might become infected, even though the causative agent had not been identified. RTC blood bank staff came into the category of staff that were at risk because of the need to handle blood samples for the open manual procedures for blood grouping and cross-matching for blood. These concerns, together with the known risk of handling HBV+ patient samples, subsequently lead to the adoption of "universal precautions" for the handling of all blood samples for patients in the 1980s, but to do so required considerable laboratory redesign, the introduction of automated techniques, staff training etc. at the same time as the first data emerged that HIV could be transmitted by blood products (plasma from 1000s of donors). This was the background against which all SNBTS Directors had to contend in 1983 while discussing what precautions might be taken to identify, and exclude blood donors, that carry the agent subsequently identified as the HIV virus.

11. Responsibilities at NEBTS as Regional Director, and Consultant in Transfusion Medicine (1983 - 1999)

    I was appointed as Director Designate for the NE Region in late 1982 so that I could "shadow" Dr. Brodie Lewis, the Regional Director, at the Directors' meeting for some months until he formally retired on 3rd March 1983. His last official meeting with the other Directors was at the BTS Coordinating Group meeting on 22nd February 1983, when he was thanked for his service. The first Directors meeting that I attended in my own right, without Dr. Lewis present, was that of 29th March 1983, when the matter of blood collection from Prisons was on the agenda (see later). The Regional Director was the only Medical Consultant present at the NEBTS, this being a single-handed post covering every aspect of blood transfusion (as listed in my SEBTS post

above), from Donor selection, donation testing, blood component manufacture, laboratory testing of antenatal pregnant women, the regional blood bank, the regional HLA laboratory and transplant organ and donor matching service, i.e. including all the aspects of services that I had no Consultant-level experience of managing whilst in Edinburgh. I had the support of one elderly Associate Specialist who would share the 24hr on call medical support for the RTC blood bank, the second having retired before I took up post.

12. This was an extremely busy time for me at Consultant level since I was now dealing with a Blood Bank with a workload similar to Edinburgh RTC Blood Bank at ERI (which had 4 Consultants), in addition to all the administrative, managerial and budget-holding responsibilities unique to the Regional Director. Furthermore, I had been asked by Dr. Cash (PRSE0002460 / SGN.003.5175) to take responsibility for addressing urgently the many criticisms in the Inspector's report (PRSE0004141), of which the root cause was lack of space and unsatisfactory design. This involved completely re-doing the plans of my predecessor for a temporary upgrade of the RTC (predating the MI Inspection of 24.3.82, whilst also leading on planning and making the case for a new Regional Transfusion Centre.

13. Please see my curriculum vitae of 1988 for details of my earlier posts (WITN6960002)

14. In 1989, a second Donor Consultant was appointed in ANESBTS (Dr George Galea), who took over from me the responsibility for the management of Donors and microbiology testing of blood donations on a day-to-day basis. This was later shared with Consultant Dr Philip Yates, appointed in 1992, until Dr Galea, moved to Inverness in 1993.

15. I remained in the above posts until the major reorganisation and centralisation of the SNBTS, when I relinquished the managerial responsibilities of Regional Director, to take up a Professorial post at the University of Aberdeen (UoA). I became Director of the newly established

Academic Transfusion Medicine Unit, jointly supported by the SNBTS and the UoA. I maintained my Consultant post at the ANESBTS as a working clinician (including Consultant on-call duties) and also providing advice at a National level (as below).

16. *Posts from 1999-2010 (date of retirement):*

Director of Academic Transfusion Medicine Unit, Department of Medicine & Therapeutics, and Professor of Transfusion Medicine, UoA
SNBTS Immunohaematology R&D group Leader (multicentre)
Consultant in Transfusion Medicine, ANESBTS
National Adviser in Immunohaematology, SNBTS (Board level post)

3. Membership of committees, societies etc relevant to the Infected Blood Inquiry's Terms of Reference

17. A list of my committee and society memberships are given below:

Member of the following committees/professional bodies relevant to the IBI:

Member of Grampian Regional Committee for Hospital Medical Services, 1983-1986
Member Grampian University Hospitals Trust (GUHT) control of Infection Committee 1992 – 2002
Convenor, GUHT Hospital Transfusion Committee 1999 – 2002
Member GUHT Clinical Risks Management Committee 2000 – 2003
Member of the following SNBTS National Committees:
Regional Transfusion Directors' Committee 1983-1990
Medical & Scientific Committee 1990 - 2010
Regional Directors' Coordinating Group 1983-1990
SNBTS Management Board 1990 - 2010
Product Development Group at PFC 2000 – 2005

Member NHS in Scotland Clinical Resource and Audit Group (CRAG) Working Party on Blood Utilisation 1992 – 1994

Chairman of UKBTS Immunoglobulin Working Party 1996 - 2002

Member of UKBTS Committee on Codes of Practice for Plasmapheresis 1981 – 1995

Member of UKBTS working party on anti-D immunoglobulin 1978-88

18. *Member of the following learned societies (to 2010) :*

Aberdeen Medico-Chirurgical Society

British Society of Immunology,

British Society for Haematology,

British Blood Transfusion Society (assistant secretary 1982-1985)

Scottish Society for Experimental Medicine

American Association of Blood Banks (International Member),

American Society of Haematology (International Member),

European Society for Haemapheresis (Councillor, later President 1993 – 1995),

World Apheresis Association, (Executive Committee Member 1994 – 2000),

International Society for Blood Transfusion (Chairman International Platelet Immunology workshops (2002-2008).

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

19. I kept up to date on medical and scientific developments and research during my career by regularly reading the major scientific journals in my field (e.g. Blood, Transfusion, Vox Sanguinis, British journal of Haematology, British Medical Journal, Lancet), attending medical and scientific conferences annually, where advances and reviews were presented, and by participating fully in the Accreditation and Continual Professional Development scheme of the Royal College of Pathologists. The SNBTS Directors Committee meetings, and the SNBTS MSC were a valuable source of information from

colleagues' expert knowledge, briefing papers, and feedback from various expert committees/ working parties, often in advance of the published data.

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

20. I was not involved in the original stages of the Penrose Inquiry, and was not cited as a witness to appear before the Inquiry. After the first Draft Report was compiled, I received several Warning Letters in 2014 because I had been cited by name in the Draft Report. I provided detailed written answers to each of criticisms implied, providing evidence explaining my position. In some cases my comments were accepted, and the final report amended; in other cases, they were noted but no change was made in the final Penrose Report. I was not involved in any other inquiries, investigations, criminal or civil litigation.

General Comments

21. I hope the IBI will appreciate that it is now 30-40 years since the events questioned took place, and 7 years since I responded to the Penrose Inquiry, and my memory of the events questioned is no longer fresh at the age of 76. I will therefore have to rely on my notes made at the time of the P.I., and on electronic retrieval of files from the Penrose archives, and the documents provided by the IBI to answer the questions put to me under Rule 9, since these are much more detailed than I could hope to provide afresh.

<u>Section 2: Your role at the Aberdeen and North East Scotland Blood Transfusion Centre</u>

6. **Please describe the roles, functions and responsibilities you had at the Aberdeen and North East Scotland Blood Transfusion service]**

("ANESBTS") during your period as Director and explain how these changed over time.

22. Details of my Director and Consultant responsibilities at ANESBTS from 1983 to 1999 are given in questions 2 and 3 above. My post as Director of ANESBTS in 1983 included acting as "General Manager" for the centre, including budgetary and staffing matters, as well as professional duties as a full-time Consultant in Transfusion Medicine, and teaching and research as a Senior Lecturer at the University of Aberdeen. This was rather unique at the time, because other medical Consultants did not have the same managerial responsibilities, or financial autonomy. As General Management evolved in the NHS, and the SNBTS in particular, the major changes were the introduction of a General Manager (GM) of the Common Services Agency, to whom one reported on such matters (mainly financial targets), rather than to SNBTS HQ. This evolved further with the appointment of a GM for the SNBTS, further removing the SNBTS Directors from interaction with the CSA (and the SHHD as it was then). Professionally, there was little change in responsibilities, with the concept of "clinical freedom" pertaining, although always within the constraints of professional probity and budgetary responsibility.

7. **Please describe the organisation of the Aberdeen and North East Scotland BTS during the time you worked there, including:**
    a. **its structure and staffing and in particular to whom you were accountable;**
    b. **how the ANESBTS was funded and how this changed (you may find PRSE0000734 useful);**
    c. **its remit, including the geographical area it covered and the hospitals within its area;**
    d. **its place in the SNBTS together with information as to whom the centre was answerable to at the SNBTS, if anyone.**
    e. **whether the ANESBTS was associated or linked with other Blood Transfusion Service ("BTS") in Scotland and, if so, how and for what purpose;**

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

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

h. The ANESBTS's relationship with any pharmaceutical companies involved in the production of blood products; and

i. the approximate number of donations collected each year (you may find NHBT0002935 (page 13), NHBT0002937_001 (page 5-6), PRSE0000415 (page 5 paragraph C) and PRSE0000633 (page 3 paragraph VIII of assistance).

23. **a, b, c, d, e.** The organisational structure of the SNBTS, and its governance and financing from 1974 to 2009, are described in the documentation submitted by SNBTS HQ to the Penrose Inquiry. I cannot provide greater detail than this for the overall position. Regarding the ANESBTS, as a recently appointed Director, and a strong supporter of national cohesion within SNBTS, I always followed whatever procedures were required at the time, and common to all SNBTS regions, as were developed from the SNBTS RTD meetings, the Directors Coordinating Group, and later, the MSC. Details of these activities are recorded in the minutes of these committees (too many for me to list here). The area for which I was responsible, and the services that ANESBTS provided, are detailed in question 2 above. The staff organisation chart for ANESBTS at 1982/83 is given in reference (PRSE0004141).

24. **f.** In common with all the SNBTS centres, blood collection, processing to components, and the provision of FFP to the PFC, ANESBTS was regulated by the Medicines Inspectorate. The centre was subject to regular inspections in order to maintain our manufacturer's licence, and had attracted an adverse report at the time of my appointment, mainly for the physical environment (PRSE0004141). The Blood Bank and related laboratory services were also included in the inspections, but not the other clinical or laboratory reports provided by the Clinicians, which were later inspected under the CPA

schemes set up by the RCPath. and the Institute of Biomedical Scientists (IBMS).

25. **g.** ANESBTS' relationship with the PFC was as an integral part of SNBTS.

26. **h.** ANESBTS had no relationship with pharmaceutical companies.

27. **i.** The annual statistics of blood collection at ANESBTS are referenced elsewhere in the full internal management annual reports compiled by SNBTS HQ. I do not have access to these reports now, but ANESBTS had one of the highest donation rates per capita (56/1000) in the UK during my tenure as Director.

Section 3: Blood Collection at ANESBTS

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

28. Blood collection at ANESBTS is documented (WITN6960003, pages 3,4,5), with further comments below.

9. **The Inquiry understands there were numerous iterations of the Memorandum on the Selection, Medical Examination and Care of Blood Donor's which were published in 1977, 1983, 1985 and 1987. According to PRSE0005010 (page 40, Chapter 18, paragraphs 18.26 - 18.29) you indicated that you used the 1977 Memorandum during your tenure as Regional Transfusion Director.**
    a. **How long did you use the 1977 iteration, as opposed to the subsequent iterations?**
    b. **Given that there were subsequent versions of the Memorandum which were published after 1977, why did you continue to use an outdated version and advice?**
    c. **At paragraph PRSE0005010 (Chapter 18, paragraph 18.29), The Penrose Inquiry found that in the National Blood Transfusion**

Service ("NBTS"), a move away from the 1977 Memorandum began in 1982. Was this also the case at ANEBSTS? If so, when did this occur? If not, why not?

d. **According to PRSE0005010 (Chapter 18, paragraphs 18.26 - 18.29) the 1977 iteration stated that, on assessing the suitability of donors "*A donor is the best judge of whether he is in normal health and truthful answers to simple questions concerning his medical history and general health for the main part of the examination.*" What was your view on this guidance?**

29. **a, b, and c.** Contrary to what is asserted above, I did not use the 1977 Memorandum throughout my tenure, only until taking over from Dr Brodie Lewis in March 1983. As soon as I was in full post, and the 1983 Memorandum was available through the SNBTS, I changed to the updated version, and subsequently to other updates at the same time as all the Regional Directors. Details of the changes are provided below.

30. At the time of my appointment, the Donor selection guidelines, and the document used by ANESBTS session medical staff in answering any medical referrals, was the NBTS December 1977 Memorandum, referred to elsewhere in the Inquiry documentation (PRSE0004358). I saw no reason to change this. The NBTS Memorandum was updated in 1983 as a Guidance note (SGF.001.01377, 1983), and this too was applied locally, until eventually replaced by an SNBTS version in 1987 (PRSE0004115). The ANESBTS donor session questionnaire used at the donor selection desk was based on the content of these documents, and, as far as I am aware, the other SNBTS Regions did likewise. The only archive material that I have been able to obtain was that used by my predecessor, Dr Brodie Lewis (WITN6960004, NEBTS donor session health check) and discussed further in my responses to Q11 and Q106 below. The NBTS and SNBTS donor selection guidelines included a specific reference to tattooing as a deferral criterion. As tattooing and ear piercing became ever more popular among the general public, these criteria were modified to allow donation only if such took place in

licensed/regulated premises, otherwise there would have been a significant drop in new, younger donors being accepted, so affecting the blood supply. I have given a detailed comment about tattooing as a high-risk action that results in viral transmission by blood in Q11e below. But it is worth pointing out that Dr Lewis had tattooing as a deferral criterion on the ANESBTS donor selection "leaflet" in advance of the NBTS 1977 Memorandum, this being in response to an outbreak of HBV associated with tattooing in Aberdeen in 1972 (WITN6960005).

