Witness Name: Jonathan Peter Wallis

Statement No.: WITN6982001

Exhibits: WITN6982002 - WITN6982005

Dated: 2 February 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR JONATHAN PETER WALLIS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 21 December 2021.

I, Jonathan Wallis, will say as follows: -

Section 1: Introduction

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

1. Dr Jonathan Peter Wallis

GRO-C

DoB: GRO-C 1954

BA Oxon 1976 MB.BS Lond 1979 MRCPath 1989 FRCPath 1995 FRCP (UK) 1996. GMC registration number: 2497406

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

2. Training posts:

August 1979 - July 1980: House Surgeon Bury St Edmunds. House Physician Royal Victoria Hospital Bournemouth

August 1980 - August 1981: Senior House Officer in paediatrics. Westminster Children's Hospital

January 1982 - December 1984: Senior House Officer in General Medicine. RDE Hospitals Exeter

3. 1984: Registrar in Haematology. St Mary's Hospital London

1984-1986: Registrar in Haematology RDE Hospitals Exeter

1986-1990: Senior Registrar in Haematology. Newcastle Hospitals

1990-2019: Consultant Haematologist, Freeman Hospital, Newcastle upon Tyne. Substantive post with laboratory and clinical responsibilities. Please see question 5 for details.

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

4. Regional and National transfusion committees:
   A. Member of Zonal Blood user group (ZBUG) 1995-1999
   B. Inaugural Chair of Northern region Regional blood transfusion committee (RTC) 2000-2005
   C. Member of Blood stocks management scheme during initial development 1999-2001
   D. Member of National Blood Transfusion Committee (NBTC) 2001 -2005 and ?2010-14
   E. Chair of NBTC 2015-2019

5. Learned society committees and positions

A. Chairman of Clinical transfusion special interest group of British Blood Transfusion Society (BBTS) 2000-2007
B. Elected member of BBTS council 2005-2008
C. Chairman of BBTS Scientific meetings advisory committee. 2007 to 2012.
D. President of BBTS 2015-2017
E. Invited chair of International Society of Blood Transfusion (ISBT) working party for Clinical Blood Transfusion 2009- 2013.

6. Other relevant transfusion related committees and other positions:

A. Member of Scottish National Blood Transfusion Service scientific advisory panel 2005-2009.
B. Associate editor of journal 'Transfusion Medicine', published by Blackwell/Wiley.
C. Referee for scientific articles from JAMA, Transfusion, Transfusion medicine, BMJ, and other journals.
D. Reviewer on invitation, research grant proposals from Canada, Ireland, Scotland, and Netherlands.

4. 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, Hepatitis C ("HCV"), Hepatitis B ("HBV") in blood transfusions. Please provide details of your involvement and copies of any statements or reports which you provided.

7. I have not provided evidence to, or have been involved in any other inquiries, investigations, criminal or civil litigation in relation to HIV, Hepatitis C ("HCV"), Hepatitis B ("HBV") in blood transfusions.

Section 2: The Freeman Hospital

5. Please describe:

a) Your role and responsibilities at the Freeman Hospital and how these changed over time;

8. I was appointed to the post of Consultant Haematologist at Freeman Hospital Newcastle upon Tyne in May 1990. The hospital had a modest in-patient and out-patient workload of haematology patients. Our neighbouring hospital, The Royal Victoria Infirmary had an active bone marrow transplant unit, paediatric haematology unit and comprehensive haemophilia care centre. As consultant, I cared for named patients with a wide variety of Haematological diseases (but not haemophilia patients, paediatrics or marrow transplantation) some of whom required sporadic or regular blood transfusion. My workload included a considerable amount of 'liaison haematology' with other speciality groups within the hospital such as cardio-thoracic surgery, vascular surgery, elective orthopaedics, and liver diseases including liver transplantation i.e. specialities with high blood use. I was also responsible for laboratory management and laboratory reporting. This work was shared with one other consultant, Dr Patrick Kesteven (died 2018).

9. Early in my appointment, I forget the precise date, I became nominated lead for the Blood Transfusion laboratory at Freeman Hospital. Around the year 2000 our hospital trust was merged with our neighbouring institutions, the Royal Victoria hospital (RVI) and Newcastle General Hospital forming the Newcastle upon Tyne Acute Hospitals Trust (NUTH). From that time I had increased links with other haematological colleagues and shared some specific clinical workloads for particular diseases (namely Myeloproliferative disease, Chronic Lymphocytic leukemia and Myeloma). From about 2005 to 2018, I was responsible for haemophilia patients when on call out of hours but did not participate in routine care or policy formation in this sub-speciality. In the new merged trust I continued to take a major role in management of the Blood transfusion laboratory until my retirement in 2019.

b) Your work at the Freeman Hospital insofar as it involved treating patients with blood transfusions;

10. See above

c. Your work insofar as it involved the care of patients who were infected with HIV, HCV and HBV viruses and/or other diseases patients may have been exposed to as a result of receiving a blood transfusion or blood products.

11. My work did not involve particular care of patients who were infected with HIV, HCV and HBV viruses and/or other diseases patients may have been exposed to as a result of receiving a blood transfusion or blood products, other than out of hours responsibility for Haemophilia patients from around years 2005-2018.

6. Please:

a. Describe the roles, functions and responsibilities of the Haematology department ("the Department") within the Freeman Hospital during the time you worked there. Please also explain how the Department worked with other departments within the Hospital, such as critical care, emergency, birth or surgical units in so far as it relates 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.

12. The responsibilities of the haematology department at Freeman hospital, and subsequently the Newcastle upon Tyne Acute hospitals trust (NUTH) can be roughly divided into laboratory, indirect and direct clinical care.

13. The laboratory was responsible for providing accurate haematological testing of blood samples for routine and specialist tests e.g. blood counts, bone marrow tests etc. providing patient blood group and antibody screening tests, testing some supplied blood components for blood group. Stocking, selecting, 'cross-matching' and releasing blood components on demand.

14. Indirect clinical care. The consultant haematologists, and trainees working in the department, were responsible for providing clinical advice to other clinicians about their patients. This included aspects of blood clotting and blood transfusion. This advice might be sought during normal working hours or out of hours (on-call).

15. Direct clinical care. The consultant haematologists were responsible for looking after haematological patients for whom they were the named consultant. These included in-patients and outpatients. These included patients who might be given blood transfusions.

16. Primary responsibility for a decision to transfuse lay with the clinician with direct clinical responsibility for the patient. The type of transfusion given was also their responsibility though they received guidance from the laboratory on components and products available and appropriate to the situation.

b. Outline the facilities and staffing arrangements for the care of patients in relation to the use of, and treatment with, a blood transfusion.

17. The clinical facilities and staffing arrangements for the care of patients requiring a blood transfusion were those of the hospital department where they were receiving their care. This included day case wards, in-patient wards, emergency admission units, operating theatres and intensive care facilities. Medical and nursing staffing levels and arrangements were appropriate to the units.

c. 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 undergoing blood transfusions and/or patients infected with hepatitis and/or HIV in consequence of a blood transfusion.

18. My haematological responsibilities at Freeman hospital were shared with Dr Patrick Kesteven (died 2018).

7. *Please describe the practical steps that were taken when you decided that a patient required a transfusion of blood or blood components, including:*

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

19. Although there would have been considerable change in the detail of how things were done during the period I was working at Freeman hospital, many of the principles remained the same.

20. If a patient either required a transfusion on medical grounds, or might require a transfusion (e.g a patient being admitted for surgery), blood samples together with a detailed form were sent to the laboratory (known as the 'blood bank'). The patient's blood group was analysed and the results entered on an electronic information technology system. If blood was definitely required either immediately or on a planned day, then units of blood were selected and cross-matched either serologically (a test tube procedure using a patient blood sample and a sample from the selected blood unit) or electronically ("electronic cross-match", introduced in late 1990s). They were then either sent to the clinical location of the patient or stored in the blood bank fridge until collected. If blood might be required, say for a surgical operation, then either the same was done, or after the late 1990s and where the request was deemed suitable, the request was noted and blood supplied promptly on demand using an electronic cross-match. On rare occasions where blood components were required with extreme urgency, suitable components were issued prior to patient blood grouping or crossmatching procedures having been completed.

b. What the record keeping requirements were;

21. Details of the patient's test results, and of units issued and taken for that patient were kept indefinitely in the blood bank. In the first few years after Freeman Hospital opened in 1977, these were kept as a paper ledger (some of these paper records were later lost in a basement flood at the document storage unit). Subsequently a blood bank computer was installed and records backed up daily.

22. Details of the transfusion were also kept in the patient notes. This included the prescription of blood to be given, made and signed by a medically qualified person (or, after year 2000, by a small number of trained and assessed nurses or para-medical staff), donation numbers of the units transfused, who actually administered the transfusion and other details such as rate of transfusion and any medications to be given concurrently. It was recommended by the department that the reason for transfusion was also recorded in the medical notes by the prescribing doctor. The medical notes were kept according to the Department of Health guidance by the hospital medical records department.

