Witness Name: Dr Chitra Bharucha

Statement No. WITN6967001

Exhibits: N/A

Dated: 31 January 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR CHITRA BHARUCHA

I provide this statement in response to requests under Rule 9 of the Inquiry Rules 2006 dated 27 July 2021 and 17 August 2021.

I, CHITRA BHARUCHA, will say as follows: -

Section 1: Introduction (Q 1 to 5)

1. CHITRA BHARUCHA

   DOB GRO-C 1945

   GRO-C

   MBBS FRCPath

   Honorary doctorates D Med SC and FCGI

2. 1974 – 1980, SHO, Registrar and Senior Registrar, all part time, Royal Victoria Hospital, Belfast

   1981 – 2000, Consultant Clinical Haematologist (Belfast City Hospital ("BCH")) and Deputy Director Northern Ireland Blood Transfusion Service (NIBTS)

   1999 - June 2015, General Medical Council (GMC)/Medical Practitioners Tribunal Service (MPTS)

2001 – 2003, Independent Television Commission (ITC: non-executive director-Board)

2002 – 2004, GM Science Review Panel (UK)

2002 – 2008, Chairman Advisory Committee on Animal Feeding Stuffs (ACAF)

2004 – 2007, Advertising Standards Authority (ASA: non-executive director-Board)

2006 – 2010, British Broadcasting Corporation (BBC), Vice Chairman (Acting Chairman 2007)

2006 – 2017, Marie Curie Cancer Care (MCCC) - Trustee Board

2011 - present, Council member of City and Guilds Institute of London

2018, Chairman FIT Biotech Oy 2016 Director

3. Royal College of Pathologists 1979 onwards

International Society of Blood Transfusion

International Society of Haematology

I cannot recall the dates

General Medical Council 1974 onwards

WHO

LEPRA

The Leprosy Mission

WNO (Welsh National Opera) Board member

CTS (Cardiff Theatrical Services) Board

FOV (UK Christian Charity for supporting the work in India of Christian Medical College, Vellore.) Patron and Council member

No recollection or record of dates.

4. By attending Local, National and International meetings and Conferences, Seminars.

Reading publications in peer reviewed professional Journals.

In 1993, I gained a Certificate in Commercial Law from Queen's University Belfast after completing a 3 year extramural Course, in preparation for NIBTS becoming "an Agency".

5. No other involvement.

Section 2: Your roles at Belfast Transfusion Centre and the Northern Ireland Blood Transfusion Service (Q 6 - 13)

6. Belfast Transfusion Centre and the Northern Ireland Blood Transfusion Service were one and the same. From 1981 – 2000, I was both Consultant Clinical Haematologist and Deputy Director, Northern Ireland Blood Transfusion Service (NIBTS). My position as Deputy Director (NIBTS) was essentially in name only and limited to deputising for the Director, Dr McClelland, in the event of his absence for any reason. I had no managerial or administrative duties delegated to me. I was accountable to and would report to Dr McClelland, as would all NIBTS staff. Dr McClelland was very much in full control. Due to my relatively limited involvement, I am unable to answer many of the questions set out below and many of the documents disclosed I have never seen previously.

7. Organisation of the BTC:

7(a) When I joined, I cannot recall any formal structure. There were several Laboratories, each with several Medical Laboratory Scientific Officers ("MLSO"). Donor Services was separate and managed by a person with non-scientific background and he reported to Dr McClelland only. I was accountable to the Director.

7(b) I have no knowledge of funding of BTC.

7(c) I know that Dr McClelland had administrative meetings with the EHSSB for some years and at some stage administration was transferred to the Belfast City Hospital. I have no knowledge of the type of administrative responsibility. At some stage (I cannot recall theyear), NIBTS was assigned Agency status and a new Board was appointed for NIBTS. I had no access to the Board or Board papers/discussions.

7(d) To my recollection, BTC was the sole supplier of blood and blood products for all the hospitals in Northern Ireland. I do not know how many hospitals.

7(e) Not to my knowledge.

8. To my knowledge there were no ad hoc units in N Ireland.

9. Please see my response at Q6.

10. See 7(d) above.

11. "Independent" of UK Blood Services. My recollection is that the Director of NIBTS attended meetings of Directors of Blood Services in England and Scotland and made decisions for NIBTS based on information that he gathered at those meetings. The Director would be able to provide more accurate information on the scope of decision making. The Director was responsible for making decisions. When a new Board was created, the Director was accountable to the Board.