31. **d.** This was considered satisfactory in general, as donors were considered to be altruistic, and would not wish to harm others through their donation. But in certain circumstances there could be peer pressure to donate (e.g. in workplace sessions or prisons) rather than explain to colleagues why they were not donating "as expected". Also, in some community donor sessions there was very little privacy (due to the physical environment) and prospective donors would not want their neighbours (next in the queue) to know about their medical status. Therefore, a move to more (intrusive) questions combined with enhanced facilities for privacy was an important development, especially when enquiring about sexual health, as became essential on the discovery of AIDS/HIV and HCV.

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

32. The ANESBTS held "fixed" donor sessions in the Donor Centre in Aberdeen on the Foresterhill medical campus (headquarters of the Centre). These were held on several days and evenings each week and were publicised in local newspapers and local radio, as well as in the centre itself, on posters. In addition, the Service had a program of "mobile" donor sessions scheduled throughout the calendar year in various locations in Aberdeen city, and the surrounding villages and towns of the ANESBTS catchment area. These sessions were (usually) repeated twice each year at each location. At each location there was an honorary Donor Organiser working with the Centre's

(professional) Donor Organising Secretary in publicising in advance each of the sessions, and actively recruiting local donors. Donors who had given previously at a particular donor session were sent a letter of invitation to attend at the forthcoming session. These activities were highly successful in maintaining a "repeat donor" base of regular donors, and led to self-sufficiency in red cell donations (except for the occasional rare blood group) in the ANESBTS region.

11. To what extent did the ANESBTS collect blood from prisons, borstals and similar institutions? In particular:

a. How many donations did the ANESBTS collect from borstals and similar institutions? Please identify and set out the number of such institutions from which blood was collected, and the frequency of sessions.

b. What role, if any, did you have in this practice? You may find MACK0001108 (page 10) and PRSE0005007 (page 25, paragraph 26.100) of assistance.

c. According to MACK0001108 (page 10), at an SNBTS meeting on 29 March 1983, Dr Cash reported that the 'Medicines Inspector had commented adversely on the practice of collecting blood from prisons and borstal institutions'. At this meeting, you expressed the view that prison collection was undesirable and that you intended to review this practice in your region (you may find PRSE0004996 at page 68 of assistance).

i. **Please explain the steps you took to review the practice in ANESBTS and what the result was.**
ii. **Please explain what informed your view at the time and whether other Directors shared your view.**

d. When did the ANESBTS stop collecting blood from borstals and similar institutions?

e. In oral evidence given by Dr Dow to the Penrose Inquiry, Dr Dow stated that he thought that drug abuse was a likely explanation for the higher prevalence of Hepatitis B in male prisoners. The Penrose Inquiry Final Report states that you opined that before the marked increase in intravenous drug use in the early 1980s, tattooing was a more likely explanation for the increased prevalence of Hepatitis B, as prisoners were liable to tattoo themselves or others, in unhygienic circumstances. Please explain how you came to this conclusion. You may find PRSE0005007 (page 25, paragraph 26.100) of assistance.

What were the relative costs of collecting blood from prisons as compared to collecting blood at the ANESBTS?

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

33. **a.** At the time of my appointment, donor sessions were being held in HMP Craiginches in Aberdeen, and HMP Peterhead, but no other penal institutes. I think sessions were held every 6 months (twice a calendar year). The number of donations is given in the SNBTS report on prison blood collection submitted to Penrose (PRSE0002164).

34. **b.** I had no direct involvement in this practice. The session program was set up, one year in advance, by the Aberdeen Donor Organising secretary (Miss Anne Cordiner), under the direction of the then Regional Director, Dr Brodie Lewis. When in post as Director, I discontinued any further sessions, as discussed in Q11c.

35. **c.** I was not involved with any of the Medicines Inspectors (MI) visits to ANESBTS (SBTS0000407), or Edinburgh and South East BTS (SEBTS) (SBTS0000407_006), which did mention prison sessions, nor the Inspectors' visits to Glasgow and South West BTS (SSWBTS) (SBTS0000407_006) and North Scotland BTS (NBTS) (PRSE0002428), that did not mention

prisons. I was not involved in the MI visit to ANESBTS in 1982 either, so I was not aware of the Inspectors' opinion about prison sessions before the meeting with Dr Cash on 29th March 1982.

36. I was appointed as Director Designate for the ANESBTS Region in late 1982, so that I could "shadow" Dr. Brodie Lewis. I accompanied him to my first Directors' meeting on 14th September 1982 PRSE0000451, and subsequent meetings, until his retiral on 3rd March 1983. The first Directors' meeting that I attended in my own right, without Dr. Lewis present, was that of 29th March 1983, when the matter of blood collection from prisons was on the agenda. As the minute records, I was to review the situation in the ANESBTS region.

37. From the discussion around the table on 29th March 1983, I had formed the opinion that it was probably undesirable to continue with prison blood collection, and it is noted in the minute (page 5, item 7) that I intended to review the situation in my region. After this meeting, I took 2 courses of action.

38. 1) I reviewed the blood collection program with the Organising Secretary (set 1 year ahead) and noted that 2 prison sessions were scheduled for 7th July 1983 (HMP Craiginches WITN6960007), and 28th July 1983 (HMP Peterhead (WITN6960008). I informed her that I was of the opinion that these sessions should not continue, but that I would visit them personally to see at first hand the environment and procedures before making a final decision. This I did, and my experience was similar to that of Dr. Brookes regarding potential undesirable peer pressure to donate, confidentiality problems, and the unreliability of the medical history given (PRSE0001873). All of my donor team staff was female, including the session Medical Officers (MOs), and I felt very uncomfortable about them being present in the highly charged all-male environment, particularly at HMP Peterhead. I had no hesitation in deciding that no further sessions should be held, on these grounds alone.

39. 2) Since it was known that the prevalence of HBV among populations, and prisons, varied from region to region, I set about doing a cluster analysis of the historical data in the ANESBTS records, noting where the HBV positive donors had come from. Since I was the only person authorized to break the code between the numbered donor samples that were identified as HBV positive and the donors' personal record, I had to do this personally, so it took some time to complete. Nevertheless 2 "hotspots" emerged – HMP Peterhead and HMP Craiginches. I therefore had the objective evidence to present to the Prison Governors as to why this long-standing practice would discontinue, and I informed them that, regrettably, we would discontinue donor sessions in future. This they accepted.

40. The only reason that the last prison session was 4 months after the 22.3.83 Directors meeting was that I decided to visit the prison sessions personally to observe the procedures, and the time taken to review the incidence of HBV in prisoners' donations.

41. **d.** On 28th July 1983, at HMP Peterhead.

42. **e.** As I recall, at the time (1982/83) intravenous drug abuse (IVDA) had not yet become a serious issue in NE Scotland (unlike Edinburgh and Glasgow) and the prevalence of drug abuse was much lower. Tattooing was a known risk factor for transmission of Hepatitis B, and recent tattooing became an exclusion criterion for acceptance of blood donors at ANESBTS before the other centres (see question 9). On the balance of probability, I felt that, at the time, IVDA abuse was less likely than prison tattooing. This is discussed in more detail below.

43. Several references to tattoos are made in the Penrose Report (PRSE0005007) For example, a study in Finland quoted by Prof. Leikola (paragraph 26.37); a comment in Dr. Wallace's book (paragraph 26.88); and in oral evidence by Dr. Mitchell (paragraph 26.99), when referring to increased HBV in prisoners. It is well known that prison inmates will tattoo themselves, or each other, and that the circumstances in which they do so

are far from hygienic. Before the explosion of IVDU in Scotland some time after 1983, tattooing is a more likely explanation for the increased prevalence of HBV in prisons before 1982 (in the NE at least), and one of the reasons behind the "social habits and hygiene' comment made at several points in the Draft Report. Dr. Dow also refers to the other means of transmission within prisons such as "homosexuality and the sharing of razors and toothbrushes etc"(PRSE0006007, paragraph 26.100. We in the NE were well aware of the risk posed by unregulated tattooing (and ear piercing), having a significant population of sailors, peripatetic merchant navy seamen and fishermen, and the ANESBTS donor selection health check included a specific reference to tattoos as a deferral well before 1983 (WITN6960004). This was prompted by a minor local outbreak of HBV associated with a tattoo parlour in 1972. (WITN6960005)

44. Later versions of the NBTS and SNBTS donor selection guidelines included a specific reference to tattooing as a deferral criterion. As tattooing and ear piercing became ever more popular among the general public, these criteria were modified to allow donation only if such took place in licensed/regulated premises, otherwise there would have been a significant drop in new, younger donors being accepted, so affecting the blood supply.

45. **f.** I do not think there was any difference in costs with other mobile sessions using the same resources of staff and equipment.

46. **g.** No incentive was provided by ANESBTS other than tea/coffee and biscuits, as offered to all donors at all of our sessions. There may have been some incentive for the prisoners in getting "time off" from whatever they normally did during the day.

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

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

b. According to PRSE0002912 page 10, at an SNBTS Co-Ordinating

Group meeting in May 1985, you expressed the view that "it was a major advance that someone would be appointed as managerially in charge of each donor session." Please explain what you meant by this and how this differed from previous sessions.

c. Where did these sessions take place?

d. How frequently could a person donate blood?

e. How were blood donors recruited?

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

47. **a.** When I first became Director, a member of the Donor Office staff would be in attendance with all the records of donors who had given blood previously. This was a manual system using index cards. At the interview/questionnaire stage, the Office staff would look at the records (if any), whilst a donor attendant took the finger prick sample to determine the Haemoglobin level (pass/fail). There would be a team of Donor Attendants (DA) who see to the donors before, during and after giving blood, with a Team Leader (a senior experienced DA) organising their duties. These were not qualified nurses, but trained "on the job". There would usually be 2 medical staff that undertook the actual venipuncture of the donor, and were available to answer any questions arising during the donor history that required a medical opinion. At "mobile sessions" outside the Centre, all the staff and equipment travelled together on a specially designed bloodmobile driven by ANESBTS drivers, who also assisted with the physical setting up of the donation beds etc., acting as porters. At the larger sessions, where donations needed to be processed within 6hrs for the preparation of fresh frozen plasma (FFP) and cryoprecipitate, a second driver would attend with a refrigerated vehicle to take the donations already collected back to the Centre for processing. Latterly, with the introduction of specially trained nursing staff (RGN or SRN), they would assume overall responsibility for the donor session, including participating in venepuncture.

48. **b.** With multidisciplinary staff of differing seniority/experience at donor sessions, there was no formal management structure as to who could "give orders" to whom. It might be assumed that this was the medical staff, but at mobile sessions they were not always tenured members of staff, but employed on a sessional basis (often anaesthetists in training who were good at venepuncture). Once we started recruiting Head Nurses (usually Sister grade), and donor session nurses (staff nurses) as trained venepuncturists, they gradually replaced most of the "casual" medical officers. Since they reported to the Donor Consultant at the Centre, it was logical that the Sisters/Staff Nurses would take delegated responsibility for managing the donor sessions.

49. **c.** As above, about 1/3 in the Donor Centre, and 2/3 at factory, office, community halls and school halls throughout the NE Region. Sessions were usually held twice per year at each location, so regular donors could donate every 6 months.

50. **d.** Donation every 6 months was the norm in the 1980s, later relaxed to 12 weeks.

51. **e.** See my response to question 10. above.

52. **f.** Session management evolved as per b. above.

53. The organising of sessions at ANESBTS is also discussed in my answer to Question 2, and WITN6960003, pages 2, 3, 4.

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

54. As far as I recall, Regional donation collection targets were set at a level to meet the requirement for blood demand within that Region, with rare exceptions of rare blood groups, or massive transfusion that exceeded local stocks temporarily. In those circumstances, other Centres would assist. Initially, the blood stock collected within each region remained within the Blood Centre of that region, but in the 1990s a "clearing house system" was developed as computerisation made it possible for the concept of a National Stock to emerge, with visibility on the stock position of every Region. When blood processing was centralised after the reorganisation of the SNBTS, all blood collected in the ANESBTS was sent to Edinburgh, and in return we received the blood stocks required to maintain the supply to all hospitals within the region. During my tenure, ANESBTS always met its targets, and indeed was a net exporter to the SNBTS as a whole.

14. In 1990, in a response to the Medicines Inspector's Report you agreed that many of the problems of the ANESBTS Centre identified in both the 1982 and 1990 inspection are of an environmental nature which are inherent in the location and design of the building. Please can you clarify what was meant by this and how you think these shortcomings impacted the Centre and in particular the amount of donations that could be collected and the safety of those donations. You may find SBTS0000707_167, page 2 of assistance.

55. When I inherited the Aberdeen Centre, the laboratories, donor centre, blood processing, and staff offices were housed in a block of 2 floors of old Nightingale wards in the Aberdeen Royal Infirmary, with a wooden hut for the donor office and records in the car park area. (WITN6960009) I was able to procure an additional 3rd floor from ARI in order to improve the blood donation area and blood processing area (on the ground floor) temporarily, after the initial critical Medicines Inspector report of 1982. The full MI report is PRSE0004141.

56. Nevertheless, there was limited scope for improvement due to the shape of the narrow building, bisected by a corridor through the middle of the ground floor (which happened to be a corridor access from the Aberdeen Royal Infirmary (ARI) to the adjacent University Pathology Labs) and which was needed by ARI staff to deliver blood samples, and obtain blood from the Blood Bank, which was housed on the 2nd floor. It was therefore not possible to improve the environment of the blood processing area to satisfy the Medicines Inspector, as noted 8 years later, in 1990 (SBTS0000707_167). In the meantime I had embarked on a mission to obtain a completely new Blood Centre on the ARI site, to bring the centre up to the required standards. I was eventually successful, with a new centre opening on site in 1993, meeting all the required pharmaceutical standards for processing blood and blood products. The building had no particular impact on the number of donations collected, because the majority were collected at sessions outside the Centre. Before this, the laboratory and blood processing staff did their best in the circumstances, using sterile laminar flow cabinets for processing, in place of the required "clean rooms" and, as far as I am aware, no incidences of contamination were reported due to the processing environment.

