Witness Name: Michael Murphy
Statement No.: WITN7001001
Exhibits: WITN7001002-060
Dated: 4th February 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR MICHAEL MURPHY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 11 November 2021.

I, Professor Michael Murphy, will say as follows:

1. Firstly, and most importantly, I would like to express my sadness for what happened to patients infected as a result of blood transfusion. The tragic evidence presented to the Inquiry has highlighted to me how this has affected both them and their families over many years. I hope the evidence presented to the Inquiry will provide the answers that they have been looking for and the learning to help our patients in the future.

2. I consider that the most relevant evidence I have to give is about:-

    a) the provision of information about blood transfusion to patients and obtaining their consent to transfusion as it was in hospitals in the late 1980s when I was first a Consultant Haematologist, and how it has progressed since then.
    b) the efforts made to minimise patients' unnecessary exposure to blood transfusion through national *'Better Blood Transfusion'* initiatives from 1997 onwards.

3. I have tried to address these two issues throughout the statement where relevant, and about patient information in more detail at the end of the statement.

4. My evidence focusses on patients receiving blood transfusion and not plasma concentrates such as factor VIII which have a much greater risk for transmitting infection as they are made from multiple blood donations. The principles about providing information and obtaining consent are the same, but my experience is in blood transfusion.

Section 1: Introduction

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

5. Professor Michael F Murphy

NHS Blood & Transplant, John Radcliffe Hospital, Oxford OX3 9BQ

DOB: GRO-C 1951

Qualifications: MD, FRCP, FRCPath, FFPath

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

6. See Table below. I 'retired and returned' at the end of May 2021 and now work 3 days/week (7 Programmed Activities).

7. My national responsibilities for transfusion practice extended from 2000 when I was appointed Lead Consultant for Hospital Liaison for the National Blood Service (NBS) (2000 to 2004), then Clinical Director (Patients) NBS/NHS Blood

& Transplant 2004 to 2014), and Secretary of the National Blood Transfusion Committee (2001 to 2015).

8. Since 2015, my work has focused on transfusion practice at the Oxford University Hospitals, research and teaching, and international activities for the Biomedical Excellence for Safer Transfusion (BEST) Collaborative and for AABB (American Association of Blood Banks, now the Association for the Advancement of Blood & Biotherapies).

9. Current Positions:

   a) 1996-present. Consultant Haematologist, NHS Blood & Transplant and Department of Haematology, Oxford University Hospitals NHS Foundation Trust, Oxford.
   b) 2004-present. Professor of Blood Transfusion Medicine, University of Oxford.

10. Previous Posts:

   a) 1974-1978 House physician and SHO medical posts at St. Bartholomew's Hospital (gastroenterology and diabetes), St. Leonard's Hospital (general medicine), Guy's Hospital (renal medicine), Brompton Hospital (chest medicine), National Heart Hospital (cardiology).
   b) 1978 Research Registrar in Haematology, St. Bartholomew's Hospital.
   c) 1978-1980 Registrar in Haematology, St. Bartholomew's Hospital.
   d) 1980-1984 Senior Registrar in Haematology, St. Bartholomew's Hospital.
   e) 1985-1996 Senior Lecturer (Honorary Consultant) in Haematology, St. Bartholomew's Hospital.
   f) 1998-2004 Senior Clinical Lecturer in Blood Transfusion, University of Oxford.
   g) 2000-2004 Lead Consultant for Hospital Liaison, National Blood Service.
   h) 2004-2014 Clinical Director, Patients, NHS Blood & Transplant.

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.

11. National and international committees

a) *Department of Health Committees:*

i) 2000-2007 Member, National Commissioning Group

ii) 2001-2015 Secretary, Chief Medical Officer's National Blood Transfusion Committee

iii) 2004-2005 Member, Barcoding Group of the National Clinical Advisory Board for the National Programme for IT

iv) 2006-2011 Member, Emergency Planning Clinical Leadership Advisory Group

v) 2007-2010 Chair, Connecting for Health/National Patient Safety Agency Blood Safety IT Pilot Steering Group

vi) 2008-2011 Member, Pandemic Influenza Clinical and Operational Advice Group

vii) 2009-2011 Member, Pandemic Influenza Advisory Group

viii) 2009-2010 Chair, NPSA 'Right Patient-Right Blood' Committee

ix) 2018-present Member, Advisory Committee for Safety of Blood, Tissues and Organs (SaBTO)

b) *External Scientific Committees:*

i. British Society for Haematology:

- 1992-1995 Secretary, British Committee for Standards in Haematology
- 1995-2001 Member, British Committee for Standards in Haematology Blood Transfusion Task Force

ii. Biomedical Excellence for Safer Transfusion Research Collaborative (BEST):

- 1999-present Scientific Member
- 2000-present Member, Executive Committee
- 2000-2001 Co-Chair, Clinical Trials Group

- 2001-2014 Co-Chair, Transfusion Safety Group
- 2014-2018 Chair
- 2018-2022 Treasurer

iii. American Association of Blood Banks (AABB)

- 2001-2005 Member, Clinical Transfusion Medicine Committee
- 2005-2008 Member, Annual Meeting Program Unit
- 2010-2017 Board Member
- 2016-2017 Vice President
- 2017-2018 President elect
- 2018-2019 President (as the first non-North American President)

iv. Royal College of Pathologists

- 2004-2006 Member of Transfusion Medicine Committee
- 2006-2008 Chair of Transfusion Medicine Committee and Member of Council

v. International Society of Blood Transfusion

- 2002-2005 Co-Chair, Platelet Immunology Scientific Sub-Committee, International Society of Haemostasis and Thrombosis

vi. American Society of Haematology

- 2021 Lead for Education Program in transfusion medicine

4. Please explain how you kept abreast of medical and scientific developments and research in your field in the course of your career.

12. Being active in research through conducting clinical studies, attendance at scientific meetings, discussions with colleagues and reading the scientific literature relevant to my specialty, including the British Medical Journal, the Lancet, New England Journal of Medicine, British Journal of Haematology, Blood, Transfusion, Vox Sanguinis, and Transfusion Medicine.

5. Please confirm whether you have provided evidence or have been involved in any other inquiries, investigations, criminal or civil litigation in relation to

the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement.

13. I have not been involved in any such inquiries.

Section 2: Your role at St Bartholomew's Hospital, London

6. Please describe the role, functions and responsibilities you had at St Bartholomew's Hospital, London, during your period as Consultant Haematologist and explain how this changed over time.

14. I was Consultant Haematologist from 1985 to 1996 with responsibility for haemostasis and thrombosis and for blood transfusion. My responsibility for haemostasis and thrombosis was to provide an anticoagulant service and to provide clinical advice about patients with acute bleeding, for example after trauma or major surgery; Barts was not a Haemophilia Centre. I also had general haematology duties including clinics for non-malignant haematology conditions. In my blood transfusion role, I supported the blood transfusion laboratory in providing clinical and laboratory advice to clinical colleagues about good transfusion practice, and investigating adverse events. I also conducted research (see later).

7. What experience did you gain in this role which led you to be given the role as Consultant Haematologist, National Blood Service and Oxford Radcliffe Hospitals in 1996?

15. The experience I gained in transfusion medicine at Barts led directly to my appointment in Oxford in 1996. My hospital transfusion experience at Barts and leadership nationally was what was required in the Oxford hospitals which did not have a consultant haematologist with expertise in transfusion medicine at that time. The National Blood Service was interested in supporting hospitals by

providing consultant sessions in Oxford and in demonstrating its continued commitment to the Oxford region at a time it was withdrawing some of its services such as processing and testing of blood donations from Oxford to Bristol.

16. The further experience I subsequently gained in Oxford enabled me to contribute to many national initiatives for better transfusion practice including those for *Better Blood Transfusion* and *Patient Blood Management*.

17. My work at Barts involved efforts to improve the quality of the hospital transfusion process through:

    a) Education of doctors (WITN7001002);
    b) Developing guidelines (NHBT0135088);
    c) Conducting audits of transfusion to identify where practice needed to be improved (WITN7001003) especially to avoid ABO incompatible red cell transfusions, which can be fatal (and are now designated to be 'never events');
    d) Establishing a Hospital Transfusion Committee along the lines of British Committee for Standards in Haematology guidelines led by my colleague and mentor Professor Alan Waters (WITN7001004);
    e) Clinical research (see answer to Q13).

8. Please describe:

a. Your work at St Bartholomew's Hospital insofar as it involved treating patients with blood transfusions.

18. I provided advice about good transfusion practice, as described above. I also provided specific advice for the indications for transfusion and how to avoid complications of transfusion primarily in relation to the management of patients being treated for malignant haematological conditions as I had a close relationship with the Medical Oncology team caring for those patients, and for patients cared for by other clinical services as required.

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

19. I had no direct involvement in the care of these patients. As described above, Barts was not a Haemophilia Centre.

9. Please:

a. Describe the roles, functions and responsibilities of the Haematology department ("the Department") within St Bartholomew's Hospital during the time you worked there.

20. The Haematology Department provided a diagnostic laboratory service (blood counting, blood film and bone marrow morphology, haemostasis and thrombosis testing, blood transfusion service) and managed patients with benign haematological conditions. Patients with malignant haematological conditions were managed by Medical Oncology.

b. Outline the facilities and staffing arrangements for the care of patients who needed to undergo or were undergoing blood transfusions.

21. Patients needing blood transfusions were managed by the relevant clinical service. The blood transfusion laboratory was responsible for ordering blood from the Regional Transfusion Centre and providing compatible blood for patients as requested by clinical services.

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.

22. Consultant colleagues:

Professor Alan Waters – Head of Department

Dr John Amess (Consultant) – General Haematology

Dr Adrian Stephens (Consultant) – Haemoglobinopathy

10. Describe the relationship between the Department and other Departments in the Hospital, particularly in relation to determining whether a patient required a blood transfusion, and the transfusion policies and practices of the Hospital. a. Please explain how this changed over time.

23. See answer to 9b. This did not change during my time at Barts.

11. Please describe the relationship that you had with the National Blood Transfusion Service ("NBTS") on behalf of the Department.

24. The transfusion service at Barts had a close relationship with the Regional Transfusion Centre at Brentwood for the provision of blood, reference services and advice. I do not remember any specific relationship with the NBTS.

12. Please outline approximately:

a. How many patients per week would receive a transfusion under the care of the Department?

25. The Haematology Department did not have direct responsibility for the clinical care of patients who might receive transfusions except for a very small number of patients under its own care with benign haematological conditions such as autoimmune haemolytic anaemia and thrombocytopenia, iron deficiency anaemia, megaloblastic anaemia, and haemoglobinopathy. The Department's transfusion service provided blood as requested by clinical services such as surgery, medical oncology, obstetrics, and paediatrics.

26. I cannot remember the exact numbers of transfusions administered per year or per week, but they would have been of the order of 6,000 units of red cells per

year and other blood components such as platelets and fresh frozen plasma. This would suggest an average of 120 red cell units per week.

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

27. I have no recollection of any patients infected with HIV, HCV or HBV as a result of transfusion.

13. Was any research undertaken within the Department regarding blood transfusion patients? 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 if consent was obtained.

28. The research interest of the Department was closely allied to the Medical Oncology Department for the diagnosis and treatment of patients with malignant haematological conditions.

29. My research interest was primarily for the supportive care of these patients with transfusion. My specific interest at that time was to prevent these multi-transfused patients developing antibodies which would reduce the effectiveness of platelet transfusions and cause febrile reactions. I collaborated with the Medical Oncology and transfusion service colleagues on a number of small observational studies to determine the best transfusion care. An example of the methods used for such a study is given below:-

Eighty-six patients with newly diagnosed acute leukaemia entered the study. Those found to have HLA or platelet-specific antibodies at presentation, and those subsequently receiving granulocyte transfusions or dying within 2 weeks of commencing chemotherapy, were excluded. The remaining 61 patients received one of three transfusion programmes, depending on the availability of leucocyte-poor blood components and HLA-matched platelet donors for each patient: 'Control' group. Plasma-reduced red cell transfusions. Single platelet concentrates from random donors.

'Leucocyte-poor 'group. Filtered red cell transfusions. Leucocyte-poor single platelet concentrates from random donors. 'HLA-matched' group. Filtered red cell transfusions. Leucocyte-poor platelet concentrates from platelet donors matched for at least three out of the four HLA-A and HLA-B loci. Patients received red cell transfusions for anaemia (Hb < 10 g/dl), and prophylactic platelet transfusions when the platelet count was less than 20 x 10^9/l. In the few patients where prophylaxis failed to prevent bleeding, additional platelet transfusions were given (WITN7001056).

30. Patient consent was not obtained for this study as it was considered that the two 'test' transfusion programmes were superior to the standard 'control' programme, and indeed this was shown to be the case.

31. Another study in 1996, just before I left Barts, involved asking patients about consent to transfusion. It was a project conducted by 2 medical students under my supervision, and is summarised below:-

> *There is no current requirement in the United Kingdom to provide patients with information about blood transfusion or to seek their written consent to transfusion. To study patients' attitudes to these questions, a questionnaire survey was carried out on 51 patients during an admission to hospital in which they received a blood transfusion. Only 16 (31%) of patients were given any information before the transfusion; the remainder were either given none or simply told they had to have the transfusion. On the other hand, 42/51 (82%) patients thought they had received enough information, and 47 (92%) understood why the transfusion was necessary, because of anaemia or to replace blood loss during surgery.*

The patients in this survey, although mostly satisfied about the information they were given before they were transfused, would have welcomed more general information about transfusion, mainly because of concerns about the risk of viral infections. Nearly 40% of patients thought that written consent should be obtained before transfusion, but the ethical and practical aspects of this issue are complex. Further debate would be required before implementation of written consent to transfusion could be considered as a routine policy (NHBT0017564)

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

32. See the answer to Q13.

15. What national or regional policies, guidance, standards, or protocols were in place during your time at St Bartholomew's that governed blood transfusions? a. Did these change during your time as a clinician? If so, how?

33. We followed recommendations from the Regional Blood Centre and the guidelines for blood transfusion in hospitals provided by the British Committee for Standards in Haematology.

16. Were these policies/guidance/standards/protocols advisory or binding upon you? Please consider this with particular reference to the giving of a blood transfusion in the following medical situations:

a) Obstetrics;
b) Trauma and emergency care;
c) Surgery;
d) Non-haematological cancer treatment;
e) Haematological cancer treatment;
f) Thalassaemia;
g) Sickle cell anaemia.

34. The guidelines (a-g) were advisory.

17. Please outline at which level generally a patient's haemoglobin count would be considered low and thus require a blood transfusion. Please also explain how this level may have changed over time.

In the 1980s and 1990s, patients generally received red cell transfusions for anaemia (Hb < 100g/L). This was generally accepted practice at that time in the absence of

evidence that restrictive transfusion practice for transfusion at lower Hb levels (Hb <70g/L) was superior or non-inferior to liberal red cell transfusion (Hb <100g/L). The first study to demonstrate this was the TRICC trial in intensive care patients (WITN7001057).

Evidence for the safety of restrictive transfusion increased in the following years (WITN7001058; WITN7001059)

35. The plain language summary WITN7001060 is provided below:

> *Is it safe to use lower blood counts as a trigger for blood transfusion in order to give fewer blood transfusions?*
>
> *Background*
>
> *Doctors and healthcare professionals often give blood transfusions to people after loss of blood from surgery, bleeding, or medical illnesses. Blood is a limited resource, so for this reason, and because some low-income countries do not test the blood used in transfusions for the presence of dangerous viruses such as HIV or hepatitis, it is helpful to give blood transfusions only when they are really necessary.*
>
> *A normal blood count is above 12. This review summarised all randomized controlled trials (RCTs) that investigated whether it is safe to give blood transfusions when the blood count drops to between seven and eight (thereby reducing the number of transfusions), rather than giving transfusions at higher blood counts of nine to 10.*
>
> *Study characteristics*
>
> *We examined the results of RCTs that randomly allocated participants to one of two groups. In one group, trial participants received blood at lower*

blood counts. In the other group, trial participants received blood at higher blood counts. The data are current up to May 2016.

Key results

We identified a total of 31 relevant trials, which involved 12,587 participants. All of the studies compared different policies for blood transfusions. We found that participants who were assigned to receive blood at lower blood counts were 43% less likely to receive a blood transfusion than those who were given blood at higher blood counts. The risk of dying within 30 days of the transfusion was the same whether the participants received transfusion at lower or higher blood counts. We also evaluated harmful events that occurred after participants received, or did not receive, blood transfusions, including infection (pneumonia, wound infection, and blood poisoning), heart attacks, strokes, and problems with blood clots, and found that there was no clear difference in the instance of these events between the group that received transfusions at lower blood counts and the group that received transfusions at higher blood counts.

Quality of evidence

We found that most of the RCTs provided a high quality of evidence, in that they were adequately conducted and used appropriate methods that minimised any possible biases that could make the validity of the results uncertain.

Authors' conclusions

We concluded that it was not harmful to the participants' health status to give blood at lower or higher blood counts. If a policy of giving blood only at lower blood counts were followed routinely in clinical practice, it would reduce the amount of blood patients receive substantially and reduce the risk of patients receiving blood transfusions unnecessarily, as transfusions can have harmful effects. Additional studies are needed to establish the blood count

at which a blood transfusion is needed in patients who have suffered a heart attack, brain injury, or have cancer.

18. Where applicable, were alternative treatments made available to patients under the care of St Bartholomew's Hospital throughout the time of your employment but specifically in the 1970s and 1980s?

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

36. 'Alternative treatments to transfusion' such as the use of tranexamic acid to reduce bleeding in surgical patients and intra-operative cell salvage were not used to the same extent that they are in 2021. The evidence for the benefit of tranexamic acid in reducing blood loss in surgical patients came many years later, and the equipment for intra-operative cell salvage was not widely available in the 1970s and 1980s. I was responsible for blood transfusion as a consultant haematologist at Barts from 1985 to 1996 not in the 1970s or early 1980s.

b. Did the doctor/patient relationship have an effect on the way in which an agreement would be reached in selecting an alternative treatment? If so, please explain.

37. It is difficult to comment on this given my answer to question 18a about the lack of availability of 'alternative treatments' to transfusion in the 1970s and 1980s.

c. Referencing your answer to 18(b), did any aspect of this change over time?

38. The provision of information to patients about transfusion including about the availability and use of 'alternative treatments' remains less than perfect (see later in this witness statement).

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

39. Transfusions were recognised to carry risks but were generally regarded as a safe treatment to be used when the benefits outweighed the risks.

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 not?

40. Alternatives to transfusion were not considered in the 1970s and 1980s in the same way as they are now primarily because of the lack of evidence for their effectiveness and their lack of availability.