12. I was not involved with NIBTS relationship with BPL and PFC. The Director had sole responsibility.

13. I do not know. This should be available from NIBTS.

Section 3: Blood collection by the NIBTS (Q 14-20)

14. Blood donor sessions were held in HQ as well as by mobile units which collected blood at different venues. I do not know how venues or schedules were determined.

I recall that the routine procedure was that clerical staff sent a letter to call donors to donation sessions. Information leaflets were included.

All sessions were staffed by medical officers (doing regular sessions with NIBTS for blood collection only), nurses and clerical staff. Clerical staff greeted donors, handed donors a questionnaire for completion while waiting, spoke to donors individually, took confidential history and details of questionnaire responses, screened for anaemia using a standardised copper sulphate solution before donors were received and escorted to a couch by nursing and medical staff, where needles were inserted by medical officers and the collection process was overseen by nurses. After collection was completed, donors were escorted to a resting couch and subsequently, received refreshments before they left the premises. This is my recollection. The whole process had to be conductedefficiently in order to avoid a build-up of too many people waiting to donateblood.

15. I recollect that there was extensive publicity, in broadcast and print media, highlighting need for blood and seeking volunteers to donate blood. Blood donation sessions were announced in my church. It is likely that there were similar announcements in all churches.

16. I do not know about sessions held in prisons, borstals etc. I had no involvement. I am therefore unable to answer a. to e. As to f. I have no knowledge of incentives for prisoners. I do recall that there were no incentives offered to any member of the public who donated blood voluntarily.

17. My recollection is that sessions were staffed by medical, nursing and lay staff teams. I cannot recall any other details.

18. My recollection is that staffing at sessions was by medical officers, nurses and clerical/administrative staff. As to the frequency of donations, I was a practising haematologist. At that time, I treated several young female patients with significant iron deficiency anaemia and I was concerned that frequent blood donation would lead to depletion of iron stores in many

donors. I advised that people should not be asked to give blood more than twice per year. I recall that there was general pressure in the UK transfusion services to accept donations more frequently.

19. I do not recall being informed or was I aware of any targets.

20. As 19 above.

Section 4: Plasma procurement and production of fresh frozen plasma at BTC (Q 21 -33)

21. All FFP produced in Northern Ireland would have been produced by NIBTS in the blood processing laboratory. I am unable to answer the questions because I had no involvement. I do recollect that SOPs were produced and should be available now in NIBTS.

22. I was not involved with discussions or decisions relating to capacity or proportion of blood collections allocated to this process.

23. I had no knowledge of funding arrangements for plasma. The Director took responsibility for all discussions and decisions regarding management and funding. From the documents made available to me, it appears that funding was negotiated by the Director NIBTS with DHSS NI.

24. I recall that all requests for blood products came to NIBTS from hospital Blood Banks. There was a documenting process for recording such requests.

25. I was not involved in any discussions or decisions regarding plasma targets.

26. See 25 above.

27. See 25 above.

28. See 25 above.

29. I had no involvement in any plasmapheresis. I recall that some medical officers expressed concern to me about their inability to provide medical

assistance for donors who had any adverse reaction during machine plasmapheresis. .

30. I had no involvement in plasma collection.

31. I do not know. I was not involved.

32. I do not recall being aware of any cross charging arrangements.

33. Plasma reduced blood and red cell concentrates: To my recollection, red cell concentrates were used by haematologists in NI in preference to whole blood. As a trainee, I recall being reprimanded for prescribing whole blood for a patient.

Section 5: Arrangements for obtaining and allocating blood products at the NIBTS (Q 34 – 47)

34. I had no involvement with supplies of blood products. The Director had total control.

35. I don't know. I do not recall attending any Forum.

36. I had no involvement with the purchase of blood products.

37. I did not contract with any pharmaceutical company. I am unaware if anyone in NIBTS contracted directly. Having seen the documents which were made available to me by the IBI, it would appear to be unlikely because of the administrative arrangements in place at that time.

38. I was not involved with products supply from BPL and I am unable to answer.

39. My recollection is this was a decision for the Haemophilia Director, taking account of agreed decisions at their national UK meetings.

40. Only the Director of NIBTS liaised with the Haemophilia Director in NI.

41. As 40 above.

42. I have no knowledge of advice from pharmaceutical companies regarding the use of blood products.

43. I had no involvement.

44. As to 44 a to c, I am assuming that the letter to Dr Mayne (NIBS0001721) is a reference to patients with "inhibitors". The last time that I had clinical contact with patients who had Haemophilia was when I worked as a trainee in Royal Victoria Hospital Belfast. My recollection is that the subject of complex decisions regarding treatment of Haemophilia patients who developed “inhibitors” was discussed during regular ward rounds.