15. Dr Gunson wrote to you in January 1988 to compare the statistics on new donors against the official figures from HQ. While two RTCs in Scotland had close numbers, the other three showed significant discrepancies (NHBT0006788). Do you recall the reasons for the discrepancies and how this was resolved?

57. No, I do not recall this operational detail. The compilation of ANESBTS laboratory statistics for the PHLS England Register was delegated to the microbiology laboratory Chief Medical Laboratory Scientific Officer (MLSO).

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

Production of fresh frozen plasma

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

a. where the production of FFP took place;

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

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

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

58. **a.** On the ground floor of the Blood Centre, adjacent to the corridor to the 2nd floor, as noted in the 1982 MI report (PRSE0004141).

59. **b.** The procedures followed were those common to the SNBTS at the time. In brief, whole blood donations were spun in specifically designed refrigerated blood centrifuges to separate the red cells from the plasma, using plastic blood bags with attachments. The plasma was separated manually from the red cells using pressure to transfer the plasma into the attached plastic bag, which was then sealed and detached. The plasma was then frozen in deep freezers. After 1993, in the new RTC, blast freezers were available to freeze the plasma more quickly, thus preserving the factor 8 content better.

60. **c.** I do not recall the proportion. The annual production figures for blood, FFP and other components will be in the SNBTS Annual Reports. The decision was based on 1) the amount of FFP that was required to maintain the Blood stock at the level experience had shown was required for clinical needs, 2) the amount required for conversion to cryoprecipitate (for factor 8 and fibrinogen), and 3) the amount of FFP that the PFC required for the

production of factor 8 concentrate. This changed over time with targets of meeting self-sufficiency in factor 8 concentrate, so that by the late 1980s almost all donations collected were processed to red cell concentrate, and plasma frozen within 6 hrs of collection being sent to PFC.

61. **d.** In 1983, our ability to increase FFP production was limited by the number of blood donations that could be processed, the number of available centrifuges, and available staff. Any increase would require additional funding, which was budgeted on an annual basis. Subject to available funding, we were able increase FFP production from 5691 units in 1983 to 7856 units in 1986 (WITN6960006).

17. At an SNBTS Directors' meeting in October 1985, Dr Forrester identified users in Aberdeen and Glasgow who complained of a shortage of certain plasma products. In response to this, you stated that in Aberdeen, "there was no limitation on the issue of current products and could only assume that the complaint came from plastic surgeons regretting the absence of the former product dried plasma. Please explain why you held this view. Did you investigate these complaints further? You may find MACK0000911 page 13 of assistance.

62. We withdrew freeze-dried plasma (produced in the Glasgow BTS) because of the risk of hepatitis B transmission with this product, prepared from pooled plasma donations. It was replaced with Stable Plasma Protein Solution (SPPS), which did have the slight disadvantage of a larger fluid volume. No one complained to me directly about this "shortage", so other than the hearsay of Dr Forrester, I had no complaint to investigate. I had, however, explained to all clinicians at ARI about the planned removal of freeze-dried plasma, and the reasons for it, and was aware that some of the plastic surgeons had expressed some regret at the loss of this product.

18. As far as you are aware, how was plasma procurement at ANESBTS

funded throughout the 1980s?

63. At my appointment, funds were provided to ANESBTS via SNBTS HQ as a block grant from the SHHD. At the inception of the CSA, this organisation received the funding from the Scottish Office and disbursed this direct to the SNBTS HQ, and then to the Regions. The block grant/budget for ANESBTS included the funding for an agreed amount of blood donations/FFP.

19. Please describe the arrangements for supplying FFP to hospitals and haemophilia centres within the region covered by the ANESBTS.

64. ANESBTS region was very centralised, with all major surgical, obstetric, orthopaedic and trauma surgery concentrated on the ARI campus. This is where the major Blood Bank facilities resided, within the BTS building, and supervised by the ANESBTS Consultant staff. The Regional Haemophilia Centre was also in the ARI, in the Haematology Department, and run by the ARI Consultant Haematologists. The FFP and cryoprecipitate for the Region were stored in the Blood Bank freezers, and issued to patients on the basis of clinical need. There were small hospitals in Elgin, Orkney and Shetland with blood refrigerators for blood storage only. In the event of a patient ill enough to require FFP, they would usually be despatched to ARI by air ambulance, or helicopter, where the specialist expertise resided. Further details are given in my answer to Question 2 (see pages 3 and 4).

20. In a letter from Dr McIntyre to Mr Murray dated 2 December 1985 (SCGV0000123_010 page 3) regarding the supply of stable plasma protein solution in Scotland, Dr McIntyre stated that St John's Nursing Home "has been reluctantly refused supplies by Dr Urbaniak, who has sent a copy of Dr Cash's letter requesting him to do so". What do you understand was the reason Dr Cash instructed you to refuse supplies of stable plasma protein solution to St John's Nursing Home?

65. St John's Hospital was only about 15 minutes by road from the ARI, where the stocks of SPPS resided. The issue of SPPS was supervised by the

ANESBTS on-call Consultant on the basis of clinical need, as a substitute for albumin replacement to maintain blood volume. The nature of the elective procedures undertaken at St John's Hospital was such that SPPS would only be used in a dire surgical emergency, in which case the patient would be transferred to ARI because St John's Hospital did not have the staff, expertise, or facilities to treat such patients. In an emergency, the ANESBTS could provide all the SPPS needed within 15 minutes and prior to the transfer of the patient, so there was no need for St Johns Hospital to hold its own stock of SPPS.

Plasma targets

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

66. The plasma target for ANESBTS was 1) sufficient to meet the transfusion needs of patients needing FFP and cryoprecipitate in the hospitals served by ANESBTS; this was determined locally by the Director, and 2) plasma to be sent to PFC for processing; this was set nationally by PFC to meet the demands for SPPS and factor 8 based on input from the Directors on usage in their own region.

67. Initially, plasma collected was a "by-product" of blood donation targets to meet transfusion requirements. Later, plasmapheresis was introduced, which meant that plasma collection could be "decoupled" from red cell requirements, to sustain elective surgery, obstetrics, trauma and so on. This became more important as the need for FFP to produce factor 8 at PFC was increased. Since the drive was for "self-sufficiency" in factor 8, the target for ANESBTS was to produce as much as we could, within logistical and financial constraints. This we did, producing more plasma per head of population than other Scottish centres, because of our stable donor

population. Details will be in the SNBTS annual statistics reports, to which I no longer have access.

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

68. On the basis of plasma collection by donor population size, we had no problem meeting our targets. The only decision-making was to ensure sufficient funding was available to deliver.

23. What were the consequences if the targets were not met?

69. We met our targets.

24. Were there any benefits to the ANESBTS if the targets were exceeded?

70. Only the satisfaction that we had contributed towards self-sufficiency.

25. During a SNBTS meeting on 1 July 1986, you suggested that "it might be better for Regions to concentrate on specific plasma targets known to be achievable rather than calculating targets on a population basis" (SBTS0000246_008 at page 8). What were the reasons behind this suggestion?

a. After discussion, it was agreed to not change the previously agreed principle of Regional targets. Do you recall why the other members of the meeting decided not to adopt this change?

71. The reference SBTS0000_008 para. 6, records a discussion about the supply of plasma, both for the production of FFP (mainly for F8), and also "immune plasma" for the production of specific immunoglobulins (anti-tetanus, anti-HBs, anti-Rubella, anti-CMV etc). These could only be sourced from individuals who had previously been exposed to these infections, and developed antibodies in their plasma, and their distribution was not

proportional to the population size of each Region. ANESBTS was particularly good at recruitment for some immune plasmas, but not others, likewise the other centres. I think my suggestion was to accept the reality and allocate targets according to ability to collect, rather than artificially on population size. Given that the national target was being met, I think colleagues were content with the status quo. Over time, however, allocations were apportioned more appropriately, according to opportunities available in each Region, e.g. ANESBTS took the lead on producing anti-D plasma.

26. In 1989, cross-charging was introduced in England and Wales to act as an incentive for RTCs to increase the amount of plasma being sent to BPL (NHBT0057426_002). As far as you are aware, what effect (if any) did cross-charging have on the plasma supply in Scotland?

72. None as far as I am aware, because SNBTS did not adopt cross-charging.

Plasmapheresis:

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

a. whether manual or machine plasmapheresis was preferred;

b. the relative cost differences between each method;

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

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

You may find SBTS0000243_035 of assistance.

73. During my Consultancy in SEBTS I introduced the first cell separator machines in the SNBTS, having received training at the Royal Marsden in London, and Glasgow Haematology Department. I became an expert in plasmapheresis and machine plasma exchange (in patients), and later transferred these skills to Aberdeen.

74. **a.** I preferred machine plasmapheresis because it was quicker, safer and more productive than using blood centrifuges, but it did take some years for the machines that had been developed for patients, to be adapted to be run on donors so that they could be used outside of a hospital setting in most BTS centres.

75. **b.** I do not recall the cost differentials, but using dedicated apheresis machines with closed systems of plasma collection was far safer and more efficient.

76. **c.** As soon as I was in post, I implemented a redesign of the Donor Centre area, to accommodate plasmapheresis machines that could operate when there were no regular blood donor sessions, increasing the productivity of the staff, and the use of the building. I also trained our donor nursing staff in the use of these machines so we were not limited by the availability of medical staff.

77. **d**. Yes, and it did, substantially.

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

78. I pioneered the use of machine plasmapheresis in the SNBTS, and undertook trials of the suitability of the various donor equipment available. Because of the central location of our Donor Centre in Aberdeen, the population density, and the enthusiasm of our donors, we were able to operate our machines at

maximum capacity. This enabled us to produce FFP at a greater volume per capita in ANESBTS than many other UK centres.

29. According to PRSE0001767 page 7, in 1984 you were nominated by the Scottish Directors to represent SNBTS on the NBTS Working Party on the Code of Practice for Plasmapheresis. Please advise what was discussed and what conclusions were reached by the Working Party. Did you agree with the conclusions reached by the Working Party, if so, why? If not, why not?

79. As I recall, the major purpose was to set guidelines for the safe operation of plasmapheresis in Blood Transfusion Centres, both in terms of safety for the donor (selection criteria, how often etc), and in terms of product quality and safety. Almost all of the English Centres (and West of Scotland BTS) were in locations that were not physically connected to a Hospital, and therefore there were concerns about safety if there were adverse events outside of a hospital environment where emergency backup was available. Some of the membership (like me) also had experience of working with very ill patients on plasmapheresis machines, but others did not. The guidelines produced were the result of a consensus agreement among all the participants, and set out a Code of Practice that could be adopted, and followed, by all UK Blood Services. This was achieved, and I agreed with the conclusions.

30. What steps, if any, did ANESBTS 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?

80. We held meetings with all colleague specialties, and agreed a series of schedules (MSBOS – Maximum Surgical Blood Ordering Schedule) for each operation and procedure that might require blood, by default red cell concentrate. The only major exceptions being open-heart surgery, major gastrointestinal bleeding, major obstetric haemorrhage, and major trauma, where massive rapid blood loss occurs. I also set up a Hospital Transfusion Committee in ARI to monitor usage and compliance. As a result of the

introduction of MBOS, the number of "unnecessary" whole blood transfusions was reduced (enabling more FFP production), and the total number of transfusions per operation was reduced, reducing the risk of adverse events associated with blood transfusions.

Hepatitis B

31. In a letter dated 23 November 1989, you wrote to Dr Cuthbertson regarding investigations into HBV positive plasma sent to PFC by ANESBTS (SBTS0000352_023). You stated that "no HBsAg confirmed positives had been detected during the time period of the source donations". Please can you comment on the reasons why this was not detected at the time and how this was rectified for future batches.

81. I do not recall the circumstances, but the implication of the letter is that none of ANESBTS' donors tested HBsAg positive at routine screening, and all negative plasma was sent to PFC.

82. When a plasma pool (containing ANESBTS plasma) was found HBsAg positive by the more sensitive reference test used by PFC, repeat testing on archived ANESBTS donor samples by the SNBTS microbiology reference laboratory, using more sensitive tests, identified the implicated donor. The HBsAg donation was "missed", either because ANESBTS was using less sensitive tests than the reference laboratory, or there was a product defect in the testing kit. Test kit sensitivity and consistency of manufacture was not in our control.

83. By way of background, the ANESBTS used a mass-screening test using microplates (50-100 samples at a time) that gave a result in a few hours, so donations could be released for transfusion. The reference centre did multiple tests on one sample at a time, used equipment not suitable for mass screening, and took longer (sometimes a day) to get results. There was not anything practical that a Centre could do to rectify product defects, since we

did not design the testing kits, nor evaluate them for introduction to routine testing – that was the role of the SNBTS Microbiology reference centre.

84. Regarding the infected plasma pool, unlike BPL, PFC had a "small batch manufacture process, and the loss of this pool would have had a negligible impact on overall factor 8 manufacture.

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

32. Please describe the arrangements in place in the Aberdeen and North East Scotland region for the purchase and holding of, and the allocation to haemophilia centres within the region, of (a) PFC factor concentrates and/or other blood products ("PFC" blood products:) and (b) imported factor concentrates and/or other blood products ("imported blood products"). In particular:

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

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

85. **a.** There was only one Haemophilia Centre, based in the Haematology Department of ARI. This did not change over time.

