Witness Name: Professor Sir Magdi Yacoub
Statement No.: WITN4129001
Exhibits: WITN4129002-6
Dated: 26 October 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR MAGDI YACOUB

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 23 November 2020. Due to ill health I was not able to provide this statement earlier for which I apologise. I would also like to express my sympathy for those who are and have been infected and affected due to the matters which are being investigated by this Inquiry. I have the utmost respect for the Inquiry and I hope that its outcome can not only provide explanations to those affected but also bring about positive and constructive recommendations for the future beneficial management of patients and their care.

I, Professor Magdi Yacoub, will say as follows: -

Section 1: Introduction

1. Name: Magdi Habib Yacoub
   Address: GRO-C
   Professional Qualifications:
   Bachelor of Medicine. MBBCH
   FRCS England
   FRCS Edinburgh
   FRCS Glasgow
   MRCP

FRCP

FRS

Membership of committees, associations, parties

Relevant to the Inquiry's Terms of Reference?Member of Society of Thoracic Surgeons.

Fellow of the Royal Society of Medicine

Fellow of the Royal College of Surgeons

Fellow of the Royal College of Physicians

Fellow of the Royal Society

Society of Thoracic Surgeons of Great Britain and Ireland.

Fellow of the Thoracic Surgeons of Edinburgh, Glasgow.

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

2. I have not been involved in any such enquiries.

Section 2: Your roles at the Harefield and Royal Brompton Hospitals

Roles, Functions and Responsibilities at Harefield Hospital.

5. Please outline the roles, functions and responsibilities you had at Harefield Hospital during your period as a consultant cardiothoracic surgeon, including any management responsibilities for other clinicians.

3. I was a consultant Cardiothoracic Surgeon at Harefield Hospital from 1969 to 2001.

4. I was director of Paediatric and Adult Cardiothoracic Surgery and director of heart-lung transplantation. I was working with a team of Senior Registrars, 2 Registrars and 2-3 housemen who worked in my department. I was leading the development of the cardiac surgical department which was evolving over time as a relatively new discipline in heart and heart-lung transplantation, as a result protocols were evolving all the time.

6. Please outline the management structure at the Harefield Hospital including how, as a senior clinician, you were managed.

5. Management Structure at Harefield. Mr John Hunt was the CEO of the hospital and Dr Rosemary Radley Smith was the medical director.

7. Please outline the roles, functions and responsibilities you had at the Royal Brompton Hospital during your period as a consultant cardiothoracic surgeon, including any management responsibilities for other clinicians.

6. My role at the Royal Brompton Hospital was a Consultant Cardiothoracic Surgeon, working with a team of paediatric and adult cardiac surgeons. I was responsible for a team of senior registrars and registrars and housemen.

8. Please outline the management structure at the Royal Brompton Hospital including how, as a senior clinician, you were managed.

7. I was reporting in to the Medical Director of the Royal Brompton Hospital. Harefield and the Royal Brompton merged into one NHS trust in 1998.

Section 3: Knowledge of, and response to, risk of blood borne infections

Knowledge of risk

9. **When you began work as a cardiothoracic surgeon, what did you know and understand about the risks of infection associated with blood transfusion and,**

in particular, the risks of infection with (i) HBV (ii) HCV (also referred to as Non-A, Non-B Hepatitis) and (iii) HIV? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

8. I was aware of the risks of infections associated with blood transfusion – HBV, HCV and HIV and blood reactions from the medical literature. My understanding developed over time from the scientific literature. I also relied on the experience of the haematology team who supplied the blood.

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

9. AIDS was not discovered when we were working in the 1960s and 1970s. I became aware of an association of AIDS and the use of blood in 1983 when the disease was discovered.

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

10. My understanding of the nature and severity of the different forms of blood borne viral hepatitis evolved over time, learning from the different specialities and the medical literature.

12. What advisory and decision-making structures were in place, or were put in place at (i) the Harefield Hospital and (ii) the Royal Brompton Hospital, to consider and assess the risks of infection with hepatitis and/or HIV associated with blood transfusion?

11. I am asked about matters which are perhaps at least 23 years and as much as 38 years ago from the documents that have been supplied with the Rule 9 request. I am sorry but I cannot now recall at 86 years of age whether I saw these documents or whether I knew about the details of any Advisory and

Decision-Making Structures to assess the risks of infection with Hepatitis and/or HIV associated with Blood transfusion. More specifically:

(i) I do not recall the details of the Advisory and Decision-Making Structures that were in place at Harefield Hospital to assess the risks of infection with Hepatitis and/or HIV associated with Blood transfusion.

(ii) I do not recall the details of the Advisory and Decision-Making Structures that were in place at the Royal Brompton Hospital.

13. What, if any, enquiries and/or investigations did you, or the above hospitals, carry out, or cause to be carried out, in respect of the risks of the transmission of hepatitis or HIV through blood transfusion? What information was obtained as a result?