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

23. The information given to the patient prior to transfusion varied depending on circumstance. After a national recommendation (SABTO 2011) that all blood transfusion should be preceded when possible by informed patient consent, new procedures were put into place to document the giving of that information at an appropriate time. The guidance specifically did not require signed consent and this was not asked for at Freeman hospital/NUTH. Staff were asked to document and sign in the notes that they had given this information which was provided in written form on an information sheet attached to the transfusion request form booklet. The standard form to be sent to the laboratory requesting blood subsequently included a tick box to confirm that this had been done. Prior to that time practices varied. Patients attending for elective surgery, or urgent surgery when circumstances permitted, signed a standard NHS consent form for the procedure. This included a statement that other medical procedures including blood transfusion might be required. I believe but cannot be sure that this form was introduced in the mid-1990s and cannot recall the wording of surgical consent documents prior to that time. Any questions that arose about transfusion would be answered by the consenting doctor, though they could consult myself or other haematology staff if they wanted further information or advice. Patients having transfusion for medical reasons were usually conscious and consent was taken as implicit if the patient did not refuse the transfusion once it had been explained to them. Leaflets about the risks and benefits

of transfusion were made available on all wards. These were mostly the standard NHSBT information leaflets. I do not recall what or whether written information was made available prior to the introduction of these information leaflets. The verbal information given to the patients about the risks and benefits was up to the prescribing doctor. Training on this and other aspects of transfusion will be discussed in answer to question 23.

8. ***Did you, on behalf of the Department, have a relationship with the Regional Blood Transfusion Centre? If so, please describe that relationship. Specifically, please include:***

a) Who within the Regional Transfusion Centre you interacted with;

24. On the behalf of the department, I had close relationships with the Regional Blood transfusion centre.

25. In addition consultants and sometimes senior scientific officers took part in regular regional haematology meetings, hospital transfusion committees and other meetings both in the centre and in the local hospitals.

b) How frequently you interacted with them; and

26. Interactions were dependant on need but might have been once every 2 weeks on average. Most frequently I would communicate with the consultant haematologists at the centre but also with the senior scientific officers.

c) What your interactions were primarily concerned with.

27. Our interactions will have covered a number of areas including:

- Component stocks
- Projected demand
- Service provision eg delivery times

- Price of blood (more so when the price was set locally prior to formation of the zonal blood units in 1995)
- Requests for specialist components
- Request for specialist advice on transfusion matters
- Requests for specialist tests on transfusion matters
- To discuss adverse reactions to transfusion experienced in my hospital
- Clinical or laboratory research in transfusion
- New developments in transfusion
- Quality assurance of the centre's procedures
- Requests from the centre for look back information

9. ***Please consider the enclosed article titled 'Current controversies in blood transfusion', published in the Biomedical Scientist in 2005 [NHBT0086402]. At page 1, you are quoted as saying that the Regional Transfusion Committees 'are largely about the safe use of blood, disseminating guidelines and educating users' and that arranging educational meetings was a key way in which RTCs got these messages across to their various regions. Please explain:***

a. The role of Regional Transfusion Committees ("RTCs");

28. The regional transfusion committees were set up to act as a two-way interface between the users/prescribers of blood transfusion and the National Blood Transfusion service (later the NHSBT) as providers of blood. The quote given is an accurate assessment of much of their work. It was also the role of the RTCs to feedback disquiet about any aspect of the NHSBT both to the local transfusion centre and to the National blood transfusion committee set up at the same time.

b. Your understanding of the nature of the relationship between the RTCs and hospitals within their region;

28. Overall I believe there was a very good and productive two-way relationship

between the hospitals and the Transfusion centre through the RTC.

c. An overview of the types of information shared within the RTC meetings;

29. Educational sessions for blood users organised by the RTC have nearly always been well attended in the Northern region and more widely in the country and have covered many areas including surgery, obstetrics, paediatrics, emergency care, gastro-enterology and others.

d. How, if applicable, RTCs were responsible for developing policy or guidance on better transfusion practice.

30. The RTC did not have a specific responsibility for developing guidance on clinical transfusion matters. However it could help develop local policies, usually about service provision; examples I can recall are policies for exchange of blood between hospitals, blood delivery schedules for hospitals and training of nurse prescribers. Clinical guidance usually came via national bodies such as the British Society for Haematology guideline committee or equivalent surgical or anaesthetic bodies.

10. Did you, on behalf of the Department, have a relationship with the National Blood Transfusion Service ("NBTS")? If so, please describe that relationship.

31. My relationship on behalf of the department was not directly with the NBTS, but through the regional transfusion centre. Because I sat on a number of bodies with the NBTS I had direct contacts with those outside of the regional centre, but these were not typically about local matters. On occasion where a particularly difficult case or unusual problem arose, I might speak directly to a colleague outside my regional centre. We also spoke to medical staff outside our regional transfusion centre on call when their out of hours service had been consolidated nationally.

11. Approximately how many patients per week would receive a transfusion under the care of the Department?

32. I cannot recall accurate figures for this and in any case they changed considerably over the period from 1990 to the present. The number of units of red cells transfused per annum was to the best of my recollection around 18,000 for Freeman hospital alone in the 1990s, increasing to 36,000 for the combined NUTH trust in year 2000. Subsequently, this fell to around 24,000 units by year 2018. On average a patient received between 2 and 3 units of red cells at a single transfusion episode. Therefore, as a rough estimate, 100-150 patients were transfused per week at Freeman hospital in the 1990s, 250-300 per week in the combined trust (NUTH) after 2000, falling to 150-200 per week in more recent years. I cannot give figures for platelet and plasma transfusion, but most patients receiving these will also have been receiving red cells so will be included in these figures rather than being extra to them.

12. Were you aware of any patients who subsequently developed HIV, HCV or HBV under the care of the Department? If so, how many patients were infected? If you are able to give exact rather than approximate figures, please do so.

33. I do not recall being made aware of any patient who developed HIV, HCV or HBV following transfusion at our hospital from 1990 onwards. I do recall look-back studies generated by the NHSBT following the introduction of new donor tests. The results of these were not made known to me unless the patient involved was under my care. I also recall occasional individual requests from NHSBT after a regular donor had become positive for a viral marker, and sending requests to the NHSBT after a patient with HIV/HBV/HCV was diagnosed in my hospital and had a history of transfusion either in my hospital or elsewhere. To the best of my memory I do not recall any of these resulting in proof of transmission through blood transfusion. From 1996, we reported all serious transfusion reactions including infections to the national haemovigilance scheme (SHOT) and I do not recall reporting HIV/HBV/HCV to that body.

Research

13. Was any research undertaken within the Department regarding blood transfusion patients?

a. If so, please explain what the research entailed, what the aims of the research were, whether patients were informed of their involvement in the research and consent was obtained.

b. What, if any, involvement did you have in this research?

c. Please provide details of any publications relating to the research.

34. While working at Freeman Hospital/NUTH I carried out a number of research projects which I have detailed below divided according to type of research. These projects were designed and led by myself unless otherwise stated. The question asks me to refer to NHBT0040352. I was not previously aware of this document. Please refer to my answer to question 59 and the section that follows on Transfusion Epidemiology.

35. Transfusion epidemiology: These studies were retrospective or prospective surveys. All data were anonymised at source in the relevant hospital blood bank. Local Ethical approval was obtained. Caldicott guardian approval was obtained for use of the anonymised data. Patient consent was not sought. Patient care was not affected in any way by the data collection. The purpose of the research was to better establish the use of blood and the long-term survival of patients who had been transfused. This was done in part to help estimate the population at risk for long term infective risks of transfusion, in particular variant CJD. It was not done to assess long term effects of transfusion itself.

1. **Where Does Blood Go? Prospective observational study of red cell transfusion in north England.**
   Wells A, Mounter P, Chapman C, Stainsby D and Wallis JP. **BMJ 2002; 325: 803-8. (data referred to in the paper NHBT0040352) [RLIT0000811]

2. Transfusion medicine 2006, 16: 411-417 **Changing indications for red cell transfusion in the north of England.** Wallis JP, Wells aw, Chapman CE [RLIT0000821]
3. Transfusion Medicine 2014 **Ten-year pattern of red blood cell use in the North of England** Tinegate H, Chattree S, Iqbal A, Plews D, Whitehead J, and Wallis JP Transfusion 2013;53: 483-489. [RLIT0000832]
4. **Where Did Platelets Go in 2012? A Survey of Platelet transfusion practice in the North of England**. Charlton A., Tinegate H., Iqbal A., Watson D., Robertson J., Wallis JP. [RLIT0000830]
5. **Is fresh frozen plasma overtransfused in the United States?.** Wallis JP, Dzik S. Transfusion. 2004 Nov;44(11):1674-5. [RLIT0000838]
6. **Long term survival after blood transfusion: A population based study in the north of England.** Wallis JP, Wells AW, Matthews JN, Chapman CE. **Transfusion. 2004. 44; 1025-32. [RLIT0000824]

36. Prospective clinical research: These studies were done with full informed consent of the patients involved and approval from the local ethics committee.