86. **b.** Before PFC undertook ordering on behalf of NHC Scotland (in the late 1980s), ANESBTS had an arrangement with the Chief Administrative Medical Officer (CAMO) of Grampian Health Board (GHB) that the Haemophilia director would order, GHB would pay, and we would store and issue any commercial products. We held all the stocks of PFC factor 8, cryoprecipitate, and any other commercial (imported) blood clotting factors, in the controlled cold room facilities of ANESBTS Blood Bank, on behalf of the Consultant Haematologists managing haemophilia patients. We would order stocks from

PFC, to the level advised by Haematologists. If commercial products were required for special reasons (e.g. not manufactured by PFC), then PFC would order stocks on behalf of the Haemophilia directors (at a discounted price), which would then be sent out to the Regions on the basis of need. Occasionally, e.g. due to factor 8 antibody resistance, porcine factor 8 would be ordered by the local Haematologists, but be stored by us. This did not change significantly during my tenure from 1983 to 1999.

33. Please explain whether any forums were established between the ANESBTS, PFC, the relevant RHA, and haemophilia centre directors to discuss and facilitate these arrangements. Were meetings held regularly? Were they minuted? If so, by whom? What was discussed at these meetings?

87. I had no particular involvement in the various forums related to Haemophilia, since this was not my special interest. On a few occasions I attended the joint Scottish RTC Directors/Haemophilia Directors" meetings, but felt that I had little to contribute. At the local level, we had good working relations with the Haematologists at ARI, (one of whom was the local Haemophilia Director), since we were in daily professional contact, and had no particular issues with the supply of blood products for local haemophiliacs.

34. As far as you are aware, were arrangements for the purchase, holding, and distribution of (a) PFC blood products and (b) imported blood products similar in other regions, or was there a degree of regional differentiation (and if so what)?

88. As far as I am aware, our arrangements were similar to other regions, other than SSWBTS. This was because the SSWBTS did not have a blood bank, and blood products would be distributed to the blood banks in the major hospitals in the West, under the control of the local Consultant Haematologists, including their Haemophilia Centre in Glasgow.

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

a. how and by whom the decision was made to contract with the particular pharmaceutical company;

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

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

89. No, we had no arrangements with pharmaceutical companies at ANESBTS.

36. What was the impact on the ANESBTS of shortfalls in PFC product coming from PFC? How frequently did this occur? You may find PRSE0002769 of assistance.

90. The reference PRSE0002769 (para 4a) records that the input of plasma to PFC has fallen, and the usage of F8 has fallen in 1998 (para 4b); there is no reference to any shortfall of product from PFC to ANESBTS. However, I do not think there was a particular impact locally, and I do not recall any particular shortfalls.

37. Was the ANESBTS 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?

91. No, we merely held the stocks of product, and issued at the request of the Haematologists.

38. If haemophilia centre directors were responsible for these decisions, did the ANESBTS have any influence over their product choices? You may find SBTS0000338_045 of assistance.

92. No, I do not think so. Factor 8 allocations were made between PFC and the Haemophilia Directors in Scotland, and ANESBTS acted as the custodian of the agreed allocations.

39. What, in your view, were the key factors influencing the choice between PFC blood products and imported blood products? You may find SBTS0000338_045 of assistance.

93. I think availability and suitability for individual patients played a part locally. I do not think there was any particular preference for commercial blood products. Some patients would appear to respond better to particular brands of factor 8 (as happens with generic drugs versus branded drugs).

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

94. As far as I am aware, PFC blood products were only available to Clinicians in Scotland, whereas BPL blood products were restricted to the rest of the UK.

95. In the UK in general, I think that the concept of clinical freedom may have been overplayed in some cases by local Haematologists who insisted that the (commercial) products they preferred were inherently "better" than the BPL or PFC blood products. I do not think that this attitude prevailed at ANESBTS.

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

96. I do not know what influence they had since I did not interact with them. We just stored whatever commercial products the Haematologists wanted.

42. You wrote a letter to Dr Perry in 1990 (PRSE0002427) and specifically in relation to Factor VIII allocation, you wrote "I would be most grateful if one person could be seen to be seen to be in charge of all these transactions since as far as I am concerned any formal transactions relating to Factor VIII in this Region are between myself and the PFC as secondary and primary suppliers."

a. Please explain why you held this view and what your views were on decision making processes at SNBTS in relation to Factor VIII allocation.

b. Can you recall how Dr Dawson suggested that Factor VIII be reallocated? You may find SBTS0000338_045 at page 2 of assistance.

97. I think I was arguing for logistic simplicity. Dr Bruce Bennet and Dr Dawson were co-Directors of the Haemophilia centre, but Dr Bennet was de facto the Director since he was the coagulation expert with whom I usually corresponded. I would have preferred a single point of contact for discussion about local matters. PFC and the Haemophilia Directors negotiated the allocation of PFC stocks to their Centres at their joint meetings, which would then be requested via the local Regional Centre. I was not involved in deciding the allocations of factor 8, and I do not recall what Dr Dawson was proposing.

43. According to SBTS0000338_045, Robert Stewart, Clinical Trials Manager at SNBTS HQ, wrote to you in 1990 explaining that "the SHS demand is tantalisingly close to being covered by the Z8 supply." The shortfall was supplemented by 1.1 million IU of commercial product. In response to this letter (PRSE0003400), you offered to reduce your stock level at ANESBTS from 1499 vials to 500 vials. Please explain the reasons behind this suggestion and whether you had concerns about

SHS supply being supplemented by commercial product in the SHS. You may find PRSE0003400 and PRSE0003449 of assistance.

98. I presume that the ANESBTS Haemophiliac usage was at a level that allowed the stock reduction. With relatively few patients, there could be large fluctuations in monthly usage, and unused stock could build up. Reducing our stock level would have decreased the risk of stock outdating locally, whilst, hopefully, reducing the need for importing commercial products in other centres.

Section 6: Production of cryoprecipitate within the ANESBTS

44. Did ANESBTS produce cryoprecipitate? If not, where was this produced for the Aberdeen and North East Scotland region and what were the arrangements in place?

99. Yes, cryoprecipitate was produced at the Centre.

45. If ANESBTS did produce cryoprecipitate, please describe:

a. where the production of cryoprecipitate took place;

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

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

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

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

100. **a.** In the component production area of the Centre. At the time of the 1982 Medicines Inspectors report, cryoprecipitate production had been suspended at ANEBTS. After my appointment, I was able to reinstate production in 1983 after some improvement to the production environment.

101. **b.** We followed SNBTS common procedures. Briefly, for the production of cryoprecipitate, plasma was rapidly frozen in a tank of liquid carbon dioxide (dry ice) and ethanol, and then allowed to thaw in a 4oC water bath for 30 minutes. Then, the plastic bag containing the cryoprecipitate suspended in plasma is spun in a refrigerated centrifuge until the precipitate is at the bottom. Then the surplus plasma is removed, leaving concentrated cryoprecipitate, which is then frozen again and stored at minus 20 or 40oC. This is a laborious and labour-intensive process requiring extensive space for the equipment, and cannot be scaled up for mass production without significantly affecting the normal processing of blood and other blood components (clinical FFP and platelets) for patients.

102. **c.** As much as was required for clinical use in our region. We did not send any to BPL.

103. **d.** There was no specific allocation for cryoprecipitate. It was within the overall budget from SNBTS.

104. **e.** This would have been almost impossible, given the environment in the Centre, as noted in the Medicines Inspectors reports of 1982 and 1990. Furthermore, HM Customs and Excise severely restricted the amount of industrial ethanol (alcohol) that we were allowed to store in the Centre under licence. However, as we increased FFP production, we had the potential to produce more cryoprecipitate, but mass production would not have been possible without significant disruption of normal blood component processing (see question 5).

46. Please explain what consideration ANESBTS 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.

105. In April 1983, I discussed the possibility of increasing the availability of cryoprecipitate for local haemophiliacs with the Haemophilia Director Dr Bruce Bennett, when the risk of HIV transmission became apparent (WITN69600010), and arrange for a stock to be available on demand.

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

106. Notwithstanding the physical constraints at ANESBTS (as noted by the Medicines Inspector), I was able to increase cryoprecipitate production from 153 units in 1983 to 425 units in 1986 (WITN6960006). This was to provide enough for the needs of our local Haemophilia Director.

48. Please describe the arrangements for supplying cryoprecipitate to hospitals and haemophilia centres within the region covered by the ANESBTS.

107. We supplied cryoprecipitate to patients from the Blood Bank in the ANESBTS centre (organisational details are given in question 74).

Section 7: Self-sufficiency

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

108. To me, as a Director of the Scottish National Blood Service, self-sufficiency was the goal of collecting sufficient blood donations from within Scotland to meet the needs of patients in Scotland requiring blood and blood

components (FFP, cryoprecipitate, platelets), as part of their treatment. This would exclude self-sufficiency in products manufactured from plasma that the PFC could not make. Initially, this definition was restricted largely to whole blood donations, but as technology allowed, blood component therapy became more prevalent, with red cell concentrate prevailing as the product of choice for blood loss. This allowed much greater collection of FFP (from all but a small number of donations) for PFC to process to various products, significantly, factor 8.

109. Neither was the production of FFP for clinical use in our blood bank a supply issue, given that almost all donations were separated into red cells and plasma. This meant that, at ANESBTS, any increase in blood donations more or less resulted in an automatic increase in plasma for PFC. This did mean that there was, over time, a trend for increases in blood collection to be driven by the need for more plasma for factor 8, as the haemophiliac population used ever increasing doses of factor 8 towards achieving a more normal lifestyle. As a result, the number of blood donations outdating increased because more were collected than required for the transfusion of patients within the regional catchment area. This had two consequences: one was the introduction of a blood sharing system among all the regions, coordinated by SNBTS HQ, and secondly, the introduction of machine plasmapheresis, which could be performed much more frequently than blood donation because the red cells were returned to the donor.

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

a. plasma procurement;

110. See Q 49 for details

b. decisions with regard to cryoprecipitate production;

111. I do not think there was a specific National concept of self sufficiency for cryoprecipitate production because this was always produced locally in response to clinical needs of all patients.

c. purchases of commercial blood products;

112. The greater the input of FFP to PFC for factor 8 production for Scottish haemophiliacs, the less commercial factor 8 would be required. Under ideal circumstances, there should be no need for commercial products, except for special circumstances noted earlier. We did reach self-sufficiency in FFP production at some point, but the targets for factor 8 kept being revised upwards, so it was becoming ever more difficult to meet.

d. funding received from SNBTS.

113. I do not think there was any problem with ANESBTS funding from SNBTS. Where we could contribute "over and above" our national targets based on population, we received the funding required to facilitate this.

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

114. In the 1980s self-sufficiency in England was always going to be a problem because it was not a truly National service (until later), but rather a geographic collection of Regional Health Authorities, each with its own Regional Transfusion Centre and funding model. This made it difficult to plan any increase in plasma production to send to BPL. The English Regions were also very large compared to Scotland, which made the logistics of blood collection and FFP production more complex. This improved considerably when machine plasmapheresis became available, and the Code of Practice that we introduced was very helpful in raising plasma production. However, even though FFP production increased, the factor 8 demands kept

increasing, so it was unlikely that self-sufficiency would have been achieved throughout the whole of the UK.

115. It was only with the advent of recombinant factor 8 that the link between the drive to increase FFP production and blood donation collection was broken, since this (commercial) product could be produced safely and effectively without the need for blood donors.

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

116. I think we were of a common purpose in Scotland, where we had a National service committed to self-sufficiency, and the means to deliver it, but I suspect our English colleagues might have been less enthusiastic because the NBTS Regions had significant challenges in obtaining the financial resources needed to recruit the increased number of donors required. (see question 51)

Section 8: Services for donors at ANESBTS

53. What counselling was offered to donors prior to (i) HIV testing (ii) HCV testing and (iii) HBV testing taking place? Please describe the process. You may find PRSE0005009, at page 18, paragraph 31.94 and SBTS0000242_068 at page 4, item 2f of assistance.

117. We followed SNBTS protocols, as agreed at the Directors' meetings, or later, at MSC. Initially I undertook the interview of any donors who had positive microbiology results on donor screening (HBsAg and HIV), until 1989 when the second Consultant, Dr. Galea, was appointed. He then assumed responsibility for the care of Blood Donors, including counselling and referral until he moved to Inverness in 1993. In fact, we had no HIV positive donors detected from 1985 until early 1989, and only 4 by 1995, 10 years after the introduction of HIV screening (SCIEH report, HIV, 1999 (WITN6960011) Dr

Yates would have done any HCV counselling after his appointment in 1992. It is not appropriate to offer counselling to donors before they have been tested for virology markers since their infection status would not be known before donating. Once a donation was confirmed positive for HBV, HIV or HCV, the donor was invited to the Centre and entered the SNBTS system for the handling of such donors.

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

118. We did not test donors for hepatitis or HIV, we tested their donations, and called them for counselling before referral to a clinician. As far as I recall, we followed standard procedures that involved referral of donors with positive microbiology to a designated Consultant specialising in Liver Diseases (HBV), or Infectious Diseases (HIV) via their GP.

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

119. As far as I recall, recipients of infected donations were followed up by the clinician.

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

120. I consider that the SNBTS procedures were adequate, but I have no knowledge of the clinicians' discussions because of patient confidentiality.

57. In a SNBTS Co-ordinating Group meeting in May 1985 that you attended, the subject of counselling and care of people who were

HTLV-III antibody positive was discussed. In this meeting you stated that you had met the CAMO whose view was that counselling and care should be the role of the GP in consultation with an ID consultant, as is the case of hepatitis. Please advise whether you agreed with this position and why. You may find SBTS0000242_068 (page 4, item 2f) of assistance.

121. Yes, I was in agreement. At the point of a donor being identified as infected with these viruses, they became patients requiring care and management by doctors with expertise in infectious diseases.

Section 9: Meetings of various committees

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

122. These meetings were established before I became Director, so I do not know who initiated them. I considered them to be the forum whereby we coordinated and conducted activities relevant to the performance of the SNBTS Regions. These were a mixture of managerial, financial, medical and scientific matters required to run the Service. This was separate from the day-to-day responsibilities as a medical consultant providing clinical and laboratory services and expert advice to patients and colleagues within our respective Health Boards.

