Witness Name: Gamal Gabra

Statement No.: WITN5495001

Exhibits: None

Dated: 16/12/2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF GAMAL GABRA

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 1 July 2021.

I, Dr Gamal S Gabra, will say as follows:

Section 1: Introduction

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

1. Name: Gamal S Gabra
2. Address: Known to the Inquiry
3. Date of birth: GRO-C 1937
4. Professional qualifications: Mb BCh 1961, Cairo. MRCPath, 1978 FRCPath, 1990

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

5. 1970-1972 Senior House Officer in Clinical Pathology and Haematology, Isle of Thanet group of hospitals and Haemophilia Centre.

6. 1972-1974 Registrar in Clinical Pathology and Haematology, Laboratory Services based at Stirling and Falkirk Royal Infirmaries, Scotland.

7. 1974-1980 Registrar and Senior Registrar in Haematology and Blood Transfusion at the Glasgow and West of Scotland Blood Transfusion Centre, with secondments to Glasgow Teaching Hospitals.

8. 1980-1989 Consultant Haematologist, Glasgow and West of Scotland Blood Transfusion Centre. Honorary Clinical Lecturer, Faculty of Medicine, University of Glasgow. Honorary Consultant Haematologist, Greater Glasgow Health Board.

9. 1989-1992 Blood Programme Adviser League of the Red Cross/Red Crescent Societies (LRCCS) and Secretariat of the World Health Organisation Global Blood Safety Initiative (GBSI).

10. 1992 – 2003 Consultant then Deputy Director then Lead medical consultant at Birmingham Regional Transfusion Centre

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

11. Former membership of all societies mentioned below

    a) Haemophilia Society UK and World Federation of Haemophilia

    b) International Society of Blood Transfusion

    c) British Society of Haematology

d) British Blood Transfusion Society (Founder member)

e) British Society of Haemostasis and Thrombosis

12. Former coordinator and Current Chairman, Arabic-Speaking Transfusion Medicine Forum ATMC, 2004.

13. I am not able to include dates for membership of other organisations.

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

14. Reading most of the relevant scientific journals, articles and publications, with relevance to transfusion medicine practice as well as memberships of learned societies (Q3). Regularly attending and participating in scientific meetings including ISBT, BBTS and Scottish Blood transfusion society, AABB and others.

15. Specialist professional training in Haematology and Blood Transfusion started in Britain in 1970.

16. Accreditation by the UK Joint Committee of Higher Medical Training in 1979.

17. Limited involvement in scientific research.

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.

18. I was neither involved nor provided evidence in any of the above-mentioned blood related infections nor was I involved in any public or governmental inquiries, certainly not while I was in Scotland. I have however been involved in the HCV look back in England and I retired before trace-back of patients with ("vCJD") was implemented.

Section 2: My roles at the Scottish and English blood services

Glasgow Blood Donor Centre

6. Please describe the roles, functions and responsibilities you had as a consultant haematologist at the Glasgow and West of Scotland Blood Donor Centre ("Glasgow BDC") and explain how your roles and responsibilities changed over time, if applicable.

19. As a Consultant in Glasgow, I was Involved in donor care and plasma collection that was part of the programme for selection and boosting donors for collection of high titre plasma donors and donations used for preparation of anti D immunoglobulin for protection of pregnant woman at risk of developing haemolytic disease of the new-born. I also shared the medical responsibility for serology testing laboratory of patients and blood donations, as well as investigation of red cell antibodies.

7. Please describe the organisation of the Glasgow BDC during your tenure, including:

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

20. During my tenure in the Glasgow and West of Scotland Transfusion Centre I was accountable to the Centre Directors, Dr John Wallace followed by Dr Ruthven Mitchell. The medical team included 2 other Consultants, rotating registrars and senior registrars.

b. how the Glasgow BDC was funded and how this changed;

21. I was not involved in matters of funding. I remember there was a central Scottish national NHS unit responsible for all these administrative aspects. I can't remember the exact name of this office.

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

22. The West of Scotland Blood Transfusion Service had a "static blood donation facility" in Glasgow city centre. It was mainly used for blood and plasmapheresis collection from specially selected plasma donors with high antibody titres. Main blood donation sessions in the rest of the west of Scotland depended on off-site mobile collection units. The Glasgow blood centre itself was situated on the grounds of Law Hospital Lanarkshire and had a small facility for manual plasmapheresis.

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

23. I remember Blood Transfusion (BT) centres were managed as individual units based on agreed centralised policies, formulated at the meetings of the directors of the five Scottish centres. Later on, management was centralised with one Scottish SNBTS director and regular meetings of the directors for national decision-making and harmonisation of policies. If I remember correctly, Dr Cash was the first SNBTS director.

e. whether the Glasgow BDC was associated or linked with other Blood Donor Centres ("BDCs") and, if so, how and for what purpose;

24. The centres were managed as individual centres, with agreed policies by the directors.

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

25. I can't recall any specific form of regulation.

g. the Glasgow BDCs relationship with the Protein Fractionation Centre ("PFC") and any other laboratory involved in the production of blood products or processing of blood;

26. The West of Scotland Blood Transfusion Centre had its own primitive World War II type plasma drying facility to produce dried plasma, small pool freeze dried Cryoprecipitate and heat-treated albumin. This was put out of action following establishment of the Scottish PFC at Liberton. Consequently, from then, all plasma destined for fractionation was shipped over from all Scottish centres to Edinburgh.

h. the Glasgow BDCs relationship with any pharmaceutical companies involved with the production of blood products; and

27. No relationship with pharmaceutical companies that I know of or heard about.

i. the number of donations collected each year.

28. Can't recall exact figure but it was around half of the total collection in Scotland.

Birmingham Regional Transfusion Centre

8. Please describe the roles, functions and responsibilities you had at the Birmingham Regional Transfusion Centre ("Birmingham RTC") during your period as consultant

29. As consultant Haematologist I had responsibility for clinical aspects of irregular antibodies and red cell serology teams, providing support at a weekly Queen Elizabeth Hospital (QEH) clinic for haemolytic disease of the new born, organisation of the required compatible blood support for intrauterine transfusion of women with haemolytic disease of the newborn and platelet antibodies.

30. I also shared the responsibility for Medical aspects of blood collection and blood donation teams, in particular the responsibility for clinical support and counselling including the follow-up plans for clinical support; referral for appropriate management and care of donors with positive serology results for transfusion-transmissible infections.

31. In addition, I also shared responsibility for organisation, support and liaison with all Midlands hospitals and promoting activities of Hospital Transfusion Committees for safer transfusion practice.

32. I was the Director of the WHO coordinating centre for training and development in transfusion for local trainees and overseas transfusion practitioners. I shared with Dr Ala and the scientific and technical staff the responsibility of organising the yearly courses including the programme, the selection of speakers, sharing in lecturing, conducting the practical laboratory exercises and the daily Q&A sessions.

a. Lead Consultant; and

b. Any other roles held.

c. Please explain how your roles and responsibilities changed over time, if applicable.

33. As the lead medical consultant, I was responsible for the coordination of all medical matters in the Centre and with the hospitals in the region. With the medical consultant team, we were responsible for liaison with the blood collection, processing, testing and

quality teams to ensure that the products and components were adequate, safe and clinically appropriate for the patients in the region and were available at a national level for other regions if and when required.

34. Change in the management of the Centre was minimal and continued until the zonal restructuring phase. I became medical lead consultant and with the technical scientific colleagues, we participated and became involved in several zonal and national committees for all activity aspects.

35. Management was later restructured within an overall National approach. I cannot recall the details.

36. This period was not easy to handle as the general management of the service in England had gone through several phases of almost continued restructuring, reducing the role of medical staff and their contribution in hands-on management and effective involvement in decision making at centre and national levels. I retired in March 2003.

9. Please describe the organisation of the Birmingham RTC during the time you worked there, including:

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

37. This question has already been partially touched upon in the answer to Question 8 above.

38. When I started, I was professionally accountable to the director Dr Ala. At some stage a Chief Executive was appointed. My position was then changed to deputy director and my accountability became difficult until the zonal restructuring phase was introduced. My title and position were again changed and I became the medical lead consultant, accountable professionally to the Zonal Medical Director, an excellent colleague, Dr Tim Wallington, who actually saved the quality of performance at a zonal level. At this stage I participated with the technical and scientific colleagues in several zonal and

national committees for quite a range of activity. Management was later restructured within an overall national approach. This is as far as I can recall as it is difficult to remember the exact details.

b. how the Birmingham RTC was funded and how this changed;

39. A central organisation was responsible for these aspects. I was not involved in these issues and hardly participated in introducing and planning and implementing changes in structure, funding and financial policy. This was explained in as much detail as I am able to give in answer to question 8 above, after so many years – 30 years since the events concerned and 18 years since I retired.

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

40. The Birmingham Centre was one of the 13 centres of the National Blood Service in England, UK.

41. The centre served the West Midlands region, which has a population of 5.2 million inhabitants and 24 regional and university hospitals.

42. The centre had three static sites and 10 mobile blood collection teams. The yearly blood collection was approximately 250,000 blood donations and daily collection approximately 10 thousand units.

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

43. This detailed witness statement by Dr Gunson is excellent and I support all the details that are mentioned. It is obviously a conscientiously prepared document and in my view the changes he describes were intended to save the quality of the service. The creation of the National Directorate facilitated the changes that followed, funded and managed by the DHSS. Although the Directorate did not have any executive authority, nevertheless through persuasion and successful management with understanding and collaboration between the Directors, substantial progress was achieved and the UK managed to save an internationally renowned blood transfusion service that I believe is second to none.

e. whether the Birmingham RTC was associated or linked with other Regional Transfusion Centres ("RTCs") and, if so, how and for what purpose;

44. I am not aware of any links until the zonal restructuring when the south-west zone was established and included Bristol, Birmingham, Oxford and Southampton.

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

45. The National Regulatory Authority (The Committee for the Safety of Medicines) regulated all centres through well-organised inspection visits.

g. the Birmingham RTCs relationship with the Bio Products Laboratory ("BPL") and any other laboratory involved in the production of blood products or processing of blood;

46. I simply understood that plasma was sent to BPL but was not aware of details of the amount or frequency of delivery. I had no role or responsibility in this area. I vaguely recall that hospitals received their Plasma Derived Medicinal Products (PDMPs) via the transport system between BPL and our centre.

h. Birmingham RTC's relationship with any pharmaceutical companies involved with the production of blood products; and

i. the number of donations collected each year.

