Witness Name: Sally Davies

Statement No.: WITN6929001

Exhibits: WITN6929002

Dated: 7 February 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF SALLY DAVIES

I provide this Statement in response to a request under Rule 9 of the Inquiry Rules, dated 9 December 2021.

I, Sally Davies, will say as follows: -

Section 1: Introduction

Introductory Remarks

1. This Statement has been provided in response to a R9 witness statement requests from the Infected Blood Inquiry ("the IBI"). The IBI's R9 Request asks me general questions about my experience and practise as a Consultant Haematologist at the Central Middlesex Hospital, as well as limited questions about my time as Chief Medical Officer (CMO). As will be seen from the further answers below, I was at the Central Middlesex Hospital as a consultant from 1985 – 1996. I do not have access to documents still held by the hospital. I have been given some documents, such as national clinical guidelines, relating to clinical practice at the time by the IBI, but they are not comprehensive. Inevitably, I have only a limited recollection of practices across the decade or so about which I have been asked. As a result of all these factors, and working on the basis of my present recollection, the answers which I have given in this statement are fairly general and sometimes brief. If further documents are brought to my attention which add further details or suggest that my personal account needs amendment, I would be happy to consider them.

Q1. Please set out your full name, address, date of birth and professional qualifications.

2. My name is Dame Sally C Davies FRS, MBChB, MSc, FRCP, FRCPath, FRC Paed and Ch.H. My date of birth is GRO-C 1949. I am the Master of Trinity College, Cambridge (from October 1, 2019) and Her Majesty's Government Special Envoy on antimicrobial resistance (AMR).

Q2. Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.

3. My career history is as follows:

After qualifying as a doctor in 1972, I undertook two years training in Manchester and then took a four-year career break. I returned to London for one year Paediatrics training, followed by Haematological training at the Middlesex Hospital - including rotations to Central Middlesex Hospital ("CMH") for 12 months and the North London Blood Transfusion Service for 6 months, Colindale. This was followed by two years of research in molecular biology at the Middlesex Hospital (1982 - 1985).

4. I was appointed in 1985 as Consultant Haematologist at CMH, with a specific remit for sickle cell disease. Dr Milicia Brozovic was head of department, including the Blood Bank.

5. In 1996 I was seconded full-time to the NHS Executive (NHSE) as Director of Research and Development for North Thames Regional Health Authority. CMH replaced me with a full-time haematologist on site. My CMH role was unpaid and limited to Sickle Cell outpatient clinics, advice on inpatients and mentoring the younger consultants.

6. From 1999 till 2002 I was the Director of Research and Development (R&D) for London, Department of Health and Social Care (DHSC), and then the Deputy Director of R&D for the Department of Health (DH).

7. In 2004, I was appointed Director General of Research and Development and Chief Scientific Advisor (CSA) to the Department of Health. In 2006, I set up the National Institute for Health Research (NIHR) and I was the NIHR Inaugural Director, continuing also as CSA, until 2016. In 2010, following the general election, I became the interim Chief Medical Officer (CMO), being formally appointed to the substantive job following open competition, in 2011. I retired as CMO on September 30, 2019.

Q3. Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of membership and the nature of my involvement.

8. I was registered with the General Medical Council and a member of the Medical Defence Union, British Society for Haematology and the American Society for Haematology. I was not a member of any working groups for these specialist societies.

Q4. Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to HIV, HBV and/or HCV in blood transfusions. Please provide details of your involvement and copies of any statements or reports which you provided.

9. I have not provided evidence to, nor have I been involved in, any other inquiries, investigations, criminal or civil litigation in relation to HIV, HBV and/or HCV in blood transfusions.

Section 2: Central Middlesex Hospital (CMH) Role

Q5. I have been asked to describe the following matters:-

a. ***My role and responsibilities at the Central Middlesex Hospital (CMH) and how these changed over time.***

10. My post was the first to be established in the UK specialising in sickle cell disease (SCD). I treated all ages of patients who suffered from SCD, seeing them in the outpatients and leading their care as Consultant Haematologist when in-patients on the wards of CMH. I also supervised the sickle cell counselling service of the Brent Sickle Cell Centre.

b. ***My work at CMH insofar as it involved treating patients with blood transfusions particularly in relation to your work with patients with sickle cell anaemia;***

11. In addition to the SCD care described above, I did a general haematology outpatient clinic for patients with anaemias, leukaemias (generally chronic or smouldering), lymphomas and 'shared care' patients with Great Ormond Street Hospital for Children, NHS Trust. In the haematology laboratory I routinely reviewed blood film and bone marrow slides, blood test results and advised the clinical teams of CMH alongside the other Haematology consultant and junior staff, as needed.

12. Policies for the general laboratory, the clotting tests and blood bank were decided by Dr Brozovic and later Dr Kate Ryan, while I supervised the haemoglobin laboratory. When on call, Dr Brozovic, other consultant haematologists and I gave advice to our laboratory technicians and doctors in the hospital respecting the Haematology patients including those with SCD and other acute problems as they arose across CMH inpatients and the Emergency Department. When on call, we routinely attended on Saturday mornings and

often did a ward round on a Sunday in addition. From 1996 when I was seconded into R & D I stopped playing a role in the laboratory, looking after inpatients or doing on call. I continued outpatient clinics, stopping them in 2006.

13. Sickle cell disease is a family of inherited anaemias sharing at least one sickle cell gene that arose in the historically endemic areas of malaria including sub-Saharan Africa, the Middle East and India. The sickle cell gene has moved with migration of peoples across the world ever since and in Britain is most prevalent in the Afro Caribbean and sub Saharan communities.

14. The sickle gene gives rise to sickle haemoglobin as a result of a mutation in the gene changing the beta globin chain of haemoglobin. There are two genes for beta haemoglobin production, one from each parent. The normal gene gives rise to haemoglobin A, the sickle gene gives rise to HbS: When the gene from one parent is HbA and from the other is HbS then the resulting haemoglobin is AS and the person is said to have sickle cell trait. Two copies of the sickle cell gene results in HbSS known as sickle cell anaemia, one of the family of sickle cell disease.

15. Other types of sickle cell disease arise from an S gene from one parent and an abnormal beta haemoglobin gene from the other parent e.g. HbC or D, or a beta thalassaemia gene.

16. The role of haemoglobin, packaged in red blood cells, is to take oxygen from the lungs to the tissues. Sickle haemoglobin on giving up oxygen forms stiff crystals and in sickle cell disease (SS) these can distort the red blood cell into the classic sickle cell shape. These stiff red blood cells can then block small blood vessels preventing blood flow and delivery of oxygen to tissues.

17. Tissues deprived of oxygen become painful and can scar, damaging their functioning. When it happens in patients with sickle cell disease in bones and muscles it is called a sickle pain crisis. SS children are at risk of subclinical brain damage and stroke. A frequent and life-threatening complication is the sickle chest syndrome when sickling in the lungs prevents red cell uptake of oxygen - and this can result in a vicious cycle of sickling, which can be lethal. When overwhelming sickling occurs, this can result in death.

18. Treatment has always been symptomatic with intravenous fluids, effective pain relief and oxygen. In the past the only really effective treatment was to give normal HbA i.e. donated blood to ensure effective blood flow and oxygen delivery.

19. Patients with sickle cell disease have normal blood viscosity despite their marked anaemia. So, it can be dangerous to give a straightforward additive blood red-cell transfusion as raising blood viscosity carries a risk of stroke and other complications. The exception is when the patient is suffering from an aplastic crisis, almost invariably caused by parvovirus, or there is significant haemorrhage reducing the haemoglobin level.

20. When sickle cell patients need blood transfusion therefore, it is usually performed as an exchange transfusion. Now this is generally undertaken using machines but historically we did this manually: an intravenous line would be set up and the patient would have 10 to 20 mls removed and the same amount replaced with donated blood. We generally aimed to exchange between 2/3 and 1 & 1/2 times the patient's blood volume over three or four days. It is difficult because of poor venous access in sickle cell patients and it is very time consuming.

21.Some severely affected patients, including those with stroke or repeated sickle chest syndrome are treated with regular red cell transfusions (every 2 to 4 weeks) in order to maintain their HbA and suppress the production of HbS.

22. The side effects of red-cell transfusion and sickle cell patients were the risks of increasing viscosity, fluid overload, alloimmunisation, iron overload and transfusion related infection. All the severely affected patients were well aware of these risks because we explained them in both the outpatients' clinics and when they were inpatients, and there was frequent discussion within the community of the risks of transfusion. Blood transfusion in sickle cell patients was never undertaken lightly but it also saved many lives.

c. My work insofar as it involved the care of patients who were infected with HIV, Hepatitis C ("HCV"), Hepatitis B ("HBV") viruses and/or other diseases patients may have been exposed to as a result of receiving a blood transfusion

23. I can only remember one patient I cared for who had acquired HIV through blood transfusion. He was a child with sickle cell disease, (perhaps) six years old who was transfused with infected blood in Nigeria. A couple of other patients presented with low platelet counts which were found to be caused by HIV infection. Their care was taken over by the HIV specialists following diagnosis.

24. During my time at Central Middlesex Hospital we cared for over 400 patients with sickle cell disease. I remember only one sickle cell patient infected with HIV who is the patient I have previously described. I think I would remember if I had looked after other sickle cell patients with HIV and I do not recall any.

Q6. I have been asked to describe the following matters:-

a. The roles, functions and responsibilities of the Haematology Department ("the Department") within Middlesex Hospital during the time I worked there;

25. CMH was a routine district General Hospital offering routine services including accident and emergency, inpatient medicine, surgery, obstetrics and gynaecology and orthopaedics. We had specialists in gastroenterology, liver disease, diabetes, respiratory medicine, cardiology and sexually transmitted diseases among others.

26. As a result of the early work of Dr Brozovic, we were famous for our care of patients with sickle cell disease and we had one of the biggest clinics in the UK. Haematology at CMH was both a clinical specialty with inpatient beds and outpatient clinics as well as providing laboratory services alongside chemical pathology, microbiology, histopathology and pathology.

27. The services provided were routine haematology including: full blood counts, blood film and bone marrow review, clotting studies and assays, haemoglobinopathy testing and, routine blood banking in order to provide blood and blood components for the patients of CMH.

28. We held supplies of red cells for transfusion and fresh frozen plasma (FFP). We would order, as needed for individual patients, platelet concentrates for transfusion. We held no clotting factor such as Factor VIII nor, as I remember it, cryoprecipitate. I do not remember prescribing or giving clotting factor concentrates to any patients at CMH.

b. ***Please also explain how the Haematology Department worked with other departments within the Hospital, such as critical care, emergency, obstetrics/gynaecology, or surgical units in so far as it related to blood***

transfusions. In particular, please explain which Department took primary responsibility for deciding whether or not to transfuse a patient and/or the type of transfusion to give;

29. Our Haematology team took all the clinical decisions respecting haematology patients. The decisions for non-haematology patients, i.e. all the rest of the hospital patients, were taken by the clinicians in charge of those patients. We would advise when a request or referral was made and, also, sometimes we would contact clinical teams to advise depending on the laboratory tests that we saw. So, on occasions we were proactive in our advice, but the final decisions rested with the clinician in charge of the patient - including for Blood Transfusions. However, for fresh-frozen plasma or platelets to be issued / dispensed from the blood bank the haematologist on call would have had to have been involved and agreed their use.

c. ***Outline the facilities and staffing arrangements for the care of patients who needed to undergo or were undergoing blood transfusions, particularly in relation to patients with sickle cell anaemia.***

30. During the relevant period (1980 - 2020), all patients requiring blood transfusion were admitted as inpatients to the CMH wards. Our sickle cell patients were generally cared for on the same wards as our other haematology patients and the paediatric ward or, when severely ill on the intensive care unit. Sickle cell patients were rarely treated with simple additive red-cell transfusions, because of the risks of raising blood viscosity and thus causing stroke. The exception was when they suffered aplastic crises, becoming seriously anaemic. Patients with the sickle chest syndrome, stroke and other serious sickle complications were treated with exchange transfusions. This was a difficult process, because they generally had poor venous access, and a laborious process because we would need to suck out 10-20 mls of sickle blood and replace with 10-20 mls of donated blood - aiming over three days to exchange

about eight to 12 units of blood. In an adult this was undertaken by the haematology medical team and the ward nurses assisted.

d. *Identify senior colleagues within the Department and their roles and responsibilities during the time that you have worked there, insofar as they were involved with the care of patients receiving blood transfusions and/or patients infected with hepatitis and/or HIV in consequence of a blood transfusion.*

31. Dr Milicia Brozovic was Head of Department until her retirement, leading the Blood Bank. Dr Hannah Cohen was with us for a few years (she moved to St Mary's Hospital and then UCH), then Dr Kate Ryan (who moved to Manchester Royal Infirmary) who took over as Head of Department including the Blood Bank, and later Dr Jo Howard (who is now at Saint Thomas' Hospital) were the consultant haematologists over the period.

Q7. I have been asked to describe the practical steps that were taken when I decided that a patient required a blood transfusion, including:

a. *How blood was requested from the hospital blood bank; and*

b. *What the record keeping requirements were*;

32. Over the period of concern, blood tests and transfusion requests were written on standard forms, in the later years generated from the computer. The blood bank laboratory, as I remember it, recorded their work including results with requests and collections of blood manually, in books. I do not remember when the Blood Bank was computerised.

c. *What the patient was told before the transfusion.*

33. The CMH Haematology team would always discuss with our own patients and their families as appropriate, the reasons for transfusion and ensure verbal agreement. It was not standard practice at that time to go through a formal

consent process, nor to have a signed consent from the patient. I do remember discussing the pros and cons with patients and the risks.

34. One of the biggest risks for repeatedly transfused patients including sickle cell disease is that of iron overload and thus iron poisoning. We were always clear about this - as the treatment was really rather unpleasant, being 8 to 10 hour infusions subcutaneously, being at that time 5 to 7 nights each week, of desferrioxamine.

Q8. I have been asked if I had, on behalf of the Haematology Department, a relationship with the Regional Blood Transfusion Centre, and to describe that relationship, including:

a. Who within the Regional Transfusion Centre I interacted with;

35. When on call I might need advice or a specialist product from the Regional Centre e.g. special/rare red cell for an SCD patient. I would ring the 'on call' technician or consultant.

b. How frequently I interacted with them;

36. I do not remember - perhaps twice every month or so?

c. What my interactions were primarily concerned with.

37. They were primarily concerned with their specialist advice as above or for neonates needing transfusion, for instance. We were scrupulous in ensuring that we followed all British Committee for Standards in Haematology (BCSH) and British Society for Haematology (BSH) guidelines for transfusion medicine laboratory practice as soon as they were published. Dr Brozovic as head of the laboratory was in charge, working with the senior CMH Blood Bank technician.

38. I was only involved for particular patients if they were my patients, if I was on call, or if Dr Brozovic was not available. So, for instance, following a ward round I might ring up to order the platelets for transfusion for a patient with leukaemia. The blood for sickle cell patient exchange transfusions was generally ordered from our Blood Bank.

39. I think that perhaps I rang NHSBT a couple of times each month to make an order or discuss a patient - for instance one of the sickle cell patients could have had allo-antibodies which made for difficulties in transfusion.

Q9. I have been asked whether I had, on behalf of the Haematology Department, a relationship with the National Blood Transfusion Service ("NBTS")?

40. As to this, please see paragraph 8.4 and following, above.

Q10. I have been asked approximately how many patients per week would receive a transfusion under the care of the Department.

41. It would not be unusual to have two or three sickle cell patients receiving a red cell transfusion each week and a couple of leukaemia / lymphoma patients as well needing red cell or platelets.

Research

Q11. I have been asked whether any research was undertaken within the Department regarding blood transfusion patients and if so, to explain:

a. what the research entailed, what the aims of the research were, whether patients were informed of their involvement in the research and whether patients' consent was obtained;

b. What, if any, involvement I had in this research; and

c. Details of any publications relating to the research.

42. The only relevant research that I have records of and can recollect, was a paper looking at levels of red cell alloimmunisation in sickle cell disease:

Davies SC, McWilliam AC, Hewitt PE, Devenish A, Brozovic M. "Red cell alloimmunization in sickle cell disease." *Br J Haematol* 1986;63:241-245 (Exhibit WITN6929002).

43. I reviewed the patient notes and the CMH blood bank records in order to determine the prevalence of alloimmunisation in our transfused sickle cell population.

44. I was assiduous in ensuring Local Research Ethics Committee (LREC) permission when needed and seeking written consent from patients for research. However, this paper would now be considered audit performed in order to improve services. It was a retrospective review of records. There was no intervention for the patients nor randomisation. So, we would not have sought LREC permission nor individual patient permission.

Q12. I have been asked to list all research studies that I was involved with in any other relevant positions of employment relevant to the Inquiry's Terms of Reference.

45. I was not involved in any research studies in any other positions of employment relevant to the Inquiry.

Section 3: Policies and practices regarding blood transfusions

Q13. The Inquiry has asked whether guidance was provided to me and/or other medical professionals by Middlesex Hospital as to transfusion policies and practices during the time of my employment. Specifically, I am asked to:

a. outline in as much detail as possible the policies in place which would apply in relation to the use of blood transfusions; and

b. If possible, refer to how many units of blood would be used, alternative treatments, autologous transfusions, applicable haemoglobin threshold levels for transfusion, as well as any other considerations such as when not to transfuse, the risk of infection or adverse reactions, or resource and cost considerations.

46. My memory is that we used standard BCSH and BSH guidelines for our blood banking and blood transfusion. The Inquiry has provided a number of examples of such guidelines with its Rule 9 Request, including:

- NHBT0111389_001 - 'Guidelines on Hospital Blood Bank Documentation and Procedures', The British Society of Haematology (1984);
- BSHA0000031 - 'Guidelines for platelet transfusions' by the British Committee for Standards in Haematology (1992);
- BWCT0000093 - 'Guidelines for administration of blood products: transfusion of infants and neonates', British Committee for Standards in Haematology Blood Transfusion Task Force (1994);
- BSHA0000017_003 - Transfusion Medicine, 'Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories', prepared by BCSH Blood Transfusion Task Force (1996).

47. Our greatest concern was to address clinical need and generally we advised that transfusion was contraindicated when the Haemoglobin was at, or above 10g/dl. Transfusion for the patients with sickle cell disease is a specialist area and we advised many other hospitals on transfusion need for individual sickle patients.

Q14. I have been asked to outline the types of blood and blood products that were most commonly transfused to patients under my care and how this changed over time.

48. Routinely we used red cells for transfusion, often packed, platelet transfusions for leukaemia patients with counts <20 and fresh frozen plasma as required e.g. for massive transfusion following trauma such as a road traffic accident.

Q15. I have been asked whether, in my experience at Middlesex Hospital, any particular blood products or transfusion methods carried a higher risk of viral infection.

49. At CMH we used routine blood products, i.e. red cells, platelets (on order) and FFP that carried I understand, the highest risk of viral infection. We did not hold or use clotting factor concentrates or cryoprecipitate.

Q16. The IBI has asked me to outline the level at which a patient's haemoglobin count would generally be considered low and thus require a blood transfusion and to please explain:

a. How this level may have changed over time; and

50. We rarely advised red-cell transfusion if the haemoglobin was at or above 10g/dl. This level may have changed since I stopped giving general haematology advice in 1996.

b. How a patient's haemoglobin levels were monitored before, during and after a transfusion.

51. We monitored haemoglobin levels in patients before and after transfusion, allowing time post transfusion for equilibration. In sickle cell patients we additionally monitored the percentage of sickle haemoglobin.

Q17. The Inquiry has asked whether, where applicable, were alternative treatments made available to patients under the care of Middlesex Hospital throughout the time of my employment but specifically in the 1970s and 1980s; and whether:-

a. In my view, the advantages and disadvantages of alternative treatments were adequately explained to patients where possible;

b. The doctor/patient relationship had an effect on the way in which an agreement would be reached in selecting a treatment;

c. Any aspect of this changed over time;

d. How generally were transfusions regarded within the Department;

e. Alternatives could have been used in preference to blood transfusions so as to reduce the risk of infection.

52. Sadly, at that time, there were no effective alternatives to transfusion.

Q18. I have been asked what considerations were considered by the Department for the use of red blood cell concentrate transfusions and in particular:

a. In what circumstances would red blood cell concentrate transfusions be considered necessary by the Department, and if applicable, necessary over other blood components; and whether these circumstances differed for sickle cell anaemia patients.

53. Red Cell transfusions were given for acute bleeding (trauma or operative), symptomatic clinical anaemia and selectively in patients with sickle cell disease.

Standard guidelines were used, recognising that care must be taken with total blood viscosity when transfusing patients with sickle cell disease - hence the use of exchange transfusions. BSHA0000017_003, 'Transfusion Medicine', 'Guidelines for pre-transfusion, is an example of the Standard guidelines that were used. I did not routinely read the journal Transfusion Medicine, but the content is as I remember practice at that time. These guidelines refer to sickle cell disease and cross matching referred to at para 7.2.6, pg. 8. We did the checks recommended in the article.

b. The perceived benefits and/or risks of red blood cell transfusions known to the Department and how this changed over time.

54. Red cell exchange transfusions were frequently life-saving for patients with sickle cell disease and others with major haemorrhage.

c. Any measures taken by the Department to minimise the risk of infection, including post transfusion testing.

55. All blood used came from the Regional Transfusion Centre and had been tested before issue, so no extra tests were undertaken at CMH.

d. The process for obtaining informed consent and informing patients or their relatives of the risks associated with red blood cell concentrate transfusions.

56. At the time, it was not routine to record consent to transfusion by patients, but for our own haematology patients we always discussed the risks and benefit and, of course there was trust between our patients, who knew us well and the Haematology medical team.

e. How many units of red cell concentrates would be administered in one sitting to one patient, and what factors would be taken into account in determining this number?

57. A sickle cell exchange transfusion could use 8 to 12 units blood in an adult. Ideally this would be done over 3 to 4 days but, when the patient was extremely ill this could be undertaken over a single period of hours. In other patients it was rare to give more than four units of red cells sequentially.

f. The use of red cell concentrates in relation to treating sickle cell anaemia patients.

58. The use of red-cell transfusions in sickle cell disease was a specialist area and we were practised at CMH in recognising when and how to transfuse these patients.

Q19. I have been asked whether guidelines were circulated to clinicians concerning the use of red cell concentrate. I have been referred to [BWCT0000120_001], which is a set of "Guidelines for the Clinical Use of Red Cell Transfusions" from National Blood Service's Midlands and SW Zone Clinical Policies Group (March 1999, Issue 1).

59. I was not in charge of the transfusion laboratory from 1996 (and in 1999 was a Director of R & D, DHSC) so I do not recall whether these guidelines were circulated at CMH, but I would be surprised if they were not because we were scrupulous in adhering to National guidelines. Since I was not in post, I would not be able comment if any changes were made as a result of them.

Q20. I have been asked to consider [NHBT0113679_002] and to outline:

a. Whether you used platelet concentrates to treat patients;

60. Platelet concentrates were only used in patients at CMH when clinically indicated. Platelet concentrates were only transfused if the platelet count was

under 20 in leukaemia patients or in cases of massive bleeding with low platelets. The Inquiry has referred me to [BSHA000031]. These are Guidelines for platelet transfusion by the British Committee for Standards in Haematology, from 1992. They are an example of the guidelines which would have been followed in the Department.

b. How often patients would require a transfusion of platelet concentrates.

61. The frequency of platelet transfusions depended on the platelet count, the presence of bleeding or petechiae and the stage of their treatment. It was rare to use platelet transfusion more frequently than daily.

b. The perceived benefits and/or risks of platelet transfusions known to the Department and how this changed over time.

62. The objective of platelet transfusions was to prevent serious including life threatening bleeding. The risks included allo-immunisation and, potentially blood born infections.

c. Whether full testing was undergone before administering platelet concentrates;

63. Platelet concentrates were received fully tested from the Regional Transfusion Centre (RTC).

64. I have been directed by the Inquiry to consider NHBT0113679_002. This is an appendix to another document, which the Inquiry has not provided. It is undated but appears to date from 1985, probably before October 1985. It is not clear whom the author is, but it refers to the practice of the Transfusion Service in the Manchester area and surroundings. The author highlights that in *"recent"* years, increasing use has been made of platelet concentrates (particularly to treat bleeding in leukaemia patients). The author's concern is that platelet

concentrates have not been tested for anti-HTLV III. In the author's view *"it [was] still justified in serious cases of haemorrhage to issue untested treatment"* but that with respect to *"the planned prophylactic transfusions"*, should platelet concentrates subsequently be found to be positive for anti-HTLV III and the virus transmitted to the patient, the RHA may find itself suffering litigation.

65. I do not remember seeing this document which appears to have been written in the year that I was appointed as a consultant. Dr Brozovic, now deceased, was in charge of the CMH blood bank. I can say that in relation to CMH my experience was all transfusion products were supplied from the RTC and therefore were tested prior to CMH receiving them. Moreover, we tried to reduce platelet use in all patients to the minimum possible.

e. How you or the Department knew or could have known whether the platelet concentrates being administered to patients had undergone full testing.

66. Testing by the Regional Transfusion Service was according to standard national protocol.

f. How many units of platelets would be administered in one sitting to one patient, and what factors would be taken into account in determining this number?

67. I cannot remember the standard number of platelet packs used for transfusion but that number would only be exceeded in the presence of refractoriness i.e. poor response.

g. Was there ever any difficulty in obtaining platelets?

68. The Regional Transfusion Service was generally able to supply the small number of platelet transfusions needed for CMH patients. There were occasional

problems in accessing enough platelets over long bank holiday weekends, Christmas etc.

Q21. I have been asked what considerations were taken into account by the Haematology Department for the use of FFP transfusions, and in particular:

a. In what circumstances would FFP transfusions be considered necessary by the Department and if applicable, necessary over other blood components.

69. I do not remember using FFP frequently at CMH. FFP was used when a patient suffered a massive bleed and needed a massive transfusion and on occasions in the presence of disseminated intravascular coagulation (DIC) or thrombotic thrombocytopenic purpura (TTP).

b. ***The perceived benefits and/or risks of FFP transfusions known to the Department.***

70. FFP contains normal levels of blood clotting factors, albumin etc. The risks were those of fluid overload and blood-borne infections.

c. ***Any measures taken by the Department to minimise the risk of infection, including post transfusion testing.***

71. At CMH, we were always keen to minimise the use of blood and blood component transfusions. We did no extra testing of the blood components and supplied it as it had been tested by the RTC.

d. The process for obtaining informed consent and informing patients or their relatives of the risks associated with FFP transfusions.

72. Most FFP was used in an emergency and patients were often unconscious. If there was time and opportunity then the clinician in charge would have discussed its risks, as for red cells, with our patients or any next of kin that had been reached e.g. parents.

e. How many units of FFP would be administered in one sitting to one patient, and what factors would be taken into account in determining this number;

73. FFP carries the risk of infection, fluid overload and immunisation against protein, so our objective was to use, or dispense the minimal dose possible. I am unsure of numbers of packs uses in different circumstances, given the passage of time and that it was infrequently used.

Q22. I have been whether guidelines were circulated to clinicians concerning the use of FFP, and if so, did the usage pattern of FFP change as a result of these guidelines.

74. I am sorry that with the passing of time, I do not remember. The Inquiry has referred to NHBT004535_004, an article by Hannah Cohen, Senior Lecturer in haematology at St Mary's Hospital Medical School, titled, 'Avoiding the misuse of Fresh Frozen Plasma' published in British Medical Journal (1993). The Article's sub-hearing is *"No scientific basis for most of is uses; hospital transfusion committees should draw up guidelines"*. The article notes that the use of fresh frozen plasma had increased ten-fold in the past 15 years and that studies had shown that it was often misused. The advice and views expressed by Dr Cohen in this article accord with my memory of practice at CMH. Dr Cohen was a Haematology Consultant at CMH for a few years; I think in the early nineties, prior to this publication.

Q23. I have been asked to consider document [DHSC0035471] which discusses concerns about unnecessary single unit transfusions of blood in the UK and to consider the following:

a. ***With reference to my experience at Middlesex Hospital and in any other relevant roles, to outline in what circumstances single-unit and two-unit transfusions were administered to patients. Did these circumstances differ for sickle cell anaemia patients?***

b. ***What I understood to be the risks and benefits of single-unit transfusions and two-unit transfusions and how, if at all, did this understanding change over time;***

c. ***Approximately how often single unit transfusions would be administered.***

d. ***The use of single unit transfusion in relation to treating sickle cell anaemia patients.***

75. At CMH we did not use single unit transfusions.

Q24. The Inquiry has referred to a study titled 'Autotransfusion, an experience of seventy six cases' (1986) which states that a primary benefit of autologous transfusion is 'the absence of risk of transmission of blood borne infection' [RLIT0000485]. I have been asked to explain my knowledge and experience of autologous blood transfusion, including: the circumstances in which it was considered appropriate and any benefits or risks as compared to other methods of transfusion; as well as:

a. ***The circumstances in which autologous transfusions were considered necessary or beneficial.***

b. ***Approximately how often this practice occurred;***

c. ***The perceived benefits and/or risks of autologous transfusions; and***

d. The process for informing patients or their relatives of the risks associated with autologous transfusions.

76. At CMH we did not do autologous transfusions. We did not have in place the necessary infrastructure.

Q25. The Inquiry states that it has received evidence that on some occasions when a blood transfusion was needed urgently, fresh warm blood donated by hospital staff or other local authorities was administered to patients. I have been asked whether, to my knowledge, this practice occurred at Middlesex Hospital and if so to explain in as much detail I can, ensuring that my answer addresses:

a. The circumstances in which fresh warm blood transfusions were considered necessary.

b. Approximately how often this practice occurred;

c. The perceived benefits and risks of fresh warm blood transfusions. You may wish to refer to [NHBT0000037_013, page 8];

d. Any measures taken to minimise the risk of infection, including assessing donor suitability and post transfusion testing; and

e. The process for obtaining informed consent and informing patients or their relatives of the risks associated with fresh warm blood transfusions.

77. Over the time I was a Haematology Consultant at CMH we never bled a donor or used 'fresh warm blood', that I can recall.

Q26. I have been asked, with reference to any of the groups outlined in Question 3, to identify any significant policies relating to blood transfusion practice created by those groups in which I was involved, insofar as relevant to the Inquiry's Terms of Reference.

78. I was never a member of working parties writing guidelines for transfusion medicine, so this question is not applicable.

Q27. I am further asked, by reference to all of the committees named in my answer to Question 3, to outline the extent to which any of those committees were involved in the following matters:

a. ***Awareness of national guidelines for promotion of good transfusion practices;***

b. ***Development of local hospital guidelines on blood transfusion;***

c. ***Transfusion policy induction procedure for new staff;***

d. ***Review of nursing procedures for administration of blood and blood products;***

e. ***Promotion of new information regarding transfusion matters;***

f. ***Ensuring patients are adequately informed of matters relating to blood transfusions, such as availability of alternative treatments;***

g. ***Blood transfusion record keeping and documentation;***

h. ***Review and notification of post transfusion complications (included adverse reactions and transfusion associated infections);***

i. ***Assessment of transfusion practices in light of product usage; and***

j. ***Consent for blood transfusion.***

79. My answer is as given at Q26 above and so this is not applicable.

Q28. Asks me, with reference to all of the committees named in my answer to question 3, to outline any specific transfusion policies created by those committees in relation to:

a. ***Obstetrics;***

b. ***Trauma and emergency care;***

c. Surgery;

d. Haematological cancer treatment;

e. Thalassaemia; and

f. Sickle Cell Anaemia.

80. For the reasons explained already this is not applicable.

Q29. I have been asked whether there was there a Hospital Transfusion Committee at Middlesex Hospital and, if so, insofar as I am able:

a. To provide a brief overview of the Committee, including when the Committee was created, its roles and responsibilities at Middlesex Hospital, and its relationship with the (Haematology) Department at Middlesex Hospital.

81. I do remember that a Hospital Transfusion Committee was set up at CMH, but I cannot remember when. I have explained at the beginning of this statement that I hold no papers from CMH and have not been supplied with any for this statement.

b. With reference to any of the matters identified in Question 27 of this request, please outline any significant policies or practices established by the Committee.

82. Relevant papers from CMH would need to be found and reviewed for an accurate answer to this question.

c. Please explain the relationship between the Hospital Transfusion Committee and the Regional Transfusion Centre.

83. I do recollect that there was a member of the committee from the RTC.

Q30. The Inquiry has noted that during Parliamentary questions on 10th December 1985, Mr Hayhoe stated that *'supplies of whole blood are not*

imported since the United Kingdom is self-sufficient in its needs for blood for transfusions; it is only certain blood products which are imported' **[HSOC0018830]. I have been asked whether, to my knowledge, was the UK self-sufficient in its need for whole blood for transfusions; and whether during my tenure at Middlesex Hospital, I was aware of patients being given blood transfusions with red blood cells imported from the USA. Further, if so, was there any concern about its use at the time.**

84. I believed that the UK was self-sufficient for whole blood for transfusions.

I was unaware of any blood transfusions with red cells imported from the USA. I do think there would have been concern with imported red blood cells from the USA because their blood supply was not all given altruistically, as in the UK; that is, some donors were paid or possibly even coerced.

Section 4: Knowledge of risk

General

Q31. I have been asked, when I began working at the Department (i.e., at CMH), what I knew and understood about the risks of infection associated with blood transfusions; and what were the sources of my knowledge. I have further been asked how my knowledge and understanding developed over time.

85. My knowledge about infections in the blood supply came initially through my training as donations were tested for hepatitis B and we were aware of non-A, non-B hepatitis. Over time, my knowledge increased as I read medical journals including the BMJ, British Journal of Haematology and I attended British Society for Haematology education meetings and other continuing medical education sessions including briefings from the NHSBT. I did not generally read the specialist transfusion journals, but I ensured that I kept abreast of the understanding that was relevant to my practice as a haematologist in a District General Hospital.

Q32. Asks what was my knowledge and understanding of the risks and transmission of hepatitis, including HBV and HCV from blood transfusion; what were the sources of my knowledge; and how did that knowledge and understanding develop over time.

86. As paragraph 31.2 above. Generally, my focus was upon on sickle and transfusion reduction. I took the view that experts were ensuring our blood supply was as low risk as possible.

Q33. I have been asked, when I began work at the Department (at CMH), what my knowledge and understanding of HIV and AIDS, and in particular of the risks of transmission through blood transfusions was; and how that knowledge and understanding developed over time.

87. As paragraph 31.2 and 32.2 above. As a District General haematologist, I was aware of the risk of blood transfusions transmitting infection. I therefore tried to minimise the use of blood components at CMH. I have always looked to the experts in this field to guide my work.

Q34. The Inquiry has asked, if I was responsible for making decisions and actions on behalf of the Department in response to any known or suspected risks of infection, to explain what decisions were involved.

88. At CMH we followed national guidelines and only used blood from the RTC which had been tested routinely according to national guidelines. I have been asked if I consider that the decisions made were adequate and appropriate: as haematologists we tried to ensure transfusions of red cells and components were only used when really clinically necessary throughout the hospital i.e. transfusion reduction.

Q35. The Inquiry has asked whether any audits or surveillance programmes regarding the use of blood transfusions by the Department were conducted at the Middlesex Hospital.

89. I do not remember any further transfusion audits apart from the one I reported at paragraph 11.2.

Q36. I have been asked whether the Hospital had any procedures in place to ensure patients reported any adverse reactions or symptoms and if so, please explain:

a. What procedure did the Hospital have in place?

90. Patients receiving transfusions were in-patients over this period, therefore, any adverse reactions or symptoms were highlighted to nurses, who reported them to medical staff and ensured recording in the medical notes. The haematologist on call was contacted if there were significant problems.

b. Did this procedure extend to after a patient had been discharged from Hospital?

91. Patients were able to report adverse events at follow-up.

c. Were patients asked to report any adverse reactions or symptoms within a certain timeframe?

92. I do not remember this being normal practice at that time.

d. If clinicians were informed and/or became aware of a patient having suffered any adverse reactions or symptoms, who were they required to report this to?

93. Adverse events were expected to be reported to the Blood Bank or the haematologist on call.

e. Was there any mechanism for the Hospital to report any adverse reactions or symptoms to the Regional Transfusion Centre?

94. Significant adverse events were always reported through the Blood Bank to the RTC.

f. In the event of a patient's death after receiving a blood transfusion, what process was followed? Specifically, in relation to the registration of the death and/or any consideration of what was recorded on the death certificate.

95. I cannot remember a patient dying where we thought the cause was related to the blood transfusion, rather than the blood transfusion being used to try and save the patient. If there had been a massive adverse event, e.g. the wrong ABO blood-group transfusion, we would have reported this to both RTC and the Coroner, if the patient died.

Section 5: Treatment of patients

Q37. Asks if I was involved in discussions with patients regarding risks of infection by blood transfusion and if so, what information did I provide or cause to be provided to patients under my care at the Department about those risks prior to treatment commencing.

96. I remember frequent discussions with sickle cell patients about the risks of acquiring HIV infection through blood transfusion when abroad, particularly in Africa.

Q38. If the nature of the provision of information changed over time whilst at the Department, I am asked to explain how this was so and why changes were made.

97. The risks of HIV infection from blood transfused in low-income countries e.g. many countries in Africa, have risen over time and then reduced as HIV testing of transfusion products has been brought in in these countries. I do not know the present state of play.

Q39. I have been asked whether the Department had a process of informing patients that they had been or might have received infected blood through a transfusion; and if so, how were patients and/or their relatives informed.

98. I can remember only one case of a possible patient infection from a blood product: a baby who had had a very low platelet count at birth, who was treated with high dose intravenous immunoglobulin made from pooled plasma. One donor to the pool died sometime later with Creutzfeldt Jacob disease, I think not new variant type. I contacted the mother, met her and counselled her. I ensured there was documentation on the child's medical notes for the future. CMH also had a few patients involved in "look back studies" led by the RTC, but I do not remember being involved in any of these.

Q40. Asks whether blood samples taken from patients under the care of the Department and if so, for what purposes; was this information shared with patients; was patient consent recorded and if so, how and where.

99. The only blood samples taken from haematology patients were either routine for their care or as a part of Local Research Ethics Committee agreed research to which each patient gave written consent.

Q41. Are you aware if patients under the care of the Department were treated with blood transfusions without their express or informed consent? If so, how and why did his occur?

100. No, I am not aware of patients transfused against their wishes or without their consent (unless unconscious, in emergency circumstances).

Q42. To the best of your knowledge, were any patients under your care or the Department's care infected with HIV as a consequence of a blood transfusion? If so, how many?

101. Please see the answer to Q44 below.

Q43. Are you aware if the Department tested patients for HCV? If so, please describe the process at the Department for HCV testing, including pre-test and post-test counselling. What was your involvement in this process?

102. No routine tests were instigated at CMH over that period for patients with HCV that I am aware of.

Q44. For patients who had contracted viral infections through blood transfusion or any other means, how did their infective status affect your practices and the treatment you were able to provide?

103. The only patient I am aware of, that I looked after who contracted viral infection through blood transfusion was the child with sickle cell disease and HIV transfused in Nigeria. When in Britain and under my care I treated him as other children with the same clinical problems.

Q45. How was the care and treatment of patients with sickle cell anaemia and or thalassaemia who also had HIV managed within the Department? In particular:

a. *What steps were taken to arrange for, or refer patients for, specialist care?*

104. We had no thalassaemia major patients at CMH, just a large sickle cell clinic. At that time we saw occasional other patients from sub-Saharan Africa with low platelet counts, who we would then refer to the CMH specialists for HIV for counselling and testing - and a few of them were diagnosed with HIV infection.

b. *What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?*

105. All patients at that time with HIV or hepatitis were looked after by specialist clinicians.

Q46. How was the care and treatment of patients with sickle cell anaemia and or thalassaemia who also had HCV managed within the Department? In particular:

a. ***What steps were taken to arrange for, or refer patients for, specialist care?***

b. ***What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HCV?***

106. I am not aware of any of our patients at that time who had HCV but all patients were always referred to the CMH specialists for management of any non-haematological problems.

107. After such a long time it is difficult to be definitive, but I have no memory of any of the CMH sickle cell clinic patients being contacted during the national HCV lookback. Nor do I remember any of the sickle cell patients having Hepatitis C acquired from blood transfusion.

Q47. How was the care and treatment of patients with sickle cell anaemia and or thalassaemia who also had HBV managed within the Department? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?

b. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HBV?

108. I do not remember any of our sickle cell disease patients being diagnosed with HBV, but all patients were always referred to the CMH specialists for management of any non-haematological problems.

Section 6: Your Role as Chief Medical Officer

Q48. I have been asked to describe my understanding of:

a. Your role and responsibilities as CMO and how these changed over time.

109. In 2010 I was appointed interim Chief Medical Officer (CMO) following the general election. I was then offered and accepted the substantive CMO role, joining the civil service at Permanent Secretary level in 2011. This was following an open competitive process, run by the Civil Service Appointments Commission. I was CMO for England (there are CMOs in the three devolved Administrations: Scotland, Wales and Northern Ireland) and I was the senior medical advisor to the UK government. I also represented the UK in Global Health, for instance joining the World Health Organisation (WHO) Executive Board, representing the UK.

110. My role as CMO was primarily advisory across Government to Ministers and policy teams on issues relating to health generally and global health. I was required to author an independent CMO Annual Report on the state of the nation's Health. I also, at the request of Ministers authored three special reports on: the role of technology platforms in children's mental health; the legalisation of marijuana within a clinical context; and obesity in children:

- "Cannabis Scheduling Review part 1: the therapeutic and medicinal benefits of cannabis-based products" (3 July 2018)[1]
- United Kingdom Chief Medical Officers' commentary on "Screen-based activities and children and young people's mental health and psychosocial wellbeing: a systematic map of reviews"[2] (7 February 2019)
- "Time to Solve Childhood Obesity: An Independent Report by the Chief Medical Officer" (October 2019)[3] .

[1] https://www.gov.uk/government/publications/cannabis-scheduling-review-part-1

[2] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/777026/UK_CMO_commentary_on_screentime_and_social_media_map_of_reviews.pdf

[3] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/837907/cmo-special-report-childhood-obesity-october-2019.pdf

111. For the Prime Minister I led work, authored by the experts on safe drinking guidelines for the four CMOs; I chose the committee chairs and in discussion with them the committee members, followed by arranging expert peer review. As four CMOs we also appointed an expert committee to advise on and write the expert guidelines on physical activity for the UK.

112. An important part of my advisory role was to join, as necessary Cabinet Office Briefing Room (COBR) meetings on emergencies. To play this role effectively I was security checked and trained in the processes. During emergencies, if there was a health aspect then I generally (for those issues) co-chaired the Scientific Advisory Group for Emergencies (SAGE) alongside the Government Chief Scientific Advisor (GCSA). I also, during emergencies would convene and chair health and service-related meetings, bringing the appropriate experts together and coordinating advice into Ministers - supported by the appropriate DH team and bringing in external experts as necessary.

113. I did little with the NHS as the Lansley 2011 reforms separated them from the DH and gave them a senior Medical Director, but I reserved the right to advise, comment, quiz etc as necessary.

114. As an independent senior doctor, the CMO also has an important role in public communication, particularly when there are problems and in emergencies e.g., the annual flu vaccination program and the regular 'stop smoking' campaigns. The CMO in this role is sometimes referred to as the "Nation's Doctor'.

115. My predecessor CMO, Professor Liam Donaldson had a broad managerial role within the Department of Health and took a significant role in the NHS, working particularly on patient safety. My only managerial role was to continue, until 2016, the R & D portfolio, including as Director of the NIHR.

b. The role of a CMO during a public health emergency.

While I was CMO there were three public health emergencies:

a) Wave 3 of the 2009/10 flu pandemic in the winter of 2010/11
   Here, my role was primarily that of reviewing data and explaining to Ministers what was going on and advising on the need for vaccination as well as public communication;

b) The West African Ebola outbreak in 2014/15 when Britain, at the request of the WHO led the response in Sierra Leone. I advised on the inside UK preparation and response both from a public health and NHS perspective. I also interacted with WHO on behalf of the UK.

c) The Novichok poisonings in Salisbury. Again, in the emergency I advised on the Public Health risk and response.

c. The role of a CMO in providing information and/or advice and/or guidance to clinicians.

116. The role of the CMO is of leadership and predominantly focuses on policy and advice into government; whereas guidelines are prepared by experts including from specialist societies, NICE and the NHS Executive (who also do the logistics).

117. An example of this distinction was with marijuana where: I authored a report for the Home Secretary; the Home Secretary took a decision to change the legal status for medical reasons; and Paediatric Epilepsy experts wrote the guidelines for when to use marijuana as treatment. The NHSE meanwhile, arranged the

process for importation, licensing, prescribing and dispensing. We worked as a 'system' to improve patient outcomes.

Q49. I have been asked to describe in broad terms the interactions between a CMO and Ministers, including when and how a CMO tended to, and was expected to, interact with Ministers, the nature of such interactions and the role of the CMO when interacting with Ministers.

118. I interacted regularly and quite frequently with Ministers, generally either the Secretary of State for Health or the Public Health Minister; but also the Home Secretary, Agriculture Minister, Transport Secretary, Foreign Office and Development Secretaries.

119. Ministers could ask my advice on an issue, there would be meetings where I, they or the policy teams thought my input would be useful, and there would be times when I would ask for a meeting on a subject or a one-to-one.
I and my CMO support team, including Deputy CMOs, Private Secretary and Assistants (13 in total) would be in daily contact with Ministers' Private Offices, senior Private Secretaries and teams. I would, as I judged needed, call expert discussion meetings and workshops both to feed into my advice as CMO and to prepare my CMO annual reports.

120. My role was to advise Ministers and the public without fear, based on the evidence as I understood it. It is the Ministers' and Government's role to decide and take the final decisions on policy. Meetings were always respectful and cordial on both sides.

Statement of Truth

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

Signed GRO-C

Dated February 7, 2022.

Exhibits

Exhibit number	Date	Description
WITN6929002	17/09/1985	British Journal of Haematology, 'Red cell alloimmunization in sickle cell disease', by Sally C. Davies, A. C. McWilliam, Patricia E. Hewitt and A. Devenish, 1986