45. I have no recollection of seeing any operational plan. Patients with Haemophilia were treated by clinicians on the advice agreed by the UK Haemophilia Directors. A degree of frustration regarding clinical freedom is apparent in the comment by NIBTS Director. Their decisions were informed by extensive discussions among experienced treating specialists and I do not recall any discussion with me regarding the ability or responsibility of NIBTS to influence agreed practice.

46. The document NIBS0001721 which was provided to me is a letter sent to Dr Mayne from EHSSB stating that there were substantial numbers of people for whom the NHS product does not appear to be appropriate and requesting substantial evidence to obtain finances for the continued use of commercial products. Dr Mayne's response is not available. Dr Mayne was the Haemophilia Director and had expertise in treatment of Haemophilia. I am not qualified to comment on the clinical risks and benefits in this specialist area. The Director NIBTS was the person who dealt with requests for all blood products, including commercial products. I do not recollect any discussion with me on this matter.

47. Both documents RHSC0000066_031 and RHSC0000066_049 are Operational Plans 1989/90 with summary of costs prepared by Dr McClelland. There is no indication of the context or recipient. I do not recollect any discussion with me of planning or financial implications. I am

unable to speculate as to Dr McClelland's reason(s) for a sense of demoralisation.

Section 6: Production of cryoprecipitate (Q 48 – 52)

48. My recollection is that all cryoprecipitate would have been produced in NIBTS, in the blood processing laboratory.

49. NIBTS /blood processing laboratory staff would have produced cryo. The process was documented in SOP and should be available from NIBTS. As to b., c., d., and e, I am unable to answer because I had no involvement.

50. To my recollection, NIBTS produced cryoprecipitate. I am unable to offer answers to Q 50 and 51. SOPs should be available in NIBTS. The Director had sole responsibility.

51. The Director had sole responsibility.

52. Clinicians in hospitals placed their requests with the respective Blood Bank. Blood Banks sent requests to NIBTS. I recall there was an agreed procedure for documenting all details.

Section 7: Self-sufficiency (Q 53-57)

53. As NIBTS was the sole provider of blood and blood products to all hospitals in Northern Ireland, my recollection is that we aspired to be able to supply all blood products for patients requiring them in Northern Ireland.

54. I was not involved in any of the decisions pertaining to plasma procurement, cryo precipitate production, purchase of commercial blood products or funding.

55. My recollection of the impression I gained from meetings which I attended in England is this: UK BTS was confident that self-sufficiency could be achieved. All staff in centres were working energetically to ensure that quality and safety standards were agreed and implemented nationally, despite the emerging challenges of "new" infections which had to be identified and characterised. Suitable and reliable testing were priorities in

order to provide "safe" blood products without destroying blood components because of "false" positive results or processing blood components which were "false negative" on tests and could infect recipients. In addition, during the time that studies and discussions were inprogress, donor screening had to be more rigorous because ofuncertainties about the accuracy of new tests. Funding requirements for all these activities was increasing exponentially and I recall widely held concern that self-sufficiency could not be achieved as quickly as everyonewould have liked to achieve.

56. To the best of my recollection, self-sufficiency was a shared aspiration to ensure that the clinical requirement for all blood and products in NI could be met by using blood donated voluntarily by people in Northern Ireland. Blood donors did not receive financial or other compensation.

57. MACK0002271_012 makes reference to Scotland and N. Ireland "are virtually self- sufficient in Factor VIII". Expansion of production capacity was being ruled out. I do not recall being aware that N Ireland was self-sufficient in Factor VIII.

Section 8: Services for donors at the NIBTS (Q 58 – 62)

58. I do not recall counselling being offered to donors prior to testing. I do recall that there was a leaflet which was sent when potential donors were invited to sessions. The leaflet gave information which could be studied at home before giving blood. If there were questions, the medical staff at sessions were trained to discuss individual queries in detail.

59. PRSE0002617 clarifies the initial NIBTS position. My recollection stated in my answer above relates to DHSC0101652_002. The Director explained that leaflets would be "posted after the advent of computerised system". I recall that there was a view that N Ireland was "low risk". I was not convinced. Potential donors could not be expected to exclude themselves after they had arrived to give blood. Nor were they likely to give such information during the initial interview with session staff.