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

123. I do not remember these details, but they should be recorded in the SNBTS archives. As I recall, Directors debated matters that were relevant to

all Centres, and when consensus was reached, this would become agreed policy, recorded in the minutes, and it would be the responsibility of each Director to implement the policy, with an agreed timetable. Progress would be monitored at subsequent meetings. Where policy changes required additional financial resources, these would be included in the annual budget requests to the SHHD. This continued until General Management was introduced, when the Directors' recommendations were put to the SNBTS management board.

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

124. This was set up before my time as Director. As far as I could tell, this was a positive development, enabling an exchange of information between the two organisations. It was always informative to hear what was going on in the other Services. The NBTS representatives attended as observers at SNBTS Directors' meetings, and vice versa.

61. It appears that a representative of the Northern Ireland Blood Transfusion Service ("NIBTS") was also sometimes present at meetings of SNBTS directors (PRSE00026170). Was the NIBTS similarly represented in an observational capacity? Please explain the level of cooperation between SNBTS Directors and the NIBTS and whether this differed in any way to the SNBTS' cooperation with the NBTS.

125. Likewise, it was useful to hear of the activities in Northern Ireland. The NIBTS representatives attended as observers at SNBTS Directors' meetings, and vice versa

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

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

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

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

You may find PRSE0000171 of assistance in answering these questions.

126. **a., b., and c.** As a result of the introduction of general management, the medical and professional activities of the Directors were separated from their policy-making decisions, the former taking place in the MSC and chaired by the NMSD, and the latter at SNBTS management board level, chaired by the GM. Formal details about formal structures and membership would be available in the National archives, and papers presented to the Penrose Inquiry.

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

maintained following the conclusion of the SNBTS Directors' meetings?

127. From my perspective, there was very little difference.

64. Do you consider the Medical and Scientific Committee ("MSC") which replaced the meetings of the SNBTS Directors to have improved on the SNBTS Directors meeting format?

128. From my perspective, there was very little difference.

65. In 1990, you wrote to Mr McIntosh regarding management of the SNBTS in the 1990s. You wrote "There should be, in my view, a clear distinction between those who are empowered to make and vote on policy matters (or indeed perhaps power of veto in some circumstances), and those who serve the decision makers". You explain that you "foresee potential difficulties in managing my Region in a clear and consistent way" (SBTS0000008_015).

a. Please can you comment on the circumstances which prompted you to write this letter.

b. Please elaborate on what potential difficulties you foresaw in managing your Region.

129. Prior to the introduction of General Management of the SNBTS, the Regional Director would chair a group of staff that actually ran the service (the Centre Management Team). These included the Laboratory Manager/ Chief Technician (organising all the blood testing and processing), the Donor Organiser (responsible for the donor sessions and blood collection), the Administrator (budget, personnel and administration), the Head Nurse (donor staff and donor care), the Quality Assurance Manager (Standard Operating Procedures and compliance with regulations pertaining to RTCs), and the medical Consultants providing clinical services.

130. After the introduction of General Management, SNBTS HQ created a number of extra posts at National level e.g., National Donor Manager, National Personnel Manager, National Finance Director. The equivalent staff in the Regional Centres were required to report to the National post holders, who held their own meetings with the Regional staff, independent of the Regional Directors. This meant that there was potential for conflict between the instructions of the National staff and the local Director who actually ran the centre, and had the budgetary responsibility for delivery of the outcomes.

SNBTS Co-ordinating group

66. The Inquiry understands that you attended meetings of the SNBTS Co-ordinating Group between 1982 and 1990.

a. As far as you are able, please describe:

i. the remit and composition of this group; and

ii. the frequency of these meetings.

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

131. a. **i and ii.** I do not recall a written remit, but I presume there is one in the SNBTS archives. The standing members (as per the list of attendees in the minutes) were the Regional Directors and the PFC Director, chaired by the National Medical and Scientific Director, Professor Cash. Others attended as observers, or to speak to particular papers presented for discussion. I think the meetings alternated with Regional Directors' meetings on a monthly basis.

132. b. Yes, I found these meeting invaluable when I was newly appointed, for learning about the organisational aspects of SNBTS outside my region.

67. In November 1985, you wrote to Dr Cash to say "I think I must protest

at the recent addition of Non-Director staff to the co-ordinating group meetings." Do you recall if there were any particular issues you felt that you could not discuss in front of Non-Directors? Did any other Directors hold your view? Please refer to SBTS0000244_056.

133. When we were a group of Consultant colleagues, we often spoke on confidential medical matters concerning the health of individual patients or donors that we would not otherwise have discussed in an open forum. I do not recall if others agreed or not, but I suspect we changed the way we discussed medical matters in an open forum. It was also a forum where Directors could, informally and in strict confidence, discuss particular personal experiences or difficulties in running their Regions.

68. On 18 August 1987, minutes from the SNBTS co-ordinating group meeting state that in relation to reference testing, "Dr Urbaniak was not entirely satisfied" with the service South East Scotland was receiving in contradiction of Dr McClelland's views (PRSE0001722). Why was there a differing opinion between you and Dr McClelland? How was this resolved?

134. The IBI has misinterpreted this statement in the minutes. Dr McClelland was satisfied with service his Centre was getting from the reference centre; I was not satisfied with the service I was getting for my Centre. This is not a difference of opinion between us.

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

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

135. The donor records were kept on index files, with pre-printed boxes for data entry, with the personal details of the donor e.g. names, address etc.; the date of each donation recorded, and the non-confidential laboratory (such as blood group) test results, the data was input manually by the Donor Organiser, her deputy, or one of the donor office clerical staff. The files were kept in drawers in locked filing cabinets, held within the Donor Office, which was always locked if unattended. Only the Donor Office staff, or the BTS medical staff had unrestricted access to the donor cards. These cards were kept indefinitely, and if the donor was excluded from giving blood permanently e.g. ill-health, died, retired, tested positive for HBV, HIV, HCV, or moved away, the donor records would be kept in "inactive" files under the same confidential system as the active donor files. There was also a "quarantine" file holding the records of donors who were suspended temporarily for health reasons, either temporary illness, or a "suspect" laboratory testing result that required explanation. These donors were not sent call-up letters to attend a donor session.

136. The laboratory tests consisted of blood groups, performed in the donation testing laboratory, and the microbiology testing (initially for syphilis, then Hepatitis B, then HIV, then Hepatitis C) in the microbiology lab. Each donor had their own unique donor number, which linked to each donation they gave. As blood was collected, the donation blood pack, and the attached laboratory test tubes, were given a unique number on a sticky label. A copy of the same donation number was added to the donors' card at the blood session, and to a laboratory worksheet, which accompanied the blood and blood tubes back to the Blood Centre in Aberdeen. The laboratory paper records consisted of worksheets for the blood grouping of the donors per blood session, and were stored in the laboratory in files in date and blood session order, until transferred to the records store. Similarly, the microbiology test results were recorded on paper files, initially in the laboratory, then to records store. These laboratory records were kept under lock and key, either in the laboratories, which would be locked when

unoccupied, or in the records store, which was in the Blood Centre, which was also kept locked at night.

137. The donor staff only knew the donor's personal details, and the date and laboratory number of the donation. The laboratory staff never knew the identity of the donor, only the donation number. The only person who had the authority to make the link between donor identity and the test results of the donation was the Director, and later, the Donor Consultant.

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

138. As far as I recall, the donor records were kept indefinitely in the Blood Centre until superseded by computerisation, the data recorded on the cards being transferred to the computer files. Likewise, the donation session and donor testing records, until they were microfiched, and stored centrally in commercial record stores because of lack of space. The laboratory results were also transferred to the main SNBTS computer files.

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

139. As above, they were kept indefinitely in the Centre, until transferred to SNBTS HQ. after the records had been computerised.

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

140. I think all RTCs initially used the same index card format, with some regional variations in layout."

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

donations at that centre?

141. Yes, we had a good system of "quarantine" of donors who were suspended, and later either reinstated or permanently excluded from giving blood. We had a small catchment population (about 580,0000) with a high percentage of repeat donors, the exceptions being mainly the University students who finished their courses, and then left the area.

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

142. About 90% of blood and product usage in the region was in the Aberdeen Hospitals complex, and was served from the Blood Bank in the RTC, so we had all the records of the transactions. Any blood not used at the bedside was returned to the RTC for reuse, if within date. We also had a number of dedicated Blood storage refrigerators adjacent to the main centres of use e.g. cardiac surgery, the Maternity Unit, the GI Bleeding Unit, and orthopaedic surgery. Blood for elective surgery, or planned transfusion at the bedside, was delivered by ARI blood porters (under our direction) to these locations, and checked daily for any unused blood, which was then returned to the RTC after 48 hrs (all blood being kept in special cool boxes to maintain the temperature when out of the refrigerators. The blood sent to the Blood Banks in Elgin, Orkney and Shetland were also kept in cool boxes in transit, and stored in a controlled blood storage fridge in the respective hospital laboratory blocks. We had a rotating system for the peripheral blood banks so that blood nearing the expiry date was returned to the RTC and replaced with fresh stock, since we had the biggest turnover, and we wished to minimise any blood going out of date unnecessarily. All unused blood, and empty bags after transfusion, was to be returned to the RTC for safe discard,

since we had the facilities for this. It also provided material for laboratory investigation should there be a delayed transfusion reaction, which, by definition, could not be predicted.

143. Compliance was excellent with all of our colleagues. Since FFP and cryoprecipitate were held in our central blood bank and issued only on need, we had full records of these donations as well. I do not recall ever "losing" any blood units, since we kept duplicate records of everything issued, and would chase up any non-returns to confirm that the blood had been transfused. Occasionally, the nurses might discard a used blood bag via the hospital incinerator in error, but the patient's notes would confirm usage.

75. What information did ANESBTS provide to SNBTS? The document at NHBT0006788 suggests that ANESBTS sent monthly returns. Is this correct? If so, what information was contained within these documents?

144. I think these were records for stock control, so we would just record the number of blood donations by major blood group, with no donor or patient information. Eventually a relatively sophisticated form of stock control was evolved at SNBTS level, so shortages/ surpluses could be redistributed between the RTCs. The final evolution was for all the blood donations to be sent to either Edinburgh or Glasgow for processing to components, and the RTCs received an allocation from the central depot according to the needs of their region.

76. The Inquiry is aware that the Communicable Disease Surveillance Centre ("CDSC") maintained a database to keep track of reporting of blood donors who tested positive for HIV (NHBT0004742_001). The Inquiry understands that this database was in existence in 1989, although it is unclear for how long the CDSC operated it. Please answer the following questions regarding this database, as far as you are able:

a. **Were you aware of the database, if so, when did you become so aware?**
b. **Who proposed the creation of the database?**
c. **Did ANESBTS contribute data on HIV positive donors to the database? If not, why not?**
d. **Are you aware of whether other RTCs contributed data on HIV positive donors to the database?**
e. **Did ANESBTS maintain a separate, or additional, database to track HIV positive blood donors?**

145. **a. .** This reference relates to the English PHLS CDSC, which did not apply in Scotland, which had its own notifiable disease centre, the Scottish Centre for Infection and Environmental Health (SCIEH. Yes, I was aware of SCIEH, and its database because it was discussed at Directors' meetings; I do not recall exactly when, but it would have been when it was proposed that Directors feed in data on any of the donors or patients that they had come across in their region, as a result of HIV testing.

146. **b. I** have no idea

147. **c.** Yes.

148. **d.** As far as I am aware, all the Directors did.

149. **e.** No, we did not maintain a separate database. We had so few HIV positive donors that I kept their records in a locked drawer, in my locked office, within the locked RTC building. These donors would be reported (anonymised) to the SCIEH in the usual way, as per para c.

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

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

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

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

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

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

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

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

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

150. This was something specific to the NBTS in England and Wales. I have no idea what it was about.

78. In addition to the database(s) mentioned above, did ANESBTS share information with other BTS' 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 ANESBTS used to share this information, if any.

151. I do not think so, other than indirectly through the statistics held by the SNBTS Microbiology Reference Centre on all the confirmatory positives that they had identified from samples sent in from all regions. Latterly, in 1992 or thereabouts, when all SNBTS donor records were computerised, it became possible to flag donor records if they had been deferred for any medical reason (including testing positive for viruses) so they would be prevented from donating in another region should they move home. The actual reason would be confidential to the Donor Consultants. Each National service maintained its own database. If a donor crossed the border, I think they would be re-registered as a "new" donor, and tested as such.

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

152. I believe so. I think this placed an obligation on Health Board Consultant Microbiologists to report these to SCIEH who compiled the national statistics on communicable diseases. However, these were set up on the assumption that the reporting would be on patients identified in hospital microbiology laboratories, and I think that the reporting was to the Health Board CAMO (Chief Administrative Medical Officer), who later became the local Director of Public Health. The SNBTS was a bit of an anomaly, since we were testing donors, not patients, and these individuals would not have been notified to SCIEH via normal channels (i.e. via the CAMO/DPH), unless the donor subsequently became a patient under the care of a Hospital Consultant. I recall there were discussions to avoid duplicate reporting on patients/donors, or indeed no reporting, since donors referred to clinicians became patients, but unless retested by hospital laboratories, might not be reported to SCIEH by Consultant microbiologists. Hence the setting up of a "failsafe" system of SNBTS notification of positive donors to avoid gaps in reporting.

80. Did the requirement to notify change during your tenure? If so, how

and when?

153. See Q79 for details. Initially, only HBV was reportable, but subsequently, HIV and HCV became notifiable. I do not recall the dates of the additions, but I would have been informed by SNBTS HQ and SCIEH when the changes occurred.