47. I am not aware of any relationship with any pharmaceutical companies. The centre in Birmingham collected approximately 10% of all collections by English centres. The figure I remember was approximately 250,000 units per year.

Please answer the questions in Sections 3 to 15 in relation to both the Glasgow BDC and the Birmingham RTC unless otherwise stated.

Section 3: Blood collection

10. Please explain the system for blood collection during your employment at the centres. Did this system change over time? If so, please provide details.

48. The basic standard systems and procedures for blood collection were followed carefully with any additional or necessary changes as and when required.

49. Blood collection sessions originally carried out in hospitals, were replaced by community blood collection sessions. There were no substantial differences in the UK centres generally.

50. Each centre would build panels of voluntary non-remunerated, locally accessible donors. Regular repeated donors constituted a large proportion of the daily collections (up to 90%). Recruitment programmes were essential to maintain relationships with the community and the altruistic voluntary donors. They were usually well equipped and well designed. Programmes for blood collection sessions were planned well in advance and assigned to mobile blood collection teams to meet the required blood supply.

51. Mobile team blood collection relies on selected community sites. Some centres use specially designed mobile buses, but the majority of sessions would take place in organised collection sites.

52. Blood collection centres usually have one or two static blood collection facilities in busy city areas. These provide the opportunity for new donors mainly, as well as "multiple-components individual donors", by apheresis.

53. The Red Book Standards are mostly adopted across the UK with thorough Guidelines documented for donor deferral, donor-care and the necessary clinical safety parameters for blood donation. These guidelines were regularly updated at local and national levels as and when required.

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

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

54. Staffing was adequately provided and well-trained. Medically qualified staff were required on site, but were later on replaced by well-trained nursing staff. On occasion centres may have had a static site for blood collection when the blood centre was situated on hospital grounds, but the technically stand-alone newly-developed centres usually do have local facilities for blood and plasma collection.

b. Where did these sessions take place?

55. See details above.

c. How frequently could a person donate blood?

56. Standards for frequency of blood donation were adopted almost nationally. They varied according to age, gender and followed the national guidelines for donation and deferral. Any changes to the Red Book were introduced after thorough evaluation and careful consideration for donor care and clinical safety of recipients.

d. How were blood donors recruited?

57. Each centre has a department or a donor motivation and recruitment team. They produced leaflets and other material to promote blood donation.

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

58. All matters above, from a to e, were standard activities used by all centres in the UK with minimal differences in application. At some stage a national programme for donor recruitment based on scientific marketing approaches was introduced, while also allowing individual centres to use motivation and recruitment materials and methods that were in keeping with local culture and customs.

12. Did the centres have donation collection targets during your tenure? If so, who set these targets and what were they? If not, why not? What was the purpose of the targets?

59. Targets were planned to meet the transfusion requirements, depending roughly on the population size in the area or zone covered by the centre. These targets for blood and various components varied between centres. They depended on the developments in therapeutic approaches and on the availability of guidelines to control wastage of blood and components. They also depended on the adoption of criteria for good clinical transfusion practice, making sure to meet local self-sufficiency measures in labile components and plasma for fractionation, according to the targets based on the available population and the optimum number of donors expected from its surrounding inhabitants.

13. What measures, if any, were taken to improve blood collection at the centres? In your view, do you think these measures were sufficient? Please provide details, including information about any barriers to improving blood collection (if applicable).

60. The measures in use were standardised. I believed that they were sufficient and promptly revised as and when required.

14. What steps, if any, did the centres take to publicise themselves to potential donor populations in order to increase donations? How successful were these steps?

61. Procedures for donor motivation, recruitment and retention of donors were excellent. They were well funded with well-trained professional staff. They were regularly reviewed and updated at regular intervals.

15. To what extent did the Glasgow BDC collect blood from prisons, borstals and similar institutions? Please set out the number of institutions from which blood was collected and the frequency of sessions. In particular:

a. When did this practice cease?

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

c. What were the relative costs of collecting blood from prisons as compared to collecting blood at the Glasgow BDC?

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

62. This approach to collection of blood from all high-risk communities and institutions was abandoned early in the 1980s in Scotland and I also believe this was the same approach in all blood collection facilities in the UK.

63. I am not sure when the decision was taken to stop blood collection from all institutions with donors at high risk for transmitted blood borne infections. It could also have been a national policy rather than a Scottish decision. I believe that in general the concept of incentives to donate blood was basically not acceptable in the UK since the early days when voluntary non-remunerated policy was adopted and established nationally.

64. There should be records available about this important safety and ethical decision in which I had no role, except that I supported it. However, I believe that this must have resulted in extra costs to replace and in my view blood collection from "captive donors" is unacceptable in the first place. I am also not aware of any study that was done to compare the cost between mobile community collection and blood collection in prisons.

16. In 1994, you wrote a letter to Dr Ala in which you stated that "Blood Procurement and Apheresis, for which I am responsible, is very sensitive" and that "you would be most grateful if any changes in the planning and the day-to-day running of these three departments... are left to me" (NHBT0095599). Please expand on this letter. Were you free to implement measures to increase blood procurement?

65. Yes, we were continuously trying to take the necessary decisions to maintain the required levels of red cell preparations, the range of components, as well as plasma for fractionation. I believe that was during one of the waves of restructuring to introduce the zonal/regional management phase. The local manager of the centre was removed (Mr Jinks) and I wanted to make sure that the remaining Medical Director (Dr Ala) would continue to support the integrity of the existing system so that this managerial vacuum would not adversely affect decision making, maintenance of blood collection, and availability of components through processing or by apheresis, to maintain the supply and availability of the range of red cell preparations and other components as well as plasma.

17. As far as you are able, please comment on whether the methods and systems employed by the Glasgow BDC and Birmingham RTC to collect blood varied. If so,

how? What effect, if any, did this have on the amount and/or quality of blood collected?

66. Blood collection systems were more or less similar with very little difference all over the country. I was not aware, except rarely, of shortages in supplying patients' needs in red cells while I was in Scotland. Platelets were provided to hospitals on request for patients, but by the time I was about to leave Scotland, tertiary hospitals acquired platelet storage facilities and had platelet stocks delivered on a routine basis; in the early 1980s blood collection was starting to become driven by plasma supply to provide FVIII, Albumin and immunoglobulins, especially Anti-D and other high titre antibodies from special donors. The then former Director, Dr John Wallace, had established very close relationships with hospitals and the Glasgow centre was able to bridge the hospital/BTS interface. From my experience the Glasgow centre was in many ways able to reduce the clinically unjustified use of plasma, leading to increased recovered plasma for production of albumin and later of other plasma derived products, including FVIII concentrate when the plasma fractionation facility was established in Scotland. That was already the case when I joined Birmingham.

Section 4: Self-sufficiency

18. During your time at the centres, what did you understand the term 'self-sufficiency' to mean? Did your view or understanding of what constituted self-sufficiency change over time?

67. Self-sufficiency is a worldwide concept, particularly in nationally established blood transfusion facilities that are responsible to meet the needs and provide the required supply of blood components and derived products, for the respective facilities and communities that they serve.

68. Whether this can be achieved completely or partially is another matter. However, I always believed that this has to be considered as a legitimate need for communities

and it is an important target to try and put in place adequate systems to provide through national blood collection all the appropriate clinical needs for blood and its derivatives.

19. As far as you are aware, did your views on self-sufficiency accord with the views of your peers and the Blood Transfusion Services? In particular, as far as you are aware, did the way Scotland and England defined 'self-sufficiency' differ in any way?

69. I believe that most of my peers, whether in England, Scotland or anywhere else, accept it as a target that requires effort to achieve but also that on occasions the circumstances lead to acceptance of the fact that it is difficult to achieve. It is also essential to promote the use of blood, its components and products according to clinically established guidelines and reduce waste.

20. During your tenure at Glasgow BDC, what was your view on the prospect of Scotland achieving self-sufficiency?

70. Dr John Wallace, the then Director in the West, started early attempts to achieve self-sufficiency in Scotland earlier than the time before I joined West of Scotland SNBTS centre as a senior registrar. Dr Wallace introduced the concept of reducing the use of whole blood transfusion. He promoted the use of components instead. Clinicians gradually accepted this approach.

71. This resulted in processing a significant amount of blood donations and consequently the Centre was able to produce platelets and also using its freeze-drying facilities to produce plasma to store as frozen fresh plasma as well as dried plasma, to produce cryoprecipitate and heat-treated albumin.

72. I recall, and there may be records to confirm this, that processing reached around 70% of blood collection and allowed a degree of self-sufficiency in components and

recovered plasma to produce plasma-derived products. This was achieved by mid 1988. Purchase of commercial factor VIII had then to be introduced to meet the needs that followed the introduction of home therapy of haemophiliac patients, before starting to increase the supply of source plasma using plasmapheresis systems.

21. During your tenure at the Birmingham RTC, what was your view on the prospect of England and Wales achieving self-sufficiency?

73. The situation was different in England because of the late and more difficult introduction of the use of components in place of whole blood and in the higher number of centres which led to a higher dependence on source plasma and the use of the costly plasmapheresis machines to meet the targets of source plasma for fractionation. I believe that is the reason that it took more time and effort to achieve some degree of self-sufficiency in England. I do not remember Wales except that they had a very good and effective physician and transfusion specialist.

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

a. plasma procurement;

b. decisions with regard to cryoprecipitate production;

c. purchases of commercial blood products; and

d. the funding of the centres.

74. The concept of self-sufficiency was certainly affected by the difficulty in meeting the targets because of a range of factors that limited efforts and resources to achieve the plasma targets. It soon became clear that it was not possible to depend on cryoprecipitate to meet the targets for self-sufficiency, particularly with the introduction of home treatment and prophylactic therapy, and following the spread of HIV infection. This certainly required importing commercial concentrates and establishing facilities for plasmapheresis at substantial cost and limited funding resources. The NHS was able

to provide funds to maintain therapeutic sufficiency albeit not from nationally and locally manufactured products in a number of centres.

Section 5: Production of plasma and plasma targets

23. The Inquiry understands that the centres produced fresh frozen plasma ("FFP") (NIBS0001490 (page 15)). Please describe:

a. the capacity of the centres to manufacture FFP, and whether this changed during your tenure;

b. what proportion of blood collections were allocated to this process and what sent to PFC and/or BPL, and how this decision was made; and

c. how the production of FFP was funded.

75. In the early days of my career in the UK as a trainee in Haematology, whole blood was mainly used for transfusion. FFP was used mainly as a volume expander and for the preparation of cryoprecipitate. In response to these clinical needs, clinicians requested whole blood. Gradually it became acceptable to use mainly concentrated red cells unless whole blood was requested for specific clinical conditions. Each single blood donation can be separated into plasma and concentrated red cells. Plasma can also be used to prepare cryoprecipitate. The preparation of these various components depends on the local needs of the hospitals served by each individual centre. Accordingly, the capacity of the centres to manufacture these products is determined by taking into consideration the range and quantity of the components required. A proportion of frozen fresh plasma is kept as stock in the centre after supplying the hospital needs and the rest is sent to the fractionation facility for preparing the required PDMPs. The NHS provided the funds required through a cost recovery arrangement with hospitals.

76. At some stage changes were required to increase the supply of plasma to increase the quality and range of PDMPs. This was met by using the labile components in place of whole blood and also by introducing national guidelines for use of the various blood

components in order to increase the volume of recovered plasma supplied for fractionation. There came a point where SNBTS and NBS were supplied with funds to establish plasmapheresis facilities for the collection of source plasma to meet the demands for coagulation factors, albumin and immunoglobulins and other safer virus inactivated products.

24. Please describe the production facilities for FFP at the centres.

a. In particular, please describe: where this took place within the centres;

77. Production took place in special laboratories with special machines for weighing, centrifugation, separation into components and freezing.

b. the processes by which these products were produced;

78. The processes used were all conducted by specially trained staff according to national standard operating procedures.

c. whether the production procedures and processes could affect the quality of the blood components themselves, and the quality of the finished blood products;

79. Yes, any of these procedures had to be conducted with strict adherence to the standard operating procedures based on the directions of The Red Book. Any errors at any step, or improper defects in the machines used could affect the quality standards and safety of products.

d. the factors that could affect the quality and/or potency of plasma and Factor VIII content;

80. These factors that affect quality recovered and source plasma and Factor VIII content include; storage temperature after collection and during transport, length of period before centrifugation, temperature and speed of centrifugation, storage time and

temperature before freezing of plasma and time to complete freezing in special temperature controlled freezers before despatch to fractionation. All the above-mentioned conditions and procedures were to be followed carefully and SOPs prepared based on the national Red Book that contained the GMP guidelines for blood transfusion services of the UK. These guidelines are revised at regular intervals.

e. whether the facilities were sufficient to produce FFP;

81. The facilities in Glasgow and Birmingham where I worked were always adequate and sufficient. Any requirements and problems were promptly attended to in order to meet the GMP guidelines and quality standards of all components of PDMPs at every step of the production processes.

f. whether the facilities were sufficient to increase the amount of FFP produced;

82. Any decision to increase the amount of FFP was planned and funds released to upgrade the facilities, the staffing and the training.

g. whether the centres had the capacity and/or funding to make improvements to the production process; and

83. Any decision to increase the amount of FFP was planned and funds released to upgrade the facilities, the staffing and the training.

h. whether you consider the FFP produced by the centres during your tenure to have been of a high quality and if so, how this was measured.

84. The quality standards were monitored at every stage of the production processes and of the final product using quality protocol to ensure expected quality and safety. Batches of production were only released when processing criteria met the quality standards required.

85. Any decision to increase the amount of FFP was planned and funds released to upgrade the facilities, the staffing and the training.

86. The quality standards were monitored at every stage of the production processes and of the final product using a quality protocol to ensure expected quality and safety. Batches of production were only released when processing criteria met the quality standards required.

25. Please describe the steps taken by the centres, if any, to increase production of FFP during your tenure.

87. Please see answer to question 23 above.

26. Did the centres have targets for the amount of plasma to be collected by the centres? If so, who set these targets and what were they? What was the purpose of the targets?

88. The targets were established to ensure maximum use of recovered and source plasma from national blood collection. The decision to set the targets was explained in detail earlier in answer to question 23C.

27. Were there consequences for the centres if the targets were not met? If so, please provide details.

89. Any failure to meet the targets were investigated and the necessary steps were taken to resolve the problems and reduce the resulting shortage. However I was not aware of the detailed actions taken or of consequences for centres.

28. Were there benefits for the centres if the targets were exceeded? If so, please provide details.

90. I do not recall whether there were any benefits or incentives to exceed the targets.

29. What factors, if any, affected the centres' ability to meet their plasma targets? In particular, did BPL and/or PFC's production capacity affect the achievement of plasma targets at the centres?

91. I am not aware that there were set targets for plasma collection, however the availability of adequate fractionation facilities in the UK prompted centres up and down the country to increase the supply of recovered plasma. This also encouraged centres to consider establishing plasma collection centres using machine plasma collection. The major important factor is usually the size and number of donor panels.

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

92. As I have said, I do not recall that there were set targets for plasma collection. The aim was to reduce the inappropriate use of whole blood and increase the processing of as many blood donations as clinically possible while maintaining adequate stock of whole blood to ensure its availability when required for patients.

93. The availability of adequate fractionation facilities in the UK encouraged centres up and down the country to increase the supply of recovered plasma and also to consider establishing plasma collection centres by machine plasmapheresis. However, by the time I arrived in Birmingham I was no longer involved in plasma collection related to haemophilia management. Dr Ala, the centre director, was known to have had experience and a special interest in clinical haemophilia care and management.

31. What steps, if any, did the centres 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?

94. The approach to maximise blood and plasma collection is limited by the availability of the potential donor population, in spite of every marketing effort for motivation and recruitment in the community.

95. That is why persuading hospital clinicians to use less whole blood and more red cell concentrates and/or plasma-reduced blood was an essential approach for releasing more recovered plasma for fractionation before considering increasing source plasma by machine plasmapheresis, mainly by promoting the concepts for using the required blood component rather than whole blood.

Plasmapheresis

32. As early as 1981, plasmapheresis was being considered as a means of increasing the plasma supply to help achieve self-sufficiency in both Scotland and England (CBLA0001287). Please explain, as far as you are able, what consideration Glasgow BDC 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 Glasgow BDC to introduce plasmapheresis; and

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

You may find PRSE0003741 of assistance.

96. I am aware that in 1982 the Glasgow and West of Scotland service conducted a comprehensive study to assess the role of machine plasma collection as an alternative procedure to manual collection, to meet the increased requirement for PDMPs, particularly driven by the introduction of home and prophylactic management of haemophilia.

97. The following factors were certainly pursued in Scotland to increase the required amount of plasma; a) increase the size of donor panels, b) increase the number of plasma donors, c) evaluation of costing and funding of increasing the number of plasmapheresis centres, d) training extra staff and expertise to handle the increased plasma donors.

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

98. The existing manual programme was not adequate to meet the increase required of source plasma. The existing facilities at that time for plasma collection were limited and inadequate. The trial conducted at the static centre in Glasgow was comprehensive and the cost of setting up the required facility was calculated. Eventually funds were made available. This allowed plasmapheresis to increase gradually to cover the needs required by the introduction of home therapy and prophylaxis for patients with Haemophilia. This development coincided with the setting up of the Liberton fractionation plant near Edinburgh.

Cross-charging

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

a. the plasma supply in England;

b. the production of plasma via plasmapheresis?

99. I was out of the country when this was introduced and I am not sure how this did affect source plasma collection. The document NHBT0057426_002 gives the details of the cross charging but it is difficult to assess the effect on the plasma supply for fractionation. It is generally accepted that the concept of cost recovery is essential to maintain sustainability of services.

35. As far as you are aware, how did the funding for plasma procurement differ between Scotland and England?

100. It is difficult for me to comment on the funding systems and the effect on plasma procurement. I came back from Geneva in 1992, and was not aware that this system was still in use.

Section 6: Production of cryoprecipitate at the Glasgow BDC

36. Did the Glasgow BDC produce cryoprecipitate? If not, please describe where cryoprecipitate was produced for the Glasgow BDC region.

101. All cryoprecipitate used in the west of Scotland was produced in the Glasgow BTC at Law Hospital, Carluke, Lanark.

37. If the Glasgow BDC did produce cryoprecipitate, please describe:

a. Where this took place within the Glasgow BDC;

b. The processes by which cryoprecipitate was produced; Consisted in separating the plasma

c. The capacity of the Glasgow BDC to manufacture cryoprecipitate and whether this changed during your tenure;

102. Cryoprecipitate was produced in the processing laboratory, I really cannot recall where this lab was, as it is now more than 40 years ago and the overlapping layers of

my memory are not allowing me to come up with the details. All I can say is that the donation was separated into red cells and plasma. The plasma was frozen and stored overnight in cold rooms, thawed in the morning and separated by centrifugation into cryoprecipitate and satellite bags of cryo-free plasma.

103. This procedure was replaced by fast freezing of larger batches of plasma using large fast freezing fridges at -70 degrees centigrade within a much shorter freezing time. I cannot recall the time without consulting the process description in the relevant SOP.

104. New changes were introduced depending on the development of newer techniques that improved the yield and quality of the products.

d. What proportion of blood collections were allocated to this process, and how this decision was made;

105. I am not able to recall the exact quantity of cryoprecipitate produced nor the estimated proportion of blood collections to be allocated for this process. However, it needed to be increased in response to the introduction of newer haemophilia management therapeutic approaches for home and prophylactic therapy.

e. How much funding was provided for the production of cryoprecipitate;

106. I seem to remember that the costing of this expansion was calculated and funding was not available in view of the plan for a new Scottish fractionation facility.

f. and How quickly the Glasgow BDC could have increased its manufacture of cryoprecipitate, had it wished to.

107. This would have naturally meant increasing the size of the laboratory, the required staffing and the extra funding which usually required planning, time and organisation to meet the GMP standards.

38. Please explain what the demand for cryoprecipitate was from the haemophilia centres in the Glasgow and West region during your tenure at the Glasgow BDC and how this changed over time.