Section 3: Your role at Oxford Regional Transfusion Centre

19. Please describe the role, functions and responsibilities you had at the Oxford RTC ("RTC") during your period as Consultant Haematologist, NHS Blood & Transplant and Oxford Radcliffe Hospitals and explain how this changed over time.

41. In December 1996 when I was appointed as Consultant Haematologist for the National Blood Service (NBS) based at the Oxford Regional Transfusion Centre and for the Oxford Radcliffe Hospitals, the Regional Transfusion Centre in Oxford was undergoing major changes as a result of national changes being made by the NBS. It was changing from one that provided a comprehensive transfusion service for the Oxford region including blood collection, blood processing and donor testing to one focussing on distributing blood provided by other Blood Centres, primarily Bristol, to the hospitals in the Oxford region and providing other support for the hospitals such as reference testing, for example for patients where the hospital was experiencing difficulty in identifying compatible blood, and clinical advice.

42. The Oxford Regional Transfusion Centre became part of the National Blood Authority (NBA) South West Zone; its main centre was located in Bristol with other centres in Birmingham, Southampton and Oxford. Blood was provided to the

Oxford Centre from the Bristol Transfusion Centre and was then distributed from the Oxford Centre to the hospitals in the Oxford region.

43. My job description is provided in WITN7001005 . My main role for the NBS was to provide clinical advice to the hospitals in the Oxford region, drive quality improvement in transfusion practice, teach and conduct research.

44. There was also an expectation of my appointment to develop greater interaction with the Oxford Radcliffe Hospitals and research in transfusion medicine taking advantage of the opportunities for research in Oxford. It was hoped that my appointment would mitigate the local disappointment of the perceived downgrading of the Oxford Regional Transfusion Centre.

20. Please describe the organisation of the Oxford Centre during the time you worked there, including:

a. its structure and staffing and in particular to whom you were accountable;

45. I was accountable to the Chief Executive of the NBS Midlands and South West Zone, Gary Austin, and its Medical Director, Dr Tim Wallington. In the Oxford Radcliffe Hospitals, I was accountable to Dr Chris Bunch, Medical Director, and the lead Consultant Haematologist, Dr Tim Littlewood.

46. I initially had one consultant colleague, Dr David Collins, in the Oxford Regional Transfusion Centre. He retired soon after I joined. Over the next 5-6 years, other consultants were appointed, Dr Cynthia Beatty, from a trainee haematology post in the Oxford Radcliffe Hospitals, was recruited to support my routine service duties, and Dr David Roberts from the Institute of Molecular Medicine (now the Weatherall Institute of Molecular Medicine) to help me develop research in transfusion medicine.

b. how the Oxford Centre was funded and how this changed;

47. The Oxford Centre was funded by the NBS until it was disbanded in 2005 when the NBS amalgamated with UK Transplant to establish NHS Blood & Transplant.

c. its remit, including the geographical area it covered and the hospitals within its area;

48. See answer to the first part of Q19.

The Oxford Centre covered Oxfordshire (Oxford Radcliffe and Banbury Hospitals, later to be combined in one NHS Trust), Berkshire (Royal Berkshire Hospital), Buckinghamshire (Stoke Mandeville, Wycombe and Wexham Park Hospitals), Northamptonshire (Northampton General and Kettering Hospitals) and also the hospitals in Swindon.

d. its place in the NBTS together with information as to whom the centre was answerable to at the NBTS, if anyone. When answering this question, please refer to paragraphs 4-16 of Dr Harold Gunson's statement in A and Others v National Blood Authority and another [2001] 3 All E.R. 289 (A & Others) and explain whether you agree with what is stated (NHBT0000026_009);

49. I agree with Dr Gunson's statement, much of which describes events before I came to Oxford in 1996.

e. whether the Oxford RTC was associated or linked with other Regional Transfusion Centres ("RTCs") and, if so, how and for what purpose;

50. See answer to Q19. The Oxford Regional Transfusion Centre became part of the NBA Midlands and South West Zone; the main centre was located in Bristol with other centres in Birmingham, Southampton and Oxford.

f. whether the Oxford RTC was subject to any form of regulation and if so, what;

51. It was subject to the same regulation as other Transfusion Centres set out in the 'Red Book', Guidelines for the Blood Transfusion Services in the UK (in its 3rd edition in the mid-1990s) (NHBT0203827).

g. the Oxford RTC's relationship with the Blood Products Laboratory ("BPL") and any other laboratory involved in the production of blood products or processing of blood; and

52. The Oxford Regional Transfusion Centre was associated with BPL through their relationships in the National Blood Service. The Oxford Regional Transfusion Centre stopped collecting, processing and testing blood in 1996 as I arrived in Oxford apart from platelet collection and collection of a very small number of whole blood units mainly for the convenience of the staff working at the John Radcliffe Hospital wanting to donate blood on site. All blood donations collected in the Oxford region were tested and processed in the Bristol Transfusion Centre. The Oxford Transfusion Centre had no direct relationship with BPL or any other laboratory involved in the production of blood products.

h. the approximate number of donations collected each year.

53. I don't know the answer to this. I had no responsibility for blood collection or the care of blood donors. This responsibility lay with Consultants in the Bristol Transfusion Centre.

Section 4: Your role as National Clinical Director for Hospital Transfusion Practice

21. In WITN0643001, Lorna Williamson stated that in the 1990s, '*the NBA embarked on a major programme to ensure that there was much more expertise and resource available to improve transfusion practice in hospitals. The objectives were to ensure that blood was used appropriately, that transfusion errors in hospitals were minimised and that hospital staff and patients were better informed. This included: creation of a national*

Clinical Director post for Hospital Transfusion Practice (Professor Mike Murphy, Oxford), plus a team of joint consultant posts with key hospitals; creation of a nursing team to lead on educational activities with nursing and other staff in hospitals; promotion of hospital transfusion committees and transfusion practitioners in hospitals.'

a. What did you understand to be the reasons why the role of Clinical Director was created?

54. The title you have given to the post I held may be misleading. It was not National Clinical Director for Hospital Transfusion Practice but NBS Clinical Director (Patients). I think it is important to avoid the interpretation that I held a NHS National Director role, possibly with greater authority for driving improvements in hospital transfusion practice than I actually had.

    The Clinical Director posts were created 'to participate in the broader remit of the NBS Clinical Directorate and '*to share responsibility for driving forward a culture of change and innovation, of development and modernisation in the NBS*' (WITN7001006). There were 4 posts, one each in Donors, Diagnostics, Patients and Products.

b. How did you become aware of the position?

55. I became aware of the posts through a letter from Dr Tim Wallington with an invitation to apply for a Clinical Director post and the job description (WITN7001006).

c. Why do you believe you were given the job of Clinical Director for Hospital Transfusion Practice? If you are able to recall specific requirements that the position involved, please explain these.

56. The covering letter for my application to this post and my full application are provided as WITN7001007 and WITN7001008 . The application provides many details of my work in the NBS and the Oxford Radcliffe Hospitals as well as

my involvement and leadership in national initiatives such as guideline development and the *Better Blood Transfusion* initiative.

57. I had been given the role of NBS National Medical Lead for Hospital Liaison in May 2000 (WITN7001009) and established Regional Leads for Hospital Liaison throughout England from existing NBS consultants (about 10 posts) and in later years with some new appointments of joint NBS/NHS Trust Consultants. Their job purpose (WITN7001010) was :

    a) To promote good blood transfusion practice in hospitals, and the initiatives set out in *Health Service Circular 1998/224 'Better Blood Transfusion'* (NHBT0083701_002).

    b) To provide the medical support for Hospital Liaison in the NBS Directorate of Public and Customer Services with the aim of improving delivery of services to link hospitals by understanding their requirements and monitoring the delivery of services.

58. Dr Tim Wallington as Medical Director of the NBA Midlands & South West Zone had asked me to be Chairman of its *Clinical Policies Group* (CPG) in 1997. The objective of this group was to develop clinical guidelines for transfusion in collaboration with clinical haematologists and other hospital clinicians. I was asked to take on this role because of my experience in day-to-day transfusion practice gained at Barts and the Oxford Radcliffe Hospitals and in guideline development as a member of the British Committee for Standards in Haematology (BCSH) Blood Transfusion Task Force from 1995. The CPG had membership from senior haematologists including Dr Adrian Copplestone from Derriford Hospital, Plymouth, who I later worked with when he was Chairman and I was Secretary of the National Blood Transfusion Committee. The other 2 NBA Zones did not have CPGs, and when the National Blood Service came into being, I chaired the National CPG.

d. What was the remit of this role?

59. The Clinical Director (Patients) role was to contribute to and support the implementation of the strategic direction of the NBS for patient services.

e. What was your understanding of transfusion practice at that time? Was there a need for improvements in transfusion practice? If so, please set out what the particular issues were that required improvement.

60. This was succinctly summarised in the rationale section for the *Health Service Circular Better Blood Transfusion 2002/*009 (AHCH0000055), which I had a major role in drafting:-

> *The appropriate use of donor blood and the use of effective alternatives to donor blood are becoming increasingly important public health and clinical governance issues.*
>
> *i. Appropriate blood transfusion is an essential support to many medical treatments and is life-saving.*
>
> *ii. Donated blood is a limited resource. As a result of further measures that may have to be taken to reduce the unknown risk of transmission of vCJD by blood transfusion, such as the introduction of a future screening test and limitations on the number of donors, blood supplies may be reduced.*
>
> *iii. The safety of blood transfusion is highlighted yearly through the Annual reports of the Serious Hazards of Transfusion (SHOT) scheme (a confidential enquiry for the reporting of serious complications of blood transfusion and near miss events in the UK). This scheme has shown that avoidable, serious hazards of blood transfusion continue to occur in NHS Trusts, the most common being giving the wrong blood to patients.*
>
> *iv. There is continued wide variation in the use of blood (particularly in surgery and surgical specialities) even with the existence of national*

and local clinical guidelines developed by clinical professionals on the appropriate use of donor blood.

f. Were there any particular problems that it was hoped the position would solve? (You may find the following documents useful: DHSC0006775_053; HSOC0008493).

61. The two documents refer to the earlier review of the NBA conducted by Professor John Cash.

62. The remit of the newly established post that I held was clear as set out above. I hoped it would generate impetus to improving hospital transfusion practice and that the NBS and the Department of Health would actively support hospitals to do so.

g. What were your key priorities when you started the role and why? Did these priorities change over time?

63. The key priorities were:

(a) To promote good blood transfusion practice in hospitals, and the initiatives which were subsequently set out in the *Health Service Circulars on Better Blood Transfusion* in 1998, 2002 and 2007 (NHBT0083701_002; AHCH0000055; WITN7001011)..

(b) To provide the medical support for the NBS Directorate of Public and Customer Services with the aim of improving delivery of NBS services to hospitals by understanding their requirements and monitoring the delivery of services.

64. These key priorities changed very little over time.

h. What steps did you take in your role to improve transfusion practices during this period? In particular:

i. What did you consider to be '*best practice*' that should be followed at that time?

65. There was (or is) no formal definition for '*best transfusion practice*'. A general definition, along the lines of any medical treatment, might be that patients should only be transfused when the benefits outweigh the risks, and that alternatives to transfusion should be considered and used where appropriate.

We were trying at that time to ensure that transfusions were safe and appropriate given the best evidence available. We strive to do the same today.

ii. What steps did you take to educate and inform professionals as to best practice?

66. I played a major role in the organisation and output of the Chief Medical Officer's *Better Blood Transfusion* Seminar held in October 2001 (and indeed subsequent Better Blood Transfusion and Patient Blood Management Seminars held in 2007, 2012 and to a lesser extent in 2019).

The 2001 conference was jointly organised by the National Audit Office, the National Blood Service and the Department of Health and chaired by the UK four Chief Medical Officers.

67. The aim of the 2002 Seminar, for example, was to share views on how clinical blood transfusion practice could be improved with the following aims:

a) *Ensure that Better Blood Transfusion is an integral part of NHS care*
b) *Make blood transfusion safer*
c) *Avoid unnecessary use of blood in clinical practice*
d) *Provide better information to patients and the public about blood transfusion*

68. In advance of the conference, I led a survey of NHS Trusts in England to determine the progress that had been made in blood transfusion practice since

the first *Evidence-Based Blood Transfusion* conference held in 1997 and I presented the results of the survey at the conference (DHSC0004261_012).

69. The survey highlighted that in some areas of blood transfusion practice, there was very good progress:

    a) *The establishment of Hospital Transfusion Committees*
    b) *Participation in the Serious Hazards of Transfusion (SHOT) scheme*

70. In other areas, more needed to be done:

    a) *Multidisciplinary staff training in the process of blood transfusion*
    b) *The availability of Hospital Transfusion Practitioners*
    c) *Local approved protocols based on national guidelines for the appropriate use of blood*
    d) *Audit of blood transfusion practice*
    e) *The use of autologous blood transfusion*
    f) *The provision of written information to patients on blood transfusion*

71. The subsequent *Health Service Circular on Better Blood Transfusion* published in 2002 (AHCH0000055) provided excellent advice for hospitals on how to implement best transfusion practice. Key actions, primarily for Chief Executives of NHS Trusts working with clinical governance leads, clinicians, hospital staff, blood transfusion laboratories, Hospital Transfusion Committees and Teams included:-

    a) *Secure appropriate arrangements for Better Blood Transfusion and the appropriate use of blood*
    b) *Ensure senior management and Board level commitment*
    c) *Secure appropriate membership and functioning of the Hospital Transfusion Committee*
    d) *Secure appropriate composition and functioning of a Hospital Transfusion Team including support staffing and resourcing*
    e) *Ensure that appropriate blood transfusion policies are in place, implemented and monitored*

f) *Ensure that education and documented annual training on blood transfusion policies are administered to all health care staff involved in the process of blood transfusion and is included in the induction and orientation programmes for new staff*

g) *Improve the quality of service provision through clinical audit and continuing professional development*

h) *Review the blood transfusion content of clinical multi-disciplinary audit and CPD programmes for NHS Trust staff, including the Hospital Transfusion Team*

i) *Ensure participation in the Blood Stocks Management Scheme*

j) *Ensure that information for the traceability of blood is recorded and retrievable*

k) *Ensure that information is available for monitoring the safety and appropriate use of blood*

l) *Ensure that reporting of serious adverse events related to blood transfusion and near misses is being undertaken*

m) *Ensure the appropriate use of blood and use of effective alternatives in clinical practice*

n) *Implement existing national guidance (see Annex A) on the appropriate use of blood and alternatives*

o) *Ensure patients at risk of transfusion are informed of their choices*

p) *Ensure that timely written information is made available to patients on blood transfusion and alternatives*

q) *Promote the safe and appropriate use of blood and cost-effective alternatives in Trusts*

r) *Ensure that services commissioned are safe and value for money in relation to Better Blood Transfusion*

s) *Ensure that services for Better Blood Transfusion being provided are operating effectively and are part of local performance management arrangements*

72. The need for further work to support the *Better Blood Transfusion* initiative was highlighted at the CMOs conference. Several of the following areas were already in initial development and I was involved in most of them, including:-·

a) *Development of electronic systems to improve the safety of the process of transfusion and to monitor the appropriate use of blood*
b) *Systematic review and research into the clinical and cost-effectiveness of transfusion practice including alternatives to donor blood transfusion*
c) *Development of national training and educational materials*
d) *Continued development of patient information leaflets*

Further information about two of these initiatives (Electronic transfusion systems and the Systematic Reviews Initiative and *the Transfusion Evidence Library)*

73. Electronic transfusion systems

a) *In order to make a step change in transfusion safety and efficiency in hospitals, my team in Oxford developed in the early 2000s and implemented in 2006/07 an 'end-to-end' electronic (paperless) process for safe transfusion throughout the acute hospitals in Oxfordshire. This work won several national awards, and was the subject of a Proven Case Study for the NHS Quality, Innovation, Prevention and Productivity (QIPP) initiative (DHSC0004233_041).*

b) *It demonstrably improved the safety and efficiency of transfusion practice, delivered cost savings, and is being implemented in some but not all NHS hospitals (see later in this section) and in hospitals in other countries.*

c) *When the 'electronic patient record' (EPR) was introduced in Oxford we subsequently developed an electronic process for blood ordering and providing clinical decision support, and this was effective in further reducing inappropriate use of blood.*

d) *We published our work in stages as individual projects were completed - see WITN7001012; DHSC0004261_017; WITN7001013; WITN7001014; WITN7001015; WITN7001016. Some of these articles were 'How do Is….' written with the intention of explaining to other hospital teams the steps we had taken and to encourage them to do the same.*

e) *Winner of national awards including:*

i. *Health Service Journal Efficiency in Pathology Services 2013*

ii. *Health Service Journal Awards Improving Care with Technology 2009; Guardian Public Service Awards Innovation and Progress: Transformation category 2008*

iii. *British Computer Society and Computing UK IT Awards Public Sector Project of the Year 2009*

iv. *Government Computing Awards Government to Citizen Category and overall Winner of Innovation Award 2008*

v. *Our work also contributed to the Oxford University Hospitals being named 'Digital Hospital of the Year' in the E-health Insider Awards 2015*

f) In 2011, the Department of Health conducted a *'Commercial Review'* of NHSBT (DHSC0041309_035). One of its recommendations was:

Development of centralised and integrated transfusion services. There is evidence from within this country and from abroad that centralised or integrated transfusion systems offer a range of benefits in terms of cost, efficiency and safety; for example assisting in the reduction of inappropriate use.

Such services introduce a higher level of specialism and co-ordination across a geographic area rather than all services being replicated on a site-by-site basis.

Services can be provided across a number of trusts from a co-ordinating central point that can be led by a trust (or trusts) coordinating across a particular area; or alternatively, NHSBT is looking to develop capability to co-ordinate transfusion services within hospitals.

NHSBT has supported work involving trusts and specialist providers in places such as at the Oxford Radcliffe Hospitals NHS Trust, where

the IT systems and hardware are provided under a managed service by private providers to very good effect.

NHSBT will be undertaking pilots this year to examine the scope to offer or assist with integrated transfusion services to a broader range of trusts.

NHSBT has limited resources in terms of both workforce and risk capital to be able to develop projects at multiple trusts. The primary focus needs to be on locally developed solutions, which link to the national NHSBT blood supply network. Where capabilities are available in the trusts, NHSBT's resources are likely to be best-spent facilitating services rather than developing the whole system as an extended monopoly provider. Such an approach is also likely to allow quicker adoption.

g) In 2018, I conducted a survey with the Serious Hazards of Transfusion scheme which found that the implementation of electronic transfusion systems in the United Kingdom had been patchy and that they were rarely used to their full functionality (WITN7001017).