1. **Cardiopulmonary exercise testing before and after blood transfusion**: **A prospective clinical study**. Wright S, Pearce, B., Snowdon, C., Anderson H., and Wallis J.P. Br J Anaesth. 2014; 113: 91-96. This study was performed to better understand the relationship between haemoglobin level and cardiac output to help inform the benefits or otherwise of red cell transfusion in the transfusion dependant patient. [RLIT0000837]

2. **Recovery from post-operative anaemia**. Wallis JP, Wells AW, Whitehead S, Brewster N. **Transfusion Medicine. 2005, 15(3); 413-18. This study was performed to better understand the rate of recovery from post-operative anaemia. This helped inform subsequent policies on per-operative transfusion and pre-operative 'optimisation'. [RLIT0000840]

3. **Effect of WBC reduction of transfused RBC's on postoperative infection rates in cardiac surgery. (A prospective randomised controlled trial.)**Wallis JP, Chapman CE, Orr KE, Clark SC, Forty JR. **Transfusion. 2002;42: 1127-34 . This study was performed to investigate a postulated effect of red cell transfusion and in particular the residual white cells contained, on rates of post-operative infection. We found no evidence of a significant effect on post-operative infection. Shortly after the study was completed Leuco-filtration of all red cells was introduced in the UK as a precautionary measure against the risk of transfusion transmission of vCJD rendering the results of less relevance to UK transfusion policies. [RLIT0000834]

4. **Effect of storage age of transfused blood on 48 hour Hb increment and recovery of 2,3 DPG in haematology patients** Wallis JP, Wells AW, Babb RG, Stainsby D, Hamilton PJ. British Journal of Haematology: 45th Conference Proceedings Annual Scientific Meeting of the British Society for Haematology 2005. A pilot study of the storage age of transfused red cells on some laboratory parameters, transfusion interval and quality of life. We established that such a study was feasible, but did not progress to a full scale study. [BSHA0000217]

5. **TOPPS study**: NUTH was a participating centre for this multi-national study on prophylactic platelet transfusion co-ordinated from Oxford. The results showed some benefit for platelet prophylaxis in patient groups with longer periods of thrombocytopenia. Stanworth SJ, Estcourt LJ, Powter G, Kahan BC, Dyer C, Choo L, Bakrania L, Llewelyn C, Littlewood T, Soutar R, Norfolk D. A no-prophylaxis platelet-transfusion strategy for hematologic cancers. New England Journal of Medicine. 2013 May 9;368(19):1771-80. I facilitated this study locally but was not a named investigator. [RLIT0001004]

6. **REDDS study**: NUTH was an active participant in this study of transfusion threshold for patients with myelodysplasia who are transfusion dependant.

Stanworth SJ, Killick S, McQuilten ZK, Karakantza M, Weinkove R, Smethurst H, Pankhurst LA, Hodge RL, Hopkins V, Thomas HL, Deary AJ. Red cell transfusion in outpatients with myelodysplastic syndromes: a feasibility and exploratory randomised trial. British journal of haematology. 2020 Apr;189(2):279-90. I was the local investigator for this study but not part of the design or writing team. [RLIT00010003]

37. Immunological complications of Transfusion: These reports and surveys highlighted non-infective complications of transfusion.

1. **Single hospital experience of TRALI** Wallis JP, Lubenko A, Wells AW, Chapman CE (A case series) Transfusion. 2003; 43: 1053-9
2. **Transfusion Associated Alloimmune Neutropenia: an undescribed complication of blood transfusion**. Wallis JP, Haynes S, Lucas GE, Green F, Chapman CE. LANCET 2002; 360:1073-4
3. **How much residual plasma may cause TRALI**?
   Transfusion Medicine 2008. 18; 276-80 N. Win, C. E. Chapman, K. M. Bowles, A. Green, S. Bradley, D. Edmondson & J. P. Wallis.
4. **Acute lung injury after ruptured abdominal aortic aneurysm repair: The effect of excluding donations from females from the production of fresh frozen plasma**. Wright,S.E.; Snowden,C.P.; Athey,S.C.; Leaver,A.A.; Clarkson,J.M.; Chapman,C.E.; Roberts,D.R.; Wallis,J.P., Critical Care Medicine 2008; 36: 1796-1802
5. **Transfusion Related Acute Lung Injury: A look back investigation.** Nicolle, A.L., Chapman C.E., Carter V., and Wallis J.P. Transfusion Medicine 2004, 3; 225-31.
6. **Transfusion-related acute lung injury (TRALI)—under-diagnosed and under-reported.** Wallis, J. P. British Journal of Anaesthesia 90.5 (2003): 573-576.

38. Infective complications of blood transfusion: These papers used epidemiological study data noted above to estimate risks of transfusion acquired vCJD

1. **Blood transfusion and spread of variant Creutzfeldt-Jakob disease.** Dietz K, Raddatz G, Wallis J, Müller N, Zerr I, Duerr HP, Lefèvre H, Seifried E, Löwer J. Emerging infectious diseases. 2007 Jan;13(1):89. [RLIT0001002]
2. **Strategies to reduce transfusion acquired vCJD**. Wallis, J. P. Transfusion Medicine 21.1 (2011): 1-6. [RLIT0000833]
3. **Variant CJD and blood transfusion**. Wallis, J. P. (2015). Vox sanguinis, 108(4), 432-433 [RLIT0000829]

39. Transfusion process: These laboratory/clinical interface reports were performed to improve the efficiency of supply and usage of blood components.

1. **Audit of red cell transfusion** Wallis JP, Stainsby D, McClelland DB.. Transfusion Medicine. 2002 Feb;12(1):1-9. [RLIT0000822]

2. **'Tag and label' system for checking and recording of blood transfusions** Whitehead, S, Kenny-Siddique, S, Scott, Y, Parker,PI, Hardy, J, Wallis, JP. TRANSFUSION MEDICINE 2003; 13: 197-204. [RLIT0001000]

3. **A transfusion prescription template and other human factor interventions to improve balanced transfusion delivery in major haemorrhage due to trauma. ,** Swieton J, Hawes R, Avery S, Watson H, Scott Y, Lannon M, Wallis JP. Transfusion Medicine. 2018 Aug;28(4):284-9. [RLIT00010001]

14. Please list all research studies that you were involved with in any other relevant positions of employment insofar as relevant to the Inquiry's Terms of Reference, ensuring your answer addresses:

a. What the research entailed, what the aims and findings of the research were, whether patients were informed of their involvement in the research and consent was obtained;
b. Your involvement in this research; and
c. Details of any publications relating to the research.

Please ensure your answer makes specific reference to the following:

i. NHBT0040352: D. Stainsby (2001) 'Transfusion Epidemiology', to which you contributed data.

ii. NHBT0011323_002: J. P. Wallis, A. W. Wells, J. N. Matthews & C. E. Chapman (2004) 'Long-term survival after blood transfusion: a population based study in the North of England', Transfusion.

The Inquiry would be grateful to receive copies of any relevant research studies discussed in your answer.

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40. Please see my answers to question 13 for this detail.

<u>Section 3: Policies and practices regarding blood transfusions</u>

15. To the best of your knowledge, was guidance provided to you and/or other medical professionals by the Freeman Hospital as to transfusion policies and practices during the time of your employment? Alternatively, were you involved in establishing any such policies and practices at a hospital level? If so, please outline in as much detail as possible the policies in place which would prompt the need for a patient to receive a blood transfusion.

If possible, please 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.

41. A number of national bodies wrote guidelines on transfusion that we implemented locally. These are too numerous to mention individually but the majority were from the British Committee on Standards in Haematology (BCSH, now known as British Society for Haematology (BSH) Guidelines) and are available as current guidelines or in archived form since 1987 on the BSH website at b-s-h.org.uk. Other guidelines were from the Association of Anaesthetists, and the Royal College of Obstetricians and Gynaecologists (known as the Red Top guidelines). Local guidelines were written for specific clinical procedures/areas in Freeman hospitals including for emergency surgery on ruptured aortic aneurysms and liver transplantation and trauma. From the year 2000 onwards, we gradually developed a more assertive laboratory policy to question requests for transfusion components where these appeared to be inappropriate according to established guidelines. However, the final decision to transfuse lay with the attending physician. The best summary of our policies can be found in Chapter 6 pages 39-58 of the Handbook of Transfusion Medicine, 3rd edition. ed DBL McClelland published 2001 by the Stationary Office, ISBN 0 11 322427 3 [WITN6982002]. This chapter was co-authored by myself and represented our practice in the late 1990s and subsequently. It gives details of alternative treatments such as autologous transfusion, applicable Haemoglobin thresholds and other details on transfusion management of surgical patients and bleeding patients. Guidelines changed over the years when they did so they were assessed locally and our local practice was investigated and adjusted appropriately.

16. Please outline the types of blood and blood products that were most commonly transfused to patients under your care and how this changed over time.

42. Red cells: In the early 1990s we received a majority of red cells in the form of red cell concentrates. These came with reduced plasma compared to 'whole blood'

(WB) and were often re-suspended in a saline based solution (Optimal additive solution or OAS). In Newcastle, a majority of these were in addition white cells depleted by centrifugation ('Buffy coat depleted'). Sometime after 1995, I cannot recall the exact date, all red cells were provided after they had been passed through a filter to remove more than 99.9% of the white cells as a precautionary measure against transmission of vCJD. Residual plasma in these units was low. Whole blood units were available in the 1980s but were phased out and became not available by the mid 1990s. I do not recall the precise dates over which this product was withdrawn.

43. Platelets: In the 1980s and 90s these were generally provided as single donor units and transfused in multiples. By about year 2000, they were provided as either single donor apheresis units or pre-pooled multiple units representing a standard adult dose according to the 'Red book' specification.

44. Plasma and cryoprecipitate: Frozen Plasma was provided as single donor units made from whole blood donations. Cryoprecipitate was provided as single donor units until sometime after year 2000 when it became available as pre-pooled units. After some time around year 2000, plasma for paediatric use was obtained as a pooled and viricidally treated product from Octapharma AG, a pharmaceutical firm specialising in plasma products.

17. In your experience at the Freeman Hospital, did any particular blood products or transfusion methods carry a higher risk of viral infection?

45. With regard to viral infection there is evidence that cytomegalovirus was rarely if ever transmitted by white cell free products which include frozen plasma products, leucofiltered red cells and some types of platelets. Otherwise all products containing any plasma were considered to have the same risk of other virus infections.

18. With reference to your experience at the Freeman Hospital and in any other relevant roles, do you recall any instances or periods of time in which you or

others had and/or raised concerns about unnecessary blood transfusions? If so, please explain in as much detail as you are able to.

46. We carried out many surveys and audits of transfusion practice in different departments in the hospital with the co-operation of those departments. In light of developing understanding about risks and benefits of transfusion we highlighted areas where we considered transfusion to be either unnecessary or necessary.

47. I cannot recall details of all of these audits but from the later 1990s we conducted continuous audits of transfusion practice in the cardio-thoracic surgical unit and fed results back to anaesthetists and surgeons in the department with the aim of optimising blood usage to the maximum benefit of the patient.

19. Please outline at which level generally a patient's haemoglobin count would be considered low and thus require a blood transfusion. Please also explain:

a. How the level of haemoglobin that was understood to necessitate a transfusion may have changed over time

48. Please see my answer to question 15 (and the reference to Chapter 6 of the Handbook of Transfusion Medicine [WITN6982002] for surgical and bleeding patients). For transfusion dependant patients, we transfused according to patient symptoms of anaemia rather than absolute Haemoglobin level.

49. In the 1970s it was common practice to use a haemoglobin of 10g/dL or Haematocrit of 30% as a threshold for transfusion in surgical patients. As a result of evidence from studies and trials of transfusion this threshold would now be considered higher than necessary. This change has occurred slowly as research has been conducted and understanding changed and there remains no firm consensus in some areas such as cardiothoracic surgery. In patients who are transfusion dependant, there remains no firm evidence from trials as to the best Haemoglobin

level to aim for. Symptoms are generally considered the best guide with some patients coping well with a haemoglobin of 7g/dL and others feeling compromised when their haemoglobin falls much below 10g/dL. Trials on the best transfusion schedules are awaited.

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

50. Monitoring of a patient's Haemoglobin level varies according to circumstance. In surgical patients it will be by repeated blood counts before, during and after surgery. In addition, near patient testing devices are commonly used during surgery. In medical patients a prior Haemoglobin is always obtained to guide the number of units planned to be transfused. In general, in our hospital, Haemoglobin levels were not monitored during or immediately after transfusion of haemodynamically stable transfusion dependant patients, until typically the patient returned in 1 to 3 weeks. Haemodynamically stable in-patients would generally have a repeat Haemoglobin level 24 or 48 hours after the blood transfusion. Haemodynamically unstable (bleeding) patients would be monitored according to need.

20. Where applicable, were alternative treatments made available to patients under the care of the Freeman Hospital throughout the time of your employment but specifically in the 1980s and 1990s?

51. Alternative treatments to allogeneic blood transfusion may be divided into
I. Autologous blood donation and transfusion
II. Acute normo-volaemic haemodilution
III. erythropoiesis stimulating agents
IV. pre-operative optimisation
V. surgical techniques.
VI. use of pharmaceutical haemostatic agents

I. To the best of my recollection a service for autologous blood

transfusion was implemented sometime in the mid to late 1980s or early 1990s. This was run by the regional transfusion centre. The impetus was concern about infectious risks of transfusion. Uptake was not high. As understanding developed with the help of studies elsewhere, it became apparent that the practice was of very limited if any benefit to the patient. At some time in the 1990s, it was discontinued as an option.

II. Acute normo-volaemic haemodilution is an intra-operative technique that had some adherents in the surgical community. It was supported at Freeman hospital for a small number of cases in the 1990s. My view was that it was of no benefit, did not reduce transfusion and carried risks. My recollection is that after a period the technique fell into disuse.

III. Erythropoiesis stimulating agents, namely erythropoietin and pharmaceutical analogues were occasionally used to support autologous transfusion donations. We also offered a pre-operative service of erythropoietin treatment to optimise Haemoglobin levels in patients who held a religious objection to blood transfusion. In addition we offered this service to those who expressed non-religious objections to allogeneic blood transfusion if they fulfilled certain criteria but we did not routinely offer this pre-operative service outside of these groups as it was considered to carry likely risks greater than that of routine allogeneic blood transfusion. My recollection is that very few patients wished to avail themselves of this service. Erythropoetin was used widely in the renal unit to reduce the burden of anaemia in patients with renal failure. Also a small number of patients with haematological disorders were treated with these agents to delay need for or reduce the amount of red cell transfusion required.

IV. To the best of my recollection, the treatment of pre-operative anaemia with the aim of reducing intra-operative transfusion was always used but became more actively pursued under the term 'Pre-operative optimisation' from the mid 1990s onwards. Subsequently it and other measures were given a wrap-around term '*patient blood*

management'. This term had originated from a very active pre-operative optimisation programme in Australia. The number of patients who gained significant benefit in terms of reducing blood transfusion usage other than by avoiding unnecessary blood transfusion based on transfusion thresholds, was in my view not great.

V. Advancing surgical techniques reduced surgical blood use during the 1980s and 1990s. I do not have detailed knowledge of these techniques.

VI. Drugs such as aprotinin and tranexamic acid were used routinely in some surgical specialities where there was evidence of benefit. Aprotinin use was discontinued for a period sometime after year 2000 when studies suggested it had a negative risk to benefit ratio. Tranexamic acid was used regularly in several surgical areas, more so after year 2000.

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

52. The 'alternatives' to transfusion noted above were in general suitable only for patients undergoing surgery. Therefore, consent for most of the options would have been obtained by the surgical/anaesthetic team in whose care they were. Where autologous collection and transfusion was considered they were as I recall referred to the RTC autologous transfusion programme. I am confident that these latter patients would have been fully consented with adequate information but I cannot recall what information was given. As we subsequently realised that autologous transfusion was of limited efficacy in preventing allogeneic transfusion it is likely that the possible advantages of autologous donation and transfusion were exaggerated. I did consent patients who received erythropoietin pre-operatively or for bone marrow failure and am confident that they received adequate and essentially accurate information.

b. Did the doctor/patient relationship have an effect on the way in which an

agreement would be reached in selecting a treatment? If so, please explain.

53. I cannot answer with complete confidence but I would expect the doctor/patient relationship to have an effect on any choice of treatment offered.

c. Did any aspect of this change over time?

54. Please refer to my answers above

d. Generally, how were transfusions regarded within the Department?

55. My belief is that those working in the department regarded blood transfusion as generally safe and effective, and on occasions, lifesaving, but not free from risk. Those risks could be divided roughly into viral infection, bacterial infection, and non-infective reactions. The commonest risks were considered to be non-infective. However all these risks were considered to be small compared to other risks entailed in any hospital admission and the benefits significant when transfusion was used appropriately.

e. Do you consider that alternatives could have been used in preference to blood transfusions so as to reduce the risk of infection? If not, why?

56. Alternatives to blood transfusion could be and were used to reduce the risks of infection from blood transfusion but had limited applicability as noted above.

Red cell concentrates

21. Were there any circumstances where red blood cell concentrate transfusions would be used instead of whole blood? Please explain:

a. The circumstances in which red blood cell concentrate transfusions were considered necessary by the Department, and if applicable, preferable over other blood components? The Inquiry is aware that you co-authored chapter 4

'Red Cell Transfusion' in 'ABC of Transfusion', 2013, which you may wish to base your answer on. [RLIT0000899]

57. Red cell concentrates were used widely in the early 1990's and always after whole blood was withdrawn as an available component by the NBTS/NHSBT.

58. Whole blood was considered of some benefit in patients with severe blood loss due to trauma, obstetric bleeding or surgical procedures. However the use of combinations of red cell concentrates and FFP and cryoprecipitate and platelets is a satisfactory alternative in nearly all circumstances.

b. What level of haemoglobin would prompt the transfusion of red blood cells to a patient?

59. Please see my answers to question 19.

c. The benefits and/or risks associated with red blood cell concentrate transfusions.

60. Please see my answers above and to question 20d. Where transfusion was being given to a haemodynamically stable patient without expected blood loss, red cell concentrates were considered preferable, as the overall volume was lower and the risk of fluid overload therefore less.

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

61. Post transfusion testing does not reduce the risk of virus infection from blood transfusion other perhaps than by early detection. However, we did not undertake routine testing for infection at any stage of the transfusion process. We did undertake testing if a patient developed signs or symptoms of infection that might have been transmitted by blood transfusion. As noted in my answer to question 12, I do not

recall ever having confirmed that HIV/HBV/HCV was transmitted by blood transfusion at the hospital during my period of employment at Freeman hospital/NUTH. Bacterial infection was also tested for, when signs and symptoms suggested it was a clinical possibility post transfusion.

62. In neonates and infants where the volume of transfusion at one transfusion episode was only a fraction of a whole donor unit, and where repeated transfusion was considered likely, we reserved a number of aliquots of a single donation for that patient so as to reduce 'donor exposure'.

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

63. These were the same as for other blood transfusions. Please see my answers to question 7 above.

f. 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?

64. Red cell concentrate units are transfused according to need. In a bleeding patient, units are transfused to maintain haemodynamic stability and the haemoglobin level at a figure considered safe in that individual. In a haemodynamically stable normal sized adult receiving a 'top-up' transfusion, one unit is expected to raise the Haemoglobin level by 0.8 to 1 g/dL. The pre-transfusion haemoglobin level and the desired post–transfusion haemoglobin level are used to determine the number of units required. In addition, the patient size and co-morbidities, particularly cardiac status, are taken into account. Typically between 2 and 4 units are transfused at one time.

22. Please consider the enclosed letter from you to Dr C E Chapman dated 19 November 1998 regarding the use of whole blood in certain surgical procedures [NHBT0073129].

a. Please explain your suggestion regarding the use of whole blood in place of other blood components, including Fresh Frozen Plasma ("FFP"), and the reasons for this proposal.