108. Demand was increasing gradually to meet the progress in demand due to improved therapeutic approaches and the establishment of comprehensive care centres introducing home treatment. This was perceived as a great improvement that increased the need for using concentrates using large pool batches of plasma with the expected higher risk of hepatitis infections along with safer large-pool fractionated concentrates.

39. In a letter to The Lancet in 1982 about Factor VIII cryoprecipitate and hepatitis risk (PRSE0001036), you and your co-authors said that after examination of studies, "large pool products had the major influence on donor exposure of patients, particularly in cases with mild and moderate haemophilia, and the contribution of cryoprecipitate to risk was small, even as the main product used in therapy." Please outline how you came to form this view. Did your view of the potential risk of hepatitis in the use of cryoprecipitate, compared to Factor VIII products, change over time?

109. A clinical trial for small-pool frozen dried cryoprecipitate was conducted around 1981-82, on the assumption that it would provide smaller donor exposure and less risk of infections. The problem of increasing demand and limited supplies remained unresolved and over time both clinicians and patients became convinced that it was acceptable that both small and large pool products had a place in the management of patients with bleeding disorders.

40. Please explain what consideration, if any, the Glasgow BDC gave to increasing the production and use of cryoprecipitate during your tenure. Include within your answer how the following factors contributed to SNBTS' response:

a. clinical treatment preferences at the time;

110. It was clear that improved clinical therapeutic approaches constituted the most important factor in clinical and patient preferences regardless of which product was available for use.

b. the infrastructure, expertise and capacity of the blood services to produce sufficient cryoprecipitate to meet demand;

111. The infrastructure was certainly a crucial factor. Space was not adequate and required development to meet GMP standards necessitating the creation of newer up-to-date facilities in Scotland in order to produce both small pool cryoprecipitate as well as a fractionation facility to produce the local factor VIII concentrate.

c. Council of Europe meetings; and

d. any research and development priorities.

112. I cannot recall the effect of the Council of Europe meeting that took place at that time, however there were certainly a lot of research and development questions that needed answers, including approaches to implement technologies for virus inactivation and safety of both products as well as increasing plasma availability by bridging the gap between the transfusion services and the community donor interface. (This is the gap in the relationship between the transfusion service and the potential donors that has to be bridged by motivation and recruitment efforts). There is a similar gap between the BTS and the clinical and hospital transfusion practice that also has to be bridged to reduce waste by following clinical guidelines for the appropriate use of blood and blood products.

41. Please describe the storage facilities for cryoprecipitate at the Glasgow BDC. Was there sufficient storage available?

113. Yes, there was just enough space and facilities to produce and store the current production of frozen dried cryoprecipitate. Strategies for increased production were considered a major problem to be resolved. Certainly, that would be the case if switching all patients from factor concentrate onto cryoprecipitate was to be considered when knowledge of HIV emerged. I suspect this would have been very difficult to achieve not only because of the storage but also because of the limited capacity for production.

42. Please describe the production facilities for cryoprecipitate at the Glasgow BDC. In particular, please describe:

a. whether the facilities were sufficient to produce cryoprecipitate;

b. whether the facilities were sufficient to increase the amount of cryoprecipitate produced;

c. whether the Glasgow BDC had the capacity and/or funding to make improvements to the production process; and

d. whether you consider the cryoprecipitate produced by the Glasgow BDC to have been of a high quality and if so, how this was measured.

114. Space and facilities needed major redevelopment to produce the required supply. The quality requirements for GMP were also a newly raised challenge requiring upgrading. All in all, the practicalities of depending on cryoprecipitate would have required considerable cost and time to complete and increase the production based on the knowledge that it has been proved to be clinically effective with a long standing safety record.

115. The details for production procedure were presented and reported in 1980 (PRSE0001701). The results of quality tests were included in the report and confirmed by the National Institute for Biological Standards in 1979.

43. Please describe the steps taken, if any, by Glasgow BDC to increase the production of cryoprecipitate during this time. If no steps were taken, please explain why

116. I cannot recollect what was done to increase the production of cryoprecipitate other than the continued effort to reduce the use of whole blood as much as possible in order to increase the available recovered plasma and use maximum available resources as far as possible in the absence of local fractionation plant in Scotland at that time.

Freeze dried cryoprecipitate

44. The Inquiry understands that the Glasgow BDC was involved in the consideration and production of freeze-dried cryoprecipitate in the early 1980s. Please describe:
a. your involvement in research relating to freeze dried cryoprecipitate;
b. how this research was funded; and
c. whether, in your opinion, the funding limited the work that was done.
You may find PRSE0001701 of assistance.

45. At a meeting of the Factor VIII Study Group in January 1982, you were recorded as expressing that the opinion in West Scotland was that freeze-dried cryoprecipitate "(1) stored better, (2) was simpler to handle, (3) was safer, because (4) dose was specified on the bottle and (5) could be used by patients of any ABO group" (PRSE0001020, page 4). Please expand on this statement. In particular, please describe:
a. the relative advantages and disadvantages of freeze-dried cryoprecipitate compared to cryoprecipitate and FFP;
b. the infrastructure, expertise and capacity of the blood services to introduce freeze-dried cryoprecipitate;

c. whether, in your view, freeze-dried cryoprecipitate could have been scaled up to make a significant contribution to the treatment of patients with haemophilia and other bleeding disorders in Scotland and the rest of the UK and if so, what that would have involved and how quickly it could have been achieved;

d. whether your colleagues agreed with this view;

e. whether you are aware of any infections or adverse reactions occurring as a result of the use of freeze-dried cryoprecipitate, either at the time of your involvement or in any period since; and

f. whether freeze-dried cryoprecipitate could be heat- treated, or subjected to other forms of viral inactivation.

117. All the above questions from 42 to 44 were answered earlier in answers to questions 36 to 41.

46. As far as you are aware, why was freeze-dried cryoprecipitate not introduced? In particular, please comment on whether any of the following factors contributed to the decision not to introduce freeze-dried cryoprecipitate:

a. The opinion of the Medicines Inspectorate;

b. The cost of introducing freeze-dried cryoprecipitate;

c. The availability of manufacturing facilities; and

d. Clinicians demand for alternative products.

118. It is possible at that time that the inspectorate would have accepted continued production of Freeze Dried Cryoprecipitate if the facilities were available to meet GMP practice. This was not the case and I recall the cost, time and actual condition of the site at Law Hospital were all not suitable to introduce the change.

119. I believe also that the long-term strategy was to invest in a new fractionation facility. The situation in the mid-eighties was pressing and clinicians and patients were aware of the importance of resolving the problems to meet the good quality of patient care.

47. In your view, what effect would introducing freeze-dried cryoprecipitate have had on the availability of SNBTS products and the reduction of risk, particularly in relation to avoiding commercial concentrates?

120. It might have temporarily reduced the risk, but there were signs that availability of having adequate supply of safer large-pool viral inactivated products was around the corner. Research in establishing methods for infection control, particularly in commercial concentrates, was already advanced in many centres.

48. In your letter to the British Medical Journal, published 11 October 1980, you and your co-authors stated that 'Factor VIII supply and demand underline a major unresolved problem. Perhaps the time has come to reassess our methods and to accept, as many other countries have done, the fact that there is room for high-technology (low-recovery) and low-technology (high recovery) products in the management of haemophilia" (BPLL0002088). Please answer the following:
a. What led you to develop this view, and did your view of the role of different technologies change over time? If so, what changed?
b. What was your view of the utility of freeze-dried cryoprecipitate as a home treatment for haemophilia? Did this change over time? If so, why?

121. Single donations were used to prepare frozen cryoprecipitate. The process of thawing and pooling the number of packs to give to the patient at home was complicated and affected the quality and FVIII content and dose required.

122. Freeze-dried cryoprecipitate (FDCP) could be prepared in pool sizes of 10, 20 or 30 and used after adding the solvent fluid according to the dose required. This was simpler to prepare and use at home.

123. With the availability of different technologies and additional fractionation facilities, to produce the required viral inactivated HBV products, it became clear then, that it was possible to meet the required demands for FVIII and other Plasma Derived Medicinal Products (PDMPs).

Scotland

49. Please describe the arrangements in place in the Glasgow BDC region for the purchase and holding of, and the allocation to haemophilia centres within the region, of (a) NHS factor concentrates and/or other blood products ("NHS blood products") and (b) imported factor concentrates and/or other blood products ("imported blood products"). In particular, please explain:

a. Which haemophilia centres were supplied with such products by the Glasgow BDC and over what period of time; and

b. The respective responsibilities of Glasgow BDC, PFC, the Scottish Home and Health Department (SHHD), and haemophilia centre directors, and how these responsibilities changed over time.

124. The West of Scotland Haemophilia and Reference Centre was established at the Glasgow Royal infirmary in the 1950s. Children were treated at the department of sick children in the Glasgow Royal Hospital for Sick Children. Treatment at that time was with fresh plasma. The 1960s treatment was provided by the West of Scotland BTS.

125. By the 1970s comprehensive care centres were established and HBV testing was introduced for donors and patients. FDCP was introduced by early 1980, along with manufactured products produced in Scotland that started to be available around 1975.

126. In 1984 HIV antibodies were detected in a number of patients in Scotland and the question of safety became as important as availability. The available virus inactivation procedures were difficult to use for FDCP, but by 1985 heat treatment was introduced and products proved not to transmit HCV although tests for non-A non-B hepatitis were

not yet used. But the advantage of small pool products became less important with the increasing degree of success of self-sufficiency by producing safe concentrates. I am not able to comment on the role of the haemophilia directors in purchasing imported products for their patients and what the role of the SHHD was in providing funds for the purchase of imported treatment if any.

50. Please explain whether any forums were established between Glasgow BDC, Edinburgh PFC, the Scottish Home and Health Department (SHHD), and Haemophilia Centre Directors, and any other groups or agencies you consider significant, to discuss and facilitate these arrangements.

127. I am only aware of the role of the UK haemophilia directors and SHHD with the SNBTS, in facilitating the progress on the direction of some form of self-sufficiency in Scotland.

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

128. I knew that imported products could be made available on prescription by the treating physician, but I am not aware of the purchase arrangements.

52. Did you, or anyone else at the Glasgow BDC, 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 when determining whether to contract with one pharmaceutical company over another.