74. Systematic Reviews Initiative (SRI) and the Transfusion Evidence Library

a. With Dr Brian McClelland (SNBTS), I established the *Systematic Reviews Initiative* (SRI) in Oxford in 2001 with a grant from NHSBT Trust Funds. It is a clinical research group established and now funded through the four UK Blood Services. It is based within NHSBT's Oxford Blood Centre at the John Radcliffe Hospital and has developed close links with both the hospital and the University of Oxford.

b. Its primary objective is to *"develop the evidence base for the practice of transfusion medicine"*. To this end, it has undertaken

over 100 systematic reviews and other evidence-based medicine research projects in the transfusion field.

c. Another core activity of the SRI is producing the *Transfusion Evidence Library*, a curated collection of systematic reviews and randomised controlled trials on all aspects of transfusion medicine, and *Stem Cell Evidence*, a comprehensive collection of high quality research relevant to haematopoietic stem cell transplantation. Updated monthly, these specialist databases and alerts highlighting recent *'top ten'* publications provide access to high quality, evidence-based information for many thousands of healthcare practitioners, policy makers and researchers around the world.

d. The SRI is supported by three transfusion medicine/haematology clinicians, three information specialists and four systematic reviewers with expertise in the methodology of systematic reviews and evidence-based medicine. Statistical support is received from the Nuffield Department of Primary Care Health Sciences in Oxford. The SRI is supported by an independent steering committee consisting of representatives from relevant professional bodies across the UK, and receives further input from clinical experts from both the UK and North America.

iii. How did you go about consulting and working with your colleagues?

75. From my appointment as Clinical Director in 2004, I worked with colleagues in NHSBT Public and Customer Services (led by Director: Mrs Liz Reynolds and Head of Hospital Liaison: Stuart Penny) to provide hospitals with information about NHSBT matters such as blood stocks, reference services, innovations in transfusion practice and the development of information for patients, and to implement some activities to improve hospital transfusion practice (see below).

76. I also worked with the Clinical Directorate led by Dr Angela Robinson (Medical Director), Dr Tim Wallington (Deputy Medical Director) and my Clinical Director colleagues, Dr Lorna Williamson (Products), Dr Liz Caffrey (Donors), and Dr Mahes Da Silva (Diagnostics).

77. I led a team of consultants in transfusion medicine in the regions in England; they generally had joint appointments between NHSBT and large NHS Trusts. There was at least one joint consultant in every NHS Region except for one in the East Midlands (where we attempted to recruit one of the excellent local haematologists but without success). To achieve this, I was responsible for making a number of new appointments, often of existing and experienced clinical haematologists wanting to focus more of their time on transfusion medicine.

78. Working with Catherine Howell, a senior NHSBT nurse, I established a team of Transfusion Practitioners within NHSBT to become part of the hospital liaison effort of NHSBT in each NHS region to be made up of medical, scientific and nursing support for hospitals with the aim of delivering better transfusion practice.

79. I established the National Comparative Audit of Blood Transfusion (NCABT) programme in 2002, initially as a collaboration between NHSBT and the Royal College of Physicians, and chaired its Steering Group until 2015.

80. The establishment of this initiative followed an earlier collaboration between the Clinical Effectiveness and Evaluation Unit of the Royal College of Physicians, the British Society for Haematology, the British Blood Transfusion Society and the Royal College of Pathologists. The output was the development of audit protocols based upon a collection of background papers. In September 1995, the National Health Service Executive (NHSE) funded a national audit initiative using two of the blood transfusion protocols. One was an institutional audit for blood transfusion practice and the other was an audit of the documentation of blood transfusion. National audits were carried out involving 50 hospitals in the first audit and 23 of the same hospitals in the second (WITN7001018).

> *Over 20% of participating hospitals did not have Hospital Transfusion Committees. Most hospitals had written policies for the taking of blood*

samples for grouping and compatibility testing. Formal training for the phlebotomists and nurses who took blood samples was almost universal, but only one-third gave training to doctors.

The audits of transfusion practice demonstrated considerable variation in the performance of standard procedures in relation to the administration of blood, and little change in practice between the two audits. It was concluded that there was a significant shortfall in the systems for monitoring and delivering transfusions in many hospitals.

81. The objective of the NCABT programme is to provide evidence that blood is being prescribed and used appropriately and administered safely, to highlight where practice is deviating from the guidelines to the possible detriment of patient care, and to make recommendations to improve practice where necessary.

82. The programme is funded by NHSBT through the blood pricing mechanism, and is one of the largest independently funded audit programmes in the UK. https://hospital.blood.co.uk/audits/national-comparative-audit/

iv. What steps did you take to educate and inform patients as to best practice?

83. My experience at Barts was that patients would welcome more information about transfusion (NHBT0017564). Over the years since my time at Barts, I have worked with others in NHSBT and the National Blood Transfusion Committee (NBTC) on developing patient information leaflets for transfusion. However, it is recognised that they are poorly distributed to patients in hospitals. Also see answer to Q101.

84. As well as a general patient information leaflet for transfusion, NHSBT has developed several patient information leaflets focussed on patients with special transfusion needs e.g. sickle cell disease. https://hospital.blood.co.uk/patient-services/patient-blood-management/patient-information-leaflets/

v. How did you go about consulting and working with patients?

85. I worked closely and constructively with the Jehovah's Witness community in Oxford, and one of their members joined meetings of our Hospital Transfusion Team.

86. When the NBTC was established, we recruited two patient representatives, one of whom remains a valued member to this day. Other committees such as the Steering Group of the National Comparative Audit of Blood Transfusion programme have patient representatives.

I also worked with Professor Charles Vincent (Imperial College) and his colleague Dr Rachel Davis to review the involvement of patients in the blood transfusion process to minimise errors. This work indicated the potential value of involving patients and that further research was necessary (WITN7001019).

Blood Transfusion Safety: The Potential Role of the Patient

Rachel E. Davis, Charles A. Vincent, and Michael F. Murphy

There are many initiatives to reduce transfusion-related errors. However, one important intervention that remains largely unexplored is that of patient involvement. This article considers the patients' role in ensuring safe care along the transfusion trajectory. Study Design and Methods: Empirical data on patients' attitudes to, and involvement in, transfusion-related behaviors were systematically reviewed. Opportunities for patient involvement in transfusion processes were identified by extant national guidelines and expert consultation. Results: A number of transfusion-related behaviors in which patients can participate were highlighted, but to date, little is known about patients' preferences for taking on an active role. Many patients have no recollection of consenting to a blood transfusion, and some are not even aware they have been transfused. Information provided to patients about transfusion is often poorly understood. Patients have a number of misconceptions about the safety of blood transfusion, and the way in which information is presented to patients can significantly affect their level of confidence and subsequent acceptance in receiving a blood transfusion. Summary: One important intervention that could help to improve the quality and safety of the blood transfusion process is involvement of the patient themselves. This article considers the patients' role in ensuring safe care at different stages of the transfusion trajectory. The literature on patients' attitudes to, and involvement in, transfusion-related behaviors was systematically reviewed and opportunities for patient involvement were identified. The evidence suggests that although there is considerable potential for patients to be involved in different blood transfusion processes, it is very unclear at present how able and willing patients would be to take on an active role in this aspect of their health care management. Research in this area is paramount in helping to inform the design and implementation of interventions aimed at encouraging patient involvement in this very important but largely under-researched area.

87. A further study provided similar evidence to the survey I did with medical students at Barts (NHBT0017564).

WITN7001020

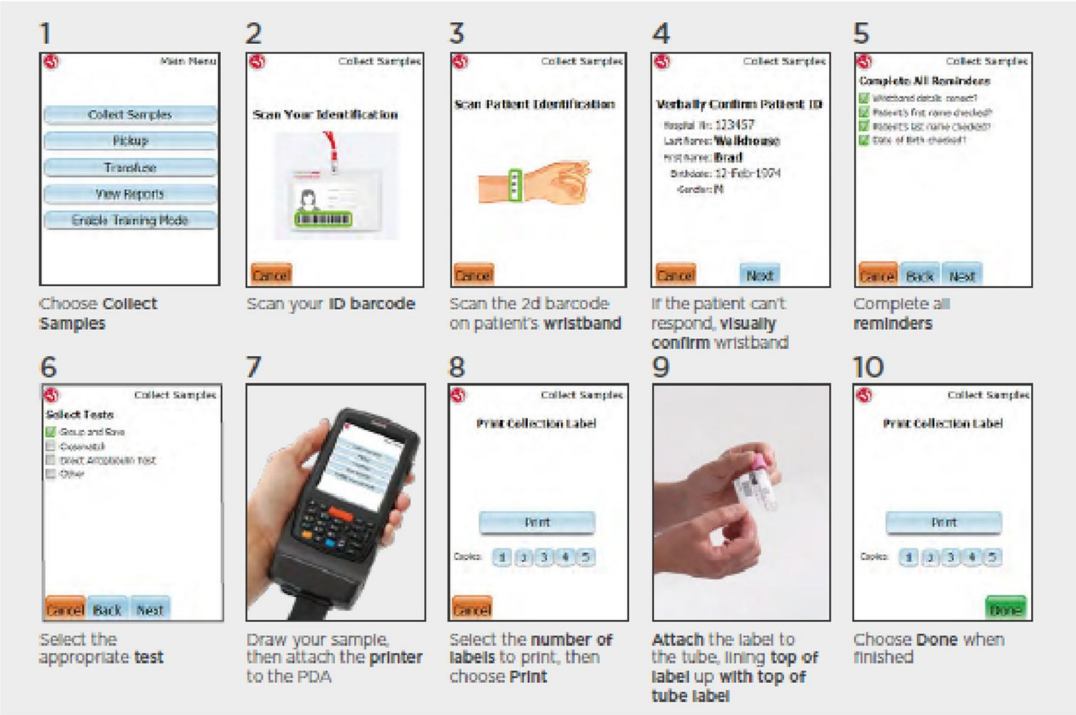
110 patients who had received a transfusion participated in the study. Sixty-one patients recalled consenting transfusion. The majority (N= 67) said they were just told they needed a transfusion and only 1 patient said a full discussion about the risks and the benefits of the transfusion took place. However, although 82 patients said they were satisfied with the information, 22 patients reported they would have liked to have been given more details. The majority of healthcare professionals (N = 83) felt that patients were often not given sufficient information about transfusion.

vi. What steps did you take to minimise transfusion errors?

88. See answer to 21 (ii). The hospital transfusion process involves many steps, many different staff (indeed almost all doctors and nurses in hospitals) and is carried out in many clinical areas in hospitals. It is prone to errors which may cause morbidity and rarely mortality. I recognised from my experience both at Barts and in Oxford that the development and publication of guidelines, efforts to improve education and training, follow up of errors and general exhortations to *'do better'* had been insufficient to improve practice and prevent errors.

89. This is why I led the transfusion team in Oxford to work on a different approach. The objective was to make it easy for staff to get transfusion procedures right every time. This was achieved by simplifying transfusion procedures into their key steps and using electronic systems to prompt staff through each step; alerts were provided to prevent wrong transfusions. This approach has subsequently been recommended by both the *Health Safety Investigation Branch* (HSIB) (WITN7001021) and SHOT in recommendations in its Annual Reports. I was recently invited to write a review for the journal *Transfusion* in which I summarised how to minimise transfusion errors using electronic systems (WITN7001022).

90. The Diagram provided below was used in the HSIB report showing our electronic pathway for the collection of a blood sample for blood transfusion: *staff are supported by bedside technology and prompted through each step (we developed a similar electronic pathway for the administration of blood).*

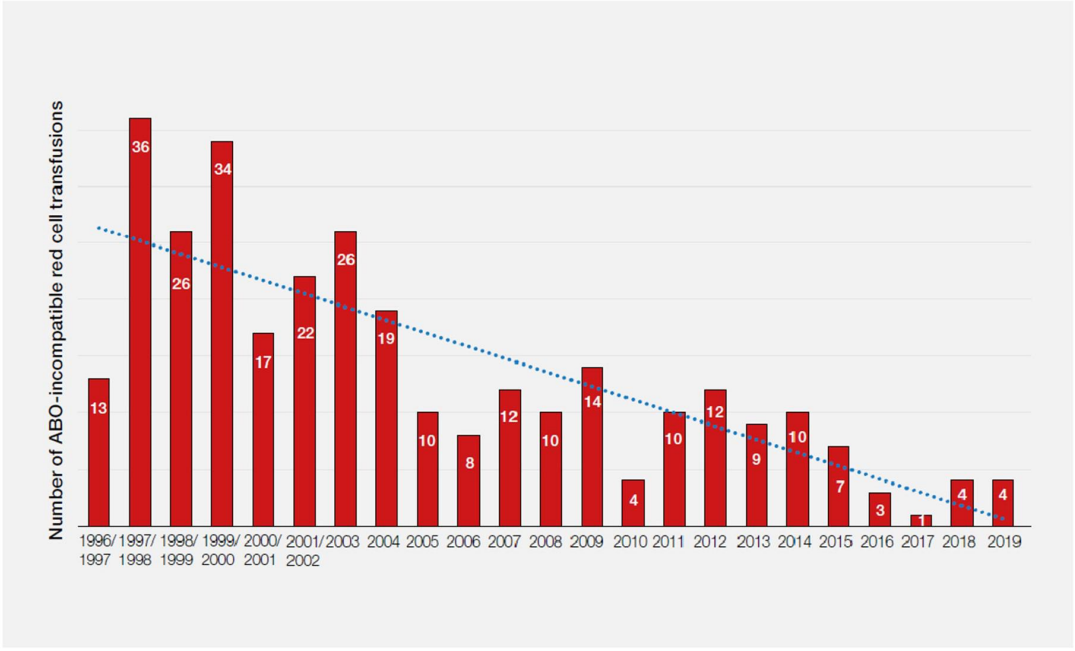


i. Why were these steps required? How successful were these steps? How were they measured?

91. Steps to improve the safety of hospital transfusion to avoid errors were required because of the recognition in the early 1990s of an unacceptably high number of events leading to ABO incompatible red cell transfusions (which are now classified as *'never events'* by NHS England) causing morbidity and mortality. This recognition led to the establishment of SHOT in 1996.

92. Work that SHOT and others have done to support hospitals has led to a major reduction in ABO incompatible red cell transfusions from 1996 to 2019 (see the Figure below).

93. Diagram showing the reduction in ABO incompatible red cell transfusions (taken from the SHOT Annual Report, 2019).



94. Unfortunately, a small number of ABO incompatible red cell transfusions are still occurring in UK hospitals. Since we implemented the electronic transfusion process in Oxford in 2006/07, there have not been any of these events (over 400,000 blood components transfused). We have also demonstrated a major reduction in *'near miss'* events using the electronic transfusion process (WITN7001015).

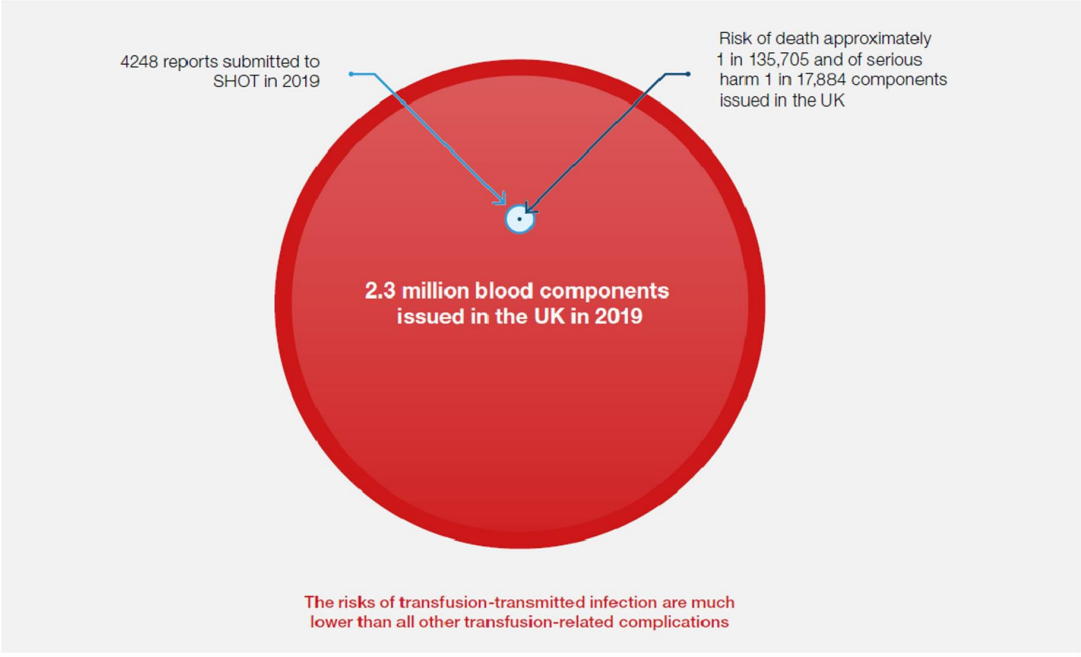
j. Did you meet with resistance from the profession, or other obstacles? Please give details.

95. Transfusion in hospitals is demonstrably safer than 20 years ago (also see Figure below). This is largely due to the efforts of SHOT to identify transfusion safety issues in hospitals and provide recommendations to mitigate them.

96. Ideally, all transfusion errors and adverse events would be prevented. However, whatever recommendations are provided nationally, the quality of transfusion practice depends on individual staff in hospitals and the resources provided to help them deliver safe care. Efforts to further improve transfusion safety may not

be prioritised in hospitals or be thought of worthy of a major initiative by NHSBT or the Department of Health because of the generally perceived low level of transfusion errors and adverse events.

97. Diagram showing the risk of harm or death from transfusion is very low (taken from the SHOT Annual Report, 2019).



k. What powers did you have to ensure that these steps were complied with on a national basis?

98. I had no *'powers'* (or national authority) in my role as NBS/NHSBT Clinical Director (Patients) to ensure compliance with good transfusion practice throughout the NHS. The resources available to me to influence practice were through:-

a) Communications from myself and Stuart Penny on behalf of NHSBT Hospital Liaison to Hospital Transfusion Teams.

b) Communication of recommendations about *Better Blood Transfusion* cascaded to hospitals via the Regional Transfusion Committees on behalf of the NBTC in my role as Secretary of the NBTC.

c) Publications of our work in Oxford as an exemplar to the NHS.

d) Guideline development through the NHSBT Clinical Policies Group and the Blood Transfusion Task Force of the British Committee for Standards in Haematology.

I. Please outline any involvement you had with the Chief Medical Officer's National Blood Transfusion Committee.

99. I played a major role in establishing the National Blood Transfusion Committee (NBTC). The establishment of the NBTC and its relationship with *Better Blood Transfusion* and the NBA/NBS/NHSBT are described in WITN7001023.

100. The NBTC in England was established in September 2001. It was created as a consequence of two major events in blood transfusion in the 1990s in the UK: the reorganisation of Blood Services in England and the United Kingdom (UK) Chief Medical Officers' (CMOs') *Better Blood Transfusion* initiative.

101. The National Blood Authority (NBA) was established in April 1993 and took over responsibility in England for what was previously known as the National Blood Transfusion Service (NBTS) in April 1994. This development sought to change a regionally based service into a national one. In September 1994, the NBA published its proposals for the future of the Regional Blood Transfusion Services, now to be called the National Blood Service (NBS). The proposals included the establishment of three administrative zones to replace the previous regional structure. Many concerns were raised about these proposals during the consultation period. When the Department of Health approved the NBA's revised plans in November 1995, an independent National Blood Service User Group (NBUG) was set up to monitor the services provided by the NBS, to bring to the attention of the NBA problems which could not be resolved at local level and to report annually to the Secretary of State. Zonal Blood User Groups (ZBUGs) were

established in each of the three zones of the NBS to inform the work of the NBUG by seeking the views of those using the services provided by the NBS.

102. In 1999, the NBS zones were integrated into a new national management structure for the NBS, and the ZBUGs were disbanded. There continued to be a need for a formal mechanism for interaction of the NBS with blood users, and it was proposed that Regional Transfusion Committees (RTCs) should be established. It was also proposed that a National Blood Transfusion Committee (NBTC) be established to replace the NBUG on the lines of recommendations by the WHO for National Committees on the Clinical Use of Blood (NHBT0035417). The remit of these committees would be primarily focused on improving transfusion practice in hospitals, and supporting the implementation of the actions recommended in the *Better Blood Transfusion* Health Service Circulars, although the NBTC and RTCs retained the role of the ZBUGs and NBUG in monitoring the performance of the NBS.

103. An Interim National Transfusion Committee met on three occasions in 2001 with the remit of establishing the Regional and National Transfusion Committee structure and set out its Terms of Reference by September 2001 (WITN7001024) and (WITN7001025). The Terms of Reference were later subject to minor revision (WITN7001026) and further minor revisions over the years. Its membership included the ex-Chairmen and blood transfusion laboratory manager members of the NBUG and ZBUGs, providing a useful link with the previous User Group structure.

104. The NBTC held its first meeting in December 2001 (DHSC0038528_050). The NBTC membership included the Chairmen of the 10 RTCs, and representatives of the Royal Colleges, SHOT, National Patient Safety Agency (NPSA), NBS, patients and the Department of Health. Its initial primary remit was to support the *Better Blood Transfusion* initiative, but the identification of problems in any aspect of blood transfusion including the delivery of services by the NBS/NHSBT remains within the remit of the NBTC. Members were generally invited to represent their respective organisations because of a known interest in transfusion medicine. The additional work undertaken by the members of the NBTC is unpaid although

their employers usually grant time away from their duties which are mainly in NHS hospitals.

105. Because of my role in supporting the work of the Interim National Transfusion Committee and establishing the NBTC, I was invited to become Secretary of the NBTC by Professor Gordon-Smith (the first NBTC Chairman) at its first meeting in 2001. I continued to hold this position until 2015 when I handed over to my colleague Dr Kate Pendry. She subsequently handed over to Dr Shubha Allard.

106. In 2005, NHS Blood & Transplant (NHSBT) was established by the amalgamation of NBS with UK Transplant. A further *Better Blood Transfusion* Seminar was organized by the NBTC and held in 2007 following an audit of the implementation of the recommendations of HSC 2002/2009 (WITN7001032). The recommendations of the third *Better Blood Transfusion Seminar* were published in a Health Service Circular *Better Blood Transfusion – Safe and Appropriate Use of Blood* (WITN7001011).

107. A further national Seminar on Blood Transfusion, *Patient Blood Management - An Evidence-based Approach to Patient Care*, was held on 18 June 2012 (WITN7001027). The event was jointly hosted by the Department of Health, the National Blood Transfusion Committee (NBTC) and NHS Blood and Transplant (NHSBT) and supported by Professor Sir Bruce Keogh, NHS Medical Director. The aim of the multi-disciplinary conference was to share views on how blood transfusion practice could be improved to:

a) Build on the success of previous *Better Blood Transfusion* initiatives and to further promote appropriate use of blood components.
b) Improve the use of routinely collected data to influence transfusion practice.
c) Provide practical examples of high quality transfusion practice and measures for the avoidance of transfusion, wherever appropriate.
d) Consider the resources needed to deliver better transfusion practice including support from NHSBT.
e) Understand the patient perspective on transfusion practice.

108. Recommendations were made for the implementation of *Patient Blood Management* (PBM) (WITN7001027) using the following headings:-

General considerations

- *Establishment of PBM programme and raising awareness amongst clinicians and patients*
- *Issues in patient testing*
- *Use of appropriate dose and thresholds for transfusion*

Specific aspects of surgical PBM

- *Preoperative Management of Anaemia and Haemostasis*
- *Intraoperative Management*
- *Postoperative Management*

Specific aspects of medical PBM

- *Management of abnormal haemostasis*
- *Management of anaemia*

Implementation of PBM

- *Implementation of good practice for blood avoidance and the use of blood*
- *The responsibilities of staff involved in Patient Blood Management (PBM) at hospital level were outlined.*

109. **Objectives and working arrangements for the NBTC**

The NBTC's overall objective is to promote good transfusion practice by providing a framework to do the following:-

i. *Channel information and advice to hospitals on best practice and performance monitoring with the aims of:*
   a. *Improving the safety of blood transfusion practice*
   b. *Improving the appropriateness of clinical blood transfusion*
   c. *Exploring and facilitating the implementation of methods to reduce the need for allogeneic blood transfusion*

d. *Listening to and informing patient concerns about blood transfusion*

e. *Promoting the highest quality and consistency in transfusion practice*

(2) Consult with national groups developing guidelines in transfusion medicine to determine best practice

(3) Review the performance of the services provided by NHSBT.

(4) Identify service development needs and provide assistance, as required, with the work of the National Commissioning Group for Blood (which sets blood prices) and the Blood Stocks Management Scheme (which monitors blood wastage in NHSBT and hospitals)

(5) Identify and respond to patients' perceptions about the provision of transfusion services

(6) Provide advice on all aspects of transfusion practice to the NHS Medical Director and also to the CMO or other DH officials.

(7) Provide information on and support delivery of appropriate education and training of blood transfusion.

110. There are two meetings of the NTBC each year. The work of the committee between meetings is carried out by an Executive Working Group comprising the Chairman, five members of the committee, two NHSBT representatives, a patient representative and one from NHS England (WITN7001028). Working groups were established for Education and Training, Patient Involvement, Transfusion Laboratory Managers, and Patient Blood Management (PBM). The members of the Royal Colleges and specialist professional organizations meet before each NBTC meeting to share experience about current issues and how best to engage and inform their respective memberships.

111. The RTCs are key to the promotion of better transfusion practice, acting as a focus for activity and a conduit between the HTCs and the NBTC. The RTCs were realigned in 2006/2007 to reflect the boundaries of the ten Strategic Health Authorities, and these boundaries continued until 2021 despite further NHS reorganisations, and HTCs valued this structure. Continuing concerns expressed by RTC Chairs from their membership include the effect on transfusion laboratories and transfusion practice of pathology modernisation initiatives focussed on high-throughput pathology services and cost saving and the challenge of engaging hospitals in PBM.

112. The NBTC has an annual work plan setting out objectives and actions to support the NBTC strategy; the working groups also develop individual work plans which are available on the NBTC website www.transfusion guidelines.org.

113. **Main outcomes of the work of the NBTC**

The focus on Better Blood Transfusion and PBM over the 16 years of the NBTC up to 2017 resulted in the following:

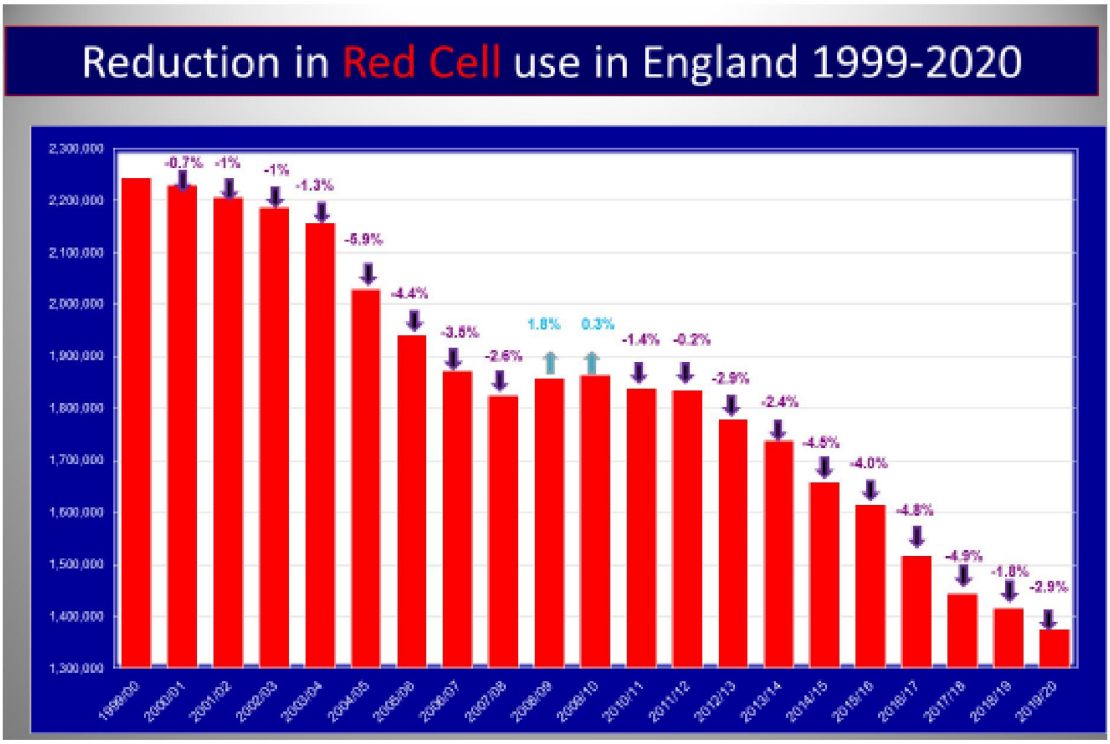
a) Low mortality and morbidity related to transfusion in the UK (respectively, 1.01 and 6.44/100 000 blood components issued in 2015).
b) 30% reduction in the use of red cell transfusions in England; current usage equates to red cell issues of 28.5 per 1000 population.
c) A stabilisation in the growing demand for platelets.

As with previous national recommendations promoting appropriate blood use, it is a major task to disseminate them to the many staff prescribing blood in the NHS and implement them effectively. Their integration into more general initiatives for reducing *'too much medicine'* and variation in clinical practice may increase the likelihood of success. In this respect, it was exciting to see that the Academy of Medical Royal Colleges brought the international Choosing Wisely campaign to the UK. I led the work of the NBTC to put forward recommendations for inclusion in the campaign, and four were selected and published in 2016 (WITN7001029), including the latter one directed to providing information to patients:

a) Use restrictive thresholds for patients needing red cell transfusions and only one unit at a time except when the patient has active bleeding.
b) Only consider transfusing platelets for patients with chemotherapy-induced thrombocytopenia where the platelet count is <10 x 109/l except when undergoing a procedure with a high risk of bleeding.
c) Only transfuse O RhD-negative red cells to O RhD negative patients and in emergencies for females of childbearing potential with unknown blood group.
d) 'You should be provided with information about the benefits and risks of blood transfusion and have the opportunity to ask questions.'

114. Other activities of the NBTC

Support for the National Comparative Audit of Blood Transfusion programme https://hospital.blood.co.uk/audits/national-comparative-audit/ National audits are conducted each year, covering the whole range of transfusion practice; for example, in relation to transfusion safety, five audits of bedside transfusion practice were conducted over 15 years with objective quality improvement in patient identification and in the monitoring of transfused patients. Large audits of blood use involving many thousands of patients in clinical scenarios such as cardiac surgery, haematology, upper and lower gastrointestinal haemorrhage, hip surgery and medical patients have found that 20–30% of transfusions are given outside the recommendations in national guidelines. These data indicate the potential for further blood reduction even though red cell usage in England has fallen by 30% in the last 20 years.



The NBTC conducts **surveys of transfusion practice**. For example, surveys of hospitals in 2013 and 2015 about their PBM practices indicated considerable potential to increase PBM activities such as preoperative anaemia management, the use of intra-operative cell salvage and the use of tranexamic acid in surgery. Between 2013 and 2015, there had been some progress in the delivery of education and training to clinicians and provision of information to patients; however, such surveys have highlighted problems in implementing Better Blood Transfusion and PBM such as lack of staff, poor information technology and lack of engagement by senior managers and clinicians in improving transfusion practice.

The last survey was conducted in 2018 (WITN7001030), and demonstrated continuing problems in implementing PBM in hospitals. A further survey is being conducted at the end of 2021.

The provision of administrative support for the RTCs, the combination of the website and the administrative support has facilitated much more effective communication from the NBTC to the RTCs and to HTCs.

The NBTC has developed national standards and requirements for training and assessment for all staff involved in the transfusion process following the abolition of the National Patient Safety Agency (NPSA).

The NBTC has developed a series of indication codes abstracted from national guidelines and regularly updated; these are used by many hospitals to guide appropriate decision-making at the time of transfusion requesting. The NBTC is working towards the development of a national transfusion request specification that can be used in electronic order communications systems to support best practice.

The NBTC works closely with NHSBT to ensure appropriate stakeholder engagement when NHSBT is making decisions about new components for development (e.g. whole blood for trauma) and new safety initiatives (e.g. pathogen inactivation).

The NBTC has worked with NHSBT to develop agreed action plans for hospitals and NHSBT in the event of shortages of red cells and/or platelets.

The NBTC is working with the National Transfusion Laboratory Managers group, the UK Transfusion Collaborative and NHSBT to explore opportunities for closer integration between NHSBT and hospital transfusion laboratories to ensure that safe practice can continue to be delivered in the face of pathology reorganisations and loss of experienced laboratory staff.

Sections have been established for the NBTC and RTCs on the www.transfusionguidelines.org.uk website to facilitate dissemination and sharing of information.

The RTCs are responsible for delivering one or two educational symposia for their regions each year. These events reach many hundreds of multidisciplinary staff involved in blood transfusion.

115. A further Blood Transfusion Seminar (the 5th in the series starting in 1997), Transfusion 2024, was held in March 2019. My involvement included giving a presentation on *Progress with Self-Assessment of Patient Blood Management* and help with drafting some of the recommendations, particularly those relating to *Electronic Systems and Transfusion Safety and Efficiency, and Research and Development* (WITN7001031).

22. Please outline any involvement you had with Hospital Transfusion Committees. In particular:

a. What was the purpose and remit of Hospital Transfusion Committees and how did these develop over time?

116. Hospital Transfusion Committees (HTCs) came into being, both nationally and internationally, in the 1990s. We established a Hospital Transfusion Committee at Barts in the early 1990s along the lines of British Committee for Standards in Haematology guidelines (WITN7001004) (see answer to Q7).

117. HTCs were also promoted internationally, for example by the WHO (NHBT0035417).

118. HTCs were promoted in the NHS and their roles and responsibilities outlined in successive *Better Blood Transfusion* Health Service Circulars.

119. NHS Executive, Health Service Circular 1998/224 (1998) 'Better Blood Transfusion' (NHBT0083701_002)**:-**

Hospital Transfusion Committees

9. Every NHS Trust where blood is transfused should have an adequately resourced, multi-disciplinary hospital transfusion committee (HTC). Some NHS Trusts may share a committee, whilst others may need more than one. Given its key role in resource and risk management, the HTC should be an integral part of local arrangements for clinical governance, with corresponding lines of accountability to the Chief executive. The structure and organisation of an HTC should be informed by the best practice of existing HTCs, and it should be in close contact with local and national blood user groups. About 65% of NHS Trusts already have an HTC and there is a wealth of knowledge about what works best. The National Blood Users' Group is an excellent information resource.

10. As a minimum, an HTC should:
    - promote best practice through local protocols based on national guidelines
    - lead multi-professional audit of the use of blood components within the NHS Trust, focusing on specialities where demand is high, e.g. haemato-oncology and certain surgical specialities
    - maintain a database that allows feedback on performance to all hospital staff involved in blood transfusion
    - promote the education and training of all clinical and support staff involved in blood transfusion
    - have the authority to modify existing blood transfusion protocols and to introduce appropriate changes to practice
    - report regularly to local, and through them to national, blood user groups
    - consult with local patient representative groups where appropriate
    - contribute to the development of clinical governance

120. Department of Health, Health Service Circular 2002/009 (2002) 'Better Blood Transfusion – Safe and Appropriate Use of Blood' (AHCH0000055).

Information for Implementation of Better Blood Transfusion
Managing Better Blood Transfusion at Trust level

1. Trusts involved in blood transfusion should establish a **Hospital Transfusion Committee** (HTC) with the authority and resources to take the necessary actions to improve transfusion practice or share a committee between Trusts.

   An HTC should:

   - Promote best practice through local protocols based on national guidelines.
   - Lead multi-professional audit of the use of blood components within the NHS Trust, focusing on specialties where demand is high e.g. certain surgical specialties and haemato-oncology.
   - Audit the practice of blood transfusion against the hospital policy and national guidelines, focussing on critical points.
   - Provide feedback on audit of transfusion practice and the use of blood to all hospital staff involved in blood transfusion.
   - Promote the education and training of all clinical, laboratory and support staff involved in blood transfusion, including the collection of specimens.
   - Have the authority to modify and improve existing blood transfusion protocols and to introduce appropriate changes to practice.
   - Be a focus for local contingency planning for and management of blood shortages.
   - Report regularly to Regional Transfusion Committees, and through them, to the National Blood Transfusion Committee.
   - Participate in the activities of the Regional Transfusion Committee.
   - Consult with local patient representative groups where appropriate.
   - Contribute to the development of clinical governance.

Department of Health, Health Service Circular 2007/001 (2007) 'Better Blood Transfusion – Safe and Appropriate Use of Blood'. **(**WITN7001011**)**

Managing *Better Blood Transfusion* in NHS Trusts

1. NHS Trusts involved in blood transfusion should establish a **Hospital Transfusion Committee** (HTC) (or share a committee with another NHS Trust) with the authority and resources to take the necessary actions to improve transfusion practice. HTCs should meet at least 3 times/year. The membership should include the members of the Hospital Transfusion Team (HTT) and representatives from clinical areas where blood transfusions are frequently used including medicine, surgery, obstetrics and paediatrics, and also from senior management and clinical governance/risk management.

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b. How effective were Hospital Transfusion Committees in your view? What were the obstacles they faced?

121. Hospital Transfusion Committees are an essential forum for discussion about transfusion matters in hospitals. However, my experience in Oxford and that of others not only in the UK but worldwide to engage clinical users of blood is that

clinicians are very stretched and the HTC does not have high priority for them. However, HTCs do provide a conduit into the organisational, governance and management structures of hospitals so that key issues can be cascaded via HTC Chairs.

122. Another important impact on improving hospital transfusion practice was the establishment of *Hospital Transfusion Teams* (HTTs) and the *Transfusion Practitioner* role based on their introduction in Oxford and elsewhere in the late 1990s, and first promoted nationally in the *Better Blood Transfusion* HSC 2002/009.

123. Department of Health, Health Service Circular 2002/009 (2002) 'Better Blood Transfusion – Safe and Appropriate Use of Blood' (AHCH0000055).

2. Trusts involved in blood transfusion should implement arrangements for promoting good transfusion practice through the development of an effective clinical infrastructure. Trusts should establish a **Hospital Transfusion Team** (HTT). This should consist of the **lead consultant for transfusion** in the Trust (with sessions dedicated to blood transfusion), a **hospital transfusion practitioner** or equivalent (e.g. nurses, biomedical scientists, medical professionals), and the **blood bank manager** with or without other members of the HTC. There should be identified clerical, technical, managerial and IT support as required, and access to audit and training resources to promote and monitor safe and effective use of blood and alternatives.

   The role of the HTT is to:

   - Assist in the implementation of the HTCs objectives
   - Promote and provide advice and support to clinical teams on the appropriate and safe use of blood
   - Actively promote the implementation of good transfusion practice
   - Be a source for training all hospital staff involved in the process of blood transfusion

3. Large Trusts or Trusts with more than one site will need to ensure they have adequate coverage by the hospital transfusion team and the hospital transfusion practitioner to ensure that good transfusion practice is implemented in all clinical areas. Further information on the role of the hospital transfusion practitioner will be made available through the *Better Blood Transfusion* website.
4. If a HTC or HTT and its members cover more than one Trust, arrangements should be in place to ensure that there is sufficient cross-Trust representation. Trusts should also ensure that there are adequate resources and mechanisms for ensuring the safe, effective and appropriate use of blood at all the Trust sites involved in blood transfusion.

c. How was compliance with transfusion policies and practices monitored?

124. Compliance with transfusion policies and practices should be regularly monitored in individual hospitals. Compliance is monitored nationally through NBTC surveys and National Comparative Audit of Blood Transfusion (NCABT) audits of practice.

d. Were there any themes or patterns of issues that you identified as arising across a number of Hospital Transfusion Committees in relation to compliance with transfusion policies and practices? If so, please set out what those issues were and what steps were taken to address them.

125. NBTC surveys and NCABT audits of practice indicate that although transfusion practice has improved there is room for further improvement on:-

a) transfusion safety to prevent errors and adverse events
b) the appropriate use of blood
c) the use of alternatives to transfusion
d) the provision and documentation of information to patients

See DHSC0004261_012; WITN7001032 and WITN7001030 .

e. How was the failure to comply with transfusion policies and practices reported and/or dealt with?

126. Feedback is provided to each hospital on their performance compared to other hospitals in each NCABT audit. It is the responsibility of each hospital through their HTT, HTC and governance arrangements to take any corrective actions that are needed.

127. In my experience in Oxford and from discussions with transfusion teams from other hospitals, improvements in transfusion practice are not necessarily viewed as a priority for hospitals unless it can be demonstrated there are concerns about patient safety or cost savings associated with them.

Section 5: Better Blood Transfusion (Appropriate use)

23. Please outline any involvement that you had within the Better Blood Transfusion Service Initiative (you may find the following document useful: DHSC0004205_021)

128. I was very involved with successive cycles of the *Better Blood Transfusion* initiative. See my answers in the previous section.

24. What role did the Handbook of Transfusion play within this initiative and any related service improvement processes?

129. The successive editions of the *Handbook of Transfusion Medicine* were useful resources for hospital staff involved in transfusion, but it is difficult to know how much they have been used and what impact they have had. The Handbook is online only now. I used to give copies to medical students and junior doctors at Barts and in Oxford, but hard copies are no longer provided by NHSBT.

130. The current Handbook was published in 2014. It has much useful information and is available through a link on the transfusion guidelines website. https://www.transfusionguidelines.org/transfusion-handbook It does need updating.

25. Please explain how information on blood transfusion practices was provided to patients. Who or what authority was ultimately responsible for the content and dissemination of these materials?

131. My experience at Barts in 1996 was that patients would welcome more information about transfusion (NHBT0017564). The same was found in a later study published in 2012 (WITN7001020). I worked with others in NHSBT and the NBTC on developing patient information leaflets for transfusion although recognising that they were poorly distributed to patients in hospitals.

132. As well as a general patient information leaflet for transfusion, NHSBT has developed several patient information leaflets focussed on patients with special

transfusion needs e.g. sickle cell disease. https://hospital.blood.co.uk/patient-services/patient-blood-management/patient-information-leaflets/

133. Also see my answer to Q101 for more information on the provision of patient information.

26. Were there any regional, centre or institutional variations in availability of these materials for patients?

134. Not to my knowledge. These materials are readily available from NHSBT or can be downloaded from its website, but are probably not reaching the majority of transfused patients. Also see answer to Q101 for more information on patient information.

27. There were some suggestions that alternative transfusion methods such as autologous blood transfusion, preoperative and postoperative blood salvage were safer, what are your views on this?

135. The term *Patient Blood Management* (PBM) was coined to indicate *'a patient-focused, evidence-based approach to optimise the management of patients and improve clinical outcomes by minimising unnecessary exposure to blood'*. It encompasses alternatives to transfusion such as cell salvage, as well as optimisation of patients' blood counts, the use of drugs such as tranexamic acid to reduce bleeding and restrictive transfusion practice.

136. PBM initiatives are very much in vogue internationally as well as in the UK. N.B. The last two *Better Blood Transfusion/PBM* Seminars have focussed on PBM as well as transfusion safety (WITN7001027 and WITN7001031).

137. I was one of the convenors of an international *Consensus Conference on PBM* in Frankfurt in 2018; its output included recommendations for PBM (WITN7001034).

138. Autologous transfusion fell out of favour long ago. A British Committee for Standards in Haematology guideline in 2007 (WITN7001035) stated: *'Pre-operative autologous donations (PAD) are not without risk, are of low clinical*

efficacy and are poorly cost-effective for the vast majority of patients in the UK. These guidelines update those previously issued by the BCSH and do not recommend the practice and use of PAD unless the clinical circumstances are exceptional'.

Section 6: Meetings of various committees

Please see the attached schedule for copies of the minutes the Inquiry holds of meetings you attended.

NBS vCJD Steering Group on Appropriate Use of Blood

28. The Inquiry understands that you attended meetings of the NBS vCJD Steering Group (see NHBT0002141_001 and NHBT0086598_007). What do you consider to have been the purpose(s) of those meetings?

139. To consider actions to minimise the risk of transmission of vCJD by blood transfusion.

29. Please explain, as far as you are able, the decision-making remit of the group(s). Please describe the decision-making process and how decisions were disseminated.

140. The group included the Chief Executive and several Directors of NBS. The group was advising them and through them the Department of Health. One key aspect of the work, certainly from the perspective of my role, was how to develop and disseminate communications with hospitals.

30. Do you consider that these meetings were conducive to fulfilling the purpose(s) for which they were established?

141. Yes.

31. Please see the minutes of the first meeting of the NBS vCJD Steering Group held at Oak House, Watford on 12 February 2001 (NHBT0002141_001). Please answer the following:

a. Point 8.8 indicates that you were involved in planning the formation of a coordinated group to look at autologous transfusion and intraoperative salvage. Please provide details regarding what action was taken by this group and what did the group achieve?

142. An Appropriate Use subgroup of the National Blood Service (NBS) Blood and Tissues Safety Assurance Group (formerly the NBS vCJD Steering Group) was established to consider how hospitals could take actions to minimise transmission of vCJD by blood transfusion.

143. The NBTC Annual report for 2003/04 indicates that the NBTC adopted a paper on *Blood Conservation Strategies: Summary of recommendations from the Working Parties on Autologous transfusion and Alternatives to Transfusion* produced by the Appropriate Use subgroup of the National Blood Service (NBS) Blood and Tissues Safety Assurance Group (WITN7001036). The report provided a summary of progress with implementing the recommendations on appropriate use of blood in *Better Blood Transfusion* and suggestions for further work.

144. This group continued to meet until 2007 and informed the NBTC and Better Blood Transfusion activities. One of the recommendations in the *'Avoid the unnecessary use of blood and blood components in medical and surgical practice'* section of the Health Service Circular 2002/009 (2002) *'Better Blood Transfusion – Safe and Appropriate Use of Blood'* (AHCH0000055) was:-

> *Develop a blood conservation strategy including the use of point-of-care testing for haemoglobin concentration and haemostasis and alternatives to donor blood such as peri-operative cell salvage and pharmacological agents such as anti-fibrinolytics and intravenous iron.*

b. It also states that "a seminar for the launch of a second CMOs' initiative was being planned for July". Did this seminar occur? And, if so, please provide details as to what it involved and what it set out to achieve?

145. Yes, it did occur. See previous section for full details and (NHBT0083701_002).

32. Please see the minutes of the meeting of the NBS vCJD Steering Group held at West End Donor Centre on 25 May 2001 (NHBT0086598_007) and answer the following:

a. What work was carried out to develop a test for vCJD in this committee (see point 6.2 and 6.5)?

146. The discussions on developing a test for vCJD were beyond my expertise as a clinical haematologist and specialist in hospital transfusion medicine.

33. The Inquiry holds minutes of this group which are provided for your assistance: NHBT0002141_001; NHBT0121252; NHBT0086598_007; NHBT0060302.

147. NHBT0002141_001: Minutes of 1st Meeting of NBS vCJD Steering Group 12/2/2001. During this meeting, the establishment of an *Appropriate Use subgroup* and the forthcoming *CMO's Better Blood Transfusion Seminar* were mentioned.

148. NHBT0121252: Minutes of 2nd Meeting of NBS vCJD Steering Group 2/4/2001. The agenda for the forthcoming first meeting of the Appropriate Use subgroup was discussed.

149. NHBT0086598_007: Minutes of Meeting of NBS vCJD Steering Group 25/5/2001.The discussion relevant to the Appropriate Use subgroup related to a request to plan for scenarios that blood donations would reduce by 10% and 50%.

150. NHBT0060302: Minutes of Meeting of NBS vCJD Steering Group 15/10/2001 (I was not present at this meeting).

National Transfusion Committees

34. The Inquiry understands that you were involved with the National Transfusion Committees. (NHBT0002141_001, point 6). What was the purpose of these committees? How frequently did they meet? Can you please explain your involvement?

151. See the answers to the questions in Section 4.

British Society for Haematology (BSH)

35. Please explain:

a. The purpose and remit of the Society?

152. Mission Statement: *BSH promotes excellence in the study, research, and practice of haematology for the benefit of professionals and the wider public.*

b. The nature of your involvement in the British Society for Haematology and how frequently meetings were held?

153. British Society for Haematology
- Member, probably from 1980 when I was a trainee haematologist at Barts
- 1992-1995 Secretary, British Committee for Standards in Haematology
- 1995- 2001 Member, British Committee for Standards in Haematology Blood Transfusion Task Force

154. I no longer have any records of the meetings of the BSH Committee but they were likely no more frequent than quarterly.

c. The Inquiry holds minutes of this group which are provided for your assistance: BSHA0000181_086;BSHA0000181_023; BSHA0000002_027; BSHA0000002_039.

155. BSHA0000002_027. The minutes of a BSH Committee meeting of 9th June 1994 indicate that I attended as deputy for Dr K Wood (Chair of the BCSH); I indicated that the BCSH had no report.

156. BSHA0000002_039. The minutes of a BSH Committee meeting of 12th January 1995 indicate that I attended as BCSH Secretary and reported that the Chairman of BCSH was concerned about the membership of the BSH European Task Force.

157. Other relevant items included:

> The President reported that he had chaired a discussion meeting on the proposal to set up a National Blood Authority (NBA). Following that meeting it was proposed that three Zones should be formed, each with its own committee seeking to provide liaison between users and providers. It was also proposed that there would be a National Watchdog (OFBLOOD). In the meantime, advisers from the Department of Health and an Independent Clinical Review Group are considering the many comments received in response to the circulation of the initial proposal to set up the NBA.

158. I gave an update on progress with BCSH guidelines.

159. BSHA0000181_023: This provides the agenda for the BSH Annual Business Meeting held in Lancaster on 9th April 1987 and the Minutes of the BSH Annual General Meeting held on 2nd to 4th April 1986 in Cambridge. I am mentioned as giving a lecture on *Platelet Transfusion - Immunological Aspects* on 2nd April 1986 as part of a Symposium to open the Scientific Meeting on the *Clinical Significance of Platelet Alloantibodies.*

160. BSHA0000181_086: This provides the Minutes of the BSH Annual General Meeting held on 2nd to 4th April 1986 in Cambridge. I am mentioned as giving a lecture on *Platelet Transfusion - Immunological Aspects* on 2nd April 1986 as part of a Symposium to open the Scientific Meeting on the *Clinical Significance of Platelet Alloantibodies.*

36. The Inquiry understands that you were the Secretary of the British Committee for Standards in Haematology, a subcommittee of the British Society for Haematology. Please answer the following:

a. What purpose(s) was the British Committee for Standards in Haematology established for?

161. To develop guidelines for clinical and laboratory practice in haematology.

b. How frequently did this group meet?

162. I no longer have any records of the meetings of the BCSH or its Blood Transfusion Task Force but they were likely no more frequent than quarterly.

c. Please describe the function and remit of this subcommittee and the nature of your involvement.

163. The remit of the BCSH was to develop guidelines for clinical and laboratory practice in haematology, and its Blood Transfusion Task Force to develop guidelines on clinical and laboratory transfusion practice.

d. The Inquiry holds minutes of this group which are provided for your assistance: BSHA0000011_023; BSHA0000011_021; BSHA0000011_020; BSHA0000011_019; BSHA0000011_018; BSHA0000011_017; NHBT0041711_047; NHBT0041711_012; NHBT0087565_001

164. BSHA0000011_023: Minutes of meeting of the British Committee for Standards in Haematology (BCSH) Committee on 3rd March 1993. At this meeting of the BCSH Committee, copies of documentation for consent to transfusion used in the United States were circulated. It was agreed that the advice of the Blood Transfusion Task Force was required on the question of guidelines on consent to transfusion.

165. BSHA0000011_021: Minutes of meeting of the BCSH Committee on 8th September 1993. At this meeting of the BCSH Committee, it was noted that a final draft of the guideline on consent to transfusion was in preparation.

166. BSHA0000011_020: Minutes of meeting of the BCSH on 26th January 1994. At this meeting of the BCSH Committee, the issue of consent to blood transfusion was discussed. It was noted that a draft guideline would be discussed at the next Blood Transfusion Task Force meeting. The Department of Health representative (Dr A Rejman) indicated he would draw the attention of colleagues in the Department of Health interested in the question of consent to the draft guidelines.

167. BSHA0000011_019: Minutes of meeting of the BCSH on 4th May 1994. At this meeting of the BCSH Committee, it was noted that this (draft guideline) will be circulated before further consultation takes place.

168. BSHA0000011_018: Minutes of meeting of the BCSH on 12th October 1994. At this meeting of the BCSH Committee, the issue of consent to blood transfusion was discussed.

169. The minutes of the meeting record that the Blood Transfusion Task Force indicated it was not able to publish a guideline on consent to transfusion. *'The Task Force considered it was an ethical duty of doctors to inform patients about blood transfusion. An information leaflet for patients produced during the drafting of the guideline document was considered to be valuable and will be published in the Transfusion Handbook. The (BCSH) Committee was disappointed that it had not been possible to take this matter forward and the Department of Health will*

inform the Task Force whether work on this project should be resumed.' The Department of Health was represented at this meeting by Dr A Rejman.

170. BSHA0000011_017: Minutes of meeting of the BCSH on 18th January 1995.There was agreement that the matter of consent to transfusion should be reconsidered, and firstly the Chairman of the Task force will send the previous document to the President of the BSH for consideration at the Joint Haematology Committee of the Royal Colleges.

171. Subsequent note: In the Discussion section of (NHBT0017564) 'Survey of the information given to patients about blood transfusion and the need for consent before transfusion', we noted the *'the Joint Committee on Haematology of the Royal Colleges of Physicians and Pathologists were not in favour of the introduction of formal consent to transfusion (Davidson, 1996).* The reference for this statement is Davidson JF. Report from the Joint Committee on Haematology. Consent for blood transfusion. The Bulletin of the Royal Colleges of Pathologists 1996;93:24. I have asked the Royal College of Pathologists to provide this reference, and I am still waiting for it to do so.

172. NHBT0041711_047: Minutes of the 2nd Meeting of the CMO's National Blood Transfusion Committee held on 11th March 2002.

173. There was discussion of two documents relevant to consent for transfusion: a draft revision of the NBS patient information leaflet and a Scottish National Blood Transfusion Service (SNBTS) document *'Transfusion: Information for Patients and Relatives'.* It was agreed that some sections of the SNBTS document should be incorporated into the English version, including the sections, *'What can I do to reduce my need for blood'*, *'What are the alternatives to blood'*, and *'How will I feel'.* It was agreed that a further draft would be produced by the Appropriate Use subgroup of the NBS Blood and Tissues Safety Assurance Group.

174. NHBT0041711_012: Minutes of the 3rd Meeting of the CMO's National Blood Transfusion Committee held on 30th September 2002.

At this meeting a revised version of the Patient Information Leaflet was agreed with an amendment in relation to an addition about the importance of patient identification checks before transfusion.

175. NHBT0087565_001: SHOT Annual Report 1996/97.

Serious Hazards of Transfusion

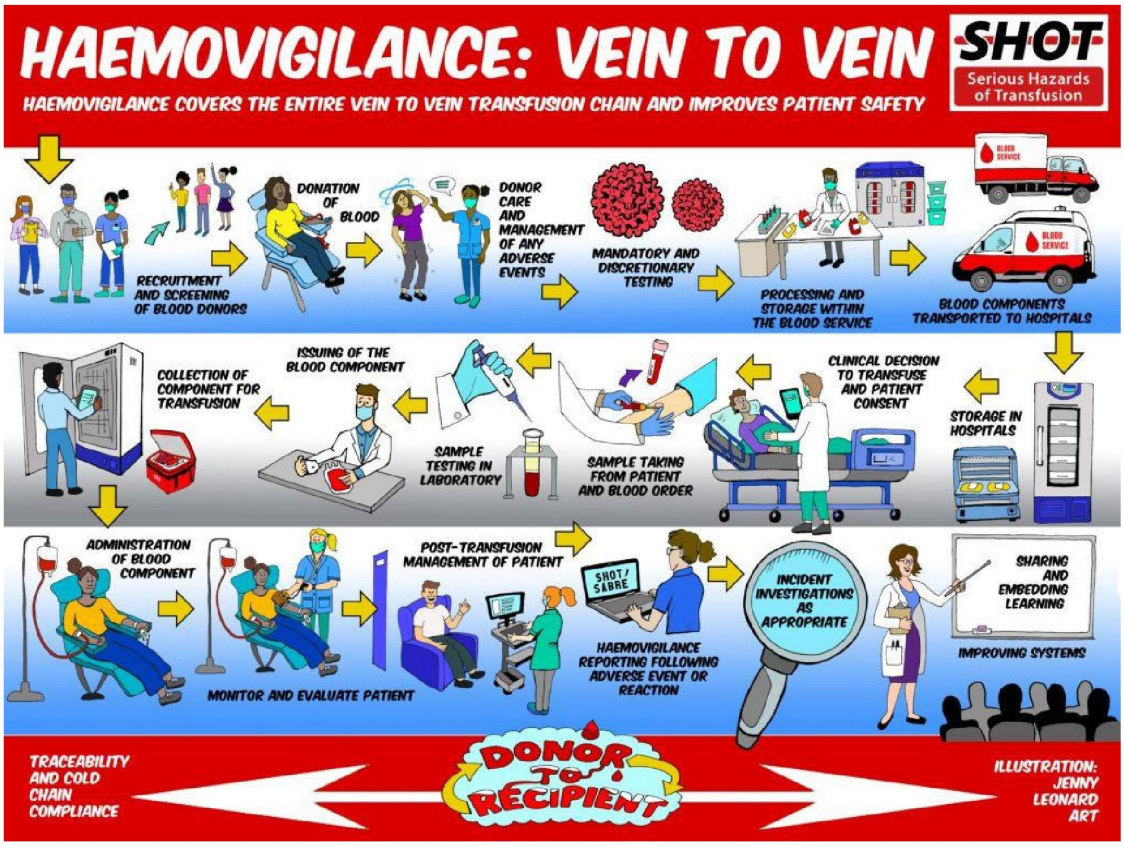
37. What is the remit and functions of the Serious Hazards of Transfusion Group (SHOT) scheme? You may be assisted by the Terms of Reference from 2001 (NHBT0077594_005). The Inquiry has also provided copies of the SHOT scheme's annual reports from 1996 to 2002 for your reference: NHBT0057437_001, SHOT0000020; NHBT0040229_001, NHBT0057438_002, NHBT0057439_001,NHBT0057439_002; SHOT0000016.

176. Quotation from Foreword to the 1st SHOT Report 1996/97 by Hannah Cohen, Chair SHOT Steering Group: *'The remit of SHOT is to receive and collate confidential reports, sent on a voluntary basis, of transfusion-related deaths and major complications'* (NHBT0000113_023).

177. Quotation from current front page of SHOT website:-

SHOT is the UK's independent, professionally-led haemovigilance scheme. Since 1996 SHOT has been collecting and analysing anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations that are involved in the transfusion of blood and blood components in the United Kingdom. Where risks and problems are identified, SHOT produces recommendations to improve patient safety. The recommendations are put into its annual report which is then circulated to all the relevant organisations including the four UK Blood Services, the Departments of Health in England, Wales, Scotland and Northern Ireland and all the relevant professional bodies as well as circulating it to all of the reporting hospitals. As haemovigilance is an ongoing exercise, SHOT can also monitor the effect of the implementation of its recommendations.

178. Cartoon from front page of SHOT website https://www.shotuk.org/



179. The current Terms of Reference are provided on the SHOT website. https://www.shotuk.org/shot-organisation/141-2/

38. What was your understanding of the relationship between SHOT and the NBA?

180. SHOT is funded by the UK Blood Services and is independent and professionally led.

39. Please explain your understanding of the voluntary basis of the SHOT system.

a. In your view, what were the advantages and disadvantages of a voluntary reporting system as opposed to a mandatory one?

181. The advantages of a voluntary scheme are that hospitals may develop confidence in the confidentiality of reporting. They may recognise they gain value from collation of reports and recommendations for improving practice. Over the years, hospitals have indeed had increasing confidence in SHOT which is reflected in the increasing number of reports. All but 2 UK NHS Trusts/Health Boards submitted reports during 2020; both of these are specialist centres and possibly low users of blood components (SHOT Annual Report 2020) (WITN7001037).

182. The main potential disadvantage of a voluntary scheme is that incidents and adverse events may go unreported.

40. Please describe how SHOT operated during the period of your involvement. In particular:

a. Who did SHOT report to, how frequently and by what means?

183. SHOT from the outset had a Steering Group with wide representation from Royal Colleges and professional bodies representing medical, nursing and scientific staff. Minutes of meetings were sent to the Department of Health for information.

The main communication means for SHOT is through its Annual Reports which are preceded by a Seminar which is well attended by staff involved in hospital transfusion.

b. Did SHOT have any powers or was it solely an advisory body?

184. Advisory only.

c. How was it funded? (NHBT0017307_001; NHBT0007856)

185. It is funded by the UK Blood Transfusion Services. It also received a start-up grant from the British Society for Haematology.

41. What was the relationship between the SHOT scheme and other bodies involved in reporting systems for infectious hazards, in particular the PHLS, CDSC, the MCA's Yellow Card System, and the National Institute for Health and Care Excellence ("NICE")? (NHBT0007848_002; NHBT0019435_010; NHBT0017300; NHBT0118019)

186. The scope of SHOT is summarised at: https://www.shotuk.org/shot-organisation/141-2/

> *SHOT encompasses all labile blood components issued by the 4 UK Blood Transfusion Services (NHS Blood & Transplant, Scottish National Blood Transfusion Service, Welsh Blood Service and Northern Ireland Blood Transfusion Service), the Ministry of Defence and the Blood Services in the Crown Dependencies. Reactions and events related to all forms of autologous transfusion, including cell salvage, are included.*
>
> *Adverse reactions and events related to virus inactivated fresh frozen plasma (FFP) and adverse events (errors) related to administration (or failure of administration) of anti-D Ig (immunoglobulin) are also included.*
>
> *New types of components regularly become available and SHOT will undertake to collect adverse events on all or any of these which are considered by the SG to be within the scope of SHOT.*
>
> *SHOT does not receive reports of adverse reactions or events related to other fractionated blood products e.g. coagulation factors, albumin, IVIg etc.*

187. Coagulation factor and immunoglobulin products, such as factors I to XIII and anti-D immunoglobulin, are considered medicines. Suspected side effects to these products should be reported using the Yellow Card system to the *Medicines and Healthcare products Regulatory Agency* (MHRA).

188. NICE *(National Institute for Health and Clinical Excellence)* provides:-

a) evidence-based guidance and advice for health, public health and social care practitioners. *NICE Guidelines for Blood Transfusion* were published in 2015 (I chaired the Guideline Development Group)

b) quality standards and performance metrics for those providing and commissioning health, public health and social care services. *NICE Quality Standards for Blood transfusion* were published in 2016 (I was a member of the Working Group)

189. The NICE Guidelines and Quality Standards for Blood transfusion will be discussed later in this statement.

190. Suspected cases of transfusion-transmitted infection are investigated by UK Blood Services and reported to the NHSBT/Public Health England Epidemiology Unit's surveillance scheme.

42. In your view, did the introduction of the SHOT scheme improve hazard reporting and recall procedures at the NBTS?

191. The introduction of SHOT certainly improved reporting of adverse events related to the transfusion of blood components. I am not aware that SHOT had any responsibility or influence on recall procedures in NBTS.

43. Do you think that the arrangements for hazard reporting and recall procedures were adequate before the introduction of the SHOT scheme?

192. From my perspective as a hospital haematologist, adverse event reporting for blood transfusion was not co-ordinated at a national level before the establishment of SHOT, limiting the ability for any learning to minimise them in the future. I cannot comment on the adequacy of recall procedures which are organised internally within the NBS.

'Alternatives to Blood Transfusion' Working Party Sub-Group'

You may wish to refer to NHBT0086599.

44. The Inquiry understands that in 2001 you were a member of the Alternatives to Blood Transfusion Working Party Sub-Group ("ABT"), could you please outline the remit for this working group?

193. It was established to provide input to National Blood Service (NBS) vCJD Steering Group Blood (which later became the NBS Tissues Safety Assurance Group). There was concern that there would be a significant drop in blood donations due to the exclusion of donors who had previously received blood components or if a test became available for vCJD.

45. In your view, why was this sub-group established and what were its objectives?

194. The purpose of the group was to consider measures that could be taken in hospitals if the current blood supply was reduced by up to 10% or up to 50%.

46. Please provide details of your contribution or involvement in the work of this sub-group.

195. Much of the discussions of and work of this group focussed on implementing measures for promoting the appropriate use of blood, optimisation of patients' blood counts and the use of alternatives to transfusion. These issues in due course became part of *Patient Blood Management* (PBM) (see Section 4).

UK Standing Advisory Committee for Transfusion Transmitted Infections ("SACTTI")

47. The Inquiry understands that you were a member of the 'UK Standing Advisory Committee for Transfusion Transmitted Infections Working Group on vCJD' ("SACTTI"). Please outline, as far as possible, the Committee's policies in relation to the following (you may wish to refer to NHBT0002578):

a. Donor selection;

b. Donor exclusion; and

c. Notification of 'at risk' patients.

196. I was a member of this group in my role as an expert in hospital transfusion medicine, and only rarely attended these meetings. My role was to advise on how blood was currently being used in hospitals and the likely impact of a reduced blood supply and how this might be mitigated

197. It is not appropriate for me to outline the Committee's policies on donor selection, donor exclusion and notification of 'at risk' patients.

48. During a SACTTI workshop in 2000, the policy of not advising patients who had received products from a donor who went on to develop vCJD was discussed. To the best of your knowledge, please outline the rationale for this policy. You may wish to refer to NHBT0003472 and DHSC0020839_041.

198. NHBT0003472 describes a NBS meeting on 18th December 2000 to set out the initial organisational arrangements in the event of a test for vCJD being developed.

199. DHSC0020839_041 is a letter dated 19th December 2000 from myself as National Medical Lead for Hospital Liaison and Stuart Penny as Head of Hospital Liaison informing hospitals that products manufactured from a plasma pool included a donation from a donor diagnosed with vCJD. The letter passed on information provided by the Department of Health (DH):

> *'The advice that that DH has received from ethics experts and other advisory bodies is that there is no need to inform patients who have received blood components or products collected from donors who subsequently developed vCJD because:-*
>
> *a) It is thought unlikely that vCJD will be transmitted in this way;*
>
> *b) There is no diagnostic test for vCJD;*

c) *Even if a test was available, there is no preventative treatment that could be offered'.*

49. Please detail any discussions which led towards the development of assays and tests for vCJD.

200. I had no role in any detailed discussions about the development of assays and tests for vCJD. They were beyond my expertise as a clinical haematologist and expert in hospital transfusion medicine.

50. The Inquiry holds minutes of this group which are provided for your assistance: NHBT0001956_002; NHBT0002578; JPAC0000088_067; JPAC0000086_019; JPAC0000114_018; JPAC0000116_011; JPAC0000118_015; JPAC0000051_056; JPAC0000061_022; JPAC0000051_021; JPAC0000051_011.

201. JPAC0000088_067: Meeting of SACTTI Working Group on vCJD 17/9/2001 (I was not present).

202. JPAC0000086_019: Meeting of SACTTI Working Group on vCJD 13/12/2002 (I was not present).

203. JPAC0000114_018: Meeting of SACTTI Working Group on vCJD 30/4/2003

204. JPAC0000116_011: Meeting of SACTTI Working Group on vCJD 27/10/2003 (I was not present).

205. JPAC0000118_015: Meeting of SACTTI Working Group on vCJD 1/4/2004 (I was not present).

206. JPAC0000051_056: Meeting of SACTTI Working Group on vCJD 16/9/2004 (I was not present).

207. JPAC0000061_022: Meeting of SACTTI Working Group on vCJD 17/6/2005 (I was not present).

208. JPAC0000051_021: Meeting of SACTTI Working Group on vCJD 7/9/2005 (I was not present).

209. JPAC0000051_011: Meeting of SACTTI Working Group on vCJD 12/1/2006 (I was not present).

210. These meetings were primarily about the risk of transmission of vCJD by blood transfusion and developing a test for vCJD. These matters were beyond my expertise and explain why I did not attend the meetings.

vCJD Sub-Group on Appropriate Use of Blood

51. The Inquiry understands that you were a member of this committee. Please outline your roles and responsibilities in this position.

211. The committee was established to provide input to the National Blood Service (NBS) vCJD Steering Group Blood (which later became the NBS Tissues Safety Assurance Group). My role was to support the work of the Appropriate Use of Blood chaired by Dr Angela Robinson. See NHBT0003472 which describes a NBS meeting on 18th December 2000 to set out the initial organisational arrangements in the event of a test for vCJD being developed.

52. Please outline the remit of this committee.

212. To provide advice to the National Blood Service (NBS) vCJD Steering Group Blood about measures that could be taken in hospitals to mitigate a reduced blood supply in the event of a test for vCJD being developed.

53. What were the aims of this committee? In your opinion, did the committee achieve these goals?

213. Please see answer to Q52. The committee's discussions were a useful forerunner to later work on *Patient Blood Management* for promoting the appropriate use of blood, optimisation of patients' blood counts and the use of alternatives to transfusion.

54. In a meeting on the 27th November 2001 (NHBT0000674), you were actioned to coordinate responses from the CJD Incidents Panel about management of potential exposure to CJD through medicinal products, please provide further information on this?

214. This is incorrect. The note and Action under item 2.2. indicates that I explained that Dr Angela Robinson would be collating responses on behalf of the NBS.

55. Please see the minutes of the meeting held on 3rd August 2001 (NHBT0086598_002) and answer the following:

a. It was suggested that vCJD positive blood should be considered for use for certain groups of patients, to the best of your knowledge, was there any action taken based on this suggestion?

215. This was not considered any further to my knowledge. The minute 6 indicates that this was referred to the Donor vCJD group through Mrs Liz Reynolds.

b. At paragraph 7.1 a paper was presented communicating a change in the message to the public, patients, and users of blood. These suggested changes included altering the following wording: "theoretical risk of vCJD in relation to transfusion" to "unknown risk" or; "'we have one of the safest blood supplies in the world" to "blood transfusion does carry a small risk" and; "blood transfusion should only be transfused to patients where it is absolutely necessary". What were your views on this change in message and do you think this adequately reflected the knowledge of risk at the time?

216. I would have supported a change in message to *"Unknown risk"* and *"Blood transfusion should only be transfused to patients where it is absolutely necessary".*

217. The first report of transmission of vCJD by blood transfusion was in 2004 (NHBT0008743_013).

56. The Inquiry holds minutes of this group which are provided for your assistance: NHBT0000674; NHBT0015710; NHBT0086598_003; NHBT0086598_002

218. At these meetings (NHBT0015710; NHBT0086598_003; NHBT0086598_002), the issues discussed included the recommendations being developed for the HSC *Better Blood Transfusion* (AHCH0000055), the drafting of a patient information leaflet in England, efforts to improve collection of data on how blood was used in hospitals, and contingency planning in the event of severe blood shortages.

Section 7: Knowledge of risk of infections

vCJD

57. How and when did you become aware that there might be an association between vCJD and the use of blood products? What steps did you take in light of that awareness? What steps were taken at Oxford RTC?

219. It was likely in 1996/97 when a surveillance system was established between the UK national CJD surveillance unit and the UK Blood Services (NHBT0008743_013).

220. Considerations at any steps to be taken would have happened at national level. The Oxford Regional Transfusion Centre was managed by the NBS Midlands and South West Zone when I came to Oxford in December 1996.

58. Please see the letter you sent to Blood Bank Managers served by the NBS on 19th December 2000 (DHSC0020839_041), which outlines the ethical advice given to DH, specifically:

"i) it is thought unlikely that vCJD will be transmitted in this way;

ii) there is no diagnostic test for vCJD;

iii) even if a test was available, there is no preventative treatment that could be offered." Please answer the following:

a. The Inquiry understands that the general view at this time was that patients would not benefit from having this knowledge. Is that your understanding of the general view at the time?

221. Yes.

b. Did you agree with this view?

222. Yes, I agreed with this view at the time, although it has never been my practice before or since to withhold information from patients

c. Has your view changed over time? If so, why?

223. My view has not changed that information should not be withheld from patients.

Section 8: Reduction of risk of infections

Donor selection

59. What donor selection policies and processes were in place during your tenure at Oxford RTC vCJD?

224. They followed the policies set by the Midlands and SW Zone. As stated before, I was not responsible for donor services when I came to Oxford in December 1996.

60. During an emergency Microbiological Safety of Blood and Tissue for Transplantation (MSBT) meeting in 2004 (NHBT0035101), an urgent policy change was considered concerning the exclusion of donors who had received a blood transfusion from someone who subsequently developed vCJD. The meeting minutes state that further risk reduction strategies were to be introduced. To the best of your recollection, please explain the relevant policy changes that were implemented.

225. There was discussion about the exclusion of donors who had previously been transfused. The other issue I remember being discussed related to helping hospitals prepare for potential blood shortages primarily by promoting *Better Blood Transfusion* activities. I have discussed those in detail in Section 4 (AHCH0000055).

61. What national guidelines, if any, informed the donor selection policies and processes at Oxford RTC? In the event that the Oxford RTC processes departed from any such guidelines, please explain how and why.

226. See answer to Q59.

62. How were decisions made as to which donors were high risk and should be excluded from donating at Oxford RTC?

a. What was your role in this process at Oxford RTC?
b. Were these decisions reviewed and, if so, how often?

227. See answer to Q59.

63. Were there any difficulties in implementing the exclusion of high-risk donors at Oxford RTC? How effective, in your view, were communications at reducing the risk of donations from high-risk individuals?

228. I was not in charge of donor services but there were no local difficulties in Oxford in implementing this policy to my knowledge.

229. I cannot answer the question about the effectiveness of communications at reducing the risk of donations from high-risk individuals as I was not involved in donor services.

Recall practice and procedure at Oxford RTC

64. Please provide an overview of product recall practice at Oxford RTC, and how this changed during your tenure.

230. In my role I was not responsible for initiating product recalls. I did have a role in communicating product recalls to hospital blood transfusion services in the Oxford region.

65. What, if anything, do you remember about any formal recall or notification procedures in place?

231. I cannot remember anything else about recall procedures.

66. In your opinion, were such practices and procedures effective?

a. From experience, did clinicians generally comply with recall requests and if not, do you recall why not?

232. My recollection of the recall procedure is that hospitals would be asked to identify the patient who received the relevant blood component or product. Communication with the patient and/or the clinician responsible for the patient's

care about any implications of receiving that component or product would come from a doctor in NBS donor services.

233. From my own limited experience in Oxford and previously at Barts, hospitals did comply with recall procedures.

General

67. Please describe all other steps or actions taken at Oxford RTC during the time you worked there to ensure blood safety and to reduce the risk to recipients of blood or blood products of being infected with a transfusion transmitted infection.

234. My main role for NBS at the Oxford Regional Transfusion Centre was to provide clinical advice to the hospitals in the Oxford region and drive improvements in safe and effective transfusion practice, teach and conduct research. See answer to Q19 (WITN7001005). I visited and gave talks at the regional hospitals on an occasional basis, gave talks at Oxford *'Blood Club'* regional meetings, and informed the hospitals about the activities the Hospital Transfusion Team were undertaking at the Oxford Radcliffe Hospitals.

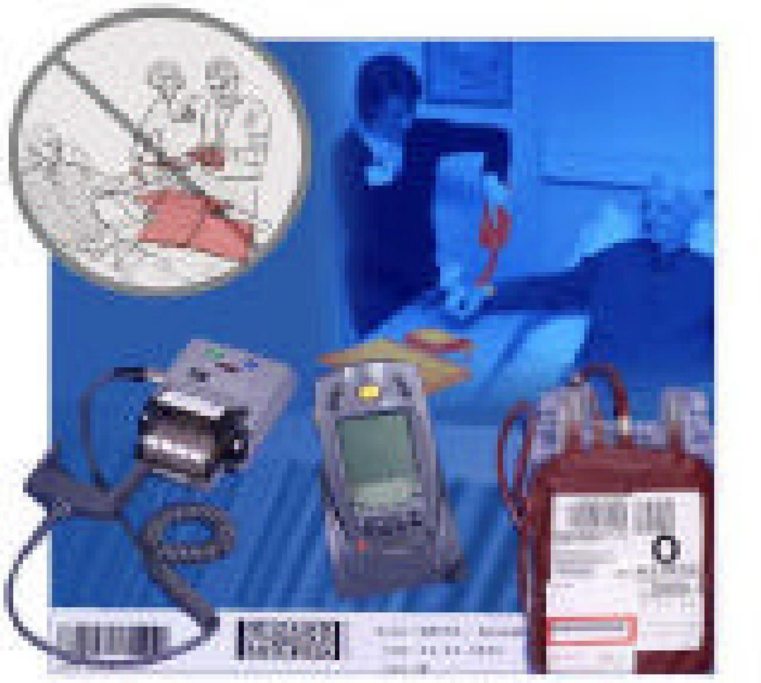
68. Was blood safety ever subject to cost, time, staffing or any other constraints?

a. If you felt a particular course of action needed to be taken to ensure blood safety, were you free to take it?

235. I am not aware that measures that the NBS needed to take to minimise the risk of transfusion-transmitted infection were subject to cost pressures, but I would not have been involved in such discussions.

236. At a hospital level, I am aware that cost pressures exist and choices need to be made about what quality improvement measures are supported. The Oxford hospitals were generous in supporting the approach that my team took to develop and implement electronic transfusion systems (see Section 4) which improve the

safety and efficiency of hospital transfusion. I presented a business case for the full roll out of electronic transfusion systems to the Executive Board of the Oxford Radcliffe Hospitals in July 2005 (WITN7001038) following successful pilots, publications in a peer reviewed journal (WITN7001012) and feature on the front cover of the journal (see below) and national awards.



237. The meeting note of the Executive Board is provided below:

EB 105/5 Transfusion safety and effectiveness programme Mike Murphy from the National Blood Service attended to present the business case for a Trust-wide roll out of the transfusion safety and effectiveness programme. The programme would ensure compliance with the EU Blood Directive requirements which come into force on 8 November 2005. The estimated cost savings of this programme were £660k per annum based on blood reduction level. The cost of implementation was £614k capital cost plus £157k per annum for the managed services contract.

Concerns were raised with regard to the Trust's existing wireless network.

There was nothing in the capital programme allocated to improving the current wireless network capacity which may require further capital investment. TCD requested that, before any decisions could be made, he would need to see clarification on the financial impact and where this project stood in the hierarchy of investment needs.

238. The business case was later approved after further discussion.

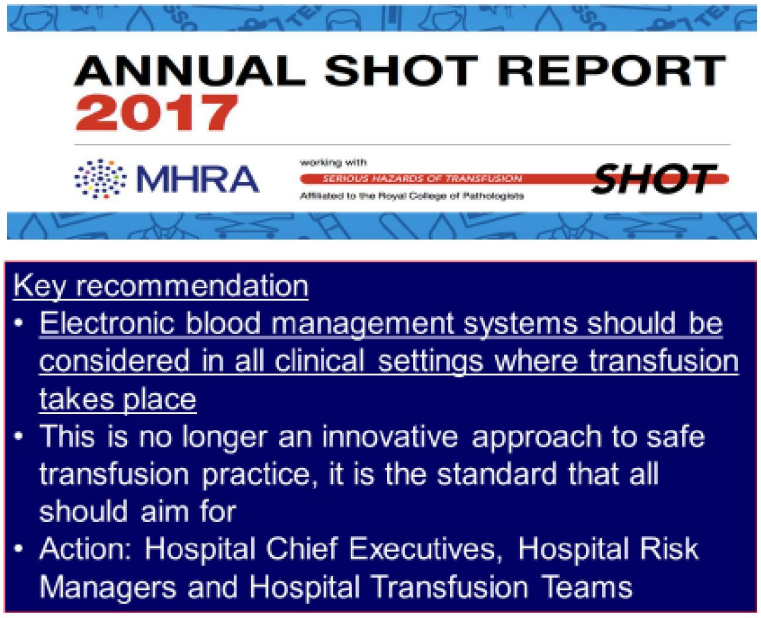
239. We also received funding from NHSBT R&D and the Department of Health for our work on the *Do Once and Share* initiative.

240. Our later work confirmed the clinical and health economic value of the implementation of electronic transfusion processes in Oxford. However, the uptake of this technology has been slow elsewhere in the NHS despite recommendations from:-

Prof Dame Sally Davies (Chief Medical Officer) wrote in the introduction to the *2015 NIHR Annual Report*:

"This system, if implemented across the NHS, could create savings of more than £50m each year and is a fool-proof way of ensuring patients' safety."

SHOT Annual Report 2017



241. In 2018, I conducted a survey with the Serious Hazards of Transfusion scheme which found that the implementation of electronic transfusion systems in the United Kingdom has been patchy and that they are rarely used to their full functionality for the hospital transfusion process (WITN7001017).

242. It is likely that concerns about providing the required resource, both staffing and the cost of equipment, is resulting in a slow implementation of this technology in the NHS.

69. How did the desire for consensus across the RTCs impact efforts to achieve blood safety at a local level?

243. I am not aware that any desire for consensus across the RTCs impacted on blood safety efforts at a local level, but as stated above I never held the role of Regional Transfusion Director.

70. To what extent were you and other RTDs reliant on the decisions of other bodies (advisory committees, directorates, NBTS, DoH) to achieve blood safety?

244. I never held the role of Regional Transfusion Director.

a. Who or what was responsible for defining what constituted safe blood?

245. I don't think that there is any agreed definition for *'safe blood'*. It is generally recognised that blood transfusion, and indeed any diagnostic procedure or treatment, does not have zero risk.

b. What happened if your own opinion conflicted with the decision or advice of that person or body?

246. I don't remember any conflict about efforts being made by me or others to do as much as possible to ensure transfusion safety.

Leucodepletion

71. Please outline your views on the effectiveness of leucodepletion as a risk reduction method, specifically as it pertains to vCJD?

247. I was a strong proponent of leucocyte reduction of blood components to reduce febrile transfusion reactions, refractoriness to platelet transfusions and transmission of cytomegalovirus infection (NCRU0000281_097).

248. I wrote an article in 1999 reviewing current knowledge about vCJD and the likely effectiveness of leucocyte reduction in minimising its transmission by transfusion, and concluded that it was unknown (NCRU0000281_054).

72. What impact has leucodepletion had on the transmission of vCJD?

249. It is unknown.

73. Do you believe that universal leucodepletion was the most prudent course of action given the NHS resources c.1999?

250. As stated above, I was a proponent of the benefits of leucocyte reduction of blood components, but I was doubtful about its value as a measure to reduce transmission of vCJD.

74. In the final NBS Leucodepletion Project medical/scientific report (JPAC0000104_012) you suggested that leucodepletion may not reduce post-operative infection? Does this remain your view?

251. I subsequently conducted a study with Lorna Williamson and others to study this question, and we did not find evidence to support this (WITN7001039).

> *BACKGROUND: A before and after study was undertaken to investigate the effect of universal leukoreduction (ULR) in the UK on postoperative length of hospital stay (LOS) and infections.*
>
> *STUDY DESIGN AND METHODS: Consecutive patients undergoing elective coronary artery bypass grafting or total hip and/or knee replacement in 11 hospitals received non-WBC-reduced RBCs before implementation of ULR (T1, n = 997) or WBC-reduced RBCs after implementation of ULR (T2, n = 1098).*
>
> *RESULTS: Patients in T1 and T2 were comparable except patients in T2 received on average more units of RBCs but had lower discharge Hct levels. Postoperative LOS (T1, 10 ± 8.9 days; T2, 9.6 ± 6.9 days) and the proportion of patients with suspected and proven postoperative infections (T1, 21.0%; T2, 20.0%) were unchanged before and after ULR (LOS, hazard ratio 1.01, 95% CI 0.92-1.10; infections, OR 0.83, 95% CI 0.77- 1.02). Subgroup analysis showed no significant interaction between storage age or dose of blood on responsiveness of primary outcomes to ULR. Secondary outcomes were unchanged overall. Analysis by surgical procedure gave conflicting results with both increased mortality (p = 0.031) and an increased proportion of cardiac patients with proven infections (p = 0.004), whereas the proportion of orthopaedic patients with proven infections was reduced (p = 0.002) after ULR.*

CONCLUSION: Implementation of ULR had no major impact on postoperative infection or LOS in patients undergoing elective surgical procedures who received transfusion(s). Smaller effects, either detrimental or beneficial of ULR, cannot be excluded.

252. A subsequent systematic review supported that view (WITN7001040).

Section 9: Look back programmes at Oxford RTC

HIV

75. Were you involved in setting up any national or local HIV look back programmes during your time at Oxford RTC? If so, please describe this process and your role in it and how it was funded.

253. I began work in Oxford in December 1996. I do not remember setting up any national or local lookback for HIV or any other transfusion-transmitted infection at any time.

76. Were you involved in implementing any HIV look back programmes during your time at Oxford RTC? Please give details (you may find DHSC0002389_221 useful).

254. DHSC0002389_221: This is a letter from Dr Carol Barton, Consultant haematologist at the Royal Berkshire Hospital, dated 7/2/1997 soon after I started in Oxford. She asked me to search for previous correspondence in January 1994 from Dr C Entwistle who was the Oxford Regional Transfusion Director at that time. I do not remember if I was able to find this correspondence or any other relevant materials.

HCV

77. Were you involved in setting up any HCV look back programmes during your time at Oxford RTC? If so, please describe this process and your role in it and how it was funded. (You may find NHBT0090646 helpful).

255. I was not involved in setting up HCV lookback programmes.

256. NHBT0090646: This is a letter from Dr Angela Gorman (Consultant Haematologist, NBS Donor Services) dated 8/1/1998 requesting me to ask for previous HCV results on a blood donor relating to a donation or donations in 1995/96 and to retest any archived samples. I would have passed this request to the donation testing laboratory at Bristol as donation testing moved to Bristol in 1996.

78. Were you involved in implementing any HCV look back programmes during your time at Oxford RTC? If so, please describe what this involved.

257. I was not involved in implementing any HCV lookback programmes.

General

79. Please confirm whether you were involved in a look back process relating to any other infection during your time at Oxford RTC. If so, please provide an overview of the relevant programmes and detail your involvement.

258. My involvement would have been limited to following up requests from NBS Donor Services to identify the patient who received the relevant blood component or product. Further communication with the patient and/or the clinician responsible for the patient's care about any implications of receiving that component or product would come from a doctor in NBS donor services.

80. Did you consider there was an ethical obligation to inform patients who may have received transfusions from infected donations? If not, why not?

259. Yes, although that did not apply to vCJD. See answer to Q48.

> *'The advice that DH has received from ethics experts and other advisory bodies is that there is no need to inform patients who have received blood components or products collected from donors who subsequently developed vCJD because:-*
>
> *a) It is thought unlikely that vCJD will be transmitted in this way;*
>
> *b) There is no diagnostic test for vCJD;*
>
> *c) Even if a test was available, there is no preventative treatment that could be offered.*

81. To what extent could an RTC implement its own local look back programme? Did Oxford RTC do this? If so please give details. If not, why not?

260. I don't know the answer to this question as by the time I came to Oxford in December 1996, it was no longer a stand-alone Regional Transfusion Centre.

vCJD (notification and de-notification of patients)

The Inquiry has heard evidence of the experiences of a number of infected and affected individuals who were notified of their 'at risk' status of vCJD. The Inquiry seeks to gain an understanding of the rationale behind policy decisions made in relation to notifying at-risk individuals and how this changed over time.

Please provide the following:

82. A chronological summary of the knowledge held within your organisation in relation to the issues surrounding notification of risk to individuals deemed to be at risk of vCJD.

261. I do not have this information.

83. Please describe how and when you learned that patients under the care of Oxford RTC may have been infected with vCJD? You may wish to refer to NHBT0035101.

262. This question refers to a meeting of the 31st Extraordinary Microbiological Safety of Blood and Tissues for Transplantation 22nd January 2004. I was present as an observer. This meeting was convened to discuss what actions could be taken to ensure blood safety following the report in late 2003 of the death of a patient who had received a transfusion from a donor who went on to develop vCJD.

263. I first learned of patients who had received blood in the Oxford region and who may have been infected with vCJD as a result of blood transfusion in a letter from Dr J Witcher dated 6th April 2005. He requested tracing of blood components donated by an individual subsequently diagnosed with probable vCJD (NHBT0047525_005).

264. I have a copy of an email I sent to the Medical Director of the Oxford Radcliffe Hospitals, Dr James Morris, informing him that 2 units of red cells and 1 unit of FFP donated by a donor who had now developed probable vCJD were definitely

transfused to 2 patients and probably to a 3rd in Oxford in June 2003 and June 2004 (WITN7001041).

265. I passed this information to Dr Derrick Crook, Consultant in Infectious Diseases, for further action including reporting to the CJD Incidents Panel.

266. NHBT0035101: Also see answer to Q60.

84. During an emergency Microbiological Safety of Blood and Tissue for Transplantation (MSBT) meeting in 2004 (NHBT0035101), an urgent policy change was considered concerning the exclusion of donors who had received a blood transfusion from someone who subsequently developed vCJD. The meeting minutes state that further risk reduction strategies were to be introduced. To the best of your recollection, please explain the relevant policy changes that were implemented.

267. The Minutes of the meeting indicate that several issues were discussed including the deferral of previously transfused donors, and the use of non-UK plasma. The 'action' item for me (Agenda Item 9) was a discussion about *Better Blood Transfusion*.

> Agenda Item 9:
> *'MSBT discussed some of the reasons underlying slower than expected progress in implementing the action plan set out in HSC 2002/009 Better Blood Transfusion – Appropriate Use of Blood. These included insufficient awareness/education within hospitals of the potential impact on blood transfusion safety, lack of effective means of enforcement by the CMO's NBTC or the lack of Hospital Transfusion Groups and the lack of will at local management level, including the lack of resources to ensure implementation. At a more fundamental level, undergraduate clinical curricula need to give greater prominence to Better Blood Transfusion as an important area of clinical care.'*
>
> *'A range of measures were proposed in MSBT 31/6, including the appointment of a 'Blood Transfusion Czar', resources for consultant*

sessions, appointment of transfusion practitioners, audit and blood cost incentives, to take the policy forward. The French model of having a haemovigilance officer in each hospital was proposed as an effective, albeit costly, intervention. Other alternatives include Preparing Patients for Surgery clinics and the use of substitutes e.g. EPO and intravenous iron.'

'MSBT agreed that renewed efforts should be made to reinforce Better Blood Transfusion, both to minimise unnecessary patient exposure to the risks of blood transfusion and to mitigate the impact of potential blood shortages, including support and involvement of DH.'

Action: Blood Policy team with the NBTC to consider how to encourage progress with Better Blood Transfusion.

85. When did you first discuss the possibility of vCJD transmission with the patients considered to be at risk at Oxford RTC? You may wish to refer to NHBT0003472.

268. NHBT0003472 is the Minutes of a NBS meeting 18/12/2000 chaired by NBS Chief Executive. This meeting was called to discuss concerns about the possibility of the transmission of vCJD by blood transfusion.

269. The actions I took in relation to Oxford patients who may have been infected with vCJD are described in my answer to Q83.

86. A summary of the views, opinions and decisions regarding notification arising from the CDJIP consultation process in 2000. You may wish to refer to DHSC0038528_046.

270. DHSC0038528_046 provides the Agenda of a meeting of the Executive Working Group of the National Blood Transfusion Committee 21/1/02.

271. The note in the Minutes of the meeting records that the relevant discussion (WITN7001028) was:

CJD Incidents Panel Consultation

- *It was agreed that the NBTC were unable to make a formal response as the NBTC is a new organisation. We should respond by indicating that we would like to be informed of further developments.*
- *MM to circulate the document to the EWG and to inform the NBTC members of its existence.*
- *MM to draft letter to the Incidents Panel.*

87. The Inquiry understands that you carried out work and wrote articles concerning leucodepletion. In addition to this, what, if any, enquiries and/or investigations did you, or others at Oxford RTC, carry out, or cause to be carried out, in respect of the risks of transmission of vCJD? What information was obtained as a result?

272. See answers to Q71-73.

88. An outline of any policies and practices which were implemented across the U.K. in relation to patient notification and de-notification.

273. I am not the appropriate person to ask for this information.

89. An account of your organisation's involvement, if any, of those notification exercises between 2003 and 2009;

274. I am not the appropriate person to ask for this information.

90. An account of your organisation's involvement, if any, in any de-notification exercises post 2013 or earlier;

275. I am not the appropriate person to ask for this information.

91. Details as to whether your organisation was aware of any circumstances where individuals were not informed of their risk status or at a later date and if so, why. You may wish to refer to DHSC0020839_041.

276. DHSC0020839_041 is a letter dated 19th December 2000 from myself as NBS National Medical Lead for Hospital Liaison and Stuart Penny as NBS Head of Hospital Liaison informing hospitals that products manufactured from a plasma pool included a donation from a donor diagnosed with vCJD. The letter passed on reassurance provided by the Department of Health (DH).

> *'The advice that that DH has received from ethics experts and other advisory bodies is that there is no need to inform patients who have received blood components or products collected from donors who subsequently developed vCJD because:-*
>
> - *It is thought unlikely that vCJD will be transmitted in this way;*
> - *There is no diagnostic test for vCJD;*
> - *Even if a test was available, there is no preventative treatment that could be offered.*

92. An account of what, how, when and where patients were told that they might have been exposed to a greater risk of vCJD.

277. I cannot provide this. I am not the appropriate person to ask for this information.

93. In NHBT0047525_005, you were asked to take part in a study to trace implicated blood components that may have been transfused into recipients. Please outline the outcome of this exercise and any similar look back exercises you took part in. You may also wish to refer to NHBT0031746_017.

278. See answer to Q83.

94. A summary of information or advice given to partners or family members of patients who were at risk of infection with vCJD.

279. I cannot provide this. I think it was provided by the CJD Incidents Panel.

95. An outline of any proposals, whether accepted or not, that were suggested or reviewed by the organisations you were a part of in an effort to protect the blood supply from the risk of vCJD, including but not limited to:

a. Filtration policy;

b. Development of screening or diagnostic tests;

c. Donor selection and exclusion policies; (NHBT0061247; BWCT0000125); and

d. Leucodepletion (NHBT0087811)

280. These issues were all suggested and discussed by NBS and others. My involvement was in providing advice to hospitals about mitigating potential blood shortages and the appropriate use of blood and alternatives to transfusion.

In providing this outline could you please provide the following:

a. Your opinion as to whether the risk of secondary transmission via blood and blood products were adequately mitigated;

b. Your views as to whether any decision or actions could, and/or should, have been made earlier and how this might have impacted the number of individuals considered to be at risk of developing vCJD.

281. I think appropriate actions were taken to mitigate the risk of transmission of vCJD by blood transfusion while at the same time maintaining a supply of blood to hospitals and to patients in need of transfusion.

A letter you sent on the 10th September 2004 (LDFT0000006) was circulated to all consultant haematologists and transfusion lab managers, you informed them of an audit of plasma products that potentially presented a possible risk of vCJD transmission.

a. Could you speak on the outcome of this audit;
b. How was the information used?

282. This letter from myself as NBS National Medical Lead for Hospital Liaison and Stuart Penny (NBS Head of Hospital Liaison) was to inform Hospital Transfusion Laboratory Managers and Consultant Haematologists about a letter sent to Medical Directors of NHS Trusts about batches of plasma products that may be at risk of transmitting vCJD. The purpose of our communication was to alert Hospital Transfusion Laboratory Managers and Consultant Haematologists to the letter to their Medical Director and that this letter provided information about the specific actions that needed to take place in the hospital.

283. This was not an audit with actions for ourselves. The letter indicated actions required in hospitals.

In and around 2004/05, there were many references to an anticipated reduction in the blood supply, one of the reasons cited were the speculative issues surrounding vCJD. Please outline (you may wish to refer to these documents NHBT0062515; NHBT0060450):

a. How these issues influenced this speculation;

b. If such a reduction in the blood supply occurred; and

c. If any of the proposed steps were implemented.

284. Much of the discussions at this time that involved me related to helping hospitals prepare for potential blood shortages primarily by promoting *Better Blood Transfusion* activities. The actions included promoting the appropriate use of blood, optimisation of patients' blood counts and the use of alternatives to transfusion. These issues in due course became part of *Patient Blood Management* (PBM). I have described them in detail in Section 4 (AHCH0000055).

285. The anticipated possible severe reduction in the blood supply did not happen, but the *Better Blood Transfusion* and *PBM* activities did result in a significant reduction in the use of red cells from 2000 (see earlier section on the Main outcomes of the NBTC).

Section 10: Your relationship with commercial organisations

96. Have you ever:

a. Provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products?

286. Since 2017, I have been a member of the Haemonetics Scientific Advisory Council.

287. Haemonetics does not directly manufacture blood products. It provides apheresis and cell salvage equipment and technological solutions to improve transfusion practice such as software for safe and efficient hospital transfusion practice.

288. November 2021: Participation on a teaching course (a lecture and round table discussion) for Grifols customers on Patient Blood Management. Grifols produces plasma products.

b. Received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture, sale and/or importation of blood products?

289. See section a.

c. Sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture, importation or sale of blood products?

290. See section a.

d. Received any financial incentives from pharmaceutical companies to use certain blood products?

291. No.

e. Received any non-financial incentives from pharmaceutical companies to use certain blood products?

292. No.

f. Received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?

293. No.

If so, please provide details.

97. What regulations, requirements, or guidelines were in place (at any time relevant to your answers above) concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?

294. I declare the involvements described in section a in the annual staff interests declaration conducted by my employer NHSBT and on my NHS electronic staff record.

98. Have you ever undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture, importation or sale of blood products? If so, please provide details.

295. No.

99. Have you ever provided a pharmaceutical company with results from research studies that you have undertaken? If so, please provide details.

296. Not relevant.

100. If you did receive funding from pharmaceutical companies for research, did you declare the fact that you were receiving funding and the source of the funding to your employing organisation?

297. Not relevant.

<u>Section 11: Other matters</u>

101. Please provide a list of any articles you have had published relevant to the terms of reference.

298. I have provided a list of R eferences and Exhibits relevant to the questions I have answered (see below).

299. I have also provided a full current CV.

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

Developments on Providing Patients with Information about Blood Transfusion and Obtaining Consent to Blood Transfusion

300. There have been a number of initiatives to improve the provision of patient information and obtaining consent to transfusion.

301. *SaBTO (The Advisory Committee on the Safety of Blood, Tissues and Organs*) is the independent advisory committee that advises ministers of the UK nations on the safety of blood, tissues and organs. In 2011, it made recommendations on patient consent for blood transfusion (ASPT0000170).

302. In 2014, *the National Comparative Audit of Consent for Blood Transfusion* (WITN7001042) involving 162 hospital sites found that the implementation of the SaBTO recommendations was sporadic and compliance was generally low; 462/2243 (21%) of patients indicated that they were not involved in the decision making process about receiving a transfusion.

303. Since 2011, the United Kingdom (UK) Supreme Court *Montgomery v Lanarkshire* ruling provided additional guidance on consent (WITN7001043).

304. In view of these developments, SaBTO decided that the recommendations needed to be reviewed and revised, as necessary, to enhance standards for the provision of information about blood transfusion and for obtaining patient consent and clarify good practice. These were published in December 2020

(WITN7001044), and were summarised in a publication in the journal Clinical Medicine (WITN7001045). The key points are summarised below:-

Key points

- Patients should be informed about and understand the purpose, benefits and potential risks of transfusion, and have an opportunity to discuss their treatment options.
- The information provided should include whether the transfusion is the only available treatment, whether any alternative treatments are available and suitable, and the risks and benefits of those alternatives to transfusion.
- The amount of information required to make consent truly informed may vary depending on the complexity and risks of treatment as well as the patient's wishes.
- Consent should be obtained and documented for those who will or might receive (as evidenced by a sending of a specimen for 'group and save' or 'cross-match') a transfusion of blood or components (including red blood cells, platelets, FFP, cryoprecipitate and granulocytes) or being exposed to blood as in, for example, ECMO.
- Where transfusion may be required long term (eg, for those with sickle cell disease or undergoing chemotherapy), written consent needs be obtained only at the start of treatment and at 5-yearly intervals, although consent should be confirmed verbally before each transfusion.
- A standardised source of information should be developed for patients who may receive a blood transfusion in the UK, and training provided for all healthcare practitioners involved in the consent for transfusion process. ■

305. Other guidance, guidelines and recommendations include:-

    a) the 2015 *National Institute for Care and Health Excellence (NICE) Blood Transfusion guideline* (WITN7001046);

    b) the *2016 NICE Blood Transfusion Quality Standard on Patient Information* (see below) (WITN7001047);

    c) the *2015 Choosing Wisely recommendations for blood transfusion* (see below) (WITN7001048);

    d) the *2015/16 James Lind Alliance Priority Setting Partnership in Blood Donation and Blood Transfusion* (WITN7001049).

306. NICE Guidelines for Blood Transfusion: Summary of section on Patient Information provided as (WITN7001050).

307. NICE Quality Standard: Patient Information (WITN7001047)

Quality statement

People who may need or who have had a blood transfusion are given verbal and written information about blood transfusion.

Rationale

It is important that people fully understand the benefits and risks of a blood transfusion, so they can give informed consent. Discussing the alternatives, and knowing that they cannot donate blood after a blood transfusion, helps people to decide if they want one. However, some blood transfusions are not planned and are carried out in an emergency. In these cases information should be given after the transfusion, including advice about the implications of the transfusion. Helping people to understand the process and its implications can improve their experience of receiving a blood transfusion.

Quality measures

Structure

Evidence of local arrangements to ensure that people who may need or who have had a blood transfusion are given verbal and written information about blood transfusion.

Data source: Local data collection.

Process

a) *Proportion of people who may need a blood transfusion who are given verbal and written information about blood transfusion.*
b) *Numerator – the number in the denominator who are given verbal and written information about blood transfusion.*
c) *Denominator – the number of people who may need a blood transfusion.*

Data source:

a) *Local data collection.*

b) *Proportion of people who have had a blood transfusion who are given verbal and written information about blood transfusion.*
c) *Numerator – the number in the denominator who are given verbal and written information about blood transfusion.*
d) *Denominator – the number of people who have had a blood transfusion.*

Data source: Local data collection.

Outcome
Patient satisfaction with information they are given about blood transfusion.

Data source: Local data collection.

What the quality statement means for different audiences

Service providers (secondary care services) ensure that systems are in place to give verbal and written information about blood transfusion to people who may need or who have had a blood transfusion.

Healthcare professionals (doctors, nurses and blood transfusion specialists) give verbal and written information about blood transfusion to people who may need or who have had a blood transfusion.

Commissioners (clinical commissioning groups) commission services that give verbal and written information about blood transfusion to people who may need or who have had a blood transfusion.

People who may need a blood transfusion, or who have had one unexpectedly (for example, because of serious bleeding during an operation), have information about blood transfusion explained to them verbally and in writing.

Source guidance

a. *Blood transfusion. NICE guideline NG24 (2015), recommendation 1.8.1*

b. *UK hospitals are currently participating in an audit of compliance with the NICE Quality Standards. The results should be available in late 2021 or early 2022. It will be especially interesting to see the results on compliance with the Quality Standard on Patient Information.*

308. Choosing Wisely. Royal College of Pathologists section (WITN7001048)

Recommendation 2
Don't give a patient a blood transfusion without informing them about the risks and benefits (although do not delay emergency transfusions)

Evidence/guidance
There is a lack of high-quality research in this field with largely observational data available. The evidence suggests that patients have a limited understanding of many aspects of transfusion, but that they do want to be part of an informed decision-making process. The evidence also indicates that patients are reassured by the provision of written information

309. **James Lind Alliance Priority Setting Partnership in Blood Donation and Blood Transfusion (WITN7001049)**

How do we decide which topics should be prioritized for research? The need for a robust process for prioritisation by key stakeholders, and not just the researchers themselves, was recognized by the *James Lind Alliance*. A methodology was established to enable clinicians, patients, and caregivers to identify and prioritise important uncertainties for research in different health areas. This methodology was applied to transfusion medicine in Oxford in 2015 to help focus the research agenda in this field. The Steering Group comprised four donor/patient/caregiver representatives and six clinicians and was

supported by an information scientist and James Lind Alliance representatives.

The scope of the priority-setting partnership included uncertainties from blood donation through transfusion but excluded laboratory aspects of transfusion and specialist blood products. Three methods were used to identify the top 10 research priorities: two widely disseminated online surveys, a search of existing literature, and a final prioritization workshop.

There were 408 respondents to the first survey contributing 817 questions, which were refined into 54 indicative questions that had not already been answered by previous research. Respondents to a second survey were asked to select the three questions they believed to be the most important. The 30 most popular research questions were then brought to a one-day workshop of donors, patients, and caregivers to produce the "top 10."

The question *'How can patients, relatives and caregivers be empowered to have greater say about their choices in relation to blood transfusion and its alternatives?'* was ranked number 5 in the 'top 10' research questions.

The list of research questions was intended to be of value to both researchers and funding bodies when considering what research should be conducted in transfusion medicine. Importantly, it gave members of the public a say and ownership in the research agenda for transfusion medicine.

310. The current UK Blood Services patient information leaflet *'Receiving a Blood Transfusion'* is provided as (WITN7001051).

NHSBT informed me in December 2021 that 19,150 hard copy leaflets had been provided to hospitals in 2021 up to 16th December 2021, and there had been 2,269 downloads.

In 2020, NHSBT issued 1,286,287 units of red cells, 145,101 units of fresh frozen plasma and 230,792 units of platelets (data from SHOT Annual Report, 2020).

311. 2021 National Comparative Audit of NICE Quality Standard QS138

Following the TRANSFUSION 2024 Seminar in March 2019 (WITN7001031), the NBTC established a working group to explore the development of performance measures for PBM. I co-chair this working group. It was decided to focus on the assessment of compliance with the NICE Quality Standards for Transfusion (WITN7001047). Reporting by hospitals of compliance with the Quality Standards will provide a comparative assessment of success in implementing PBM.

Quality Statement 4: *People who have had a transfusion were given verbal and written information about blood transfusion.*

Guidance to participants
How do I select patients to audit?
You will need to compile a list of patients who meet all of the criteria below:
- *Over the age of 1 year*
- *They were transfused with at least 1 unit of red cells*

You will need access to information to assess:
- *If there is documented evidence that verbal information was given*
- *If there is documented evidence that written information was given*

What records might be useful for me to search?
Initially, your data department might be able to help in identifying those patients admitted for the types of procedures you want to audit. Sometimes a Clinical Coding department will have this information. Either may be able to search their databases using the OPCS codes. Once appropriate patients have been identified, searching electronic records may be the best initial method, assuming they exist and you can

access them. For anything not available this way, then referring to paper records is the only option. Operation notes, Anaesthetic Charts, ITU Charts and Transfusion Care Pathways can all be useful sources of information.

How many patients are we auditing?
We are suggesting that auditing 10 appropriate patients per audit section would give a reasonable picture.

Preliminary data provided by John Grant-Casey, Programme Manager, National Comparative Audit of Blood Transfusion programme (as of 16th December 2021)

1533 audits reported:

- 542 patients (35%) received verbal information (and possibly but not necessarily written information)
- 34 patients (2%) received written information (and possibly but not necessarily verbal information)
- 405 patients (26%) received both verbal and written information
- 552 patients (36%) received no information

These data indicate that the documentation of the provision of patient Information remains less than perfect. This doesn't necessarily mean that patients were not provided with information or had the chance for discussion about blood transfusion. However, the data indicate a significant degree of non-compliance with the NICE Quality Standard,and raise concern that patients are not receiving information about transfusion.

312. I'm not sure if it is appropriate for me to provide recommendations for improvement of the provision of information to patients about blood transfusion. As indicated above, I have 'retired and returned' and I am now working part-time. I no longer have a leadership role for the NBTC or NHSBT. The suggestions below are for consideration by others who now hold those

roles in consultation with bodies such as NHS England and NHS Improvement.

313. As indicated above, there is no shortage of guidance on this issue. The problem is with its implementation. The tasks of ordering blood transfusion and providing patient information are mainly undertaken by junior doctors but also by consultants and by experienced nurses in a range of clinical scenarios from top-up transfusions for patients with anaemia to major haemorrhage associated with trauma, childbirth or major surgery. Providing education and ensuring compliance with good practice for this huge number of healthcare staff is very challenging.

314. A tool that has not yet been used to improve patient information and consent to transfusion is the *Commissioning for Quality and Innovation* (CQUIN) payment framework https://www.england.nhs.uk/nhs-standard-contract/cquin/cquin-20-21/, where hospitals receive financial incentives for achieving certain quality standard goals e.g. for appropriate antibiotic prescribing. A CQUIN could be considered for providing patient information and obtaining consent to transfusion. I have no personal experience of CQUINs, and found it difficult to find published evidence for the effectiveness of CQUINs for improving practice. I provide two references, one finding evidence for an improvement in the risk assessment for venous thromboembolism (WITN7001052), and one reviewing the strengths and weaknesses of pay-for-performance for specialised care in England (WITN7001053).

315. Another possibility, which we are working on in Oxford, is to provide an electronic alert to the doctor about the need to provide and document the provision of patient information and consent to transfusion when a prescription for blood is made. There are obvious challenges to implementing this successfully including 'alert fatigue' amongst healthcare staff and the risk of delaying an urgent transfusion, and it remains to be seen whether it is feasible and effective in the UK.

316. An advantage of integrating this task in the electronic patient record is that it would be easy to audit the process. Unfortunately, the quality of information

technology is variable in the NHS. Even in hospitals which already have electronic blood ordering, their capability for implementing a process for alerting healthcare staff to provide patient information about blood transfusion and to document consent may be limited for technical reasons.

317. A combination of a physical consent form and the documentation of consent is routinely used in the United States. A colleague at Dartmouth, Dr Nancy Dunbar, provided me with an explanation of how it works in her hospital:-

> *Consent for transfusion remains paper based* (WITN7001054). *The forms are signed by the patient and kept in a paper chart in the clinical ward. These are later scanned into the electronic medical record after the hospitalization. At my hospital, the consent is only valid for one year.*
>
> *Consent is required for transfusion unless the transfusion is an emergency. There is a specific question when ordering blood. There are usually two orders- one for the blood bank (prepare) and one for the nurse (transfuse)* (WITN7001055). *These screen shots are taken from our medical record when I pretended to order a transfusion on a patient who did not actually need one. Before they begin the transfusion they are supposed to verify that consent has been obtained. Of course we have no way to audit that but it is written into the policy and is part of the transfusionist annual training.*

318. Finally, I thank the Inquiry for its important work and hope that it will provide the information, explanations and recommendations that those infected and affected have been seeking for so long.

Statement of Truth

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

Signed GRO-C

Dated 6th February 2022

Table of exhibits:

Date	**Notes/ Description**	Exhibit number
Undated	Helpful Information for House Officers. Blood Transfusion Laboratory, Royal Hospitals Trust.	WITN7001002
01/05/1994	Chapman JF & Murphy MF. "Blood transfusion audit in hospitals." British Blood Transfusion Society Newsletter 1994;.32: 4-5	NHBT0135088
1996	The Practice for the Care of a Patient Receiving a Blood Transfusion. The Royal Hospitals NHS Trust 1996.	WITN7001003
07/10/1985	Establishment of Hospital Blood Transfusion Committee. British Committee for Standards in Haematology 1985	WITN7001004
17/06/1985	Murphy MF, Metcalfe P, