Witness Name: Lorna Williamson
Statement No.: WITN0643001
Exhibits: WITN0643002 - WITN0643009
Dated: 28 October 2021

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF LORNA WILLIAMSON

I provide this statement in partial response (in conjunction, I understand, with written statements from others which I should make clear I have not seen) to an amended request under Rule 9 of the Inquiry Rules 2006 dated 14 August 2020.

I, Dr Lorna WILLIAMSON, will say as follows: -

Section 1: Introduction

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

1. My name is Lorna Williamson.

2. My date of birth is GRO-C **1953**

3. My professional qualifications are **BSc, MB, ChB, MD, FRCP, FRCPath.**

2) **Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.**

4. I qualified in Medicine (MB, ChB) with Honours from the University of Edinburgh in 1978. I had undertaken an intercalated Honours BSc year in Medical Sciences from 1974-75 (awarded first class). I became interested in haematology in about 1975 and undertook a 4-week elective period in haematology at the Royal Infirmary, Edinburgh in 1976.

5. I have separated my employment history into training and consultant posts.

A. TRAINING POSTS

- **August 1978-January 1979: Pre-registration House Officer in Surgery, Royal Infirmary of Edinburgh.** I admitted patients, organised tests for them and occasionally assisted in theatre.

- **February- July 1979: Pre-registration House Officer in Medicine, Eastern General Hospital, Edinburgh.** I cared for patients with acute and chronic medical conditions.

- **August 1979-July 1980: Senior House Officer in Medicine, Queen's Medical Centre, Nottingham.** This post included 6 months working for a consultant specialising in liver disease, so I learned a good deal about the major causes of liver disease. I do not recall seeing any patients with haemophilia. I passed the Membership of the Royal College of Physicians examinations in summer 1979.

- **August 1980- July 1983: Senior House Officer then Registrar in Haematology, City Hospital, Nottingham.** These posts provided general training in both laboratory and clinical haematology. I treated patients with various anaemias, leukaemias and other blood cancers such as lymphoma, and examined blood and bone marrow samples in

the laboratory. This post did not involve haemophilia care as the Haemophilia Centre was at the Queen's Medical Centre, Nottingham. The training included a 1-week training course at the Regional Transfusion Centre (RTC), Sheffield, which sparked my interest in transfusion medicine.

- **August 1983-July 1985. Research Fellow in Haematology, City Hospital, Nottingham.** This was a full-time research post in the laboratory, working on white blood cells and inflammation. I did not see any patients during that time. This work formed the basis of my Doctor of Medicine (MD) thesis, awarded by the University of Edinburgh in 1988.

- **August 1985-May 1987 Full-time Senior Registrar in Haematology (Transfusion), Sheffield.** While all senior registrar posts in haematology included a 6-month period of training at an RTC, this rotating post provided extra time at the RTC. My rotation started at the Royal Hallamshire Hospital from August 1985-July 1986, where the consultants were Professor Eric Preston, Dr Mike Greaves and Dr David Winfield. One of the other senior registrars was Dr Charles Hay. Coagulation and haemophilia were major interests of the department, so although my training involved laboratory and clinical aspects of all areas of haematology, there was considerable discussion about the major issues in haemophilia at that time, i.e infection with HIV and non-A, non-B hepatitis, and the provision of virally inactivated clotting factor concentrates. I attended the haemophilia clinic with Professor Preston, and was struck by how many patients were in wheelchairs. As I had had no previous experience in haemophilia, I did not make treatment decisions without discussion with one of the consultants, usually Professor Preston. I was not involved in decisions regarding which clotting factor concentrates to use, either in general, or for individual patients. I was very much aware of the previous and on-going research undertaken by the Sheffield team on non-A, non-B hepatitis, and I can recall haemophilia in-patients having liver biopsies. The issue of virus transmission by clotting factor concentrates and blood components was

very much to the fore at that time.

- **July 1986-May 1987 RTC and Sheffield Children's Hospital, Sheffield.** My time at the RTC was spent rotating through each department, learning advanced aspects of blood typing and cross-matching, donor recruitment and selection, donation testing for viruses and other infectious agents, and manufacture of blood components (red cells, fresh frozen plasma, cryoprecipitate and platelets). I took queries from hospitals across the Trent Region regarding individual patients where there were difficulties providing compatible blood. There was a major push at that time to produce more plasma for the Blood Products Laboratory (BPL) for fractionation, and the programme of plasma collection by donor apheresis was expanding. HIV was of course a major issue, with donor testing having started in 1985, and new guidance to exclude high risk donors eg male donors who had had sex with other men. The RTC consultants were very well aware of the virus risks from blood components and clotting factor concentrates. I recall seeing samples of the first virally inactivated clotting factor concentrates coming from BPL. The first ones did not dissolve well, but when virally inactivated concentrates called 8Y and 9A became available, they were well received by hospitals and patients.

- At the Children's Hospital, most of my time was spent caring for in-patients with leukaemias and solid tumours, working closely with the paediatric team and the consultants, Dr John Lilleyman and Dr Katy Forman. I sat in on the haemophilia clinic as part of my training, but did not make treatment decisions on individual patients without discussion with Dr Lilleyman. I was not involved in any decisions regarding treatment policies.

- **May 1987- February 1988 Maternity leave.**

- **February- July 1988- Part-time (50%) senior registrar in haematology, Sheffield rotation.** For personal reasons, I reduced my

working hours, joining a national scheme for part-time training. I split my time between the RTC, Royal Hallamshire Hospital and Children's Hospital. The responsibilities were as outlined above.

- During my time in Sheffield, I passed the final examination in haematology for Membership of the Royal College of Pathologists.

- **September 1988- July 1990. Part-time (50%) senior registrar in transfusion, East Anglian Blood Transfusion Centre (EABTC), Cambridge**. For family reasons, I moved my nationally-funded training post to Cambridge. I worked solely in the EABTC, although I attended haematology departmental meetings and educational events in Addenbrooke's Hospital, Cambridge. I did not have direct responsibility for any patients in the hospital, though I took transfusion queries from hospitals across East Anglia. I continued my training by rotating through different departments in the EABTC, and with a colleague, was given the task of establishing a panel of HLA typed (tissue typed) platelet donors. Platelets from such donors are used for patients who develop HLA antibodies (HLA alloimmunisation), which can arise either through transfusion or pregnancy, and which lead to platelets from unselected donors failing to work.

- This led to a research interest in alloimmunisation, and investigation of whether it could be prevented by removal of white blood cells from blood components using specific commercially available filters, a process known as leucocyte depletion or leukoreduction. This interest later became relevant when we were investigating ways to reduce the risk of variant Creutzfeldt-Jakob disease from blood components.

- **July 1990-January 1991 - Maternity leave.**

B. CONSULTANT POSTS.

- **Background to changes in EABTC.**

- In the late 1980s, it was realised that all 3 consultants at EABTC were about to retire. A plan was therefore developed by the Professor of Haematology (Professor Robin Carrell) and the Regional Director of Public Health (Dr Michael O' Brian) to create an academic Division of Transfusion Medicine within the University Department of Haematology, as a joint activity between the University and the East Anglian Regional Health Authority. This involved converting the EABTC Director post into a University Professorship, with 50% time for research and teaching, and 50% as an Honorary NHS consultant and Director of EABTC. The other 2 consultant posts were converted into 50:50 University Lecturer/Honorary Consultant posts. In around 1989, Dr Willem Ouwehand arrived from the Netherlands to take up the first University lecturer post. In autumn 1990, I was appointed to the second University Lecturer post, to begin in April 1991.

- **January-March 1991: Locum Consultant Haematologist at EABTC** with responsibility for Blood Components. I replaced a consultant who had retired. My time in this post was largely taken up with organising EABTC's contribution to blood provision for the combat phase of the first Gulf War (Operation Desert Storm, 17th January-28th February 1991).

- **April 1991- September 2008: University Lecturer (Reader from approx. 2004) in Transfusion Medicine, Department of Haematology at the University of Cambridge/Honorary Consultant Haematologist to EABTC (National Blood Service from 1994, NHS Blood and Transplant from 2005).** In my NHS consultant role at EABTC, I had medical and managerial responsibility for the blood components and issue departments. This included line management responsibility for the scientific and technical staff, and ensuring the components met the specifications laid down by JPAC in the Guidance for Transfusion Centres ('Red Book').

- In 1990 Professor Jean-Pierre Allain took up the post as Professor of Transfusion Medicine/Director of EABTC. To cover for Prof Allain's

absence in France from 1992 onwards, Dr Morton McDougall from the EARHA was appointed Director of the EABTC. Dr McDougall was a Public Health doctor, and since I was a qualified haematologist, I sometimes gave him advice and help.

- The National Blood Authority took responsibility for the RTCs in 1994, forming the National Blood Service, initially in 3 geographic zones, then under a national structure. My NHS responsibilities were then part of the London & South-East (LSE) zonal structure from 1994-1999, then under a national structure from 1999 onwards.

- **Acting Director of EABTC in a caretaker capacity in 1995.**
- At the end of 1994, Dr McDougall returned to the EARHA as it had no longer a responsibility for running EABTC. I was given the title of Acting Director for a few months during the transition to zonal management within the NBS. In essence, this was a caretaker role, as EABTC was no longer in a position to make major decisions requiring funding.

- **1994-1999 Clinical Lead for Blood Components, London and South-East zone.**

- **1999-2007 National Clinical Director for Components.**
- The major focus of these roles was to investigate ways in which the safety and quality of blood components could be improved and to provide advice to the Medical Director. The biggest concern was variant Creutzfeldt-Jakob disease (vCJD, the human form of Bovine Spongiform Encephalopathy (BSE), commonly known as mad cow disease), and the possibility that it could be transmitted through blood transfusion. We were also particularly concerned about the risk of bacterial contamination of platelets, and the low but measurable residual risk of virus transmission. I was therefore a member of various groups within the National Blood Authority exploring options to deal with these problems as follows:

- Provision of virus inactivated fresh frozen plasma and cryoprecipitate as a vCJD risk reduction step from countries which were considered low risk for BSE (this work did not include plasma for fractionation, which was a BPL responsibility)
- Exploration of Leucocyte Depletion (white blood cell filtration) of all blood components as a vCJD risk reduction step. We provided information to the Department of Health's Microbiological Safety of Blood and Tissues committee (MSBT), and once DH had taken the decision that universal leucocyte depletion should be undertaken, I was a member of the implementation group.
- Removal of as much plasma as possible from cellular blood components (Safer Plasma in Components) group, again as a vCJD risk reduction step.

▪ I was also a member of various safety groups under the combined remit of the UK Blood Services:

- **Early 1990s. Member/Secretary JPAC Standing Advisory Committee on Transfusion Transmitted Infections**. I regret I cannot remember the exact dates. I stood down to take up the chair of SACBC.
- **1994-2000 approximately. Chair, Working Group, Serious Hazards of Transfusion.** In 1994, I was asked by Dr Angela Robinson to convene a group to develop a UK-wide reporting system for collation of infections and other serious side effects of transfusion of blood components (red cells, platelets, fresh frozen plasma and cryoprecipitate). As these are not licensed medicines, the systems for reporting drug side effects did not apply. The remit did not cover fractionated plasma products, as these are licenced medicinal products, covered by the Medicines and Healthcare Products Regulatory Authority. The public health systems in different parts of the UK had some data on infections transmitted by blood transfusions, but this was not collated UK wide. There was also on-going research on transfusion errors in hospitals and increasing

awareness of serious immunological reactions to blood components, but no comprehensive reporting system which brought them all together. I therefore established a group whose first actions were to investigate transfusion reporting systems in other countries (only France had such a system), and to investigate incident reporting systems in other areas of health in the UK. We were aided by a parallel initiative between the NBA and the Public Health Laboratory Service in England to share data on infections in donors and recipients. We recommended basing a transfusion reporting system on the UK Confidential Enquiry model already in place for maternal deaths and peri-operative deaths (NCEPOD). We launched the UK's first haemovigilance system, the Serious Hazards of Transfusion (SHOT) in 1996. Its first annual report, covering 1996-7, was published in 1998. SHOT remains an integral part of the transfusion environment in the UK and has been the model for haemovigilance systems in several other countries.

- **1998-2007 Chair, JPAC Standing Advisory Committee on Blood Components.** We wrote the specifications for all blood components produced by UK Blood Services.
- **1998-2016: Member, UK Blood Services Joint Professional Advisory Committee.** This group produced guidance for the 4 UK Blood Services on donor selection, testing and manufacture of blood, stem cell and tissue products. I was initially a member as Chair of SACBC, then from 2007, as NHSBT's Medical Director.
- **2004-2011 Chair, UK Blood Services Prion Reduction Working Group.** This was established to examine emerging technologies for the removal of infectious prions from blood components. There was a parallel group on prion testing chaired by Professor Marc Turner, SNBTS.

- My other main responsibility in this joint University/NHS post was research. I had 2 research interests:

1. Alloimmune neonatal thrombocytopenia. This is an immune condition

of newborns resulting in low platelets. It is not relevant to this inquiry and not discussed further.

2. Development of blood components to improve efficacy and safety. This dovetailed with my NHS responsibilities, in that some of my research findings were made available to decision- making groups within NBA (later NHSBT), or at UK level through JPAC or MSBT (later the Advisory Committee for the Safety of Blood, Tissues and Organs, SaBTO). These research studies included:
   - a clinical trial on leukocyte reduction to prevent alloimmunisation, and laboratory studies on removal of viruses (HTLV I and II and cytomegalovirus) by white cell filters
   - studies on virus-inactivated blood components e.g. solvent-detergent or methylene blue treated fresh frozen plasma
   - analysis of haemovigilance data from SHOT to see whether white cell removal from the blood supply was reducing the risk of serious immune complications such as transfusion-associated graft-versus-host disease and post-transfusion purpura
   - analysis of haemovigilance data from SHOT to see whether provision of fresh frozen plasma from male donors reduced the risk of transfusion-related acute lung injury (with Dr Catherine Chapman, Newcastle).

- I also co-founded the NHSBT Clinical Studies Unit, which undertakes national trials to improve the evidence base for the use of blood components.

- **October 2007- May 2016: Medical and Research Director for NHS Blood and Transplant.** (Clarification: Dr Angela Robinson and Professor Marcela Contreras retired at about the same time. Dr Tim Wallington was acting Medical and Research Director from then till October 2007). It should also be noted that my post did not cover BPL, which had a separate Medical Director (Dr Clive Dash). In this role, I had 4 main areas of responsibility:

1. As a member of the NHSBT Board, a shared responsibility for corporate decisions
2. For the medical workforce - developing new posts and appointing new consultants, and ensuring annual appraisal and revalidation
3. Governance and safety of clinical services within NHSBT. It should be noted that major policy decisions on blood safety were taken either by JPAC or by DH, the latter usually following advice from SaBTO.
4. Oversight and organisation of NHSBT's research programme. Some of the specific roles relating to blood safety were:
    - Chair, Clinical Audit Risk and Effectiveness Committee, and Lead Director for Safety, Risk and Clinical effectiveness. I completely restructured the arrangements for clinical governance to ensure systematic review of risks and solutions.
    - Chair: Francis report review group. Produced the action plan and Board updates.
    - Member, Transplant Policy Review Committee of the Board. Responsible for UK patient selection for organ transplantation and the organ allocation policies.
    - Caldicott Guardian for data protection, working closely with the Senior Information Responsible Officer on information governance.

3) **Membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of membership and the nature of involvement.**

6. I have listed here membership of non-Blood Service UK bodies relevant to the Inquiry.

    - **Early 1990s Member, British Society for Haematology's Transfusion Task Force**. I chaired a group which produced the first UK guidelines for the Irradiation of Blood Components (this is done for

patients with impaired immunity to prevent the fatal complication Transfusion-Associated Graft-versus- Host disease).

- **2007-2016: Member, Chief Medical Officer's National Blood Transfusion Committee.** This group drives optimal transfusion practice at the front line of the NHS.

- **2010-2014 Chair, Royal College of Pathologists Transfusion Medicine Committee.** We set standards for professionals working in the field.
- **2011-2016: Member, DH Advisory Committee on Safety of Blood, Tissues and Organs (SaBTO).** This group provided advice to the Health Ministers of the four UK home nations. I was Chair of three working groups producing recommendations on: donation policies for tissues and cells by men who have had sex with men; pathogen inactivation of platelets; and hepatitis E.

Section 2:

7. I have been identified as a person appropriate to address questions **1, 3, 5, 27, 28 and 35** in the amended request under Rule 9 of the Inquiry Rules 2006 dated 14 August 2020.

8. I understand that I am providing such answers along with others employed by NHSBT, on the basis that the length of time and scope of the subject matter concerned makes answers from a number of witnesses both proportionate and necessary. I have not seen the answers given by others.

9. I understand that I am the primary witness dealing with Question **27**; and that I am a supplementary witness in relation to the other Questions referred to above.

List of the Rule 9 Questions to which I am responding

10. I set out immediately below in full the Questions to which I am giving a response, identifying after each Question Number whether that response is primary or subsidiary and provide my response underneath.

QUESTION 1.

In the document titled 'Draft Report from the MSBT Subcommittee' (NHBT0005791 page 2) discussing the merits of introducing an HCV "Look-Back" policy, it is stated:

"Despite these reservations it is recognised that there is a duty of care that needs to be exercised towards these patients and the implicated donors"

a. When was this duty of care to patients and donors first recognised by NHSBT?

Answer Q1 a. (Supplementary):

11. I cannot comment on any corporate position on this point. Ever since I entered the transfusion service in 1986, there has been an implicit assumption that, as medical professionals, doctors working in transfusion services had a duty of care to our donors. We also recognised the duty we had to support hospital clinicians and GPs who were caring directly for patients who had received our blood components. This support might be specific to individual patients e.g. by providing additional information on the transfusions they had received, or generic e.g. by evaluating and implementing new methods for improving the safety of our blood components.

b. Provide an account of how this duty of care was discharged:

i. prior to the look-back in 1995; and

ii. in respect of those patients not identified by the look-back exercise.

Answer Q1 b. (Supplementary):

12. At the time I was at Trent RTC, Sheffield (1986-1988), donation testing was in place for HIV, hepatitis B, syphilis and malaria. Reactive results in the screening tests would be confirmed by additional more sophisticated tests. Donors with confirmed positive tests were contacted for a discussion with a doctor.

13. At the East Anglian Blood Transfusion Centre, similar practices were followed. An additional consultant post was created for donor health in 1990/91, as part of the preparation to commence HCV testing of blood donors. A qualified haematologist, Dr Elizabeth Caffrey, was appointed to this post. Her responsibilities included notification of, and post-test discussions with, donors testing positive for HCV. We had a list of liver specialists throughout East Anglia to whom donors with positive hepatitis C tests could be referred. Dr Caffrey was later the lead consultant for the East Anglian Region on the HCV lookback. I do not personally recall any specific discussions relating to patients who might be missed by the lookback.

14. Once the NBA was created, I had no personal involvement in the lookback exercise and cannot recall any specific discussions regarding patients who might be missed by the lookback.

QUESTION 3

In the document titled 'Summary: Intervention and Options, Impact Assessment of Better Blood Transfusions' (DHSC0004109_008), on page 3, under the subheading 'The most important aspect is SAFETY', it is noted that:

"Blood transfusions Plasma and platelets are all potentially infected. In the 1990s blood transmission of HIV was a major problem. At the same time Hepatitis C was transmitted but only in 2000 has the problem been recognised as serious."

a. Please comment on the view expressed that HCV transmission through

infected blood components was only recognised as a serious problem in 2000.

b. Does this represent the view of NHSBT either then or now?

c. If so, why was HCV transmission not recognised as a serious problem earlier?

Answer Q.3 (Supplementary)

15. I will answer these questions together. I am aware that others are also answering this question.

16. My personal perspective of this issue is very different from what is quoted in the question above from this memo.

17. When I worked in Sheffield in from 1985-88, there was important research involving haemophilia patients to establish whether 'non A, non B hepatitis' (later identified as hepatitis C) had any serious long term sequelae (Professor Eric Preston, Dr Charles Hay, Professor James Underwood, Dr David Triger and others) (PRSE0004594). This included performing liver biopsies which revealed for the first time that long term liver damage, including cirrhosis, could follow what had been previously thought to be a benign infection.

18. My recollection is that it was partly the availability of this new information which influenced the decision to commence donor testing for hepatitis C and undertake a lookback. There was no doubt as to the seriousness with which HCV was regarded by nearly all doctors who worked in transfusion by the late 1980s.

19. The key players within NHSBT in the lookback exercise nationally would have been Dr Angela Robinson, Medical Director, Dr Patricia Hewitt, and the Chief Executives and Medical Directors of the 3 zones created by the

NBA in 1995.

20. With regard to the question of how seriously hepatitis C is regarded today, an illustration is the seriousness with which a new form of hepatitis (hepatitis E) was taken when reports first appeared of this infection in humans in approximately 2012.

21. Hepatitis E is an infection of pigs, mainly transmitted to humans through eating infected pork products. SaBTO formed a sub-group (which I chaired) to consider how best to minimize the risk of transmission through blood, tissues and organs. A study was performed to see whether this infection could be detected in the blood of donors, and whether it could be transmitted (Exhibit: **WITN0643002**). This study, led by Dr Patricia Hewitt, showed that 1 in 2848 donors carried the virus, and that 18/43 recipients followed up had acquired the virus. Although its overall impact on health was not known, under the precautionary principle, we made recommendations for blood donor testing to SaBTO in April 2015 (Exhibit: **WITN0643003**).

22. We recommended as a first step, to avoid delay, provision of hepatitis E negative blood components for recipients with a highly impaired immune system, who were considered the most vulnerable for possible long-term sequelae, if indeed this virus had the potential to cause liver damage. In practice, this referred to patients who had had either an organ transplant or a stem cell transplantation from a donor (called allogeneic transplantation). This recommendation was accepted by SaBTO and rolled out across the UK. Later recommendations by SaBTO were to extend provision of hepatitis E negative blood components to newborns and those who should avoid live vaccines (November 2016) and then to provide hepatitis E negative components for all recipients of blood, tissues and organs (except sperm and eggs) in September 2017. Note: I was not involved in these later recommendations as I had retired in May 2016.

23. In summary, the simple answers from my perspective to these questions

are as follows: (a) I do not agree with the view quoted from the memo above, and (b) I do not recognise it as being or reflecting the, or a NHSBT view, or the prevailing view of its staff, at any stage.

24. It is also worth noting that the extract from the document is factually incorrect, in stating that HIV transmission from blood components in the 1990s was a major problem. Data from SHOT reports, which begin in 1996, show one confirmed transmission event (3 recipients) in 1996 (NHBT0057437_001), with the only other one to date being in 2002 (SHOT0000016)

QUESTION 5

An account of the steps taken to warn patients of the risk of HCV being transmitted through the use of blood and/or blood products since 1989 when the HCV virus was first isolated. Please include any 'look-back' patient notification exercises and details of any awareness campaigns to publicise the risk, including exercises and campaigns that were considered but rejected.

Answer Q.5 (Supplementary)

25. I had no direct responsibility for this work prior to becoming Medical and Research Director in 2007. I will report recollections of what was put in place by colleagues and myself at NBA/NHSBT.

Prior to 2008

26. Transfused patients are under the care of a hospital consultant, and it is their responsibility to ensure that the patient is informed about possible risks of any transfusions they might receive. Since the Blood Services do not hold information about most individual transfused patients, it has never been possible for us to contact patients directly. Therefore, NHSBT clinical staff have always ensured that education about transfusion-transmitted infection is included in educational activities for medical undergraduates, post-

graduate haematologists and general educational events for all hospital staff including nurses and laboratory staff e.g. launches of SHOT reports. My annual transfusion lecture to medical undergraduates at Cambridge always included material about the risks of transfusion.

27. NHSBT and Public Health England created a joint scientific post (Dr Kate Soldan) to work on transfusion-transmitted infections. One of her roles was to carry out estimates of the residual risks (i.e. after donor selection and testing) of a blood component carrying HIV, hepatitis B and hepatitis C. This information was made available to JPAC for the website and included in patient information leaflets.

28. In the 1990s, the NBA embarked on a major programme to ensure that there were much more expertise and resources available to improve transfusion practice in hospitals. The objectives were to ensure that blood was used appropriately, that transfusion errors in hospitals were minimised and that hospital staff and patients were better informed. This included: creation of a national Clinical Director post for Hospital Transfusion Practice (Professor Mike Murphy, Oxford), plus a team of joint consultant posts with key hospitals; creation of a nursing team to lead on educational activities with nursing and other staff in hospitals; promotion of hospital transfusion committees and transfusion practitioners in hospitals. In England, the Chief Medical Officer's National Blood Transfusion Committee was created in 2001.

29. These Blood Service initiatives led to release of the Better Blood Transfusion Health Service Circulars from DH (1998, 2002 and 2007), and the Handbook of Transfusion Medicine, made available to all hospital staff. In addition, patient information leaflets were produced by NBA regarding all risks of transfusion. These were provided to hospitals to be made available to patients likely to be transfused. It was the responsibility of the hospitals to distribute these. NHSBT performed audits of their availability, which was found to be variable.

2008 onwards

30. By this point, the residual risk of HIV, HCV and HBV from blood components was very low. Our safety focus was still on infectious agents, but mainly on vCJD, bacterial contamination of platelets, emerging tropical infections such as West Nile virus, SARS, and Zika and hepatitis E. Information for patients included calculations of the risk of HIV, HBV and HCV, and mentioned the other much lower risks.

31. In 2011, SABTO produced recommendations for consent for transfusion. This gave the Blood Services specific responsibility for producing up to date information about transfusion risks in the patient information leaflet.

QUESTION 27

Accepting that the recommendation of the Penrose Inquiry, that everyone who had a blood transfusion before September 1991 be tested for HCV, was directed to Scottish Government, please provide an account of any steps taken by NHSBT in response to this recommendation.

Answer Q. 27 (Primary)

Urgency of consideration of the Penrose summary by NHSBT.

32. The Penrose summary was published on 25th March 2015, and we first discussed the report at a planned meeting of the Clinical Directorate Senior Management Team (CDSMT) on 2nd April 2015 (Exhibit: **WITN0643004)**. We agreed to review the 50 page summary and consider the single recommendation and the many observations made regarding transfusion practice before our next meeting on 4th June 2015.

Response to Penrose recommendation that anyone who had had a transfusion before September 1991 should have an HCV test.

33. This recommendation was made to the Scottish Government. It did not state how it was to be achieved, and there was no specific recommendation that a further look back exercise should be undertaken. An extract from paper 4.3A from the CDSMT meeting on 4th June 2015 (Exhibit: **WITN0643005**) states:

'*The [Penrose] report made a single recommendation, which is that individuals in Scotland transfused before September 1991 (when HCV screening of blood donors was introduced) should seek a test for HCV, if not already performed. This will be led by Health Protection Scotland and is unlikely to include formal lookback since this was done in the mid-1990s'.*

34. This was understandable, as the practicalities of either NHSBT or SNBTS trying to trace the potentially millions of people who had ever received a blood transfusion before 1991 would render this a virtually impossible task. This would be lookback on a scale hundreds of times larger than the 1995 lookback exercise, which was restricted to previous recipients of donors who tested HCV positive at any point after the introduction of testing in September 1991.

35. In addition, given the 20 years that had elapsed since the original lookback, there would be far fewer hospital records available, and many patients would now be deceased, either from the illness which necessitated the transfusion, or from other causes.

36. Further points that were learned from the 1995 lookback were (a) that the patient's GP would usually not know whether the patient had been transfused, and (b) that the patient themselves might not know that they had been transfused e.g. if unconscious or under anaesthetic; (c) conversely, some patients erroneously believed they had been transfused with blood, because they had a 'drip' in their arm administering clear fluids.

Consideration of observations made in Penrose by NHSBT.

37. In addition to its single recommendation, the Penrose report also made a number of observations relating to transfusion practice in earlier decades. The Clinical Directorate Senior Management team agreed at its meeting on 2nd April 2015 that it would be useful to itemise each of the observations made in the Penrose summary, summarise the current safety steps relating to each of them, and consider whether there were any new actions which could be taken to improve safety further with regard to any of them (Exhibit: **WITN0643004**). This approach was agreed with the Chief Executive, and the CDSMT reviewed an advanced draft of the conclusions of this exercise at its meeting on 4th June 2015, with CDSMT Paper 4.3A relating to blood donations (and paper 4.3B relating to organ donations) (Exhibit: **WITN0643005**).

38. I first alerted the Board to publication of the report of the Penrose Inquiry at the Board meeting on 26th March 2015 (Exhibit: **WITN0643006)** and recommended that all Board members read the summary. The Director of Communications and I undertook to provide a short briefing document for blood collection teams and our donor call centre in case of queries from donors.

39. At the Board meeting on 28th May 2015 (Exhibit: **WITN0643007**), I reported that I would be bringing a paper on the Penrose report to the July Board meeting.

40. The final version of the CDSMT paper was presented to the NHSBT Executive Team on 22nd July 2015 and to the Board on 30th July 2015 (Exhibit: **WITN0643008**). This paper covered how the Penrose observations applied to both blood and organs. The Executive summary of this Board paper (15/61) states

'*The Penrose Inquiry, which reported on the 25th March 2015, had a remit to explore the circumstances of HIV and HCV transmissions from blood components and fractionated plasma products in Scotland between 1st January 1974 and 1st September 1991. The report made a single*

recommendation, which is that individuals in Scotland transfused before September 1991 (when HCV screening of blood donors was introduced) should seek a test for HCV, if not already performed.

In addition, however, Penrose brought attention to a number of aspects of donor policy and patient care, which were considered not inappropriate at the time, but which would not meet today's standards. This paper is intended to:

(i) summarise these additional points
(ii) describe current policies within Blood and Transplant Services that relate to them
(iii) consider how similar issues arising today would be handled.

This review has concluded that there is strong assurance that many practices of the past would no longer apply, and that today's processes are much more consistent and transparent. There remains, however, sub-optimal clarity over funding and commission of laboratory testing for organ donors (in England); discussions are ongoing with NHS England. There is also the possibility of different actions on safety matters being taken by the 4 nations of the UK.

Recommendation: The Board is asked to note the analysis and conclusions.'

41. The relevant extract from the Board minutes of 30th July 2015 states: ' The Board received paper 15/61 which covered points for reflection following the report from the Penrose Inquiry and this was well received' (Exhibit: **WITN0643009**).

QUESTION 28

In a letter (NHBT0036358) of Dr Angela Robinson (National Blood Authority) dated 1998, to Dr Mortimer, Public Health Laboratory Service, discussing the US Public Health Service's recommendation that all recipients of blood prior to

1992 should be tested for HCV, Dr Robinson suggests that there is no requirement for such a recommendation in the UK. Is this view consistent with NHSBT's position today?

Answer Q. 28 (Supplementary)

42. The proposal that all patients who received blood before 1992 should be tested for HCV is the same as the recommendation made by Penrose in 2015. It is not an unreasonable recommendation in theory, since not every single patient transfused before HCV testing of blood donors commenced will have been traced through the 1995 lookback exercise. However, as discussed in my replies to Q27 above, the practicalities of achieving such an objective through a lookback of every transfused patient make this almost impossible. It is worth noting again that the Penrose recommendation was directed at the Scottish Government and delegated to Health Protection Scotland. Blood Services cannot lead such endeavours, as we do not have names and details of individual patients who have been transfused.

QUESTION 35

In the document titled 'Protocol for clinical investigation of the significance of isolated anti-HBc or anti-HBc/anti-HBs <0.1 IU/L' (NHBT0007906_001), reference is made to a proposed Hepatitis B look-back study being conducted, following the same procedure as the HCV look-back. Assuming that the proposal and protocol was agreed, please provide an account of this HBV look-back study, and exhibit any interim and final reports.

Answer Q. 35 (Supplementary)

43. I do not recall seeing this document before. It appears to be part of a protocol for a proposed study (see below) in which 100,000 blood donors would be tested for an additional marker of hepatitis B infection i.e. antibodies to the core of the virus (anti-HBc). As individuals can acquire

hepatitis B and hepatitis C through the same route, it also used to be considered a surrogate test for hepatitis C. This role has become redundant now that nucleic acid testing is in place for hepatitis C testing. The margin notes on this document suggest that it may have come from Professor Jean-Pierre Allain, Professor of Transfusion Medicine, University of Cambridge. It does not appear to be dated.

44. I will explain the background to the document and 100,000 donor study, I collaborated with Professor Allain on a smaller study of anti-HBc testing in approximately 10,000 blood donors in East Anglia, published in 1995 (Allain J-P, Reeves I, Kitchen AD, Wenham D and Williamson LM; Transfusion Medicine 1995: 259-265. Feasibility and usefulness of an efficient anti-HBc screening programme in blood donors) (JPAC0000090_071). The conclusion of this smaller study was that although our testing algorithm allowed anti-HBc screening to be done efficiently and at moderate cost, none of the 9,238 donors tested was found to be carrying the virus when tested for virus DNA. It was not clear whether this was due to limitations of the DNA test available at the time, or because no donors were actually carrying the virus. The published paper ended by suggesting that a larger study of 50,000 or 100,000 donors would be needed to answer this question.

45. The larger study was performed in collaboration with colleagues in London and published in 1999 (Allain J-P, Hewitt PE, Tedder RS, Williamson LM. Evidence that anti-HBc but not HBV DNA testing may prevent some HBV transmission by transfusion. Brit J Haem 1999; 107: 186-195) (Exhibit: NHBT0000112_034). The purpose of the study was to establish whether anti-HBc testing of donors could identify additional donors with the potential to transmit hepatitis B, despite them testing negative by the routine test for hepatitis B surface antigen. A total of 103,869 donors from the East Anglia and S Thames blood centres were tested for additional hepatitis B markers (anti-HBc, anti-HBs and HBV DNA) according to the study algorithm.

46. As far as I recall, permission for such additional testing was covered by the routine donor consent procedures, which made provision for use of donor

samples in the assessment of new virus tests. Tested donors fell into 5 categories: (1) negative for anti-HBc and anti-HBs; (2) anti-HBc negative, anti-HBs positive; (3) anti-HBc positive, anti-HBs > 0.1 IU/ml (the level considered protective); (4) anti-HBc positive, anti-HBs positive but < 0.1 IU/ml; (5) anti-HBc positive and anti-HBs negative. In line with national guidance at the time (Guidelines for the UK Transfusion Services), components prepared from donors in categories 1-3 were issued for clinical use. Donations in categories 4 and 5 were discarded.

Lookback from this study.

47. The following paragraphs are extracted from the published paper. *Approval for a lookback exercise as part of this study was obtained from the Ethics Committees of all 64 participating hospitals in E Anglia and S Thames. For donors in categories 4 or 5, all donations in the previous 5 years were traced from blood centre records. In addition, age and sex-matched control donors were selected for lookback from those in category 3. The blood components made from the previous donations were traced through hospital records, and the case records of the recipients examined. At the request of the Ethics Committees, children were not included in the follow-up.*

48. The patient's GP was contacted and asked whether it would be appropriate to contact the recipient with a view to taking part in the study. If the GP agreed, the patient was contacted by letter, with an explanatory leaflet and the phone number of the study nurse. Patients who were interested in taking part had a telephone discussion with one of the study team, before giving written permission for a blood sample to be taken. Blood samples were tested for markers of hepatitis B infection as well as liver function tests. Test results were given to patients by telephone as soon as available and confirmed in writing to the patient and GP. Further advice was provided to the patient and GP as needed. An interview was conducted by phone, using a questionnaire in use at the North London Transfusion Centre, to try to establish whether the patient had any risk factors for hepatitis B infection.

49. Components made from donations from the 171 category 4 and 5 donors were entered into the lookback, resulting in 278 recipients. Twelve recipients had markers of hepatitis B infection, none with a history of clinical hepatitis. Six recipients had other risk factors for acquiring hepatitis B, such as country of origin. Of the remaining six, an association with blood transfusion was considered probable in two and possible in four, suggesting that 1 in 52,000 donations (1.92/100,000 donations, confidence intervals 0.3-78/100,000) contained infectious hepatitis B virus. The donors of these donations were tested for the DNA virus, and all were negative 6-40 months after giving the donation which transmitted the virus. It was unknown whether these donors were positive for HBV DNA at the time of the donation which may have transmitted the virus, as this was not a routine test at that time.

50. The conclusions from the study were that adding anti-HBc to the routine test for hepatitis B surface antigen could identify additional donors capable of transmitting hepatitis B.