81. According to SBTS0000700_104, you wrote to Professor Cash in 1991 regarding the release of a hepatitis positive unit to PFC. You state that "The most latest incident is completely unrelated to the previous and rests fairly and squarely with managerial error rather than complete failure of the organisational system". Can you recall what the managerial error was and why you distinguished this from "complete failure of the organisational system"?

154. I cannot recall these details. I can only assume that because we had adequate, approved, Standard Operating Procedures in place, they were not followed. The letter notes that the Chief MLSO in charge of the laboratory at the time of the incident was going to be disciplined for this failure of compliance.

82. According to SBTS0000700_104, you also write that "... the final documentation of the PFC audit of the previous incident rests firmly with Bruce Cuthbertson. Both George and I have asked him on at least half a dozen occasions to incorporate the final agreed revisions and to send us back the documentation for a final check before issue." Please explain what Bruce Cuthbertson's role was and elaborate on your working relationship with him.

155. Bruce Cuthbertson was the National Quality Manager for the PFC, and was responsible for the production of the SOPs relevant to the interface between the RTCs and the PFC. We had a perfectly good working relationship with Bruce, but being responsible for all the Regions he was always under pressure. Our anxiety would have been to get "sign off" on the

agreed changes to our SOPs. In practice, this would not have jeopardised our working procedures, since we would have incorporated the changes at a laboratory level, but the rules required that changes were signed off at a national level for the RTC to maintain compliance with pharmaceutical Good Manufacturing Practice.

Section 11 Knowledge of risk of infections while at ANESBTS

HIV/AIDS

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

156. As noted above, not being a microbiology specialist, I had the same general working knowledge of HIV/AIDS as any other Blood Transfusion Consultant. I was aware of the blood transfusion literature on the topic (see question 4 for list of journals), and attended seminars/meetings where experts gave updates. There were also lengthy and informative discussions at the Directors' meeting with colleagues who were more informed than I. My knowledge increased commensurate with the scientific knowledge reported in the medical and scientific literature, and by attending meetings and conferences where experts reviewed the field.

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

157. I first became aware of AIDS/HIV when I was Consultant at SEBTS from 1977-82. The background to this is given in question 2 above, and WITN6960003 page 2, para 2. I became aware of the transfusion risk of HIV/AIDS in 1982/83 at the same time as other SNBTS Consultants, as data emerged from the scientific literature.

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

158. I do not think we carried out any surveys at ANESBTS. This was left to Edinburgh and Glasgow centres that had consultants and microbiologists with a special interest in the topic.

86. According to MACK0001108, at page 3 paragraph 10, BBC Scotland highlighted that in 1983, a study carried out by Glasgow Royal Infirmary Department of Medicine Laboratories (carried out in 1982) "found the same immunological abnormalities in haemophiliacs as were found in people dying of AIDS in US and Haiti." Were you aware of this study at the time? When did you associate AIDS with blood products? At the time, did this affect your willingness to give blood products to haemophiliacs?

159. I would only have been aware of the study if it were in the literature, or discussed at a Directors meeting. I would have been aware of the association of HIV with blood products at much the same time as other Blood Transfusion Consultants, in 1982/83. I was not responsible for prescribing blood products to haemophiliacs, so my willingness was not an issue. As I recall, I did discuss this with my haematology colleagues in ARI at our weekly joint meetings to review haematology patients. At that time, we had a very stable donor population, very few known IVDA in the community, and did not have an overt homosexual community, so the prevalence of HIV was anticipated to be low (so it proved when testing started). We regularly discussed the HIV situation at Directors meetings, as per minutes.

87. According to MACK0001108, at page 3 paragraph 10, BBC Scotland highlighted that "when the virus was identified, serum samples were sent for identification. 16% were antibody positive...and they knew

Aids was in the haemophiliac population". Dr Forbes, then Head of West of Scotland Haemophilia Unit, states he "understood the implications of these results immediately, and told all the haemophiliacs that, by using factor VIII, they were at risk, not only of being infected, but of passing the infection on to their sexual partners." When did you become aware of the link between factor VIII and HIV? Once aware of the risks did you discuss the risks to ANESBTS and with other BTS directors?

160. Please see my response to question 86, and question 2 above.

Hepatitis

88. What was your knowledge and understanding of hepatitis (including hepatitis B and Non A Non B hepatitis ("NANB")/hepatitis C) and in particular of the risks of transmission from blood and blood products during your time at ANESBTS? How did your knowledge and understanding develop over time?

161. As noted above, not being a microbiology specialist, I had the same general working knowledge of NANB hepatitis as any other Blood Transfusion Consultant, since this was a known adverse risk of blood transfusion, although the exact causation was not known until HCV was discovered. Further details are given in question 2 above. I was aware of the blood transfusion literature on the topic (see journals listed in question 4), and attended seminars/meetings where experts gave updates. There were also lengthy and informative discussions at the Directors' meeting with colleagues who were more informed than I. My knowledge increased commensurate with the scientific knowledge reported in the medical and scientific literature, and by attending meetings and conferences where experts reviewed the field.

89. How and when did you first become aware that there might be an association between hepatitis (including hepatitis B and

NANB/hepatitis C) and the use of blood and blood products?

162. I first became aware of Transfusion Transmitted Hepatitis when I was Consultant at SEBTS from 1977-82. The background to this is given in WITN6960003 , and question 2. I also became more aware of HBV when investigating prison donations at ANESBTS, which is recorded in more detail in my response to question 11 and question 106 below.

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

163. I carried out an internal investigation into the location of donors who tested HBsAg positive at ANESBTS, and identified HMP Craiginches and HMP Peterhead as the 2 hotspots, as detailed in my response to question 106.

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

164. As per my response to question 88, I had the same knowledge as expected of a Consultant in Transfusion Medicine.

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

a. Were you aware of this paper and these findings at the time of

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

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

165. **a. and b.** I do not recall specific dates, but I would have been aware of this paper, and expected that these results would have been discussed, and analysed at a Directors' meeting.

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

166. My information came from my more expert colleagues at Directors' meetings, and later the MSC. Those members who attended the various working parties provided feedback on any unpublished surveys. There would have also been presentations at scientific meetings such as the British Blood Transfusion Society, and learned articles in the scientific journals (see list in question 4).

General

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

167. As a result of HIV/HCV, donor selection policies at ANESBTS were completely aligned with the national procedures and SOPs that were put in place. We did not have any separate local structures, but input our views into the national process.

95. What advisory and decision-making structures were in place, or were put in place at ANESBTS to consider and assess the risks of infection

associated with the use of blood and/or blood products?

168. Please see my response to question 96.

96. What if any role did ANESBTS 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.

169. As a teaching hospital, we gave lectures to the undergraduates about all the risks involved with blood transfusion. We did the same for the specialty trainees e.g. surgeons, anaesthetists, and obstetricians during their training. We also participated in the weekly hospital "Grand Rounds" meetings, where interesting/problem patients were discussed by the whole consultant body of all Specialists (and Trainees). Each department presented in rotation, and we used this forum to update our colleagues in developments in blood transfusion, including the emerging infections transmitted by blood. I also set up (and chaired) a Hospital Transfusion Committee for GUHT, which inter alia, acted as a forum for discussing the risks associated with blood and blood products.

Section 12: Reduction of risk of infections while at ANESBTS

Donor Selection

97. What donor selection policies and processes were in place during your tenure at ANESBTS, and how did these change following the emergence of:

a. AIDS/HIV;

b. NANB/HCV; and

c. HBV?

170. Donor selection and processes were based on the Memoranda of 1977, 1983, 1985, and 1987, as detailed in question 8, and were implemented at ANESBTS as soon as these were available within SNBTS. I was responsible for their implementation until they became the day-to-day responsibility of the Donor Consultant, Dr George Galea, from 1989 to 1983, and then shared with the 3rd Consultant, Dr Philip Yates, from 1992 onwards.

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

171. NESBTS exclusion criteria were the same as the Donor selection memoranda, as determined by the National Blood Services. As Director, I participated in formulating of the updates at SNBTS Directors' meetings.

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

172. We followed the National memoranda. Implementation was as per question 97.

100. Were there any difficulties in implementing the exclusion of high-risk donors at ANESBTS?

173. Not that I can recall.

101. 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 produce its own leaflet? You may find paragraph 20 of NHBT0018200, page 3 of PRSE0002617,

SBTS0000247_084, page 4 of PRSE0001767 and NHBT0007516 of assistance.

174. I do not recall the dates when the donor leaflets were provided, or updated, but these were provided by SNBTS HQ for all Centres. ANESBTS used the same leaflets and protocols as other Centres, including updates when these were available. See answers 97, 98, and 99 above

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

175. This was decided at SNBTS level, with input from the Donor Consultants, the Donor Organisers (later Donor Services Managers) and the Directors. I think they were updated when new information became available that would affect donor selection criteria.

103. 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?

176. I do not think that additional information was available prior to donation. They would have been given additional information when counselled by the Donor Consultants, and from the Clinicians to whom they were referred for follow up.

104. How effective, in your view, were leaflets and other communications at reducing the risk of donations from high-risk individuals? You may find PRSE0002617, page 3 of assistance.

177. I think the leaflets and other information targeted at donors were quite effective, but not completely, because people can forget, or not perceive themselves as high risk.

105. In PRSE0001442, page 2 paragraph 3, it is stated that "In early 1983, Dr Brian McClelland, the regional director of the Edinburgh and South East Scotland Blood Transfusion Service, took steps to discourage high risk donors in his region from donating blood by preparing a leaflet containing information about the groups known to be at risk of AIDS". The document also states that Dr Mitchell "had introduced into the health questionnaire a question inviting those who were worried about AIDS to consult the doctor at the session while Dr Urbaniak (SNBTS Aberdeen) had decided to do nothing locally as he was of the view that once a donor entered the session it was too late to do anything". Please can you explain why you made the decision not to do anything locally because it was too late to do anything? With the benefit of hindsight, do you consider that this was the right decision to take at the time?

178. To answer this question, I need to explain certain matters.

179. Document PRSE0001442 formed part of a submission made on behalf of a core participant to the Penrose Inquiry. The passage quoted (Dr Mitchell "*had introduced into the health questionnaire a question inviting those who were worried about AIDS to consult the doctor at the session while Dr Urbaniak (SNBTS Aberdeen) had decided to do nothing locally as he was of the view that once a donor entered the session it was too late to do anything*") was based on a Minute of a Director's meeting held on 24.5.83 (PRSE0003620).

180. The relevant part of the Minute itself states:

"*Dr Urbaniak had decided after consideration, not to do anything locally, his view being that once a donor had entered the session it was too late to make an approach and the problem was minor in NE Scotland*"

One can see that the words quoted in the question do not accurately reflect the terms of the Minute. It was not said that "it was too late **to do anything**" and furthermore, the words "***after consideration***" are missing.

181. It is important to understand that the passage quoted from the Directors' meeting refers to implementation of a question about AIDS on the donor questionnaire at donor sessions (SWBTS), or introducing an AIDS leaflet (SEBTS). My concern was that it would be too late to introduce a leaflet at the donor session, when the donor was in the process of giving blood, rather than earlier in the recruitment process, to deter high-risk individuals from attending.

182. It would be wrong to imply (were that to be the case) that I had taken no action similar to SEBTS and SWBTS on the points recorded in item 15a of the Minute (see PRSE0003620), because this only records what had been under consideration in each Region prior to the meeting. There is no comment either about the position of the other Directors (North and East) who in fact took the same position as me. The full minute continues with item 15b, page 6, paragraph 2), which clearly shows that Dr Cash would take both items forward to SHHD on behalf of all Directors after the meeting. Therefore no immediate action was required of me at that time to introduce an AIDS leaflet in the NE.

183. I had been proactive in dealing with the risk from AIDS in the NE and soon after the Directors' meeting in March 1983, I wrote to the local Haemophilia Director, Dr Bruce Bennett, on the 11th April 1983 (WITN69600010) informing him of measures I was taking to improve local safety by recommending the use of cryoprecipitate rather than Factor VIII concentrate for Haemophilia patients in the NE. .

184. I had received a draft copy of Dr McClelland's leaflet on 5th May 1983 (as had the other Directors), prior to the meeting of the 24th May 1983 and replied on 10th May (WITN69600012) that I had consulted with my

Consultant colleagues regarding the NE situation with regard to the risk of AIDS/HIV in the community and, from the expert advice given, concluded that it would be premature to introduce a similar leaflet in the NE. These colleagues were the Consultants for Infectious Diseases, Sexually Transmitted Diseases, Haematology and Public Health, and who were those most likely to encounter AIDS patients, or those with high-risk behaviour, such as IVDU and promiscuous homosexuals

185. Apart from the reasons of a unified approach by Directors, my decision not to change donor procedures immediately in the NE in May 1983 was also influenced by this being such a contentious issue in the UK at that time. So much so, that excluding high-risk donors by means of a UK-wide AIDS leaflet was embargoed by UK Ministers (SBTS0000696_067) until December 1983. This was the version subsequently introduced in NEBTS, as noted in the Directors meeting of 8.12.83 (PRSE0002604)

186. My decision for not taking the same action as SEBTS and SWBTS in May 1983 was also influenced by the following evidence:

- SEBTS & SWBTS had a visible IVDU problem in their region – ANESBTS did not.
- SEBTS and SWBTS had HIV+ persons identified in their region – ANESBTS did not.
- SEBTS had active, overt homosexual groups in their region – ANESBTS did not.
- SEBTS & SWBTS had increased prevalence of HBV (as a surrogate for IVDU and/or practicing homosexuals) – ANESBTS did not.