65. As noted above in answer to question 16, the provision of 'whole blood' had gradually been withdrawn in the later 1980s and early 1990s. "Whole blood' is essentially red cells with plasma that has not been frozen. It did not contain viable platelets as then produced. Although there is some loss of a labile clotting factor (Factor VIII) in stored but un-frozen plasma, this is not considered a concern in massive haemorrhage. Provision of 'whole blood' to such patients as detailed below provides a 'balanced transfusion' with fewer donor exposures and therefore a slightly lower risk of infection. However, in these patients with a very high early mortality, reduction of infective risk was not the major factor in the choice. It is easier to administer a unit of 'whole blood' than to administer one unit of red cell concentrate and one unit of FFP, and does not incur a delay due to the need to thaw the FFP (a 30 minute process). It can therefore be considered preferable to a mixture of red cell concentrate and FFP because it can be used promptly with a satisfactory ratio of red cells to plasma. Against its regular use, is the need to keep the blood bank stocked with two types of units. This inevitably leads to increased wastage with resultant costs. We considered it our duty to the voluntary blood donors to keep wastage in hospital blood banks to a minimum, and we are required by the hospital to keep costs down where possible. More recently there has been some evidence that unfrozen plasma from some donors when stored for more than a couple of weeks may undergo biochemical changes leading to activation of complement and possibility of non-haemolytic febrile reactions. Thus, the acceptable storage time of whole blood may be lower than that of red cell concentrates (35 days) and FFP. This further increases the difficulty of efficient stock management. This was not known in 1998/9.

b. Please explain why you believed that the specific surgical procedures you identified would have benefited from this proposal, and the link between red cell concentrates and use of FFP in those procedures.

66. In patients with anticipated massive blood loss or with significant blood loss and on-going bleeding, we routinely recommended use of both red cells and FFP, which has become known more recently as 'balanced transfusion'. Some patients can be predicted to have massive blood loss and in such patients we believed that early provision of plasma was beneficial to their survival. Patients with severe trauma and those with ruptured aortic aneurysms would fall into this category. Other patients develop severe bleeding during routine surgery and there is good evidence that they will develop a coagulopathy leading to worsening bleeding if they are given red cell concentrates only, without plasma. With the development of regional trauma centres and air ambulances, we and others increasingly used higher ratios of plasma to red cells than was historically typical, and have argued for a return of whole blood as an available component. I believe clinical trials may be presently underway in this country and elsewhere.

c. On page 1 of the document, you express a favourable opinion regarding the fact that "whole blood will now be the same price as packed cells."
Please explain:

i. Your understanding of the reason why the price of whole blood changed in line with that of packed cells; and

ii. Why you considered this to be beneficial.

67. The transfusion budget at my hospital was my responsibility. For components bought from the NBTS/NHSBT alone it amounted, I believe to around 1-2% of the hospital's annual costs. I cannot recall the precise figures but it would have been somewhere around £2 million per annum at Freeman hospital alone in the late 1990s. All healthcare has a cost and I considered it my responsibility to ensure the most efficient use of resources.

68. I do not think that the cost was in this instance a major factor. At the time of writing, as far as I can recall 'Whole blood' was not routinely available. It had I think appeared on the contract price list sent to me for the forthcoming year.

d. Please explain the reasons for preferring whole blood to be donated by 'previously untransfused male donors'.

69. We were aware that plasma from parous females or previously transfused males carried a risk of significant lung injury due to anti-leucocyte antibodies. This affected perhaps one in 5000 plasma unit transfusions. We therefore requested that all plasma rich components come from un-transfused male donors to avoid this adverse effect.

e. Were any of these proposals implemented? If not, please explain why they were not adopted.

70. I do not recall clearly the reasons but the proposals were not implemented. I think that possibly the price was included purely because one hospital elsewhere in the country had a long-standing agreement for provision of small numbers of 'whole blood' units for neonatal exchange transfusion, but that the NBTS/NHSBT had no plans to produce larger amounts.

23. ***Were guidelines circulated to clinicians concerning the use of red cell concentrate? If so, did the usage pattern of red cell concentrate change as a result of these guidelines? If not, why were guidelines not provided?***

You may wish to consider [BWCT0000120_001] when answering questions about red cell concentrates.

71. Please see my answer to question 15 with regard to guidelines. I am unable to give exact dates for the following, and clearly there will have been many changes over the period I worked at Freeman/NUTH but in general: guidelines were

discussed at the hospital Transfusion Committee on a regular basis. Meetings with individual specialities were conducted to discuss transfusion use and guidelines relevant to those specialities. Blood bank held a generic guideline on blood use. Junior house officers (now known as F1) doctors joining the hospital had teaching on the mechanics of transfusion (how to arrange it, what to tell the patient etc) at induction, and a further session on the appropriate use of blood as part of their mandatory training during their period of stay. Copies of the Handbook for Transfusion medicine were widely circulated. At one stage in the early 2000s, copies were given to every junior doctor working at the hospital, though I cannot recall how long this continued. Subsequently an abbreviated guide to transfusion based on the 'Indication codes for Transfusion' document produced by the National Blood Transfusion Committee was distributed - [RLIT0000836].

24. The Inquiry is aware that you co-authored a journal article entitled, 'Where does blood go? Prospective observational study of red cell transfusion in North England' [RLIT0000811]. If you are able, please outline how the usage of platelets has changed, comparing usage from 1980s-1990s with the usage identified in this article.

72. The study referred to, discussed use of red cells but not platelets. The use of red cells reached a peak in year 2000, and subsequently fell by about 25%. Details are available in the reference:

73. Transfusion Medicine 2014 **Ten-year pattern of red blood cell use in the North of England** Tinegate H, Chattree S, Iqbal A, Plews D, Whitehead J, and Wallis JP Transfusion 2013;53: 483-489. [RLIT0000823]

25. ***Please consider the enclosed document titled "Notes on Blood Matters meeting', held on 12 June 1988 at the Royal College of Pathologists [NHBT0007059_001]. At page 9, the document records that you suggested red cell usage could be reduced by doubling the purchase price. As far as you are able to recall, please explain this comment, including why you believed red***

cell usage should be reduced, and whether this suggestion was ever implemented.

74. The meeting referred to was in 1998 and not 1988. I have only a dim recollection of this meeting. In that comment, I do not say that reducing use is desirable, only that use would decrease if the price doubled. Nevertheless I did believe that some use was unnecessary. At that time, there was a growing belief among haematologists and anaesthetists with an interest in transfusion that red cell transfusion was being overused. There was no scientific trial evidence of note to support this until publication of the Transfusion requirements in Critical Care (TRICC trial) [Hebert PC. et al. A multicenter, randomized, controlled clinical trial of transfusion requirements in critical care. N Engl J Med. 1999;340:409-17] in late 1999 [WITN6982005]. There were also concerns about possible shortages in donor blood supply in the future as usage increased. These concerns were discussed and documented at a meeting (which I did not attend) in July 1998 which led to the issuance of Health services Circular 1998/224 'Better blood transfusion' [NHBT0083701_002].

75. As a 'transfusion budget' holding haematologist, I was aware of the pressures from hospital managements to constrain costs where possible. Whether by reducing blood bank wastage or by reducing possible unnecessary red cell transfusion, it was clear that a doubling of the cost of blood would undoubtedly exert a downward pressure on the use of blood within hospitals.

26. ***Please consider [NHBT0113679_002]. In particular, the concern that platelet concentrate "which is used to treat bleeding in patients", was being administered without full testing. Please outline:***

a. Whether you used platelet concentrates to treat patients;

76. I did.

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

77. Frequency of platelet transfusion depends on the reason for transfusion. Patients suffering massive blood loss and transfusion may only require a single transfusion. Patients with bone marrow failure may require platelet transfusions daily for days or weeks.

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

78. To my recollection the platelet concentrates we used were always fully tested

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

79. Release of any component from the RTC before full testing would have been discussed between the NBTC medical officer and the requesting haematological department.

e. The perceived benefits and/or risks associated with platelet transfusions known to the Department.

80. Benefits were the prevention or stopping of harmful bleeding. Risks were those of other blood component transfusion, chiefly infection and immunological effects, the latter including allergic reactions.

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?

81. Platelets were initially available as single donor units made from single whole blood donations. It was common practice to administer 6 units at a time to achieve a

useful increment in blood platelet counts. More recently, perhaps from the late 1990s, a pre-pooled 'adult dose' of platelets was made usually from single donations. Single donor adult doses of Platelets made from apheresis of donors were also available. The dose was relatively reduced for paediatric patients, and might be increased in patients with 'platelet refractoriness'.

g. Was there ever any difficulty in obtaining platelets?

You may wish to consider [BSHA0000031] when answering questions regarding platelets.

82. On occasion, usually at times of public holidays, platelet supplies could be limited.

Fresh Frozen Plasma

27. What considerations were made by the Department for the use of FFP transfusions? In particular:

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

83. FFP was used in cases of massive haemorrhage and in cases of anticipated massive haemorrhage. FFP was rarely used in bleeding patients with an as yet unknown factor deficiency or for some very rare factor deficiencies, where factor concentrates were not available. FFP was used to treat disseminated intravascular coagulopathy. FFP was used to treat coagulopathy due to liver disease and warfarin overdose. FFP was used to treat thrombotic thrombocytopenic purpura.