51. Although neither anti-HBc nor HBV DNA testing has ever been mandated, NHSBT introduced a 'triplex' NAT test in 2009, which added HBV DNA testing to the previous 'duplex' test for HCV RNA and HIV RNA in place since 2002. SHOT reports from 1996-2009 reveal 11 HBV transmissions in 13 years, with no deaths. In the 10 years following introduction of HBV NAT, SHOT reports reveal 4 HBV infected transfusion recipients, with 1 death.

Personal Observations on Haemophilia.

52. It seems to me that it might be of assistance when giving my evidence to add some personal observations relating to my own experiences of those with haemophilia.

53. My first encounter with haemophilia was as a teenager in the 1960s. My family had a workmate who was affected. I recall discussion at home of how he often had to take days or weeks off work and had to go to the local

hospital every time he had a bleed.

54. I became interested in haematology in about 1975 and undertook a 4-week elective period in haematology at the Royal Infirmary, Edinburgh in 1976. During this time, I vividly remember seeing a young man with haemophilia who had suffered a large retro-peritoneal bleed. This is in the area of the lower back, and the bleed had affected the major muscles which bend the hip joint. He was going to need bed rest for several weeks, and I was told that he would likely be impaired with a limp for the rest of his life. I do not remember what treatment he received, but it showed me what a major impact haemophilia could have on someone's life.

55. The next time I had contact with haemophilia care was during my senior registrar training in Sheffield. At the Royal Hallamshire Hospital in 1985-86, I was taken to the haemophilia clinic by Professor Eric Preston. I was struck by how many of the patients were in wheelchairs. As a new senior registrar with no experience of haemophilia care, I did not make any decisions about the treatment of individual patients, nor about what products the unit should prescribe as policy. As I recall, most patients with severe haemophilia received factor 8 concentrates for bleeds or before surgery, and patients with mild haemophilia received DDAVP.

56. There were 2 major issues under constant discussion among the medical staff:

    (1) The testing of patients for HIV, and what the significance was of being HIV antibody positive. It was not known what percentage of HIV antibody-positive patients would go on to develop AIDS. It was thought possible that some patients might either clear the virus over time, or carry it for life without illness. Therefore, there was a good deal of agonising over what to say to the patients when they were told they were HIV antibody positive. As far as I can recall, all patients were told the result of their HIV antibody testing, and that information was conveyed in person by Professor Preston.

(2) The studies that were going on with the liver team to work out the clinical significance of non-A, non-A hepatitis (later identified as hepatitis C). It was an exciting time to be working at Sheffield, as this was new work that would change attitudes and policy. At the same time, we worried greatly about the haemophilia patients, as it became increasingly apparent that this infection could cause progressive liver disease over time.

57. I remember working with Sister Joy Farnsworth, the haemophilia nurse, who was newly appointed. She rapidly became an invaluable member of the team and the first point of contact for the haemophilia population.

58. Due to maternity leave, I had limited time at the Sheffield Children's Hospital. I saw very few boys with haemophilia, but recall they were treated with cryoprecipitate. The treatment decisions were all taken by Dr John Lilleyman.

Section 3: Other Issues

59. From a personal point of view, I am more sorry than I can say that so many families have had to go through such loss and grief. Until I heard their stories, I had not realised how difficult it has been for a large number of people to get at the truth about what happened to their loved ones. These accounts need to be heard by anyone who takes decisions about safety of blood and of any new medicines. I think I was fortunate to have trained in a centre (Sheffield) where the doctors were truly shocked by the realisation that so many of their patients, whom they had known for years, had been harmed by their treatment, and were deeply concerned for their wellbeing.

60. These tragic events left an indelible mark on the transfusion doctors of my generation, whether working in hospitals or in the UK Blood Services. Our shared aim was to find out as much as possible about the risks of transfusion (through the new Serious Hazards of Transfusion scheme), to research

everything reasonably possible to prevent them, and to launch an education programme to make sure that all doctors could have a knowledgeable conversation with patients about transfusion risks and alternative treatments. Again, I have been fortunate to work in an era when complete honesty with patients about errors is an absolute requirement (Duty of Candour), along with consent for taking part in clinical trials. For patients harmed through transfusion of blood, who are now thankfully very few, the changes by which proof of fault was not required made it much easier for them to receive financial support, without the adversarial approach of the past and I personally welcomed it.

61. Although I am now retired, I have absolutely no doubt that the transfusion doctors who follow behind me are every bit as committed to blood safety, and will wholeheartedly welcome the report of the Inquiry.

Statement of Truth

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

Signed GRO-C

Dated 28th October 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
28 July 2014	"Hepatitis E virus in blood components: a prevalence and transmission study in southeast England", Patricia Hewit et al. Lancet 2014;384:1766-73	**WITN0643002**
15 April 2015	SaBTO "Hepatitis E Virus:	**WITN0643003**

	transfusion and transplantation risk reduction working group report"	
2 April 2015	CDSMT meeting minutes from 2 April 2015	**WITN0643004**
4 June 2015	CDSMT meeting minutes from 4 June 2015 and extract from Paper 4.3A	**WITN0643005**
26 March 2015	NHS BT Board meeting minutes on 26 March 2015	**WITN0643006**
28 May 2015	NHS BT Board meeting minutes on 28 May 2015	**WITN0643007**
30 July 2015	NHS BT Board pack for meeting dated 30 July 2015	**WITN0643008**
30 July 2015	NHS BT Board meeting minutes from 30 July 2015	**WITN0643009**
1999	Report Anti-HBc screening in blood donors by Jean-Pierre Allain et al.	NHBT0000112_034