129. I have no knowledge of any such arrangement.

53. Did the shortfalls in NHS products coming from PFC have an impact on the Glasgow BDC? Please provide details. How frequently did such shortfalls occur?

130. I am not aware of NHS product shortfall, but I can understand that this would have resulted in increased purchase of commercial products.

54. Was the Glasgow BDC 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 blood product over another?

131. I am not aware of this kind of responsibility for choices of imported products.

55. If haemophilia centre directors were responsible for these decisions, did the Glasgow BDC have any influence over their product choices?

132. I was aware of some degree of coordination in decision making between SNBTS, the haemophilia directors, the treating physicians and the SHHD.

England

133. I was not aware of any transactions between Birmingham BTS, Haemophilia centre if there was any and with BPL.

56. Please describe the arrangements in place in the Birmingham RTC for the purchase and holding of, and the allocation to haemophilia centres within the region, of (a) NHS blood products and (b) imported blood products. In particular, please explain:

a. Which haemophilia centres were supplied with such products by the Birmingham RTC and over what period of time; and

134. There were 2 centres in Birmingham; one for adults at the QE hospital and one for paediatric patients at the children's hospital. I am aware that factor VIII concentrate was supplied directly from BPL, possibly using the Centre's transport facilities. I had no involvement in the details of this activity and cannot say any more about it.

b. The respective responsibilities of the Birmingham RTC, BPL, the West Midlands RHA, and haemophilia centre directors, and how these responsibilities changed over time.

135. I am sorry - I had no involvement in the way the relationship of the bodies mentioned was conducted, whether in Birmingham or in Scotland, so am not able to comment.

57. Please explain whether any forums were established between the above groups, and any other groups or agencies you consider significant, to discuss and facilitate these arrangements.

136. As mentioned earlier, I had no involvement in the arrangements conducted with any of these bodies, groups, agencies or NHS departments.

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

137. I cannot recall that there existed any degree of regional differences, but I was not involved in any such arrangements.

59. Did you, or anyone else at the Birmingham RTC, 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 when determining whether to contract with one pharmaceutical company over another.**

138. I was not involved in these procedures and I am not in a position to give any answer to this set of questions.

60. **Did the shortfalls in NHS products coming from BPL have an impact on the Birmingham RTC? Please provide details. How frequently did such shortfalls occur?**

139. I understand that the need to establish the fractionation facility in Scotland was intended to help towards covering the insufficient supply of PDMPs in the UK in general. I am not able to give any information regarding the extent or frequency of the shortfalls if any

61. **Was the Birmingham RTC 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 blood product over another?**

140. The policies for haemophilia treatment, management and decision-making were not included in my responsibilities during my tenure in Birmingham. I am also not aware of any involvement of Birmingham RTC in the decisions taken regarding the choices or management of the patients in these centres

62. **If haemophilia centre directors were responsible for these decisions, did the Birmingham RTC have any influence over their product choices?**

141. The answer to this question was outside of my responsibilities, and I know very little about what was happening in this area.

63. What influence did pharmaceutical companies have in the way the imported blood products they supplied to the UK were used? For example, can you recall whether pharmaceutical companies provided advice on the use of the products?

142. I'm afraid I have no idea about any of the points mentioned above.

Section 8: Services for donors

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

143. I cannot remember the details of pre-donation counselling during my work in Scotland.

144. In Glasgow and the West Midlands pre-donation counselling was offered using a comprehensive written questionnaire regularly updated. At some stage it became a national document used by a trained nursing or medical officer.

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

145. The blood specimens of donors with positive results for HIV or Hepatitis were repeated for confirmation. Specimens with positive findings were repeated for confirmation of results.

146. Details of the donor were referred confidentially to a senior member of the medical staff adequately trained in counselling procedures. Communication with the donor was conducted using a specially worded letter with an invitation to come to the centre to repeat testing of a fresh blood sample. Donors once confirmed positive for HIV findings, were invited for face-to-face counselling in the presence of an HIV counsellor to be taken over for management at one of the specialised NHS departments in the region. Donors with false positive results were also informed without delay and reassured on the telephone.

147. Donors with confirmed positive results were handled according to a comprehensive standard procedure by a senior member of staff for counselling and psychological support at a specialised centre for management of patients with HIV infection.

148. Donors with confirmed HCV or HBV positive findings were also invited for face-to-face information, reassurance and to arrange a referral to be managed at a specialised unit for liver disease.

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

149. Information regarding infected donations is communicated to the hospital that requested and received the product and dealt with according to the hospital's policy for follow-up of such events.

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

150. Yes, these events were managed using comprehensive protocols based on international standards for donor and patient care.

Section 9: Meetings of various committees

SNBTS Directors

68. The Inquiry understands that the SNBTS Directors regularly met as a group to discuss issues relevant to the SNBTS. Please explain:

1. **Who attended these meetings from the Glasgow BDC?**
2. **Did you receive copies of the minutes of these meetings and any associated papers or meeting materials, and if so, how were they provided to you?**
3. **Were you aware of any discussions or conclusions reached at those meetings, and if so, how was this information provided to you?**

151. I know that the directors had regular meetings, however I am not sure I can remember how I came to know about the outcome, the issues and the topics of these meetings.

SNBTS Factor VIII Study Group

69. The Inquiry understands that you attended meetings of the Factor VIII Study Group during your tenure at the Glasgow BDC. The Inquiry has provided minutes of the meetings of this group which you attended for your assistance: MACK0001245_010; PRSE0000428; PRSE0000486; PRSE0000752; PRSE0001020; PRSE0001489; PRSE0002206; PRSE0002583; PRSE0003428; MACK0001245_010; PRSE0002206; PRSE0001489; PRSE0001020; PRSE0000752.
Please answer the following:

a. **Who established these meetings?**
b. **What do you consider to have been the purpose(s) of the SNBTS Factor VIII Study Group?**

152. I do not remember who established these meetings, but I got the invitation from the Edinburgh BDC, probably through Chris Prowse and John Cash who was the National Director at that time and he chaired these meetings.

153. At that time, I was working on a study on the quality of Factor VIII and the freeze-dried cryoprecipitate evaluation trial was conducted with John Davidson and his team at the Glasgow Royal Infirmary. At the same time the scientists in Edinburgh were also active in research in this area and I shared and discussed my current work with Chris Prowse, Duncan Pepper and others.

154. I assumed that this was a scientific group in Scotland that was exploring a number of issues to improve the quality, safety and availability and the pressing needs to deal with the shortage of Factor VIII products.

70. Please explain, as far as you are able, the decision-making remit of the group. Was the Group empowered to make collective decisions that affected the policies and procedures of the SNBTS? If yes, please describe the decision-making process and how decisions were disseminated.

155. I suppose these activities would assist the decision makers to base their plans on sound scientific findings. I assumed that the collective decisions were approved and taken by the directors of the SNBTS.

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

156. Looking back, I would say yes. The result of these joint activities both in the west and the east were supporting the efforts on the road to achieving some degree of national self-sufficiency at least for SNBTS.

72. What do you consider the impacts and contribution of the SNBTS Factor VIII Study Group to have been on the SNBTS' state of knowledge about Factor VIII and its production practices?

157. I believe the SNBTS factor VIII study group in Scotland was intended to bring together workers and activities with interest in this field from all centres in Scotland. The outcome was aimed at exploring and assessing the various policies for how best to handle the problems of supply, safety and putting in place plans for factor VIII production policies to meet the needs of Haemophilia patients in Scotland and further coordinate working efforts, in the UK in general, on the road to UK self-sufficiency.

73. The Inquiry understands that you attended meetings of the Midlands and South West Zone Donor Testing Strategy Group during your tenure at the Birmingham RTC. The Inquiry has provided minutes of the meetings of this group which you attended for your assistance: NHBT0045234_001; NHBT0045234_001; NHBT0045234_001 Please answer the following:

a. Who established these meetings?

b. What do you consider to have been the purpose(s) of these meetings?

158. I can't remember who established these meetings. I do not recall that I was involved in planning or establishing these meetings.

159. Most likely it was part of the early zonal restructuring activities. But I was not aware of the purposes of these meetings.

74. What, if any, decision making powers did this group have in relation to making policy or implementing policies compared to (i) individual RTCs and (ii) the National Blood Authority ("NBA")? In your view, were these arrangements effective in coordinating different aspects of blood transfusion and donor services? If not, why not?

160. This question is part of the information that I am not able to remember. It is likely to be part of the zonal reorganisation that took a lot of time and effort and caused difficulties that could have been avoided on many occasions, and were, in my view, quite unnecessary.

Western Division of NBTS Consultants

75. The Inquiry understands that you attended meetings of the Western Division of NBTS Consultants in 1992. The minutes of the meetings you attended have been provided for your assistance: NHBT0097468_017, NHBT0094253_001. As far as you are able, please describe:

a. The remit and composition of this group;

The meeting began by welcoming Dr. Gabra to W.Midlands and W. Division.

161. It is obvious from the copied text above (from NHBT0097468_017, dated 25th March 1992) that this was my first meeting of the western division of the NBTS directors.

b. The frequency of these meetings; and

c. The relationship between these meetings and any other informal associations between the centres.

162. I assume, from the minutes, that the remit of this long established NBTS group was to provide a forum for the western group of consultants, to share and discuss the issues and establish consensus regarding essential management and planning issues.

Section 10: Information handling and information sharing

76. Please describe the record keeping system in place for blood donations and blood donors at the time of your tenure at the centres. In particular, please explain:

a. what records were kept, in what form, where and who had access to them;

b. how long these records were kept for; and

c. what policy or practice was adopted by the centres in relation to the destruction of these records.

163. All that I am sure about for donor and donation record keeping is that a clearly defined system was nationally established.

164. I remember that the original documents were stored as paper documents and by the time I was about to retire they were to be kept for 30 years and computerised, but this may not have been implemented. I am not sure that I can remember all the details of this question. This is the sort of issue that would have been discussed in the Western Division Consultants' meetings raised in question 75.

77. As far as you are aware, did all BDCs in Scotland during your tenure at the Glasgow BDC, and all RTCs in England during your tenure at Birmingham RTC, follow the same record keeping practices, or did each centre implement its own system? Did these practices change over time, and if so, what do you consider to have driven these changes?

~~165.~~ I am not sure that there was a nationally implemented system. It is likely this may have changed when the national directorate meetings were established.

~~166.~~ All that I am sure about for donor and donation record keeping is that a clearly defined system was nationally established in the UK.

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

167. Yes, I do.

79. The Inquiry is aware that the Communicable Disease Surveillance Centre ("CDSC") maintained a database to keep track of the reporting of blood donors who tested positive for HIV (NHBT0004742_001) in England. 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?

168. Yes, I was aware all the time that the database was maintained, but I can't recall when in particular I became aware.

b. Who proposed the creation of the database?

169. I am sorry, I do not know who proposed it. Its necessity was accepted and it was just part of record keeping steps established for the surveillance of transfusion transmissible infections in the system, including HIV

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

170. As far as I am aware, yes, Birmingham contributed.

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

171. I assumed that this was the case but was not personally involved in the submission or management of the data.

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

172. Yes, this was the case and was part of the system.

80. As far as you are aware, were there any coordinated recording systems between Scotland and England to keep track of reporting blood donors who tested positive for blood borne infections? If not, why not?

173. I believe this was available when required, and it became an established necessity in order to monitor vCJD transmission. It was undertaken centrally from the North London Transfusion Centre.

81. In addition to the database mentioned above, did either of the centres share information with other BDCs and/or RTCs about excluded donors, donors that posed a risk to the safety of the blood supply, or infected blood donations? If yes, was this on a formal or informal basis? Please describe the mechanisms the centres used to share this information, if any.

174. Communication between centres was conducted in cases where it was required, but not as a formal system. Such information became available with the national use of the computerisation of data for donors and donations.

82. In his statement in A and Others, Dr Gunson expressed the view that "there was no central organisation to ensure that... all RTCs operated in a uniform manner" (NHBT0000025_001; NHBT0000026_009). Please answer the following:

a. Do you agree? In your opinion, were the information sharing measures in place between RTCs adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations?

175. Yes, I always believed that the existing system was adequate.

b. As far as you are aware, how did the system described by Dr Gunson compare to the system that operated in Scotland during your tenure?

176. I am sorry I cannot remember the details of the system in Scotland as it is well over 30 years ago.

Section 11: Knowledge of risk of infections

HIV/AIDS

83. During your time at the centres, 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?

177. My knowledge was continuously expanding with the progress in available information. My memory of the incidents of the early days of the spread of HIV is not reliable enough to give details, but it became essential to be continuously updated when I joined the WHO HIV, Global Blood Safety Initiative GBSI between 1989 and 1992.

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

178. In the early 1980s but because of the passage of time I cannot be more specific than this (see also answer to question 82).

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

179. See the answer to Q. 82 and 83 and I was not involved in inquiries or investigations.

Hepatitis

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

180. Early in my career as a trainee haematologist I spent 2 years involved in the management of Haemophilia. This took its natural progress over time by accumulation of information and knowledge about transmission of hepatitis caused by HBV and NANB that later became known to be caused by HCV when testing for this virus became available.

87. 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?

181. See answer of Q. 85 above.

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

182. I was not involved in any hepatitis virology research.

89. 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?

183. My understanding developed with the availability of information and knowledge, but I am not able to mention any specific publications about the severity and or outcome of these infections.

90. 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 not, when did you become aware of it and/or the conclusions set out within it? Were these findings circulated to BDCs in Scotland?

184. I naturally became aware of some of this information as general estimates of prevalence of NANB hepatitis but not necessarily through this paper.

185. I am aware of papers on NANB hepatitis conducted in Glasgow BTC and published early by Dr J Wallace and his virology team. However, my current recollection does not allow me to support or debate the details of these findings.

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

186. I would not be surprised that prevalence was discussed, particularly because of the early involvement in the above-mentioned research in answer to Q90.

91. In 1995, in a letter from Dr Ala to Dr John Barbara, Dr Ala suggested that "the figure of 1 in 2000 HCV positive donors in the UK was rather high", and stated that your figure was "1 in 4500 in 1992/1993" (NHBT0002761_001). Were you aware of this figure? If so, as far as you are able to recall, what was the basis for Dr Ala's figure?

187. I am not sure what was the basis on which Dr Ala suggested this lower prevalence.

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

188. I am sorry I cannot remember these details.

General

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

189. Because of the seriousness of these diseases, I have always considered that the clarity of the donor interview and the way it is conducted has been the most important and basic first step in donor selection and exclusion to ensure that blood products are safe for patients.

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

190. It is the responsibilities of the Centres to introduce testing procedures as soon as possible and I am not aware that Centres had in place advisory decision-making structures. I do however remember that there was in place a national UK decision-making structure to consider and assess the risks of TT infections and establish the policy to ensure the safety of blood and blood products.

95. What if any role did the centres 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.

191. The main role of centres is to make sure they provide blood and blood products with assured safety by using the established testing procedures for markers of TTIs; and also by introducing the appropriate tests for newly identified infections. The centres have no specific role in advising hospitals and haemophilia centres. This is usually the role of the specific National Committee. We also need to consider the accepted fact of clinical freedom of treating physicians to use the products they consider using after adequate information given to patients

Section 12: Reduction of risk of infections

Donor selection

96. What donor screening processes were in place during your tenure at the centres, and how did these change over time?

192. Donor screening has always been conducted by asking questions to exclude conditions that can cause harm to the donors or cause disease to the patient.

193. Gradually this oral interview was expanded with the availability of information, to include a larger range of conditions that can be communicated to patients, starting with syphilis then hepatitis and history of jaundice etc... The expansion of such conditions necessitated regular review of the list of conditions and the way to approach donors, in order to encourage them to communicate these risks.

194. Training also became a necessity to ensure these procedures were performed in a standardised approach.

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

195. All conditions that required exclusion or temporary deferral were listed in special documents and guidelines of the medical assessment of donors that indicated the conditions where donors were advised to refrain altogether from giving blood or to be deferred temporarily for a certain period. I was a member of the donor care team. We shared in revising these guidelines, training the staff and preparing leaflets that would explain the causes of deferral and permanent exclusion from the donor panel, after proper explanation and counselling. The update and revision of these documents as part of the detailed standard operating procedures for donor care and blood collection are based on the national UK guidelines for blood transfusion services in the United Kingdom (known as the Red Book).

98. 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?

196. There were a number of written documents to be sent to the donors at the stages of recruitment and motivation. Other special documents were circulated to the public at large. More specific leaflets explained the risks of transmission of disease. Some were handed to the donors to read before the face-to-face interview, and some to take home and also sent with call up cards. All this was conducted by regularly trained staff.

99. The Inquiry understands that the Edinburgh BDC introduced an AIDS leaflet in June 1983 (you may find MACK0001248_001 of assistance). As far as you are aware, please answer the following:

a. Did the Glasgow BDC receive and distribute the AIDS leaflet produced by the Edinburgh BDC?

197. Yes, these documents were shared and adapted for local experience.

b. If not, why not? Was a different leaflet produced and distributed?

198. The leaflets were marginally different in lay out, but basic information and content was the same.

c. What were the contents of any AIDS leaflet that was distributed by the Glasgow BDC?

199. The aim of the contents was to encourage donors to look carefully at the conditions that need to be mentioned in order to assess the risk factors, if any.

d. Was the leaflet handed to donors or left in the waiting room?

200. Some leaflets were left for the donor to read while waiting and then given by hand while going over it with the donor for the rest of the health check.

e. In your view, do you consider the AIDS leaflet to have been effective at reducing the risk of infection transmission?

201. Yes certainly, and the health check interview based on these guideline documents is essential so that donation does not harm the donor or the recipient when blood is transfused. It is important that the health check and donor interview is conducted in a surrounding that maintains privacy before testing and facilitates the donor to understand and remember the factors that make blood donation safe for the donors themselves and the recipients.

100. In a 1987 letter you wrote to Dr Mitchell about donor screening, you stated that "we have no option but to accept the word of the donors as "truthful" this is the paradoxical strength of the voluntary altruistic donor system and its major weakness." You also stated that "it is impractical and unworkable to consider the

donor's answer to our checklist as suspect because they are "compulsive liars" or "embarrassed" by their colleagues across the board" (SBTS0000680_171). Please expand on this statement. Have your views changed over time? In particular, please further describe:

a. your view of the strengths and weaknesses of the voluntary donor system;

202. Blood transfusion has never been completely safe and experience proved that like many other therapeutic interventions, it continues to have risks. The voluntary altruistic system is not only ethical but also the safest system that is available to maintain the availability of blood as well as safety for patients and donors.

203. Partnership with the transfusion services encourages donors to feel they are owners of the blood services and partners in safety and quality of their gift to the community. That is what I was trying to express by mentioning the "paradoxical strength of the voluntary altruistic donor system and its major weakness". It is in a way self-exclusion of the owners of the service as partners in the quality of the altruistic gift of blood. And I remain convinced by the contents of that letter I wrote in 1987 up to the present day in 2021.

b. What you consider to be the most important factors when screening donors;

204. The most important factors are highlighted in answer to (a) above. They are mainly represented by respecting the integrity and honesty of the well-informed donor and the confidence in the importance and the purpose of these personal questions that are aimed at the patient's safety.

c. Whether your views were shaped by wider pressures or obligations on the part of the Glasgow BDC and/or SNBTS?

205. My views were based on the voluntary and altruistic nature of the gift of blood to the community and neither by obligation to SNBTS, NBTS, Glasgow or Birmingham centres, but only by responsibility to provide safe therapeutic blood components and medicinal products by a respected and dedicated partner in the efforts of the service to maintain the values of safety and availability of much-needed blood and blood products.

Introduction of virally inactivated products

101. What role did you consider Glasgow BDC had (or should have had) in pushing for factor concentrates to be virally inactivated in the early 1980s? In particular, was the need for safe products raised by you or anyone else at Glasgow BDC with BPL and/or pharmaceutical companies (or anyone else) during this period? If not, why not?

206. The need for virally inactivated products was considered important in SNBTS not only in Glasgow. The shortage of factor concentrates and demand by the haemophilia directors was increasing particularly after introducing home therapy and prophylactic use. I do not know who was dealing with commercial products. I suspect it could have been the haemophilia directors and the NHS.

Provision of diagnostic screening kits

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

207. I was not involved in the purchase and provision of diagnostic tests. This matter was mainly the responsibility of the Director and the senior scientific staff, most likely with other colleagues in the SNBTS.

208. Once the diagnostic kits were evaluated nationally they were included in the centres for local assessment and evaluation in the testing laboratory and in staff training. The system is then introduced into routine testing protocols.

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

209. I was not personally involved in the selection of screening tests. (See answer to Q 101).

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

210. This was conducted based on a system and standard procedures for selection of kits and providers that included many factors including reliability in previous transactions and contracts.

211. All system kits were tried in the virology department to ensure specificity and sensitivity in our laboratories.

212. There were many other factors that I fail to recall and that were important before deciding on the purchase.

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

213. We had to discuss the performance and use of the kits during the trial period and certainly if we were faced with problems, however I would certainly not consider this after-sale services as exerting influence.

Introduction of HIV testing

106. When did the Glasgow BDC begin HIV screening?

214. HIV screening kits were introduced as soon as they were available on the UK market, taking into consideration the experience of other centres as well as agreement by the SNBTS directors as to the preferred range of testing kits available on the UK market. I would not be able to remember the starting date.

107. Please describe the implementation of HIV screening at the Glasgow BDC. In particular;

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

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

215. Donors were not personally screened for HIV at the blood collection sessions - they were selected using a questionnaire. Blood was collected in the usual way by the trained staff. Blood donations were sent to the centre. The blood bags were stored in the fridges for untested blood. Individual corresponding labelled specimens were sent to the virology laboratory for screening.

216. The process of testing was established on the basis of the results of the trial of the kits using positive and negative control specimens according to an established standard operating procedure. The staff were trained to perform it before starting its regular use for regular screening of the donation.

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

217. As I remember, all unscreened blood in store collected before introducing HIV screening was kept separately in quarantine and released only when corresponding

specimens were tested and confirmed to have been negative then the units were labelled and stored in a separate area as ready for use.

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

218. All HIV confirmed positive units were removed into locked storage facilities and labelled as not for use, in order to ensure it could not be used by error.

219. The steps to contact the donor and regulations for communicating this information were described in a standard operating procedure prepared and signed by the senior scientific officer, the consultant responsible and the medical director and released to the appropriate laboratory, for staff training before starting routine use.

220. Passing information to third parties was strictly forbidden without donor consent and only on special formal legal request.

221. The numbers of any positive units issued were communicated to the hospitals that had received them, according to the records. A specimen was requested from these recipients for testing, counselling and taking the necessary steps if clinical follow-up was required.

Surrogate testing

108. At an SNBTS Directors meeting on 3 March 1987, the Directors agreed to "recommend to the SHHD that surrogate testing for NANB should be implemented with effect from 1 April 1988 as a national development requiring strictly new funding. Each Director should let Dr Cash know what funds would be required in

his/her region, assuming that both core testing and ALT would be undertaken in the Transfusion Centres" (PRSE0004163). Please expand on the following:

a. Whether surrogate testing (namely ALT or anti-HBc testing) was introduced at the Glasgow BDC during your tenure;

222. I seem to remember that only ALT was introduced for use. It was also used in a study to assess its specificity.

b. If so, whether this had any impact on the Glasgow BDC;

223. The ALT proved later on that it is not specific and was just a surrogate test. I cannot remember what happened to donors and donations with High ALT.

c. How the surrogate testing was performed;

224. It was added to the range of donation testing performed along the lines used for liver function testing.

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

225. Two screening samples were taken from the blood donation. One was sent to the virology lab to be tested for markers of transfusion transmissible infections.

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

226. The testing for blood groups and antibodies was performed as usual; the specimen for infections would have been done for the available tests including syphilis, HBV and sometimes malaria. I cannot remember what was done to the donors and donations with elevated ALT results.

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

227. All HIV confirmed positive units were removed into locked storage facilities and labelled as not for use to ensure that use by error was avoided.

228. The steps to contact the donor and regulation for passing the information were described in a standard operating procedure prepared and signed by the senior scientific officer, the consultant responsible and the medical director, and released to the appropriate laboratory, for staff training on communication and counselling before starting routine implementation according to standard operating procedures

229. Passing information to a third party is strictly forbidden without donor consent and only allowed in response to a special legal request.

230. The number of the positive unit used is communicated to the hospital that received previous units provided earlier by the donor according to the records. A specimen is requested from these recipients for testing, counselling and taking the necessary steps if clinical follow-up is required.

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

231. I believed then that this was reasonable and that the UK was being forced to do it because the US was and time has proved this. We and many other centres worldwide were just being dragged to follow the USA.

110. 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 NANB 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 NANB;

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, what were your objections?

232. I fully agreed with these conclusions. Time has proved the validity of this view and that surrogate tests were not effective and it became a few years later a problem to take it off from the list of required tests.

111. The Working Group's report from 1987 commented: "If a stance is taken that blood should have maximum safety then the tests would be introduced" (NHBT0008816_002). Please explain your views on this statement. In your view, did

the decision not to introduce routine surrogate testing indicate a decision not to provide "maximum safety"?

233. The decision to introduce testing was considered very carefully by the countries attending this meeting.

234. The consensus was that there wasn't enough information to justify recommending the routine use of these tests. It was left to individual countries to perform the necessary local studies to assess the situation, the cost effectiveness, and the availability of the required resources to deal appropriately with the resulting consequences. Maximum safety is not exactly, in my view, the only decision-making factor but there are also political and economical pressures to introduce anything that may seem to make products safer.

Introduction of anti-HCV screening

112. When did the Birmingham RTC begin anti-HCV screening?

235. I started in Birmingham in 1992 and testing for HCV was already in place.

113. 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.

236. I was still with the WHO at that time and out of the UK. I thought we should have started testing in July as planned and conducted the validation at the same time. I am not sure whether that was possible or not.

114. 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?

237. I was still with the WHO at that time and was out of the UK. I thought we should have started testing in July as planned and conducted the validation at the same time. I am not sure whether that was possible or not.

115. 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.

238. As mentioned earlier, I was not in Birmingham at this point. I would have thought it made sense to start in that time and since the capability was available.

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

239. My views have not changed and as an observer I still support in retrospect Dr Lloyd's decision since he had the facilities. It would be indefensible not to do it since he had the freedom to do it and was responsible for this individual decision.

116. What impact did HCV testing have on Birmingham RTC? 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.

240. Donors give a unit of blood. A specimen is taken from the bag and this is sent to the lab with a label with an identification number. All tests are carried out on this sample. The readings from the testing machine are printed showing the identification numbers and the results.

241. I joined Birmingham in 1992 and I do not know what policy was in place to handle the unscreened blood collected prior to introducing HCV testing.

242. I assume the units that were still in date were tested for HCV before issue.

243. All units confirmed positive were removed into locked storage facilities and labelled as "not for use" to avoid any use by error.

244. The steps to contact the donor and regulation for passing the information were described in a standard operating procedure prepared and signed by the senior scientific officer, the consultant responsible and the medical director. And released to the appropriate laboratory, for staff training before starting routine use. Passing information to a third party is strictly forbidden without donor consent and only by special legal request.

245. The number of positive units used is communicated to the hospital that received previous units provided earlier by the same donor according to the records. A specimen is requested from these recipients for testing, counselling and taking the necessary steps if clinical follow-up is required.

General

117. Please describe all other steps or actions taken at the centres 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.

246. Guidelines for the appropriate use of blood were circulated among clinicians. They were encouraged to use blood and products only when absolutely necessary and according to the established guidelines

118. 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?

247. Cost should not be a factor that compromises blood safety. It is sadly a major problem in countries with limited resources. And that is why in individual situations it is often essential for risk benefit assessment to be considered.

119. How did the desire for consensus across the BDCs and/or RTCs impact efforts to achieve blood safety at a local level?

248. Consensus in evaluation of decisions and risk factors for safety is essential to make the best possible and sensible use of available resources. It is relatively easy to take individual decisions when the resources are available. It is important that individual countries do perform serious local studies to assess the situation, the cost effectiveness, and the availability of the required resources to deal appropriately with the resulting consequences.

120. In relation to your experiences at both the centres, to what extent were you and other BDCs or RTDs reliant on the decisions of other bodies (advisory committees, directorates, NBTS, Department of Health) 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?

249. Blood safety is a crucial issue where compromises should be considered and taken very seriously. I am also convinced that there are no zero-risk approaches in therapeutic decisions in general. That is where taking a second opinion and seeking views and advice from specialised bodies and committees is always recommended. Consensus is the only way as a basis for serious decision-making when there are genuine and reasonable differences or conflict of opinions.

Section 13: Look back programmes

HIV

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

250. No, I was not involved in any national or local HIV look back programmes.

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

251. I was not involved.

HCV

123. Were you involved in setting up any HCV look back programmes during your time at the Birmingham RTC? If so, please describe this process and your role in it.

252. No. The HCV look back programme was set up nationally and the final programme was circulated to all the centres. I was involved in the implementation of this programme at the local level in Birmingham.

124. Were you involved in implementing any HCV look back programmes during your time at the Birmingham RTC? If so:

a. Please describe what this involved.

b. How was any additional work funded?

You may find NHBT0012514 of assistance.

253. The records of HCV positive donors and all previous donations were identified as well as the fate of all the components.

254. The identification numbers were communicated to the hospitals that received them for use. The hospitals were requested to trace the recipients of any of these components.

255. The patients were contacted to obtain a sample to test for anti-HCV. I cannot remember exactly who contacted the patient; whether it was done by the hospital and the treating physician or by a consultant from BTC. I seem to remember that it was tested at the centre and confirmed at the central laboratories. I may be wrong.

256. I was not involved in the area of funding and this was not one of my responsibilities.

125. In May 1994, Dr Ala wrote a letter to Professor Cash in which he criticised Scotland's decision to implement a lookback policy for recipients of blood products from donors later found to be anti-HCV positive, stating that "it will now be very difficult to for England and Wales to resist the irrational pressure to adopt a similar premature, expensive and largely fruitless policy, and I greatly regret this fait-accompli we are now faced with" (NHBT0097145_001). Did you agree with Dr Ala's views? If so, why? Have your views change over time?

257. I agreed with Dr Ala's approach, not to rush it and make the necessary preparations for data collection and to allow the service to make the necessary arrangement to start on a clear basis (as happened in introducing the ALT surrogate testing following the USA). He had no access to the paper by Dusheiko that was the basis of the suggestion by Professor Cash. Dr Ala said it was impossible for him to rely on this one paper for rushing and that more information was required on how and when to start the lookback based on comprehensive and adequate organisation and resources.

258. Dr Ala wanted those who are concerned and anxious, to be reassured that all will be carried out and the decision to start will be handled with care, while continuing to investigate the findings so that the look back programme was not affected by incomplete information leading to decisions that were not thoroughly studied.

259. When a donor is found to be positive, it is important to follow all the recipients of the components that were issued from the implicated donation. All the recipients should be traced, and all who are found to be infected should be counselled, tested, investigated, and referred for specialist care.

260. This will allow the service to study and define the magnitude of the problem to establish a well-planned programme with adequate funding resources and facilitate solid studies and data without the destructive media pressures that can push the authorities to take half-cooked decisions.

General

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

261. No, I was not.

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

262. Yes of course, we should always inform patients who have received transfusions from infected donations. This has to be done in a well-planned approach, taking care not to increase their anxiety and to be ready to deal with them properly.

263. On the other hand, what is unethical is to raise the anxiety of the community unnecessarily and use this to pressurise the service into taking incomplete decisions without consideration for the consequences of a job not done properly on the community at large.

128. To what extent could a BDC or RTC in Scotland or England, during the period of your involvement with the respective Services, implement its own local look back programme? Did the centres do this? If so please give details. If not, why not?

264. It is necessary to accept the fact that look-back programmes should be planned and supported nationally. They are not just local programmes and cannot be described as "its own local look-back programme".

265. I am not in a position to comment on the look back programme in Scotland. I cannot remember whether I was involved with this area in Glasgow.

266. The implementation of the HCV look-back programme in Birmingham was a national programme and it was running smoothly as far as I remember. The main difficulty was the time it took to communicate with hospitals and the time it took hospitals to retrieve records for tracing of the recipients. This can on many occasions be unavoidable.

Section 14: Relationship between the blood services

Relationship between the SNBTS and NBTS

129. Given your roles in both the Scottish and English blood services, please describe as far as you are able:

a. Whether there were any arrangements in place to enable cooperation between the NBTS and SNBTS, including any forums or reporting lines established to aid this cooperation;

267. Yes, there were arrangements to enable cooperation and there was room for more opportunities for closer cooperation and rather less than just competition.

b. Whether in your view, the NBTS and SNBTS' approach to policy development and implementation varied

268. Yes, it seems or it may be that the approaches to arrangements for cooperation varied, but I am not too sure, in retrospect, how and why this came about.

c. Whether policy was developed and implemented on a UK-wide basis unless otherwise agreed, or whether the approach was discussed on a case by case basis;

269. As far as I remember, discussion and development of policies were shared on a case by case basis, but implementation was varied.

d. Whether the two organisations shared information with each other 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.

270. I seem to remember that the two organisations shared information, as and when required, and case by case, but I was not aware of any formally coordinated basis.

130. In his witness statement for the A v Others litigation, Dr Gunson discussed the creation of the National Directorate to oversee the work of RTCs in England and Wales, although he noted that the Directorate "did not have executive authority and its successes came about by persuasion" (NHBT0000025_001; NHBT0000026_009). As far as you can recall, what are your views on the success or otherwise of the National Directorate?

271. There were remarkable achievements under the National Directorate through NHS support and persuasion. A number of these were indeed mentioned in his report; these achievements were mainly realised by the support provided directly by the NHS.

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

272. The devolution of health budgets was disastrous and the result was expected by most of those who had genuine concern and involvement in the need in the country for a solid National Blood Service which was centrally directed and supported, but regionally organised and managed. The NBA was a step in the right direction.

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

273. Cost recovery was reasonable and one of the necessary steps taken by the NBA.

274. Leaving decision making in the hands of managers who sometimes were unable to take in consideration of the scientific and clinical aspects of the problems facing the Service was a weakness.

275. Dependence and difficulty in securing funding was to my mind one of the weaknesses of this period in the development of the transfusion services.

Outcomes in Scotland and England & Wales

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

276. I know and remember that these documents existed and at some stage I read them, but cannot remember the details (I am 84 years old and retired in 2003).

Section 15: Variant Creutzfeldt-Jakob disease (vCJD)

134. 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? What was your role, if any, in the vCJD lookbacks? You may find (NHBT0000030_048.pdf) of assistance.

277. I became aware of the risks of transmission of vCJD when the first case was published.

278. This concern was confirmed when more cases were reported.

279. I was not directly involved in the planning, but needed to follow up the findings and reports. My main responsibility was to trace and notify in writing the fate of any

previous blood or any plasma donations sent to BPL. It was also important to recall all in-date components issued from any identified donor following the ethical advice not to inform the hospital or the treating physician as if this was part of a double blind study but probably a plan was in place to change this at some stage when the information became clearer.

Section 16: World Health Organisation

135. Please explain your role as Consultant Advisor to the World Health Organisation and the Safer Blood Initiative, including how you came to be involved in the organisation, any projects or initiatives that you contributed towards, and your interactions with the UK Blood Services or other authorities during this period.

280. I applied in response to an announcement circulated to NHSBC for a joint post between the league of the International Red Cross Society and the WHO and HIV Global Blood Safety Initiative. It was funded by the Global Blood Safety Initiative (GBSI) for liaison and support of blood transfusion services in countries with limited resources including many where the national BT Services were established by the country's Red Cross and Red Crescent societies and supported technologically and financially by the Red Cross office in Geneva.

281. My main role as Consultant Advisor to the World Health Organisation and the Global Blood Safety Initiative, included liaison of WHO with national Red Cross societies to improve the safety and quality of these services.

282. The attached section below, of one of the documents (NHBT0000030_048) provided to assist this investigation answers many of the details raised in this question

GLOBAL BLOOD SAFETY INITIATIVE

CONSENSUS STATEMENT ON SCREENING OF BLOOD DONATIONS
FOR INFECTIOUS AGENTS TRANSMISSIBLE THROUGH BLOOD TRANSFUSION

The Global Blood Safety Initiative (GBSI) is a cooperative endeavour to support the development of safe and effective blood transfusion services in all countries. Core participants are the World Health Organization's Global Programme on AIDS (GPA) and the Health Laboratory Technology and Blood Safety unit (LBS), the League of Red Cross and Red Crescent Societies (LRCS), the United Nations Development Programme (UNDP) and the International Society of Blood Transfusion (ISBT). The Initiative is also supported by the World Federation of Hemophilia and other bilateral and multilateral development agencies and nongovernmental organizations.

This document was reviewed and endorsed by the GBSI Consultation on Screening of Blood Donations for Infectious Agents Transmissible through Blood Transfusion, held in Geneva from 30 January to 1 February 1990. Sixteen specialists in transfusion medicine and haematology from 12 countries participated. The participants are listed at the end of this document.

283. The other important activity was to organise meetings for international experts to produce "Consensus statements" to support the development of safe and effective blood transfusion services. GBSI produced a number of Guidelines to implement essential activities and training workshops.

284. GBSI was also involved in establishing and updating existing facilities and providing testing equipment for transfusion transmitted infections particularly to reduce the risk of HIV infection which was quite elevated in countries with Malaria attacks requiring red cell transfusion.

136. Did your views on the issues raised by the Safer Blood Initiative correlate with those of the organisation? Were they consistent with practises you observed during your employment in the Scottish and English Blood Services? You may find NHBT0000030_048 and LCAN0000018_045 of assistance.

285. Yes – totally. I am in agreement with policies and implementation with standards of good transfusion practice in Scotland.

286. I left the Scottish service in 1989, and I was very satisfied and proud that the Scottish service was exemplary. In retrospect, after coming back to the UK to Birmingham, I could feel satisfied by the quality of donor care, safety and the improved standards of hospital transfusion practice, at least regarding the West Midlands hospitals served by the Birmingham Centre.

Section 17: Your relationship with commercial organisations

137. 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?

287. No, and that has never been my interest. After retirement, I participated in consultancy services with the WHO for national blood services in developing Anglophone and Francophone countries, with the EU in Eastern Europe and other bilateral projects in other parts of the world.

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?

g. If so, please provide details of your involvement and list the names of the companies, where appropriate.

288. No, never involved in such activities, in fact during my work in Geneva we presented as members of GBSI, an open letter at the WHO General Assembly, to curb the attempts of industry to accept the use of paid donors and avoid unethical commercialisation and manufacture of PDMPs to reduce the risk of TTIs and ensure the safety of large-pool products.

138. 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 step did you take?

289. I am sorry, I know nothing about these regulations because I was not and never wanted to be involved.

139. 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.

290. No, never.

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

291. I have never provided any kind of information and in general my work was not in any way involved with pharmaceutical companies.

141. 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?

292. I never sought support of companies for any financial support.

Section 18: Other matters

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

293. The only articles relevant to this investigation are the ones among the documents provided to prepare this statement.

143. 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).

294. I found the questions raised to support this Inquiry, very comprehensive and I have no additional details other than to mention that I committed my working life and retirement as a "missionary" with conviction, to improving the quality of transfusion practice and blood safety.

295. I would like to acknowledge the pain and suffering which those who have been affected have described to the Inquiry and look forward to the Inquiry's findings as lessons to ensure the safety of future patients and our communities at large.

296. Although my statement above has been made to explore the root causes of these sad and painful events that happened in the UK, I must mention here that our service is outstanding considering. There are painful challenges that can defeat us in spite of

the goodwill, scientific dedication and outstanding standards of the scientific and community-based health discipline of our NHS UK blood services.

297. The relationship with our generous community is exemplary. Our generous dedicated donors are, in fact, made to feel they are the owners of the service. The skills, experience and standards of research of our scientists are internationally renowned; indeed, with their clinical colleagues they are pioneering advances in hospital transfusion units and aspects of safety in hospital clinical blood transfusion.

298. All in all, our NHS UK blood service can be considered a leader in this difficult field and an example to look up to by many other countries that I have visited all over the world.

299. The terrible suffering of all those affected by the issues being reviewed by the Inquiry should never be forgotten.

Statement of Truth

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

GRO-C

Signed _____

Dated _2021-12-16_____