60. NIBS0000061 I was the senior doctor who contacted donors who tested positive. I had a long initial meeting with the donor, collected a blood sample for repeat confirmation test, advised them to involve GP and GUMclinic. I made telephone contact with their GP. There was profound reluctance to involve GUM clinic and there were strong requests to anonymise any information which was sent to any health professional. Northern Ireland is a small community and there was profound anxiety about "confidentiality". I accessed support through a patient's GP as well as senior clinicians in GUM, complying at all times with the request for anonymity in letters and documents. I am confident that donors received good support. Aa to c., I followed similar procedures for donors who testedHCV positive. There was no request for anonymity. I recall making referralsto their GP and to a senior hepatologist in Royal Victoria Hospital Belfast. Ido not recall a formal process after my referral.

61. I don't recall if I was informed of recipients of infected donations.

62. I am confident that the arrangements for donors were good and documents would be available in NIBTS.

Section 9: Information handling and information sharing (Q 63-71)

63. I had no involvement with administration. When I joined the NIBTS all donor records were manual. There was a large office with numerous clerical staff. At some stage computerisation was introduced and the same staff were trained to use the system. I recall that the transition was not easy.

64. There were no ad hoc centres.

65. I had no involvement with Blood donor records/Administration section of NIBTS. I recollect that there was a manual system of cards when I started in NIBTS. Computerisation was introduced at some stage. I do not recall the date. Details should be available in NIBTS.

66. I have no recollection of a Northern Ireland CDSC. I have no recollection of a database for HIV positive donors in NIBTS.

67. I don't recall a HIV database for donors in NIBTS. To the best of my recollection, there were two blood donors who were confirmed positive for HIV. Both were female, followed up regularly and did not donate blood again.

68. NHBT0005388 describes what appears to be a clerical computerised system used in BTS for England for flagging donors who were identified in relation to notified instances of post transfusion hepatitis. I do not recall learning about such a system, although it is likely that it was mentioned in relation to the Donor Selection Committee. I was not involved in NIBTS donor administrative department and I am unable to assist further.

69. There were no ad hoc centres in N Ireland.

70. I was not involved.

71. NHBT0094549_007 appears to explain that the Director NIBTS informed the Director in England. I do not recall "publicity". I can recall that a Hospital Transfusion Committee had been established in Belfast City Hospital. It included staff from Blood Bank, haematologists and clinicians from "blood user" specialities. A range of topics were discussed at regular meetings. Other hospitals might have had similar arrangements. I can only postulate that post transfusion hepatitis would have been discussed.

Section 10: Knowledge of risk of infections (Q 72 – 87)

72. I recall that there was significant publicity about AIDS in the media (print and broadcast). There was a lot of information in professional publications, several symposia and courses organised nationally in the UK and internationally. I recall attending one of the earliest such meetings in Royal Victoria Hospital which addressed the topic of "high risk groups" and the potential for transmission by blood. My further development of understanding this "new disease" was when I attended committee meetings in England and also discussions with haematology colleagues and with a colleague in GUM in N Ireland. I cannot recall dates. I attended several symposia and conferences, which were arranged at that time because this

was a "new" disease and knowledge was evolving. I recall that there was discussion about practical implementation of policies for excluding donors in high-risk categories and the commercial tests for blood donations. The concerns were related to causing offence, our inability to persuade donors to exclude themselves, losing "safe donations" due to false positive tests and missing infective donations due to false negative tests. I cannot recall others.

73. See 72.

74. See 72.

75. I recall that the concerns were similar in all blood transfusion services and that there was interest in sharing experience. NIBS0000049 reminds me that I presented an analysis of NIBTS experience with testing blood donors for HIV, using commercial test kits which were targeted for screening blood donors in blood transfusion services. I do not recall when such screening became mandatory in N Ireland.

76. NIBS0000020: I don't recall the context of my letter. I do recall that I accepted invitations to speak at several meetings all over N Ireland and also BBC radio phone-in programmes. I recall that I was unwilling to rely on self-exclusion and I made efforts to speak widely in order to explain the evolving scientific knowledge. I trained NIBTS medical officers and nurses to obtain a detailed history, using an agreed questionnaire at donation sessions. I recall that all staff (clerical, medical and nursing) were vigilant and rigorous in obtaining information, with occasional amusing consequences. Everyone recognised that NIBTS had a responsibility to make the safety of the blood supply a priority. It was considered impractical to post leaflets when inviting people to blood donation sessions, although one could be sure that donors could not be expected to leave a session after reading the AIDS leaflet. This was particularly true when sessions were held in places of work. I provided several AIDS leaflets at all venues which I visited so that they were distributed widely.