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

84. The benefits depended on the reason for transfusion but overall might be considered as reducing mortality. The risks are infective and immunological. A

particular risk of large volume plasma transfusion whether as FFP or as single donor apheresis platelets is acute lung injury (TRALI)

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

85. As noted previously, post transfusion testing may detect infection but does not prevent it. Post transfusion testing for infection was only undertaken when signs and symptoms in the patient suggested the possibility of infection or, rarely, in lookback studies.

86. Patients receiving repeated exposure to FFP for instance as treatment of thrombotic thrombocytopenic purpura, were advised to have a Hepatitis B immunisation.

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

87. The process for obtaining informed consent was as for all transfusion components as noted in my answer to question 7.

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?

88. The number of units of FFP transfused depended on the indication. Typically in an adult we would give 4 units (approximately 1 litre of plasma) and relatively smaller amounts in a child. These doses may be repeated in cases of continuing haemorrhage. In patients with TTP, they might receive 10-12 units daily for 2 or more weeks.

28. ***Were guidelines circulated to clinicians concerning the use of FFP? If so, did the usage pattern of FFP change as a result of these guidelines? If not, why were guidelines not provided?***

You may wish to consider [NHBT0004335_004] when answering questions about fresh frozen plasma.

89. Please see my answers to question 23 on guidelines. The same applied to FFP as to red cells. Please note that NHBT0004335_004 is an editorial written to support and draw attention to recently published guidelines on use of FFP by the British Committee for Standards in Haematology. These guidelines were in my view misleading with regard to its use in massive haemorrhage. I wrote to the lead author explaining my concern. The letter and the issue were acknowledged. As a result we implemented local guidelines that differed from the BCSH recommendations.

Single Unit Transfusions

29. Please consider the enclosed document on the use of single unit transfusions of blood in the UK [DHSC0035471], which discusses concerns about unnecessary single unit transfusions of blood in the UK

a. With reference to your experience at the Hospital and in any other relevant roles, please outline in what circumstances single-unit and two-unit transfusions were administered to patients.

90. The document referenced has no date, provenance or author given. I do not agree with its basic premise that single unit transfusions are never appropriate. Single and two unit transfusions are administered outside paediatric cases to very small adults, adults with unstable cardiac state where volume overload was a concern and where it is desired to raise the Haemoglobin by only 1g/dL. In my practice, this was not a frequent occurrence but it could be entirely appropriate. We had a number of transfusion dependant patients who were out of choice treated with regular single unit transfusions rather than multi-unit transfusions at longer intervals,

in order to maintain a steadier Haemoglobin level and preserve a better quality of life.

b. What did you understand to be the risks and benefits of single-unit transfusions and two-unit transfusions? How, if at all, did this understanding change over time?

91. Please see my answer above. In addition, it is appropriate to say that single unit transfusions are now considered by some transfusion authorities to be the ideal standard of care in all situations. I do not fully agree with this view though there are circumstances as noted above where it may be an appropriate course. The viral risk of transfusion is directly related to the number of units transfused. However the benefit of transfusion is related to achieving a certain therapeutic goal, say a Haemoglobin level of 8g/dL. This might require multiple units. So an infective risk, likely very low, is balanced against a therapeutic benefit, possibly very considerable. At some point the gain in therapeutic benefit will become equal to the increase in infective risk. In general we stop transfusing well before this point because of other risks or costs.

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

92. I am unable to say

Autologous transfusion

30. Were there any circumstances where autologous transfusions would be used instead of donor transfusions? You may wish to consider the enclosed documents relating to autologous transfusions in your answer [BSHA0000017_021 and NHBT0000033_013]. Please outline:

a. The circumstances in which autologous transfusions were considered necessary;

93. Please see my answers to question 20. Although autologous transfusion enjoyed a vogue in the late 1980s and the early 1990s, it has fallen out of favour as it became clear that it was very difficult to administer efficiently and had little effect on the rates of allogeneic transfusion.

b. Approximately how often this practice occurred;

94. I do not recall how often we practised this at Freeman Hospital.

c. The perceived benefits and/or risks associated with autologous transfusions; and

95. Autologous transfusion might reduce allogeneic donor exposure.

96. By the time of the operation the patients were inevitably anaemic unless they had also received erythropoietin, a practice used elsewhere but rarely to my recollection in the UK for reasons of expense and possible side-effects. Post operatively, it was not uncommon for the stored units not to be used. Some of the risks of transfusion such as bacterial infection remained. During storage, which by the nature of the programme is likely to be longer than for voluntary unrelated donor red cells, there is some loss of cells and some loss of function of cells. The effects of these are uncertain but not beneficial. Patients who had given autologous blood pre-operatively were more likely to require per-operative transfusion because they arrived at surgery more anaemic than if they had not donated blood.

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

97. I believe that the NHSBT who administered the autologous blood donation programme had good information leaflets considered accurate at the time and I believe that they obtained written consent.

Fresh Warm Blood

31. The Inquiry 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. To your knowledge, did this practice occur at the Freeman Hospital? If so, please explain in as much detail as you are able to, ensuring your answer addresses:

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

b. Approximately how often this practice occurred;

98. To the best of my recollection, we never provided or administered fresh warm whole blood at Freeman Hospital. I believe that there were some 'walking donor' banks used to this end in some neonatal units. I am not aware whether these were ever in place at the Royal Victoria Hospital prior to our merger as NUTH.

c. The perceived benefits and risks of fresh warm blood transfusions (you may wish to refer to page 8 of NHBT0000037_013);

99. I was aware of anecdotal reports of the efficacy of this product. I am not aware of any scientific literature supporting its use.

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.

100. We did not use this product and so these questions are not applicable to my practice.

32. With reference to any of the groups outlined in question 3, please identify any significant policies created by those groups in which you were involved, insofar as relevant to the Inquiry's Terms of Reference. Please describe the reason for and impact of the policy, and the extent of your involvement.

100. The Regional Transfusion Committees (RTC) Zonal Blood User Groups (ZBUG), the National Transfusion Committee (NTC), the British Blood Transfusion Society (BBTS) and the International Society for Blood Transfusion (ISBT) were not guideline producing groups.

33. With reference to all of the committees named in your answer to question 3, please 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;

101. RTC, NTC, ZBUG, BBTS.

b. Development of local hospital guidelines;

102. HTC

c. Transfusion policy induction procedure for new staff;

103. RTC and HTC

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

104. NTC, RTC, HTC

e. Promotion of new information regarding transfusion matters;

105. All

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

106. RTC, NTC, HTC

g. Blood transfusion record keeping and documentation;

107. BBTS, ISBT, HTC

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

108. None

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

109. RTC, HTC

j. Consent for blood transfusion.

110. RTC, NTC, HTC

Please ensure your answer includes any significant policies, guidelines, decisions relevant to blood transfusion practices or blood safety that were proposed, created, implemented and/or overseen by the group.

111. Please see BCSH and other guidelines as referred to in my answer to question 15. I no longer have access to any local guidelines produced by my hospital.

34. ***With reference to all of the committees named in your answer to question 3, please 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 Anemia.

112. Please see my answers to question 33 above

35. Was there a Hospital Transfusion Committee at the Freeman Hospital? If so, insofar as you are able:

113. Yes

a. Please provide a brief overview of the Committee, including when the Committee was created, its roles and responsibilities at the Freeman Hospital, and its relationship with the Department at the Freeman Hospital.

114. The Hospital Transfusion committee (HTC) was, I believe, started by my predecessor at Freeman Hospital either in 1977 when the hospital first opened or shortly afterwards. Its responsibilities were to liaise with other users of blood, discuss and agree matters of process, guidelines and guidance on transfusion, adverse reaction reports, service developments and keep users up to date with component types and other news from the Regional transfusion centre.

b. With reference to any of the matters identified in Questions 33 and 34 of this request, please outline any significant policies or practices established by the Committee.

115. I am unable to recall the details of or provide any hospital specific policies

agreed at this committee.

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

116. We usually had representation from the Regional transfusion centre at the meetings.
They were there as observers, to answer any pertinent questions, receive complaints or compliments about their service and to offer advice or help when requested.

36. ***The Inquiry understands that you reviewed and commented on draft sections and chapters of the handbook, 'Transfusion Medicine', written by the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) in 2014 [RLIT0000812]. Please could you explain:***

a. Your relationship with JPAC;

117. I had no formal relationship with the main JPAC and never attended their meetings. I was an advisory expert on one sub-committee on component development chaired by Dr Rebecca Cardigan.

b. How guidance from JPAC is used by clinicians including your understanding of how influential the guidance is upon clinicians and hospitals; and

118. Guidance from JPAC was largely about component specifications and blood centre related issues. The handbook of transfusion medicine does, I hope, have influence on clinicians but I have no measure of this.

c. Your involvement with the 2014 guidelines mentioned above, including whether you made a significant contribution to any of the guidelines

eventually published.

119. I had more involvement with the third and fourth editions of the handbook. I have already referred to being co-author of chapter 6 in the 3rd edition and section 3 in the 4th edition. I reviewed but did not author sections in the 5th edition

37. During your tenure at the Freeman Hospital (and throughout any other roles/committees), were you aware of patients being given blood transfusions with red blood cells imported from the USA? If so, was there any concern about its use at the time?

120. No

Haematological malignancies

38. To the best of your knowledge, was guidance provided to you and/or other medical professionals by the Freeman Hospital as to transfusion policies and practices during the time of your employment? If so, please outline in as much detail as possible, the policies in place which would prompt you to transfuse haematological malignancy patients, including but not limited to the following:

a. Leukaemia;
b. Lymphoma; and
c. Multiple myeloma.