187. In fact, the first HIV + donation at ANESBTS was not identified until 1989, some 4 years after the introduction of screening, confirming that I had not put patients at risk by waiting for the national introduction of an AIDS leaflet approved by UK ministers. Only 4 HIV+ donors were identified at ANESBTS in the 10 years after the introduction of screening (SCIEH report

of 1999, (WITN6960011), confirming this as a low prevalence part of Scotland

188. I hope that what I have set out above provides an explanation for my actions and decision-making in relation to steps taken to reduce the risks from AIDS at ANESBTS. I believe that those decisions and actions were reasonable. I include within that the specific "decision" referred to in question 105.

106. PRSE0000193 relates to minutes of a Directors' Meeting held in SNBTS Headquarters Unit on 29 March 1983. At page 5, paragraph 7, it is reported by Dr Cash that the Medicines Inspector had commented adversely on the collection of blood in prisons and borstal institutions. Furthermore, it was noted that you intended to "review the situation in your region."

a. What criticisms did the Medicines Inspector levy against the practice of collecting blood from prisons and borstal institutions? Please provide details.

b. Following this meeting, what was agreed on policy in respect to the collection of blood from prisons and borstal institutions?

c. Who had the final say among Directors when it came to agreeing policy in the Regions?

d. Did you consider that it was safe to collect blood from prisons and borstal institutions at this time?

e. Was there a concern over the supply of blood which led ANESBTS to continue collecting blood from prisons and borstal institutions?

189. I refer you to my response to question 11, in which I provided a detailed explanation of the situation with prison donations at ANESBTS that I gave to the Penrose Inquiry, and the actions that I had taken.

190. Specific answers to Q106 are:

a. I do not recall the MI's specific reasons, since I had not been involved in the ANESBTS 1982 MI inspection discussed at the Directors' meeting in 1983, nor any of the prior SNBTS Inspections of the other Centres where prison sessions were specifically mentioned.

b. I think we decided it was not a good idea to continue collecting blood from prisoners.

c. I thought that Dr Cash did, but this would be after debate among the Directors, and a consensus reached – or at least a majority.

d. No, hence the action I took, as detailed in my response to question 11.

e. No such concern under my Directorship.

107. MACK0000053_003 is a letter from Dr Cash to you dated 29 November 1984, entitled "AIDS: Donor Leaflet". Dr Cash stated that "leaflet [with information on AIDS] will be enclosed in every donor call-up letter", and that "a leaflet will be sent to the home address of known donors who are not normally individually called to sessions." Furthermore, "every donor will be given a leaflet at the session."

a. How soon after, if at all, were these decisions implemented at ANESBTS?

b. Did you agree with the decisions reached? Please explain your answer.

191. **a. and b.** As far as I recall, I initiated discussions on implementation with my Donor Organiser on the day after the letter was received (it was not

unexpected, given the points had been agreed at the Directors' meeting), and instructed her to proceed with meeting the request as soon as possible. I do not recall having a problem with this request from Dr Cash, since we had agreed collectively to take this course of action at the Directors' meeting previously. In fact, I responded to Dr Cash on 4th December confirming my actions (WITN6960013).

108. PRSE0000883 is a copy of minutes of a SNBTS meeting of the Co-ordinating Group Held in the Headquarters Unit on 19 August 1986. Page 2 stated that in relation to health checks and questionnaires, Directors were aware of the possibility of alienating donors with "paperwork". Did you share this view? Please explain your answer.

192. There was always the possibility that some donors would be upset by what they saw as intrusive questioning about their sexual preferences, and practice. There was also perceived to be a risk of losing donors because of this. However, on balance, I felt that this was unavoidable in order to improve blood safety.

Introduction of virally inactivated products

109. What role did you consider ANESBTS had (or should have had) in pushing for factor concentrates to be virally inactivated in the late 1970s and early 1980s? In particular:

a. Was the need for safe products raised by you or anyone else at ANESBTS with BPL and/or pharmaceutical companies (or anyone else) during this period? If so, please give details. If not, why not?

b. Please consider the minutes of the meeting on 18 December 1981 at paragraph 3.2 (CBLA0001565x); why was the need to produce a hepatitis free product considered to be an aim for the future, not for the present given what was known about hepatitis in 1981?

193. **a.** I was not an expert in this field, and my knowledge extended to the discussions held at the Directors' meetings after 1983. My colleagues at the PFC took the lead on this, including liaison with BPL. I was in favour of viral inactivation of plasma products, but also aware of the significant technological challenges in introducing this without significantly reducing the yield of clotting factors, potentially causing a shortage for patients.

194. **b.** I was not in post when this was discussed in 1981, and I am therefore unable to answer this question.

Provision of diagnostic screening kits

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

195. On my appointment, the system that was in place was for testing for HBsAg using the Abbot Diagnostics equipment and testing kits. This was contract was reviewed annually at ANEBTS until the SNBTS national microbiology reference centre assumed responsibility for evaluating screening kits. I recall that Ortho Diagnostics kits were recommended for some Centres. This continued until HIV testing was introduced in 1985, and HCV testing in 1991, with screening kit recommendations made by SNBTS HQ

111. Did you, or anyone else at ANESBTS, contract directly with any pharmaceutical company involved in the manufacture and/or sale of screening kits, or were contracts negotiated on a national basis? What were the key factors influencing choice of screening kit and/or pharmaceutical provider?

196. I continued with the local arrangement for HBV screening until the SNBTS Microbiology Reference Centre undertook evaluation of the various

test kits on offer, and central contract negotiation was introduced. Not being an expert in this field, I had no particular input to the decision making process, and accepted what was negotiated for ANESBTS.

112. 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?

197. In ANESBTS implementation of testing was delegated to the Senior Chief Technician, Dr Derek Farr. I believe that all Diagnostic kit companies offered training and "troubleshooting" advice on the performance of their equipment and kits.

Introduction of HIV testing.

113. The Inquiry understands that HIV screening was to commence on 14 October 1985. Please confirm whether ANESBTS were able to commence screening on this date. If they were, please explain the steps taken to ensure ANESBTS could commence screening on this date. If not, please explain when ANESBTS commenced screening and how this was achieved.

198. Yes, ANESBTS started testing on 14 October 1985 as planned. Dr Farr had spent the prior months preparing the testing laboratory, installing the laboratory equipment, training the laboratory staff, and evaluating the testing kits on donation blood samples "left over" from HBsAg screening. Laboratory SOPs were also prepared (to the national template}.

114. Please describe the implementation of HIV screening at ANESBTS. In particular:

a. What was the process for screening donors and/or blood donations, including the confirmatory process used?

b. What happened to all the unscreened blood that had been

collected prior to HIV screening being implemented?

c. **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.**

d. **What impact did the introduction of HIV screening have on ANESBTS, including but not limited to the financial impact of screening, the impact on those working at ANESBTS, and the impact on the risk of transmission of HIV through blood donations? You may find PRSE0000685 and PRSE0000734 of assistance.**

199. **a.** I do not recall the actual details. We followed the procedures and flowcharts that had been prepared nationally by the SNBTS, and Dr Farr at ANESBTS supervised implementation. Confirmatory testing would have been undertaken by the SNBTS Microbiology Reference Centre.

200. **b.** With regard to donations that were "in circulation" before the introduction of HIV testing, I cannot recall the details, but there may have been a trial period/pilot evaluation before the "official" implementation date, so that all such donations were known to be HIV negative, and there would be no need for any recalls.

201. **c.** Implementation was delegated to the Donor Consultant, and I do not recall the details, but common national protocols and local SOPs were in place, with flowcharts setting out the various decision points for handling both donations and donors. As it happens, the first HIV+ donor was not detected until 1989, 4 years after the introduction of screening.

202. **d.** The not inconsiderable changes required to implement HIV screening had to be absorbed alongside the current testing procedures without interrupting the blood supply and components to our Hospitals. During the period from the initial proposed introduction in July, we had more

time to get everything in place. We were supported financially with additional funds from SNBTS HQ to make the necessary laboratory alterations, and acquire the additional equipment and staff and train them.

115. According to PRSE0002407, in February 1985 you were amongst a group of English and Scottish directors who wrote to the Lancet to express concern over the number of false positive results from the HTLV-III antibody tests. Can you recall what prompted you to sign this letter and what your experiences were of HTLV-III antibody tests at ANESBTS?

203. I think we were all concerned that a high level of false positives would result in 1). delays in getting blood "onto the shelf" whilst this was resolved, causing temporary blood shortages, 2). a drop in blood stocks because of the discarding of suspect blood, 3). a loss of blood donors if they had to be deferred from donating because the testing was unresolved, and 4). the impact on donor counselling if results were subsequently confirmed as negative. At this point these were hypothetical concerns because we had not yet undertaken any testing at ANESBTS.

116. According to MACK0001108, at page 3 paragraph 10, a lab technician gave an account to BBC Scotland and stated that "in July 1985 I went to work for the Blood Transfusion Service of Aberdeen, and was very surprised to find that blood was not being routinely screened for HIV. They did not appear to be treating the issue of possible blood contamination and HTLV-III infection with the urgency that I felt was required." When did routine screening commence in Aberdeen? Was blood being screened for HIV in July 1985? If not, why not?

204. Routine testing for HIV was not in place in any UKBTS Centre in July 1985. This commenced in ANEBTS, on target, in October 1985, at the same time as the other Centres.

117. In 1985, an expenditure report from the SNBTS stated that "Dr Urbaniak has inherited a Centre which is somewhat underfunded in several areas". The report goes on to say "it is now clear that the introduction of HTLV-III antibody ("AIDS") screening of all donations (Expected to start in the Autumn 1985) will put new and acute pressures on NE CENTRE." Please explain the impact inheriting an "underfunded" centre had on HIV testing and whether the increase in MLSO establishment assisted. You may find PRSE0000734, page 19 of assistance.

205. As noted in my response to question 114.d, additional resources enabled ANESBTS to commence HIV testing on the planned date.

Surrogate testing - Scotland

118. Whilst you were employed at ANESBTS, what was your opinion of surrogate testing as a potential method of donor screening, and how did this change over time? Please comment on each infection with reference to specific surrogate tests:

a. HIV; and

b. NANB/HCV.

You may find PRSE0002641, page 5, item (i) of assistance.

206. Not being an expert in this field, I was more of an observer to the national debate involving my colleagues who were. I cannot comment meaningfully on this subject.

119. The minutes of the 25 March 1986 meeting of SNBTS directors record that "Certain clinicians and haematologists in this country had felt that the Transfusion Services had been slow to commence AIDS antibody testing and others had similar views in

relation to non-A non-B hepatitis surrogate tests" (ARCH0002254, page 8). What were your views on these issues at the time?

207. I can understand the impatience of the clinicians involved, but they were used to single patient interactions and testing, with days/ weeks to get their test results. Until explained to them, I do not think they fully appreciated the time constraints of needing the answers to tests carried out on hundreds of donations within hours in order to get blood on the shelf, or the implications of having to hold back donations while the tests were repeated, if equivocal.

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

a. Whether this recommendation was sent to the SHHD;

b. If it was, the response this recommendation received from the SHHD;

c. Whether surrogate testing (namely ALT or anti-HBc testing) was introduced at ANESBTS during your tenure;

d. If so, whether this had any impact on the ANESBTS;

e. How the surrogate testing was performed;

f. What the process was for screening donors and/or blood donations;

g. What, if anything, happened to the unscreened blood that had been collected prior to surrogate testing being implemented; and

h. What happened when a donation tested positive. Please set out the steps that had to be taken, both with respect to the donor,

and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.

208. **a., b**. I was not aware of Dr Cash's correspondence with SHHD, but I was aware of the discussions around surrogate testing at Director' meetings, and the implications of testing at the operational level. I also responded to Dr Cash's request for information on the resources that would be required

209. **c., d., e., f., g. h.,** We did not introduce surrogate testing at ANESBTS.

121. In July 1987, many SNBTS Directors wrote to the Lancet to state that surrogate testing was "inescapable." They stated that "no large study to answer this critical question has yet been presented, and we agree that the size of the benefit to be gained from surrogate testing cannot be accurately established without such a study. However, the time for this study has already passed" (PRSE0001444). Please expand on the view expressed in the letter, including the reasons why a prospective study was not conducted timeously.

210. I am unable to comment further on this. The letter seems clear. There was pressure to introduce definitive screening, and waiting 3-4 years for the results of a study of surrogate testing (which would be superseded by tests that had been validated for HCV testing) would risk delaying the introduction of proper screening.

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

a. the use of surrogate tests to reduce the incidence of transfusion

associated non-A non-B Hepatitis (NANBH) and its possible value as a public health measure remained controversial;

b. **there was no guarantee, in a given country, that there would be a significant reduction of NANBH;**
c. **the introduction of surrogate testing in some countries could lead to a severe depletion of donors which could compromise the blood supply; and**
d. **if surrogate testing was introduced, provision would have to be made for interviewing, counselling, medical examination and treatment of anti-HBc positive donors and donors with raised ALT.**

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

211. If the Working Group report of the Council of Europe was presented at one of SNBTS Directors meetings, then I would have been aware of it, but I do not remember if it was tabled or not. Looking at the report now, I think I would have agreed with the recommendations.

Introduction of ant-HCV screening

123. When did ANESBTS begin anti-HCV screening?

212. The same date as the rest of the SNBTS and the UK 1st September 1991.

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

213. I think this letter was addressed to NBTS Directors only so did not apply to SNBTS. Professor Cash and Dr Mitchell were copied in as observers. I do not recall seeing the letter, but I recall that discussion about timing occurred at the Directors' meetings. Dr Gunson would appear to have good practical reasons for testing kit evaluation to be completed.

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

214. Although this applied to the NBTS, I would have been of the opinion that all the Scottish regions should start on the same date, since we were a National service.

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

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

b. Dr Robinson was recorded as voicing "the dismay of the Division" at Dr Lloyd's decision at the meeting on 13 June 1991 of blood transfusion consultants (NHBT0071757). Why did you collectively express your disagreement with Dr Lloyd at the meeting?

c. Have your views changed since then? If so, why?