77. I was not involved with NIBTS obtaining blood products from PFC or purchase from commercial sources.

78. I am unable to offer comment because I have no knowledge of the respective use of European and American Factor VIII products or if NIBTS had reliable information about either source. I recall that it was widely accepted that donors who did not receive any form of inducement (voluntary) posed lower risk. All blood donors in UK are volunteers who do not receive compensation. Other risk factors, such as "peer pressure", "inducement in kind" (time off work, "award of badges", special factors, which are unknown to transfusion services) are likely to play a role in prisons, borstals.

79. I had my introduction to Hepatitis B and non A non B Hepatitis when I commenced my postgraduate training in India. The association with transfusion of blood was being identified and published in scientific literature at that time and I became more aware of it when I continued my training in N Ireland. It was of interest to me because scientific knowledge about the viruses and prevention of infection were developing over many years. I tried to keep abreast of numerous published scientific articles which were being published and I attended meetings held in N Ireland as well as in England.

80. See 79.

81. I can't recall specific investigations carried out by NIBTS. I recall that there were discussions in BCH blood transfusion committee (which I attended as a haematologist in BCH) about risk of post transfusion hepatitis, but no detail. It is likely that the information is available.

82. Clinical and scientific information was developing incrementally and enormous efforts were made to share information with all staff, in the UK, who were involved with blood and blood products and in providing services for donors and recipients. I recall that all decisions were made in consultation and after discussion in committees, almost always informed by

"experts" who were active in this area. In hindsight, I recall the steep learning curve for all of us.

83. I do not recollect seeing the paper or any discussion with me in NIBTS.

84. I cannot recollect details. I gained information from discussions in SACTTI as well as discussions with colleagues in UK Transfusion centres.

85. I had significant experience of blood borne viruses from my professional experience. I recollect that I advocated strongly for rigorous screening of volunteers before blood was collected but there was consistent resistance from Management because of the potential adverse impact on the number of units of blood collected.

86. I cannot recollect any advisory or decision making structures at the NIBTS to consider risks.

87. There was no process for advising hospitals or haemophilia centres. I enabled formation of a Hospital Transfusion Committee in BCH, where I had clinical sessions. It was a forum which included senior staff from the Blood Bank, haematologists and a wide range of clinicians. Regular structured meetings were held on matters relating to indications and risks of transfusion as well as technical formal processes and procedures, advice on blood products etc. I attended the meetings. It is likely that records of the meetings are available.

Section 11: Reduction of risk of infections (Q 88-118)

88. I cannot recollect the donor screening processes. I recollect that all donor screening was automated, using commercial "test kits". Protocols and various versions of SOPs should be available in NIBTS.

89. As I recollect, initial "reactive " donor samples were tested, using the same automated process. If reactive again, the test was repeated. I recollect that there was a written protocol for a procedure when a donor tested positive and should be available.

As I recollect, personal interviews at the donation sessions were an integral part of initial screening of donors who were assessed as high risk. Administrative/clerical staff and medical officers performed this stage of assessment and excluded volunteers from donating. My role in the process was to ensure that Guidelines were updated regularly in line with the national UK Guidelines.

90. I recollect a few occasions when there was disagreement between medical officer and administrative staff about the assessment of risk but that volunteers were "deferred" from donating in such circumstances. I recollect that there was tension between medical staff and Donor Services section relating to the degree of caution which should be exercised in assessing risk.

91. I recollect that I was deemed to be too cautious about possible routes and risk of transmission in my approach (and criticised for my support of our medical staff) to exclude volunteers at donation sessions before blood was collected. I can speculate that the document JPAC0000001_155 demonstrates my attempt to garner support from the wider Transfusion community at that time. I should add that there was evolving knowledge about HCV at that time. I was able to have professional discussions with Dr Galea and Dr Peng Lee Yap in Scotland regarding potential risk.

92. The document (NIBS0000030) supplied to me is a letter written by Dr McClelland. I am unable to speculate about the content of the letter. To the best of my recollection, decisions in NIBTS regarding policy for rejecting volunteers from donating blood were in line with UK-wide policy agreed by a committee for donor selection in National Blood Service (England). I do not recollect that government or DHSS was involved in decisions to implement policy. My recollection is this: there were 2 donors who tested positive for HIV and it would not be possible to speculate if there was a decrease in the number of donations testing positive for HIV.