If possible, please refer to how many units of blood would be used, the impact of chemotherapy and/or radiotherapy on the need for transfusions and the use of autologous transfusion. Please also refer to any other considerations such as when not to transfuse and adverse reactions. Please also explain how these policies changed over time.

121. Please see my answers to previous questions 15 and 21f. The policies for transfusion were taken from BCSH guidelines. They did not differ significantly for the

diseases mentioned. For patients with aplastic anaemia, we avoided prophylactic platelet transfusions where possible as per BCSH guidelines. Chemotherapy and radiotherapy increased immediate anaemia but if effective in disease control would lessen anaemia and thus the need for long term blood transfusion. Autologous transfusion is not appropriate in patients with bone marrow failure.

122. The threshold for platelet transfusion in an individual patient is now lower than 30 years ago. There remains some uncertainty about the benefits of liberal versus conservative red cell transfusion in this group of patients. Overall I do not think practice has changed much over 30 years.

39. What alternatives to blood transfusion were available to patients with haematological malignancy?

123. Erythropoietic agents were used on occasion but were of limited efficacy in my experience in patients with bone marrow failure other than a few patients with myeloproliferative disease. Anabolic steroids are or were occasionally used but also with limited benefit.

40. ***The Scottish National Blood Transfusion Service stated that the 'modern treatment of cancer by chemotherapy - particularly blood cancer (leukaemia) - necessitates intensive support using platelet concentrates. These patients and others requiring multiple transfusions need special platelet preparations - from single donors...' [SCGV0000159_178]. Please explore:***

a. Why leukaemia patients specifically required transfusion with platelets over other blood components

124. Leukemia patients often need prolonged platelet support during intensive chemotherapy because the disease and its treatment causes bone marrow failure and platelets are made in the bone marrow. Platelets are given to prevent or reduce significant and life threatening bleeding. Leukemia patients also need intensive red

cell support.

b. How often leukaemia patients would require a transfusion with platelets;

125. From a single dose for some patients to daily doses for several weeks for other patients.

c. 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 amount?

126. Standard practice is to transfuse a single adult dose as required. One adult dose was either made from a single apheresis donor unit of platelets, or from 4-6 whole blood donation units. Patients with active bleeding, undergoing a procedure or with severe platelet refractoriness might require 2 or more adult doses at one transfusion episode.

d. If the Department had a similar policy in relation to platelets being prepared by 'single donors'? If so, please explain the reasoning for this.

127. Single donor platelets were preferred in a patient likely to require repeated doses of platelets as this reduced the chance of Human Leucocyte Antigen (HLA) sensitisation leading to platelet refractoriness. Patients with HLA sensitisation and platelet refractoriness were preferentially given HLA matched platelets from a single donor.

41. Please consider [NHBT0113679_002] and, in particular, the concern that platelet concentrates, 'which is used to treat bleeding in patients, especially those being treated for leukemia', are being administered without full testing.

Please confirm:

a. If you are aware whether patients under the care of the Department where

transfused with platelets that had not undergone full testing; and

b. How you became aware of the information including discussions and/or any information passed to clinicians by the Hospital.

128. This document is not dated or signed but appears to come from Manchester Blood centre, when the regional transfusion centres were entirely independant, sometime prior to 1985. I do not recall that platelets units were ever issued from Newcastle Regional Transfusion Centre without full testing. Where a component was not considered ready for issue, but the clinical demand was exceptionally acute, a consultant from the centre would speak to the haematologist at the requesting hospital and issue a derogation note to that effect. This was rare and I do not recall it relating to virological testing of platelets. I do not recall when this practice started or if it was in place from before 1990.

Section 4: Knowledge of risk

General

42. When you began working at the Department, what did you know and understand about the risks of infection associated with blood transfusions? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

129. I do not recall in any detail my knowledge of the various viral infections transmitted by transfusion at that time.

Hepatitis

43. What was your knowledge and understanding of the risks and transmission of hepatitis, including HBV and HCV from blood transfusion? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

130. I was aware during training in the years before 1990 of concern at the transfusion centre with regard to Non-A non-B hepatitis (once the genome had been discovered in 1989 this became Hepatitis C). I do not believe that I was aware or knew at that time of the natural history of the infection or the possible long-term consequences of Non-A non-B (Hepatitis C). The liver unit at Freeman hospital had an interest in Hepatitis C and I think it is likely that I would have heard about this at medical rounds. I note a paper published by my colleagues in 1995 regarding liver abnormalities in patients with Hepatitis C including some patients with post-transfusion Hepatitis C (Watson JP, et al. Hepatitis C virus: epidemiology and genotypes in the north east of England. Gut. 1996 Feb 1;38(2):269-76.) [WITN6982004]. Antibody testing for Hepatitis C was initiated at our Regional transfusion centre sometime in 1990-1991. It would be fair to say that my understanding will have developed over the period from 1986 to 2000. By the year 2000, genomic testing for hepatitis C was being introduced and the risk of transmission by transfusion was estimated to be low or very low. I am aware that Hepatitis B testing remains more problematic. I do not recall the depth of my knowledge about Hepatitis B or how it may have changed during 1980 to 2000.

HIV and AIDS

44. When you began work at the Department, what was your knowledge and understanding of HIV and AIDS and in particular of the risks of transmission through blood transfusions? How did that knowledge and understanding develop over time?

131. I was aware of HIV/AIDS and the risks from transfusion from the mid 1980s. I was also aware that donor exclusion was very effective at reducing transfusion risk and that antibody testing further reduced the risks of inadvertent transmission. I was aware of possible infections from donors donating in the window period and how improvements in tests gradually reduced this window period. I studied carefully the initial and subsequent reports from the Serious Hazards of Transfusion (SHOT) haemovigilence scheme which began in 1996. My recollection is that these strongly suggested that more immediate risks of transfusion including Transfusion associated

Graft versus Host disease, Post transfusion purpura, bacterial infection, Transfusion related acute lung injury and ABO incompatible blood transfusions caused significantly more morbidity and mortality than viral transmissions.

Other

45. If you were responsible for making decisions and actions on behalf of the Department in response to any known or suspected risks of infection, please explain what decisions were involved. If applicable, do you consider that those decisions were adequate and appropriate? If so, why? If not, please explain what you believe could or should have been done differently.

132. With regard to the risks of bacterial infection, we introduced an investigation protocol for all adverse transfusion reactions that could possibly represent bacterial infection. We also introduced a temperature monitoring system for all units returned un-transfused to the blood bank from the wards. We relied on and trusted the Regional transfusion centre to perform virological testing of the units. If a patient developed signs and symptoms suggesting possible viral hepatitis, we would perform appropriate tests. Similarly if a patient who had at some stage received transfusion developed HIV or a viral hepatitis, we liaised promptly with the hospital virologists and the regional transfusion centre. I do not recall any case of acute hepatitis B or C that was proven to be due to blood transfusion, or a case of chronic hepatitis or HIV in which we established prior transfusion as the cause. I do recall one case of acute Cytomegalovirus (CMV) infection that we believed had resulted from recent transfusion in the Far East.

46. Did the Freeman Hospital have any procedures in place to ensure patients reported any adverse reactions or symptoms? If so, please explain:

a. What procedure did the Hospital have in place?

134. My predecessor had initiated a scheme for reporting all adverse reactions to transfusion. During my time at Freeman Hospital/NUTH, we continued to develop and strengthen this system. We introduced flow charts for managing and reporting

such reactions and transfusion folders on every ward with further information if required. The laboratory scientific officers were commonly the first to be alerted to a reaction and would discuss them with myself or other haematology consultants, a Haematology registrar, or other on-call staff out of hours. We introduced a new grade of staff in the late 1990s, Transfusion Nurses, one of their roles being to follow up and investigate all such reports. We reported serious cases to SHOT from 1996 in accordance with their guidance.

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

135. There was no formal procedure for patients to report back to us once discharged but we as a department were open to receive reports or queries from general practitioners or from hospital staff should a patient be re-admitted with a problem possibly related to recent transfusion.

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

136. I cannot recall exactly what patients were told if they were discharged shortly after a transfusion. Same day transfusion and discharge was a common event on the specialist haematology wards and the staff were well aware of possible adverse reactions.

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?

137. To the transfusion laboratory and /or medical haematologists.

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

138. Any reaction where there may have been concern about the quality of a donor unit was reported promptly to the Regional transfusion centre. This was both to inform them and in case other components made from the same donation should be quarantined pending further investigations, and when the transfusion centre had laboratory expertise and needed to carry out their own tests on a suspect unit.

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.

139. Should a patient have been recognised to have died as a result of a blood transfusion, the coroner would have been informed and his/her advice taken on registration of the death.

Section 5: Treatment of patients

Provision of information to patients

47. What information did you provide or cause to be provided to patients in the Department about the risks of infection by blood transfusion prior to treatment commencing?

140. Please see my answer to question 7

48. If the nature of provision of information changed over time whilst at the Department, could you please explain how this was so and why changes were made?

141. Please see answer to question 7. Changes in information leaflets were made as new facts emerged.

49. Please describe if the Department had a process of informing patients that they had been, or might have received infected blood through a transfusion If so, how were patients or their relatives informed? What if any involvement did you have in this process?

142. Please see my previous answers. I would only have direct involvement if the patient was under my direct care. I do not recall this happening during my time at FH/NUTH. I do recall liaising with other clinicians when we had been informed of a possible infected donation. We advised them in consultation with the NBTC/NHSBT and local microbiology department of what to tell the patient and what tests to carry out. I do not recall any proven cases of infection arising from such investigations.