215. These were internal exchanges within NBTS, and I would have been unaware of them, at the time and took no part in the discussions. This controversy came to my attention later when the matter became public knowledge

127. What impact did HCV testing have on ANESBTS? In particular:

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

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

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

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

216. **a. b. c.** By 1991, I had Consultant colleagues at ANESBTS who undertook the day-to day supervision of HCV testing of blood donations, and the management of blood donors. There were national SOPs and flowcharts in place, having been prepared by the Donor Consultants, under the leadership of Dr Jack Gillon of the Edinburgh Centre. These documents were presented to, discussed, and approved by the MSC, and then issued to SNBTS centres for implementation. I do not now recall the details of the flowcharts, and the handling of donations/donors was delegated to my Donor Consultant.

217. **d.** At ANESBTS, very little impact initially, since we identified very few positives (9 by 1992). I think many of the potentially high-risk donors had been prevented from donating by the donor deferral literature, and questionnaires. Overall, in Scotland there would have been reduction in the risk of HCV transmission by blood products, which were pooled from the blood of all donors in Scotland.

128. What funding and operational support was ANESBTS provided with to aid in the implementation of testing? Did this have an effect on ANESBTS's ability or willingness to commence testing earlier? You may be assisted by NHBT0000026_009 (p36-39).

218. We were able to secure sufficient funding from SNBTS HQ to prepare for HCV testing on the planned date. It would have been difficult to test earlier because of the constraints identified in the 1990 Medicines Inspector report, and which needed to be rectified. My staff had also been involved providing blood for the Armed Services in the Gulf War (Operation Granby) at the beginning of 1991 (as had all SNBTS Centres), which involved handling and processing additional blood collections for this operation and, which interrupted planning for HCV testing. (WITN6960014). As shown in the ANESBTS implementation plan (WITN6960015), equipment and kits were not available until mid-July, with a tight timetable to get everything in place by the 1st September 1991. So in retrospect, I do not think we were in a position to start earlier than we did.

Recall practice and procedure at ANESBTS

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

219. I am unable to provide details of recall procedures at ANESBTS since these were delegated to the Donor Consultant. Where they existed, we would have followed SNBTS procedures, since by 1991 we all had Quality Managers responsible for ensuring compliance with protocols and SOPs.

Since about 90% of all blood/components/products were issued direct from the Regional blood bank, we would not have had any particular problems with recall, since we knew where all the blood went. Our Health Board clinicians were always helpful in this regard.

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

220. I don't recall any particular instances, since these were delegated to the Donor Consultant.

131. 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?

221. If recall was required, our Health Board Clinician colleagues would have complied since we had excellent relations with them.

General

132. Please describe all other steps or actions taken at ANESBTS 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.

222. At ANESBTS, we took all the steps that were available to us at the time, by complying with all the regulations, procedures and guidelines for the screening of donors and blood donations. These were coordinated at national level by the SNBTS committees. I have provided more detail of the situation at ANESBTS when I first became Director, and how this evolved, in my responses to earlier questions. I was always keen to have "national solidarity" in our approach to operational matters that were common to all centres in the SNBTS. Over time, the increasing complexity of testing, and the regulatory environment in which blood and blood processing operated,

led to convergence of our practices in the regions. I have explained in earlier questions the physical and operational constraints at ANESBTS, which were also detailed in the Medicines Inspectors reports of 1982 and 1990.

133. 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?

223. I do not think that blood safety was particularly compromised by financial constraints, and I did not feel that ANESBTS was being disadvantaged compared to other SNBTS centres.

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

224. I don't think this had a particular impact on blood safety at a local level, since our donor population had the lowest prevalence of infectious markers (after Inverness)

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

225. Personally, I was reliant on the expert opinion of the various committees analysing the risks of transmissible disease. I don't think I had occasion to challenge this advice.

136. In January 1992, Dr Marcela Contreras wrote, ahead of an ACTTD meeting, that "the attitude towards transfusion safety has veered away from the concept of 'maximum benefit at minimal cost'

towards the notion that if a procedure shown to prevent transfusion-transmitted infection and disease is available, it should be introduced" (NHBT0000044_095). Do you agree that this was a shift that the BTS made? Please explain the reasons for your answer, including any relevant references to discussions with colleagues and official policy within the BTS.

226. These were discussions between ACTTD members, who were the experts looking into transfusion transmitted infection. I cannot comment in any detail, but did note the gradual changes noted by Dr Contreras as strict product liability, designed for manufactured pharmaceutical products (drugs) began to be applied to plasma products, such as factor 8 (reasonably), and also to fresh blood components (less reasonably). The Blood regulations of the EU Commission that were translated into UK Directives also had a major impact on the UKBTS.

137. If you do agree:

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

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

c. What caused the change to occur?

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

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

227. I don't recall the dates of the changes, but the formal adoption of strict product liability, and the impact of translating the EU directives into UK law, were the main drivers of the change away from cost benefit analysis. However, this change inevitably meant that disproportionate amount of NHS

funds were diverted towards testing for rare viral infections compared to the amounts spent on preventing bacterial infections, for example, in the NHS patients in general. I don't think HCV testing was particularly influenced by cost benefit considerations, since the legal implications of strict product liability trumped all other considerations.

Section 13: Look back programmes at ANESBTS

HIV

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

228. I was not directly involved in setting procedures for HIV look back, but would have had an opportunity of commenting on any proposed documents that came to the MSC. Look back would have been delegated to my Consultant colleagues, Dr Yates and Dr Galea, but as I have discussed in more detail above, for the first four years after testing started, we did not have anything to look back on, because we did not identify HIV positive donors.

139. Were you involved in implementing any HIV look back programmes during your time at ANESBTS? Please give details.

229. No, this would have been done by my Donor Consultant.

140. In a letter dated 23 September 1992, you wrote to Dr Mitchell to say "we did not carry out a look-back on the July 87 donation which was transfused, in the light of these findings and the policy at the time" (MACK0002281_061). The Inquiry understands that it was the policy of some RTC's to carry out a look back on the earliest donation. Why was it the policy of ANESBTS not to carry out a look back?

230. This is an incorrect interpretation of the letter; we did carry out a look back on this donation. What I meant in the letter to Dr Mitchell was that look back was not the policy (of any SNBTS Centre) in 1987. The 1987 donation tested negative for HIV, hence the release for transfusion. There was nothing to look back on at that time. When this repeat donor subsequently tested HIV positive in 1992, the archive sample was tested and I asked Dr Galea (Consultant at ANESBTS) to do the look back on the transfusion recipient (WITN6960016). I do not now recall the outcome, but I suspect it did not result in transmission of infection because I would have been informed of this at the time, and I found no reference in my ANESBTS files at the time of the Penrose Inquiry in 2014.

HCV

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

231. I was not directly involved in setting procedures for HCV look back, but would have had an opportunity of commenting on any proposed documents that came to the MSC. The operation of look back would have been delegated to my Consultant colleagues, Dr. Phillip Yates or Dr George Galea.

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

You may find PRSE0001852 of assistance.

232. Not personally. Implementation was delegated to the Donor Consultant.

General

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

233. When HBaAg testing was the only virological screening test on blood donations, and I was the only Consultant at ANESBTS, and before look back became a formal process I would personally follow up HBsAg positive donors before referring to Dr Peter Brunt for counselling (via the GP), and check the fate of any donations or blood components. If transfused, I would advise the clinician responsible for the transfused patient (if still alive), suggesting that they be tested for HBV, and referred to a GI consultant for follow up. I think this was just considered good professional practice at the time, rather than a look back programme as such, since there were so few cases (at ANESBTS anyway).

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

234. Yes, this was my opinion.

145. To what extent could a BTS implement its own local look back programme? Did ANESBTS do this? If so please give details. If not, why not?

235. Prior to the introduction of formal look back for HIV and HCV, when a repeat donor tested positive for HBV I would personally arrange retesting of previous donations, and liaise with the clinician for follow up. This was considered good professional practice, rather than look back as such. This was a rare event, perhaps once or twice in my time as Director. When HIV testing was introduced, we had no positive cases for 4 years, and very few thereafter, so look back was not onerous. However, in the case of HCV, the resource requirements for look back were more onerous, as has been noted

by others. We did not deviate from the National protocols to do our own look back.

Section 14: Your relationship with commercial organisations

146. Have you ever:

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

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

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

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

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

f. Received any funding to prescribe, supply, administer, recommend,

buy or sell any blood product from a pharmaceutical company? If so, please provide details.

236. I had no relationship of any kind with commercial organisations associated with blood products.

147. 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?

237. I had no relationship of any kind with commercial organisations associated with blood products.

148. 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.

238. I had no relationship of any kind with commercial organisations associated with blood products.

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

239. I had no relationship of any kind with commercial organisations associated with blood products.

150. 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?

240. I had no relationship of any kind with commercial organisations associated with blood products.

Section 15: Relationship between SNBTS and NHSBT

Relationship between SNBTS and NBTS

151. 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.

241. I had no formal relationship with NBTS as an organisation, but I did interact with NBTS colleagues who were the observers on the SNBTS committees at Director level, or with NBTS consultant colleagues when on joint working parties addressing specific issues, e.g. formulating professional guidelines. I think formal communication was through the respective National Medical Directors, Dr Cash and Dr Gunson, during my time as ANESBTS Director. We usually reached agreement on professional matters, but our organisational structures were so different that implementation could diverge.

152. 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?

242. I think efforts were made to have UK wide agreement as to what should be done on professional issues. However, policy matters were reserved to the respective countries.

153. 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.

243. See answer to question 78.

Relationship between SNBTS and Northern Ireland Blood Transfusion service.

154. 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.

244. As with NBTS, I only met the NI Medical Director (Dr Morris McClelland) at SNBTS Directors' meetings to discuss professional matters. I had no involvement in the contractual relationships between NIBTS and the PFC, or the BPL, so cannot comment on the questions raised.

155. 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.

245. I had no involvement in the contractual relationships between NIBTS and the PFC, so cannot comment on the questions raised.

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

246. I had no involvement in the contractual relationships between NIBTS and BPL, so cannot comment on the questions raised.

157. 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.

247. I do not recall if there were any formal or contractual forums, but the NIBTC Director would attend SNBTS Directors' meetings as an observer.

Outcomes in Scotland and England/Wales

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

248. I do not have any access to this information, so cannot assist.

Section 16: Variant Creutzfeldt-Jakob disease (vCJD)

159. 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?

249. I do not recall the exact dates, but I would have been informed of the risks of vCJD quite early on, through my attendance at SNBTS meetings, where we usually got information in advance of general publication, and from colleagues at the vCJD surveillance unit who often attended during this time. I was no longer responsible for ANESBTS and not involved in any SNBTS implementation programmes for vCJD, having given up the Director's post in 1999/2000.

Section 17: Other matters

160. 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?

250. I think Mr Hayhoe was probably correct. We were self sufficient for red cells at ANESBTS, and almost certainly at the other SNBTS centres, and

had no need to import blood from the USA. I have no direct knowledge of the NBTS blood situation, but would be surprised if they had to import US blood.

161. During your tenure at ANESBTS, 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?

251. No.

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

252. A full list of my publications to 2011 is provided in my reference list to the IBI. (WITN6960017)

163. 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).

253. I have provided answers to the IBI questions concerning ANESBTS to the best of my ability. It is possible that these answers may have wider relevance for the SNBTS position as a whole, and provide a wider perspective for the IBI.

Statement of Truth

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

Signed GRO-C

Dated 16/12/2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
1.01.1984	Medicines Inspectorate-SNBTS Activities - Current Unresolved Problems including "SNBTS proposal for the scope of revised version of standards for the collection and processing of blood and blood components and the manufacture of associated sterile fluids"	PRSE0002460
1.12.1982	Response to medicines inspectorate report on Aberdeen and North-East Scotland blood transfusion service'	PRSE0004141
	CV of Professor Stan Urbaniak	WITN6960002
	AIDS background	WITN6960003
1.12.1977	Memorandum on the Selection, Medical Examination and Care of Blood Donors. Discusses selection of donors, medical examination of donors and medical care of donors.	PRSE0004358
1.11.1987	Guidance for the selection, medical examination and care of blood donors	PRSE0004115
1970	NEBTS donor session health check.pdf	WITN6960004

22 May 1975	Letter of Dr Brodie Lewis - NEBTS tattoo outbreak	WITN6960005
	NEBTS workload stats	WITN6960006
15.3.2011	Penrose Inquiry - Collection of Blood in Prisons	PRSE0002164
12.5.1982	Report on visit to Edinburgh and South East Scotland	SBTS0000407_007
9.3.1982	Report of Visit to the Glasgow and West of Scotland Blood Transfusion Service.	SBTS0000407_006
5.5.1982	Visit to Inverness and North Scotland BTS	PRSE0002428
14.9.1982	Minutes of the SNBTS Directors' Meeting Held	PRSE0000451
	HMP Craiginches	WITN6960007
	HMP Peterhead	WITN6960008
26.1.2011	Witness Statement of Dr Ewa Brookes provided for the Penrose Inquiry	PRSE0001873
1986	RTC floor plans	WITN6960009
11.4.1983	Letter to haemophilia director	WITN6960010
1999	SCIEH Report HIV	WITN6960011
10.5.1983	Letter to Dr Brian McClelland	WITN6960012
4.12.1984	Letter from Dr Stan Urbaniak to Dr John Cash	WITN6960013

29 May 1991	Letter to Dr Stan Urbaniak from Colonel Michael Thomas – Operation Granby	WITN6960014
18 June 1991	Aberdeen HCV Action Plan	WITN6960015
23 September 1992	Letter to Dr Ruthven Mitchell from Dr Stan Urbaniak – Anti-HIV Lookback	WITN6960016
	List of Professor Stan Urbaniak's publications relevant to the IBI's Terms of Reference	WITN6960017