93. I recollect that I had difficulty with the implementation of an information leaflet for donors. The manual administrative system which was in place in

NIBTS could not include leaflets when donors were called to donate blood. Donors could be given the leaflets only when they attended a session. I recollect that I had strong reservations about the effectiveness of such a system because volunteers would feel unable to exclude themselves after reading an AIDS leaflet at a donation session. I recollect that this view was shared by medical, nursing and clerical staff at sessions. I think that a compromise was established and leaflets were made available at workplaces. I cannot be sure of this as this is a recollection now. I recollect that when computerisation was implemented, it was possible to send leaflets with callup letters.

94. I cannot recollect how often the leaflets were updated. The content was decided by the committee for donor selection in England and adopted by NIBTS.

95. I cannot recollect that any additional information was given to donors. I recollect that I spoke about the risks of transmission of infection by blood and risk factors which should lead to self-exclusion. I obtained opportunities to speak at several workplaces, established social groups and other social gatherings and I took part in BBC Radio phone-in programmes. Additionally. individual donors were given oral information, on request at sessions, by medical officers.

96. To the best of my recollection, medical officers were concerned that the Donor Services Manager was reluctant to implement measures that could cause adverse consequences for the number of donations collected. There were tensions between reducing risk of transmission of infection and blood collection statistics.

97. Document BPLL0007247 is an AIDS leaflet and NHBT0020668 is a letter from Dr Wagstaff to Directors of Regional Transfusion Centres in England. I cannot recollect the nature of my involvement in the preparation of this leaflet. I do recollect that I was involved in the discussions regarding the use of the leaflet for blood donors.

98. I cannot recollect if I considered that NIBTS should have played a role in pushing for viral inactivation of factor concentrates. I can speculate that it is unlikely that I did so, given that I had no involvement in the procurementor distribution of factor concentrates. I do recollect that I advocated, strongly, the importance of donor selection and exclusion of donors deemed to belong to "risk categories" in order to eliminate risk of infection in the plasma which was sent for fractionation to BPL and PFC.

99. I cannot recollect the protocol for product recall. I do recollect that there was a written procedure for product recall and should be available in NIBTS. I recollect that the Blood Bank in BCH had written procedures for issuing blood and blood products as well as for recall.

100. Please see 99. In addition, it is likely that the Blood Bank in Royal Victoria Hospital (RVH) had written protocols also. I had clinical sessions in BCH and the Director had clinical sessions in RVH.

101. I recollect that the procedures in BCH were effective and reliable. I enabled the establishment of a Hospital Transfusion Committee which was a forum for the Hospital Blood Bank staff and haematologists to engage with clinicians who used blood and blood products. I am unable to recollect details such as frequency of meetings, attendance and agenda items. It was an effective means of discussing matters relating to blood and blood products. I recollect that the forum was welcomed by clinicians generally. I recollect that clinicians did comply with recall requests. I do not recall any companies being involved after supplying products.

102. As explained above, I had no involvement with Factor VIII products and I can do no more than speculate about my view at that time. There was discussion in professional publications as well as in formal and informal meetings at that time regarding the relative safety of heat treated and non-heat treated products.

103. I cannot recollect any details regarding agreement on the date or starting donor screening because I was not involved in discussions. I do recollect

that there was a national UK-wide coordinated approach agreed by the Transfusion Directors for blood donor screening.

104. The document provided to me (WITN3082020) refers to the diagnostic service for patients started in May 1985 by the Regional Virus Laboratory. I can speculate that this diagnostic service was done intermittently on small numbers of samples arriving in the laboratory. Blood donor screening in NIBTS, as in all Transfusion Centres, involved automated testing of large numbers of samples every day, using commercial test kits, the need to establish reliability of the results obtained as well as procedures for confirmation and follow up of any reactive blood donors. Transfusion Centres had to be confident that false negative and false positive results were infrequent and make decisions as to which screening kits were compatible with the equipment that could be used in the Centres. I recall only vaguely that a "look back programme" was implemented. All records should be available in NIBTS.

105. I cannot recollect details of the procedures. All protocols were written and should be available in NIBTS, including for the management of unscreened blood. As to 105d, When a donation was found to be reactive, procedures for confirmation were implemented. I recollect that I wrote to the donor, inviting them for a consultation, during which I established if there had been any previous donation. To the best of my recollection, there were 2 confirmed HIV positive donors. Neither of them had donated blood for many years, if at all. At the donors' request, in order to maintain confidentiality in a small community, I telephoned their GPs to give them the information. I do recollect that the GPs kept me informed regularly of subsequent clinical progress.

106. I have tried very hard to recollect my knowledge of surrogate testing at that time and I am unable to recollect surrogate tests.

107. The document RHSC0000066_031 refers to a pilot ALT testing in NIBTS.I cannot recall any ALT testing in NIBTS. It is likely that written protocol for the pilot is available from NIBTS.

108. Document PRSE0001444. I do not recollect seeing this article.

109. Document NHBT0008816_002 I do not recollect seeing the Working Group Report.

110. I do not recollect anti HCV screening in NIBTS. Point 3 of RHSC0000066_031 refers to a pilot ALT testing. SOPs for anti HCV screening and processes for donors who were confirmed as positive should be available in NIBTS.

111. I do not recall.

112. My recollection is this: the Chief MLSO in the microbiology section of NIBTS sourced diagnostic kits which were available for blood donor screening. The laboratory obtained sample kits to assess the feasibility and safety for use in screening blood donors. The Chief reported results to the Director and myself and the final choice was made by the Director, on the recommendation of the CMLSO.

113. I did not contract with any pharmaceutical company or any manufacturer. I would think that it is highly unlikely that anyone in NIBTS contracted directly with any company involved in the manufacture or importation of screening kits. This is my speculation.

114. The important factors which influenced the choice of screening kits were these: whether the kits were suitable for use in existing equipment, number of false negatives/positives/number requiring retesting, support available from the supplier when there were problems with certain batches.

115. I recollect that technical staff in NIBTS required advice from time to time about the use of certain batches of kits or other technical matters.

116. The main actions taken to ensure blood safety were related to information gathering from professional colleagues and dissemination to donors, staff in NIBTS, clinicians and hospital blood banks and the public. Personally, I engaged with Blood Bank staff in BCH, haematologists and clinical

colleagues, establishing a Hospital Transfusion Committee for regular updates and discussion of risks.

117. I am unable to answer the question relating to cost, time, staff etc because I was not involved. I was not in a position in NIBTS where I could take action.

118. To the best of my recollection, NIBTS was reliant on decisions made by NBS (England) and Scotland. The Director would be able to correct me if I am wrong.

Section 12: Look back programmes at the NIBTS (Q 119 – 124)

119. I do not recall a HIV look back programme in NIBTS.To the best of my recollection, we had 2 donors who were confirmed positive and neither had donated blood for several years, if at all.

120. See 119.

121. I recollect setting up HCV look back but I cannot recollect details. I do recollect that I left detailed records of the HCV Look back and they should be available. The Director was responsible for funding and my recollection is that it was done with no additional financial implication for my time or that of my Secretary.

122. None.

123. I was not involved in look back relating to any other infections.

124. I recollect that I was firmly of the view that there was an obligation to inform patients who may have received transfusions from infected donations.

Section 13: Your relationship with commercial organisations (Q 125 – 129)

125. No

126. I received a grant from Baxter (supplied blood bags) for a pilot study before setting up the Belfast Cord Blood Bank. I ensured that the Director was

informed of the funding. I had no involvement with the selection or purchase of blood bags.

127. No.

128. No.

129. See above.

Section 14: Relationship between the NIBTS and SNBTS (Q 130 – 133)

130. I had no involvement with the policy or process of cooperation between NIBTS and SNBTS. The Director took sole responsibility and I was not involved in any discussions. I am unable to provide answers. .

131. See 130.

132. See 130.

133. See 130.

Section 15: Quality control at the NIBTS (Q 134 -142)

134. I had no role in the joint programme with SNBTS.

135. I do not recall

136. I do not recall

137.

137(a) I do not recall

137(b) I do not recall

138. This is the first time that I have seen this document. I cannot recollect that there was a lack of technical staff to oversee the process. I had no involvement with funding discussions and I am unable to assist.

139. SBTS0000070_025 accords with my recollection that "quality assurance deficiencies relate not only to facilities and equipment but to management

performance and general staff atitudes to quality". I do not recollect seeing the letter from Prof Cash during my tenure at NIBTS. I do not recollect being present during the audit. I am unable to assist with the number or nature of other audits because I was not involved.

140. I do not recall. I recall that Dr McClelland and I had a one-to-one meeting every week and a summary of every meeting should be available from NIBTS.

141. a) The document SBTS0000457_066 is a letter (1993) to Dr McClelland from Medicines Control Agency. I do not recall seeing the letter and I can speculate that I am unlikely to have seen it in 1993. b) I can only speculate that the MCA letter contributed towards the provision of a new building for NIBTS. I know that NIBTS had a new centre built. I am not aware of the circumstances or the date.

142. I recollect that I made strenuous efforts with regard to Quality control. The document SBTS0000070_025 is a letter from Dr Cash to Dr McClelland and states, "significant deficiencies seem to relate not only to facilities and equipment but to management performance and general staff attitudes to quality ". Dr McClelland and I had one to one meetings every week and I recollect that Quality matters were highlighted regularly by me. I cannot recollect details. A summary of every meeting should be available in NIBTS.

Section 16: Variant Creutzfeldt-Jakob disease (vCJD) (Q 143 – 144)

143. I do not recall when I became aware of the risks of vCJD. I do recall that it was a disease which was not known and that there was a lot of research which was reported widely in the media as well as at scientific meetings, in scientific publications etc. I recall that vCJD was discussed at SACTTI meetings, with considerable contribution from scientists all over the UK who were actively involved in studying the "new" disease. My recollection is that SACTTI was established as an advisory committee for the NBS. I do not recall any of the details requested, not even how I started as a member and subsequently became the Chair. I do recall that all the members were

"experts" and I was not an "expert". The Medical Director of NBS, England, attended meetings of SACTTI.

144. Document NIBS0000377_003 is a document from NBS and NIBS0000377_001 is a memo from me to the Director, asking if that was the agreed policy in Northern Ireland? I am assuming that the document from NBS was "the letter from Dr Robinson" referred in my memo. I recollect thatas a clinician who treated patients, I expressed a strong view that patients should be able to trust their doctor and honest discussion is in the patient's best interests. Experts dealing with vCJD at that time had a contrary view for cogent reasons which are explained in the circular.

Section 17: Your role as Chair of SACTTI (Q 145 – 150)

145. To the best of my recollection, SACTTI had an advisory role and related to the NBS committee "Microbiological Safety for Blood Transfusion (MSBT)" and the Special Advisory Committee on Care and Selection of Blood Donors. I don't recall seeing a document referring to remit, membership etc. My recollection is this: The Medical Director of NBS nominated members. Documents given to me by IBI indicate that I joined the committee in March 1998 "in order to strengthen input from UK Blood Transfusion Services". Dr Flanagan, who had chaired the committee from its inception, resigned at a meeting in September and 1998 and I was nominated as Chairman at that meeting. The committee consisted of experts in England and Scotland and I was not an "expert".

146. There was no formal relationship between SACTTI and NIBTS. NIBTS was not required to implement any SACTTI decisions. I provided information regarding discussions and recommendations after each SACTTI meeting to the Director, NIBTS, at our regular weekly meetings.

147. The Medical Director of NBS formally informed all RTCs as well as NIBTS of decisions and recommendations.

148. The document NHBT0002059 is a memo from the Medical Director, NBS England, attaching two articles from New Scientist discussing the

implications if a "simple blood test became available within two or three years". The article postulated that "a blood test would create huge pressure for routine screening of donated blood". Dr Robinson appears to be seeking to highlight the need to explore legal implications if a test became available.

149. Document JPAC0000089_002 records "the Department of health has advised that blood--------- --. The wider ethical and legal issue will be for the new group chaired by Don Jeffries, which will also review the information provided to donors etc (note added after the meeting: referral has not taken place)". I cannot recall what decision was made in due course, but I can postulate that the decision regarding process would have been implemented UK-wide and documents should be available. NIBTS would have followed UK Transfusion Services.

150. NAT testing was discussed extensively, as recorded in documents JPAC0000056_003 and NHBT0061511. Discussions were in the context of scientific developments as well as the practical implications for implementation and incorporation into the technical processes utilised in all the Regional Transfusion Centres at that time. As recorded in the documents, there were many concerns but slow progress was being made. I recollect that the demands, at that stage for extending NAT testing to include other viruses, hampered progress with implementation of NAT for HIV.

Section 18: Other matters (151 – 152)

151. I do not recollect that I published any articles apart from the poster presentation relating to screening tests for blood donors.

152. None.

Further matters to be addressed in supplemental Rule 9 request dated 17 August 2021

1. I cannot recall.

2. I do not recall that any patients in Northern Ireland were given blood transfusions with red blood cells imported from USA

Statement of Truth

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

Signed _____

Dated: _____