Consent

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

143. This will have happened on many occasions when patients were admitted unconscious, without capability and with no responsible adult (e.g. delirious or cognitively impaired). Despite our efforts, it is likely that there were times when a patient undergoing surgery received a blood transfusion having not had full informed consent even if they had signed a consent form. I am aware of at least one case where a child of parents with a religious objection to transfusion was made ward of court to enable a life saving transfusion to be administered.

Other

51. Were any audits or surveillance programmes regarding the use of blood transfusions by the Haematology Department conducted at the Hospital? If so, please explain these processes and the impact they had on blood transfusion standards and practice.

144. Please see my answers to question 18. We carried out numerous audits and surveys of blood use in different departments including on-going audits in

cardiothoracic surgical patients. As a result of these and other factors, we saw a fall in red cell usage of around 30% over 20 years despite an increase in clinical activity. We believe that the education and other initiatives improved transfusion standards. See for instance the papers referred to under Transfusion process in my answer to question paper 13/14.

52. At Freeman Hospital, were any efforts made to monitor the incidence of transfusion-transmitted infections in patients? If so, please explain these processes, the findings, and the impact they had on blood transfusion standards and practice.

145. No

53. At Freeman Hospital, were you involved in any efforts made to trace potentially infected donors or recipients of infected blood transfusions? If so, please explain these processes, the findings, and the impact they had on blood transfusion standards and practice.

146. Yes.

I. Donor becomes positive for a viral marker at a subsequent donation. The NBTC/NHSBT would request we trace the recipient. They would then inform the clinician whose patient this was and/or the general practitioner and request recipient testing. I do not recall any proven viral infections arising from these investigations.

II. A donor informs the NBTC/NHSBT that they have developed symptoms of an infection of some sort shortly after donation. The same process would be followed depending on the outcome of investigations in the donor.

III. A recipient is diagnosed with a viral infection thought possibly transmitted by prior transfusion. We would trace the donation details and liaise with the NBTC/NHSBT to have further investigations made.

IV. Donor unit develops a positive blood culture result after component issue.

This was a recent development when post donation blood culture was introduced by the NHSBT sometime after 2010.

147. I do not recall specific findings other than I do not recall ever proving a case of HIV/HBV/HCV having been transfusion transmitted. Exercises such as these reiterated the importance of maintaining good records of transfusion.

54. Please consider the enclosed letter from you to Dr Wells dated 5 July 2004 regarding an investigation into a possible transmission of HIV by blood transfusion at Freeman Hospital in 1996 [NHBT0030389_040]. If you are able to recall, please explain the circumstances surrounding the request for an investigation, including from whom the request was made, and the outcome of the investigation

148. I cannot recall the circumstance or outcome. But please see my answer above.

Section 6: vCJD

55. When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood transfusions? Please explain how your knowledge developed over time.

150. My recollection is that I became aware of a possible risk of transmission of vCJD by transfusion in 1995. About this time the first case of variant or bovine CJD in a human was described. It was noted that unlike other forms of CJD, vCJD seemed to involve lymphoid tissues. Because lymphoid cells may be present in blood components, it was considered possible that donated blood from a person incubating vCJD could in theory transmit that disease. The NBTC commissioned a study of that risk from a Cambridge based firm, Det Norske Veritas. As a result, leucofiltration of all blood units was introduced sometime in 1999. That there was a risk was confirmed with the report in 2003/4 of a case of vCJD in a recipient of blood from a donor who had later gone on to develop clinical vCJD. Throughout this time

period we remained very concerned with the possible risk of transfusion transmission but considered the risk from individual blood donations to be low. We did not consider that the risk was sufficient to change our then recommended transfusion practice.

56. Did you have any involvement in decisions as to what information to provide to patients about vCJD? If so, please answer the following questions:

151. Yes.

a. What steps were taken/put in place in the Department for informing patients about the risks of or possible exposure to vCJD?

152. Our information leaflets for patients included the risk of vCJD. I do not recall the exact dates or content of these leaflets.

b. What steps were taken to arrange for counselling, support and/or advice to be offered to patients who were being informed that they might have been exposed to vCJD?

153. I was not involved in contacting these patients or any counselling. We did not routinely counsel patients who had received a transfusion of greater than 80 (subsequently changed to >300) blood donations (the department of health's cut off for increased risk of TavCJD).

57. What measures were put in place from a public health perspective at the Freeman Hospital in relation to the care and treatment of patients in light of the risk associated with vCJD transmission by blood transfusion?

154. Certain individuals were considered to be at higher risk of vCJD from transfusion. These included patients who had received multiple transfusions (>80)

and some others. Sometime after 2010, in line with DH/NHS advice, the hospital established a group under the leadership of the microbiology department to detect and assess high risk patients presenting for surgery or other procedures thought likely to be avenues of onward transmission of vCJD. We cooperated in providing data on those who had received multiple blood transfusions (see WITN6982003 un-published paper). Look-back investigations from donors who subsequently developed vCJD were co-ordinated and managed by the NHSBT and the CJD surveillance unit in Edinburgh. Details of the local policy and some aspects of national advice were available at that time from:

a. The Newcastle upon Tyne Hospitals NHS Foundation Trust Policy for the Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt-Jacob Disease (CJD), in the hospital and community setting. Available at http://www.newcastle-hospitals.org.uk/downloads/policies/Infection%20Control/CJDInfectionControlPolicy201202.pdf (last accessed 1st February 2012). Note that the link is no longer accessible.
b. Blood borne transmission of vCJD: re-examination of scenarios [RLIT0001005]
c. The Risk of Secondary vCJD Infection of Patients Receiving a High Number of Blood Transfusions [RLIT0001006].

58. With reference to all of the committees named in your answer to question 3 above, please outline the extent to which any of those committees were involved in assessing and managing the risk of vCJD transmission by blood transfusion.

155. The national transfusion committee discussed the problems associated with vCJD transfusion risk but guidance on management of risk was led by SABTO and other groups.

59. Please consider the enclosed paper from 2001 by Dorothy Stainsby titled

'Transfusion Epidemiology", to which you contributed [NHBT0040352]

a. To your knowledge, how, if at all, did the risk of vCJD transmission through blood transfusion affect the supply and use of blood components for transfusion at Freeman Hospital (or any other institutions at which you worked during the relevant time)?

b. With respect to the risk of vCJD transmission, please outline what actions, if any, were taken in response to the collection and findings of this data.

156. I had not seen this paper previously. It includes data from a study led from Freeman hospital (see previous references on Transfusion epidemiology in answer to question 13/14). It appears to be an internal appraisal for the NBTS/NHSBT. No effective donor tests or blood treatments (e.g. filters) for vCJD carriage were developed despite much effort. Therefore, there was never any need to provide special products for vulnerable recipients except with regard to products that could be imported. It was recommended by the Department of Health that if possible blood components for children be sourced from countries with a low risk of vCJD. This was only possible for frozen plasma components. The choices were Methylene blue treated imported plasma (NHSBT) or Octoplas (Octapharma). Other than this, the risk of vCJD transmission did not to the best of my recollection affect the supply of blood components to Freeman Hospital/NUTH. Our findings were just one part of the data required to assess any longer term risk of any chronic infection such as vCJD resulting from transfusion. To the extent that most blood components were used in the older patient, and that the survival of these patients was reduced below normal in the 5 years post transfusion due to the diseases for which they were being treated, our fears regarding vCJD were perhaps eased. However the data also showed that younger patients, after a period of increased mortality, again thought to be due to the diseases for which they were being treated and not the transfusion itself, subsequently had survival on a par with the rest of an age matched population. We therefore took especial care to advocate conservative or restrictive transfusion policies in younger patients with good long-term survival prospects.

Section 7: Other issues

60. Please provide details of any complaints made about you (insofar as relevant to the Inquiry's Terms of Reference) to your employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

157. I am aware of no complaints made about myself relevant to the Inquiry's Terms of Reference made to my employer at the time, or to the GMC, the health service ombudsman or any other body.

61. Please provide any further comment that you wish to provide about matters of relevance to the Inquiry's Terms of Reference.

158. I am aware that the Inquiry's main or only concern regards infection by blood transfusion. The questions posed above are looking to establish what risks we as clinicians managing the transfusion process at the hospital level were aware of and how we responded to them. Although viral infection remained a serious concern to all in the field of transfusion, other risks of blood transfusion were more prevalent and in terms of early mortality, more pressing. The reports from the haemovigilance organisation SHOT have been fundamental to a better understanding of the true risks of transfusion and have become a model for haemovigilance organisations worldwide. The information from these schemes has led to marked improvements in transfusion safety. Over the same period there has been a steady change in use of red cell transfusion in particular, driven by better understanding from clinical research studies. The UK and its national Transfusion services have been active in these developments. The close co-operation between the national transfusion services and hospitals has been key to these advances.

Statement of Truth

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

Signed GRO-C

Dated 2 February 2022

Table of exhibits:

Date	Description	Exhibit number
01/01/2001	Chapter 6 pages 39-58 of the Handbook of Transfusion Medicine, 3rd edition. ed DBL McClelland	WITN6982002
Undated	Abstract of unpublished paper revCJD exposure - Newcastle Upon Tyne Hospitals NHS Trust	WITN6982003
01/01/1996	Watson JP, et al. Hepatitis C virus: epidemiology and genotypes in the north east of England. Gut. 1996 Feb 1;38(2):269-76	WITN6982004
11/02/1999	Hebert PC. et al. A multicenter, randomized, controlled clinical trial of transfusion requirements in critical care. N Engl J Med. 1999;340:409-17	WITN6982005