12. I understand that a Hepatitis C Look Back Study was set up at Harefield Hospital by the blood transfusion department. I do not recall details of this or of the studies at the Brompton Hospital.

14. What decisions and actions were taken at (i) the Harefield Hospital and (ii) the Royal Brompton Hospital and/or by you to minimise or reduce exposure of your patients to infection from blood transfusions?

13. I am aware that actions were taken at Harefield Hospital from June 1987 onwards where blood donors were tested retrospectively for viral serology. The vast majority of donors were tested prior to giving blood as well as after donation. This, however, was limited to the infections such as Hep B and Hep C. I am not aware that any of the blood that was tested came back as positive for these blood borne viruses.

14. I am not aware of what specific steps were taken at the Royal Brompton.

Response to risk

15. Did you take steps to ensure that patients were informed and educated about the risks of being infected with hepatitis and HIV as a result of being transfused? If so, what steps did you take and in particular did you give this information prior to treatment being carried out?

15. I cannot recall the general discussions that would have been had with patients about the risk of transfusion. These discussions would either have been through a member of the surgical team or the anaesthetic team (more probably the latter). Discussions that the surgical team would have had with the patients would have been related to the patient's severe cardiovascular disease at the time, the risk-benefit ratio of the operation and consenting to complex surgery.

16. In relation to the use of Fresh Warm Blood, at the time that it would become apparent that this was needed, the patient would be in the operating room with the operation already being performed. These operative procedures would have been for very complex cardiac conditions. Some of these patients would have been refused surgery in other centres due to the risk of surgery. I was known to operate on these types of complex patients. During the operation the patient would have continued to bleed profusely usually from everywhere (a medical rather than a surgical bleed). This would result in haemodynamic instability with a high risk of imminent death. At that point, in order to alter the outcome, to save the patient's life, I would use fresh warm blood. The alternative would have been to give up on the patient. At this point there would have been no opportunity to discuss the potential risk of infection related to the use of fresh warm blood.

17. Out of 20 to 25,000 operations which I was involved in over my career until I retired from the NHS in 2001 I estimate that fresh warm blood was used in approximately 150 procedures and therefore the percentage of patients that were treated with fresh warm blood was extremely low at approximately 0.7%. As the percentage of patients where fresh warm blood was extremely low, the need to use it was unknown before the procedure had started, the need to use

it was a matter of preserving life in extremis, and the risks of using fresh warm blood was low against the benefit of survival from its use.

18. As the use of fresh warm blood was a rare occurrence, I did not consider it necessary to discuss the issue of blood during the consent process. We were focusing on the consent to a complex cardiac procedure.

16. Do you consider that your decisions and actions, and the steps taken at (i) the Harefield Hospital and (ii) the Royal Brompton Hospital, in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

19. Yes. I refer to my answer to question 15.

20. In relation to the use of fresh warm blood, the pool of donors included hospital staff who were regularly tested for their work and would be responsible enough to volunteer if there were any issues in relation to them donating blood. The remainder was from the local police and the local RAF base. This was a completely different cohort to that from which blood was sourced for blood products from the US. Further this cohort donated their blood without charge to help patients in extremis.

21. A blood donor questionnaire was developed by the haematology department. Although I did not take the fresh warm blood myself (this would be the cardiac team with the haematologists) the donor questionnaire would be completed to assist with general suitability, blood type etc. This cohort of professionals were from a low risk group.

22. I therefore used my judgement as an experienced cardiac surgeon to weigh what I thought were the very low risks of using this blood against the very high risk of these specific patients dying unless this type of blood was given.

17. Looking back now, what decisions or actions by you and/ or at (i) Harefield and (ii) the Royal Brompton Hospital could and/ or should have avoided or brought to an end earlier, the use of infected blood?

23. I was not aware that infected blood was being used. I was focusing on the life and death of my patients at the time. Consent forms and questionnaires for donors were put into place by the Haematology department as I refer to above when we used fresh warm blood.

24. There was assistance from the haematology department to type the blood and cross match for these very rare operations where I decided that we needed to use fresh warm blood.

25. I am not aware that any of these patients were infected by the use of fresh warm blood.

Section 4: Clinical practice

General

18. Please set out how frequently in your clinical practice you transfused patients with blood or blood components and over what time period.

26. This is documented by the haematology department. I cannot remember the details so many years later.

19. **What national or regional policies, guidance, standards, or protocols were in place during your time at (i) the Harefield Hospital and (ii) the Royal Brompton Hospital that governed blood transfusions and in particular the use of fresh warm blood? Did these change during your time as a clinician? If so, how? Were these policies/guidance/standards/protocols advisory or binding upon you?**

27. I am asked about matters which are perhaps at least 20 years and as much as 40 or so years ago. I am sorry but I cannot now recall at 86 years of age whether I saw any national or regional policies, guidance, standards, or protocols that were in place during my time at (i) the Harefield Hospital and (ii) the Royal Brompton Hospital that governed blood transfusions and in particular the use of fresh warm blood. I can say that I was never prevented from using fresh warm blood when the need arose in 0.7% of my cases at these institutions or throughout my career and assistance was provided in the obtaining and use of fresh warm blood by the haematology department.

20. To the best of your knowledge, what policies, guidance, standards, or protocols were formulated at (i) the Harefield Hospital and (ii) the Royal Brompton Hospital with regard to the transfusion of blood and in particular fresh warm blood for your patient group during the time that you worked there? What if any involvement did you have in the formulation and application of these policies? You may wish to refer to the 'Interim Arrangements' issued by Mr Cosgrove on 11 November 1985 (NHBT0085683_003).

28. I refer to my answer to question 19 above. I was not involved in the formulation and application of the policies. I cannot remember whether I was aware of the interim arrangements for the use of fresh donor blood as stated by Mr Cosgrove on 11 November 1985. I am now 86, I have been retired from the NHS for 20 years and these interim arrangements are dated almost 36 years ago.

21. **Did you consider it necessary or appropriate to comply with any of the policies, guidance, standards or protocols in place? Were there circumstances when you decided to deviate from them? If so, what were those circumstances? You may be assisted by the document titled 'Interim Arrangements issued for the National Heart Hospital' dated 11 November 1985 (NHBT0085683_003), Mr Cosgrove stated that "all blood will be tested prior to transfusion for HTLV III antibodies" and "no member of hospital staff, without exception, will be used**

as a fresh source of untested blood." and the correspondence at (NHBT0085683_002) and (NHBT0085683_001).

29. I refer to my detailed answer to question 15. Mr Cosgrove was a hospital administrator. Surgeons (in contrast to the haematologists) had a view that there were benefits to the chance of survival of a small number of extremely sick surgical patients if fresh warm blood was used in the surgery. I had to put patient survival first. As I have said the donor pool was small, I believed that there was no other option in these rare circumstances. I believe that other surgeons were following the same practice, however I do not have names.

Practice of Using Fresh Warm Blood

22. The Inquiry understands that, during your time as a consultant cardiothoracic surgeon, you used fresh and/or unscreened and/or untreated (to inactivate viruses) warm blood ('fresh warm blood') in cardiothoracic surgeries where patients did not respond to standard blood component therapy. Is this correct? Please provide a detailed account. Please list the hospitals where and the time periods when you undertook this practice.

30. I refer to my detailed answer to questions 15 and 16 above. Beyond this I cannot recall where and when such practice was undertaken.

23. How many patients have you transfused with fresh warm blood? You may find the minutes from a meeting of the Harefield Hospital Blood Transfusion Committee on 18 June 1997 (RBHT0000006) useful in answering this question.

31. I refer to my detailed answers to questions 15 and 16. I do not recall the exact number of patients who received fresh warm blood, but I would approximate it to 150 patients out of the 20 to 25,000 surgical procedures that I was involved in which is about 0.7%. I have read the enclosed minutes from 18 June 1997 (RBHT0000006). I was not a member of this committee and I apologise I do not recall the matter raised in paragraph 4 of the minutes 24 years on.

24. Please describe the situations where you decided to use fresh warm blood and why you did so. Has your view changed over time? You may be assisted in answering this question by the letter you wrote on 4 March 1986 (NHBT0085683_002) in response to Dr Costello's letter of 18 February 1986 (NHBT0085683_001) in which you mention that "there are desperate situations where it is absolutely necessary to use fresh blood".

32. Please see my detailed answers to questions 15 and 16.

25. Please explain, as far as you are able, what you understood to be the clinical benefits of using fresh warm blood in cardiothoracic surgery, and the appropriate circumstances for using fresh warm blood, referencing medical journals, articles or other scientific literature where appropriate.

33. This belief stems from the fact that fresh warm blood contains all the cellular and humoral components necessary for blood clotting in appropriate proportions if blood is separated into components this misses out (some of) those components which promote clotting. My experience is that the use of components is not equal to the efficacy of fresh warm blood in these desperate situations. Whatever is done with components, this does not control bleeding in these cases. There have been publications showing improved outcomes following open heart surgery in critically ill patients, particularly in infants and neonates. Please see Exhibit WITN 4129002 attached.

34. My own observations have been that when fresh blood is given, when first going on bypass, the heart beats better and actively. The opposite happens when not using fresh blood, the heart stops and dilates with poor function. It has an immediate adverse effect on heart function which is acute and could jeopardise recovery in critically ill patients.

26. Please explain, as far as you are able, what you understood to be the risks of using fresh warm blood in cardiothoracic surgery, referencing medical journals, articles or other scientific literature where appropriate.

35. I refer to my answers to questions 15, 16 and 25. It is my belief and understanding that the risk-benefit ratio in the cases where the use of fresh warm blood is considered or used is in favour of patient survival, the alternative would be that without the use of fresh warm blood in these circumstances, the patient would not survive. I refer to the letter from Mr Alun Rees dated 22 August 1988 at document NHBT0088294.

27. Did you agree with the views expressed by Dr Cummins (Consultant Haematologist) during a meeting of doctors at the Harefield Hospital on 1 October 1997, that:

a. **There was "no hard 'evidence' but theoretical reasons and anecdotal reports", to support the clinical use of fresh warm blood (RBHT0000008); and**
b. **fresh warm blood "should be used at Harefield Hospital only as a last resort in patients with life-threatening haemorrhage"?**

If not, why not? Has your view changed over time? If so, how?

36. Dr Cummins is a consultant haematologist. Most of the documents in the IBI disclosure are from haematologists not surgeons. It is the surgeons not the haematologists who are faced with the life and death of a patient on the operating table. It is the surgeons who witness the immediate benefits of the use of fresh warm blood in critical situations to sustain life. I agree with Dr Cummins' opinion that the practice of using fresh warm blood should be limited as a last resort for life threatening conditions. However, I would like to point out that the evidence in the literature is real rather than anecdotal and published in reputable journals. For example please see Exhibits WITN4129002 to 6.

37. Further I again refer to the letter from Alun Rees dated 22 August 1988 at document NHBT0088294 provided in the Inquiry disclosure, which is the only document from a consultant cardio thoracic surgeon in the IBI disclosure (apart from a short letter from myself). Mr Rees's letter says: *"I know and so all the*

other cardiac surgeons I suspect, that fresh blood can be life saving under certain circumstances."

38. My view has not changed over time.

28. What alternative treatments were there to fresh warm blood? What were the benefits and disadvantages of those alternative treatments? Please include reference to medical journals, articles or other scientific literature as necessary. You may wish to refer to the email from Dr Contreras dated 18 March 1999 (NHBT0101360).

39. The alternative treatment was the use of component blood or stored blood but the disadvantages are set out above in answer to question 25. Please also see Exhibits WITN4129002 to 6.

29. How prevalent was the practice of using fresh warm blood in surgery in the United Kingdom and abroad during your clinical career? Did your colleagues at the hospitals where you worked also engage in this practice? If so, who were they, and in what circumstances (as far as you are aware) did they engage in this practice?

40. I refer to answers given to questions 15 and 16 specifically and generally throughout this statement. The use of fresh warm blood was dependent on the type of case being referred. My recollection was that Harefield attracted the most complex and critical cases at that time. With regards to my colleagues, I understand that there were those who were also using fresh warm blood due to its efficacy for survival of complex patients. This happened a long time ago and I cannot recollect names, but, amongst the 19 documents that were supplied by the IBI with the rule 9 request, only 2 refer to cardiac surgeons. However both documents that relate to cardiac surgeons indicate that they see the benefit of the use of fresh warm blood. (NHBT0088294 [letter from Mr Alun Rees 22 August 1988] and RBHT0000008). In the former Mr Alun Rees says *"I know and so all the other cardiac surgeons I suspect, that fresh blood can be life saving"*

41. Further in RBHT0000008 Mr Khagani says: *"Surgeons are more impressed with the benefits of fresh blood than haematologists".*

42. In addition in the same document Dr Cummins (consultant haematologist) says: *"It may exert an haemostatic effect beyond that which can be provided by standard blood component therapy"*

30. When and why did you stop using fresh warm blood in surgery?

43. I stopped using fresh warm blood in the UK NHS when I retired in 2001.

31. Were you instructed by hospital staff or the Royal Brompton and/or Harefield Hospital to discontinue the use of fresh warm blood? In particular:

b. Were you asked by Dr Seymour on or before 28 July 1988 to cease this practice? If so, please describe your interaction with him, and explain why you did not agree to cease this practice at his request. The Inquiry has a copy of a Memorandum from the Department of Health dated 28 July 1988 (DHSC0002841_007) in which your use of fresh warm blood is discussed as a subject of concern, and it is noted there that Dr Seymour had spoken to you without success.

44. Regarding the Memorandum from the DHSS dated 28th July 1988, I do not recall the details of a discussion 33 years ago between myself and Mr Seymour, but I anticipate that we will have had a professional exchange of views. Please also see my answer to question 19.

b. Were you aware that your use of fresh warm blood had come to the notice of the Department of Health and Social Security who took the view that it was undesirable and contrary to departmental guidance? If so, how did this come to your attention and what if any impact did this have on your practice?

45. Although I cannot recall the details now, I would have taken into consideration guidelines from the Department of Health. However, my primary responsibility remained to my patients with the aim of saving his or her life at that immediate time in cardiac theatre when they were losing large amounts of blood. I had to make a judgement based on my surgical experience and in the best interests of the patient. I refer to my previous answers at questions 15 and 16.

a. Was pressure brought to bear upon you to cease this practice through the 'professional network' as suggested in the Department of Health and Social Security Memorandum? If so, please describe what occurred.

46. I have no recollection of this.

b. Did the Department of Health and Social Security threaten to withdraw supra-regional funding if you did not cease the practice? If so, please give details.

47. I do not recollect this.

c. Were disciplinary proceedings threatened or brought against you in relation to this practice? If so, please give details.

48. No, there were none.

32. Were you aware that the National Blood Transfusion Services disagreed with your practice of using unscreened blood in surgery and if so, what was your response? You may find the following documents of assistance:

a. The letters from Dr Contreras to Dr Burman dated 3 February 1998 (NHBT0085681_039) and Mr Plant dated 3 October 1988 (NHBT0085681_033);

b. The letter from Dr Knowles to Dr Amin, dated 28 June 1990 and into which you were copied, (RBHT0000019) and the email from Dr Contreras, dated 18 March 1999 (NHBT0101360).

49. The National Blood Transfusion service were against the practice of using fresh warm blood. I only used this technique when in my clinical judgment, I felt it was absolutely necessary for the benefit of my patients when they were at the risk of death and I refer to my answers to questions 15 and 16. Further amongst the 19 documents that were supplied by the IBI with the rule 9 request, only 2 refer to cardiac surgeons. However, both documents that relate to cardiac surgeons indicate that they see the benefit of the use of fresh warm blood in specific situations (NHBT0088294 [letter from Mr Alun Rees 22 August 1988] and RBHT 0000008). In the former Mr Alun Rees says *"I know and so all the other cardiac surgeons I suspect, that fresh blood can be life saving"*

50. Further in RBHT0000008 Mr Khagani says: *"Surgeons are more impressed with the benefits of fresh blood than haematologists".*

51. In addition in the same document Dr Cummins (consultant haematologist) says: *"It may exert an haemostatic effect beyond that which can be provided by standard blood component therapy"*

33. Who was responsible at (i) the Harefield Hospital and (ii) the Royal Brompton Hospital for sourcing blood for patients and ensuring treatment with blood complied with best practice? Was it you as a surgeon, or the haematology department?

52. The haematology department at Harefield was responsible for sourcing blood in consultation with myself as director of cardiothoracic surgery. At the Royal Brompton Hospital the haematology department were responsible for the sourcing of blood.

Risk of infection from fresh and unscreened warm blood

34. How did you obtain fresh warm blood for use in surgery, and did this change over time? You may find the following documents helpful when answering this

question: (i) The letter from Dr Contreras to Dr Beresford of the Medical Defence Union dated 19 May 1988 (NHBT0093056) and (ii) a Memorandum from Dr Amin to Ms Sharp dated 12 November 1998 (RBHT0000013) which enclosed a policy banning, with immediate effect, the use of blood that had not been obtained from the National Blood Service.

53. I refer to my answer to question 16. In the case of dire emergencies I sought the help from a pool of donors including hospital staff who were regularly tested for their workplace and would be responsible enough to volunteer if there were any issues in relation to them donating blood. The remainder was from the local police and the local RAF base. Further this cohort donated their blood without charge to help patients in extremis. This cohort of professionals were from a low risk group. who completed a donor questionnaire. This was a completely different cohort to that from which blood was sourced for blood products from the US.

a. The Inquiry understands that you obtained fresh warm blood for use in surgery by bleeding hospital staff. Is this correct?

54. Donations of fresh warm blood were obtained from hospital staff.

b. Did you have other sources of fresh warm blood? If so, please list them.

55. Other sources of fresh warm blood donation in emergencies were the RAF and local police staff.

35. Did you consider it to be acceptable practice at the Harefield and Royal Brompton Hospitals to use blood sourced other than from the National Blood Transfusion Service? If so, why?

56. I considered it to be acceptable to source blood from sources other than the National Blood Service when I was of the opinion that there was no other alternative to stop the bleeding in the chest and as a result, in my judgement the patient was going to die. As I have indicated in the above this was in

exceptional circumstances. My view is that stored blood from the National Blood service would not have had the same clinical impact.

36. In a letter to Dr Beresford of the Medical Defence Union dated 19 May 1988 (NHBT0093056), Dr Contreras stated that you and your team were "bleeding large numbers of donors at Harefield Hospital" in contravention of the "routine pre-transfusion testing required by the National Blood Transfusion Service".

57. I am not in a position to comment on a letter by Dr Contreras seeking advice she appears to have received from her defence organisation the MDU. I cannot see any other correspondence relating to this letter in the disclosure including the advice that Dr Contreras apparently received from Dr Beresford. The letter to Dr Beresford dated 19 May 1988 indicates as follows: *" You asked me to send you the guidelines or regulations regarding the necessary tests on blood donations before they are released from the Transfusions centres to hospitals Unfortunately, there is very little in print on this matter….."*

58. The documents referred to in this letter do not appear to be attached to Dr Contreras's letter in the disclosure bundle and therefore I am unsure whether these documents have been disclosed, and whether these were actually sent to me at the time. I do not recall seeing these.

a. Please describe, as far as you are able, how your practice of bleeding donors for fresh warm blood at Harefield Hospital for use in cardiothoracic surgery differed from the National Blood Transfusion Service's routine pre-transfusion testing requirements in 1988.

59. At NHBT0093056, Dr Contreras says: *"You asked me to send you guidelines or regulations regarding the necessary test on blood donations before they are released from Transfusion Centres to hospitals. Unfortunately, there is little in print on this matter……"*The disclosure provided by the IBI does not appear to include the National Blood Transfusion Service's routine pre-transfusion

testing requirements for 1988. It is therefore not possible to answer this question at this time based on the IBI disclosure.

b. Please explain why you continued to bleed donors for fresh warm blood at Harefield Hospital despite Dr Contreras' attempts to supply you with "screened and tested blood as fresh as possible".

60. I greatly appreciated Professor Marcela Contreras' efforts and collaboration at that time.

61. I reserved the use of fresh warm blood to dire emergencies as I have explained previously.

37. In a letter to Dr Rees, Consultant Cardiothoracic Surgeon at the Harefield Hospital dated 9 September 1988 (NHBT0088294), Dr Contreras states that she has "tried in the past to cooperate with requests for fresh blood" but has "stopped this practice since it became quite clear that pre-agreed conditions were not being observed by the clinicians". What pre-agreed conditions, if any, were in place between Harefield Hospital and the National Blood Transfusion Service regarding the supply of fresh warm blood for use in cardiothoracic surgery?

62. I have been retired from the NHS for 20 years and I am being asked whether there were any pre-agreed conditions from 33 years ago and what these were. The IBI has not provided a copy of the pre-agreed conditions from 1988 and I would not wish to give a speculative answer. I cannot remember.

38. Please explain whether you continued to treat patients with blood that had not been obtained from the National Blood Transfusion Service after 10 November 1998, and if so, why?

63. In extreme conditions I did treat patients with blood that had not been obtained from the NBTS and in general terms this would have been the position until the

end of my work in the NHS in 2001. However, I cannot say if there were any patients after the 10 November 1998.

39. What donor selection procedures or criteria did you apply when you yourself obtained the fresh warm blood for use in cardiothoracic surgery between 1969 and 2001. In particular:

a. How were donors sourced for fresh warm blood and in particular what if any criteria did you apply to their selection?

64. When fresh warm blood was sourced for cardio thoracic surgery which took place between 1969 and 2001, the donors came from professional groups, medical staff, RAF and local police.

b. How, if at all, were donors for fresh warm blood screened for blood-borne infections? If they were screened please explain when, and by whom.

65. The donor venesection questionnaire was used as I have explained above and the haematology department would check for blood group and cross match. Please also see answer to 39c below.

c. What inquiries did you make as to whether a potential donor was a carrier of a blood borne infection? You may wish to refer to the letter from Mr Burman dated 11 January 1988 (NHBT0085681_042).

66. I refer to my answers to questions 16, 17, 34 and 39. Samples from donations were screened for retrospective routine microbiological testing (HBsAg, anti-HIV and TPHA) by the National Blood Service in Colindale in the 1980s. Harefield Hospital also developed its own blood donor procedures. I do not recall the full details.

40. The Inquiry understands that you bled clinical staff at the hospital and members of your surgery team. Is this correct? If so:

a. Please identify by role and/or title (the Inquiry does not require their names) the staff and members of the surgery team who were bled and how often this took place.

67. Clinical staff at the hospital and members of the surgery team were donors and this was with their consent. I cannot say how often they donated blood. They were considered a low risk professional group. I do not recall details of roles and titles.

b. What did you consider to be the risk of bleeding members of the surgical team, in particular the Inquiry understands from a letter dated 18 February 1986 to you that on occasion they would faint (NHBT0085683_001). What if any risk did this present to the patient undergoing surgery?

68. As far as I can recall, members of staff only donated blood when they offered to make the donation and when the patient's condition was judged to be highly critical. My consideration was that they were low risk in terms of blood borne infection as they were medical professionals being regularly being screened. Please refer to my letter back to Dr Costello (REF NHBT0085683_002).

69. I was not in charge of the haematology lab nor the condition it would have been left in.

70. If a blood donor fainted whilst giving blood in an adjacent room, they would not have posed a threat whatsoever to my patient in cardiac theatre.

41. Were the donations of fresh warm blood screened for blood borne viruses before they were transfused into patients? If so, how? If not, why not?

71. We were working in extreme circumstances faced with the life or death of bleeding patients in need of fresh warm blood. Emergency cross matching would be done. My general recollection is that testing for antibodies would take

6 hours, which would be too long a delay to attempt to save the patient's life with the use of the fresh warm blood.

42. Did the clinical benefits of using fresh warm blood during surgery outweigh the risk of transmitting blood-borne diseases through fresh warm blood? If so, please explain why.

72. These were patients with haemodynamic instability such that we could not keep circulation adequate by any usual means known to me. Typically the bleeding would not stop and this would not be a surgical bleed, but a medical bleed, such that the bleeding would be from everywhere. There would be a loss of blood pressure and we found the use of inotropes ineffective in spite of the patient being on the heart-lung machine. The effects of the uncontrolled bleeding would eventually be that the processes we were using were inadequate to support life and so we were faced with an imminent risk of loss of life. At this point I believed that the only option would be to use fresh warm blood. It was my belief that the clinical benefits of using fresh warm blood during cardiac surgery with these specific patients to attempt to save their lives outweighed the risk of transmitting blood borne diseases through fresh warm blood.

43. Were the donations of fresh warm blood subject to retrospective testing for blood borne viruses?

a. If so, when and by whom? How did you obtain the consent of the donors to this screening?

73. Samples from donations were screened for retrospective routine microbiological testing (HBsAg, anti-HIV and TPHA) by the National Blood Service in Colindale in the 1980s. Harefield Hospital developed its own blood donor procedures. I do not recall the full details. Consent was taken at the time of donation as I recall.

b. Who was responsible for keeping the records of this testing? Where were they kept? If not, why not?

74. The haematology department were responsible for keeping records of the testing.

75. I do not recall the details of where the records were kept. Please refer to haematology.

44. In the event retrospective donations were tested and infections identified:

a. Were the donors informed of their infections? If so, how and by whom? In answering this question please state whether you were aware that the National Blood Transfusion Service were unable to follow up the donor(s) of three patients who contracted HIV via transfusion (who were treated with blood from the Transfusion service and with fresh warm blood by you) because your record keeping was so poor (DHSC0002841_009). If this was brought to your attention, what if anything did you do to amend your record keeping?

76. Please refer to my answer to 43b relating to record-keeping. I do not recall any evidence of infected blood. The document is dated 33 years ago. It would, however, have been the Haematology department who would have been following up. I was leading a busy cardiac surgical team. Whilst I accept the importance of keeping full and accurate records, I was not the one keeping the records regarding blood donations.

77. From reading the enclosed documentation DHSC0002841_009, there is no specific evidence that those who contracted HIV via transfusion were infected from blood or fresh warm blood used at Harefield Hospital and I do not recall this being brought to my attention at the time. The letter says: *"We have three cases of HIV infection apparently transmitted by blood transfusion that we have been unable to follow up fully….."* This letter is dated 1988 and I do not recall any of my patients contracting HIV as a result of surgery that I performed.

b. Were the recipients of the infected blood informed? If so, how and by whom?

78. I do not recall this being brought to my attention, I refer to my answer to question 44a.

c. Was this information reported to any third party or agency or organisation? If so, how and by whom?

79. I do not recall this being brought to my attention. I refer to my answer to question 44a.

45. What happened to any excess fresh warm blood, not used in cardiothoracic surgery?

80. I do not recall there ever being any excess blood.

46. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at Harefield and Royal Brompton Hospitals about the risks of infection in consequence of treatment with blood, prior to such treatment commencing? Please detail whether, and if so, how this changed over time.

81. I refer to my answer to question 15. It was my policy to minimise the use of whole blood (not blood products) during bypass (including fresh blood). The number of patients receiving fresh warm blood was exceptionally small, probably 150 out of 20 - 25,000 procedures that I was involved in. The need for using fresh warm blood only became apparent during the procedure and when the need arose it was urgent so there was no opportunity of taking consent once the need arose. It was necessary to decide what risks to advise the patient of prior to surgery. The overwhelming requirement for consent related to the surgical procedure, not the nature of the transfusion that may be required in an attempt to save life in 0.7% of cases. Consequently it would not

form part of the consent process. A judgment had to be made of what to inform the patient.

47. Were you able to identify patients who would be candidates for fresh warm blood prior to surgery? If so, how?

82. No, it was always reactive as the urgency arose in cardiac theatres during the procedure. I refer to my answer to question 42.

48. Did you gain consent from patients prior to surgery, to the use of fresh warm blood? If so, what did you tell them about the risks and advantages of using fresh warm blood? What in particular did you tell them about the risks of using unscreened blood donations?

83. Please see my answer to question 46.

49. Did you ever treat patients with fresh warm blood without gaining their prior consent? If so, under what circumstances?

84. Please see my response to question 46.

50. Did you provide any information to patients who had received fresh warm blood as to their risk of contracting HIV and Hepatitis? In particular, did you suggest that they should obtain tests for these infections or should look out for signs and symptoms of infection in the future? If so, please describe what information you gave them, in what form, and when. If not, why not?

85. Please see my answer to question 43a. To my recollection none of my patients contracted a blood borne virus as a result of a fresh warm blood transfusion. Theoretically once screening came in, any positive results would have been acted on by either the haematologists or the cardiac team, but I do not recollect that any of my patients were affected and so discussions with the patients as outlined in the question did not arise to my recollection.

Record Keeping

51. What information did you record about those donors you bled to obtain fresh warm blood? Where were these records kept?

86. Please see my answer to question 16. In relation to the storing of these records, although I can no longer recall, it is likely that these records were kept by the Haematology department.

52. What information did you record about the donations of fresh warm blood you provided to patients? Where were those records kept?

87. Please see my answer to question 16. In relation to the storing of these records, although I can no longer recall, it is likely that these records were kept by the Haematology department.

53. Was any information shared with any third party?

88. Not to my knowledge.

54. Paragraph 9 of the Terms of Reference details the Inquiry's interest in the destruction of documents and disclosure of medical information, including medical records. Please describe the record keeping and record destruction practices in place for blood donations and blood donors at all Hospitals where you undertook the practice of bleeding donors for fresh warm blood.

89. I am not able to answer this question as the general maintenance of records and their ultimate destruction is a matter for the respective hospitals.

Infected patients

55. Did you follow up any of your patients treated with fresh warm blood, to establish whether they had been infected with blood borne viruses? If so, how and over what period? If not, why not?

90. All of my surviving patients were being followed up to the appropriate surgical follow up protocol. I am aware that Harefield Haematology also instigated a look back study to follow up the patients with fresh warm blood.

56. Do you know whether any of your patients were infected with either HIV, HBV, HCV, Syphilis, or any other blood-borne infection as a result of your use of fresh warm blood in surgery? How did you become aware of this and when? You may wish to refer to the correspondence at (NHBT0082402_007) and (NHBT0082402_005).

91. I do not recall knowing that any of my patients were infected by any blood borne infection.

92. NHBT0082402_007 states: "…..*I wonder whether it was as a result of this that he picked up the Hepatitis C*". I do not recall being contacted about this case and the statement.

93. NHBT0082402_005 states: *"There appears to be no other risk other than transfusion"*. I do not recall being contacted about this case and the statement is at best speculative."

94. None of this correspondence says that as a result of a procedure that I undertook whether with or without fresh warm blood these patients contracted a blood borne infection.

57. Do you know whether any of your patients were infected with HIV after October 1985? How did you become aware of this and when?

95. I do not know of any of my patients being infected with HIV after Oct 1985.

58. Do you know whether any of your patients were infected with HCV after 11 September 1991? How did you become aware of this and when?

96. I do not recall any of my patients being infected with HCV after 11 September 1991.

59. Were you ever involved in informing any of your patients that they had been infected with a blood borne virus as a result of a blood transfusion? How did you communicate this information? Were they told in person, by letter or by phone?

97. No, as I have said I cannot recall that any were so infected.

60. What, if any, information or advice or testing was provided by you or colleagues to partners or family members of people who were at risk of infection with HIV or were infected with HIV?

98. We were not aware of HIV until 1983. When it became a risk, it was the role of the haematology department to provide information, advice and testing.

61. What if any arrangements were made for post-test counselling?

99. Please see my answer to question 60. Arrangements would have been made by the haematology department.

62. What information was provided to patients about the risks of infecting others?

100. Please see my answer to question 60. This would have been the role of the haematology department.

Section 5: Look back

63. What actions or decisions were taken by you or at any of the hospitals at which you worked to trace patients who may have been infected with blood borne viruses through the use of blood and in particular fresh warm blood?

101. I understand that retrospective studies were performed but I do not recall the details.

64. The Inquiry holds evidence that a look back exercise was undertaken, identifying a number of recipients under your care who received blood donated from individuals later found to be infected with HCV (NHBT0017907_013 and NHBT0017874_022). Please describe, as far as you are able, any look back exercises that were undertaken to trace recipients of fresh warm blood from donors that were later known to be infected with HIV, HBV, HCV or any other blood borne infection. Please describe what this involved and your views of the efficacy of it. Did you counsel those of your patients who had been infected, yourself? If so, please provide details.

102. I was not personally involved in the look back studies. The documents referred to in this particular instance do not give evidence that the recipients were infected with HCV from a transfusion of fresh warm blood. Further the letters say that from records that the patient was transfused with a presumed Hepatitis C positive blood component (and therefore by implication not fresh warm blood as this is whole blood not a component) I am not aware that any of my patients were infected with any blood borne infection through the use of fresh warm blood as a result of cardiac surgery under my care.

65. Were you involved in any other look back exercises? How successful have they been? What could have been done to improve their efficacy?

103. I was not personally involved in the look back studies which were carried out by the haematology department.

Section 6: Other issues

66. Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Infected Blood Inquiry. To assist, we have provided the Inquiry's List of Issues (attached).

104. The use of fresh warm blood was only ever used in critical cases to save a life.

Statement of Truth

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

Signed GRO-C: Professor Sir Magdi Yacoub

Dated 26/10/2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
1991	Comparison of the Haemostatic Effects of Fresh Whole Blood, stored Whole Blood, and Components After Open Heart Surgery in Children	WITN4129002
July 2008	Warm Fresh Whole Blood Transfusion for Severe Hemorrhage: U.S. Military and Potential Civilian Applications	WITN4129003
Undated	Optima Uses of Blood in Trauma Patients	WITN4129004
2020	The use of warm fresh whole blood transfusion in the austere setting: A civilian trauma experience	WITN4129005
11 October 2016	The case for whole-blood transfusion in massive hemorrhage	WITN4129006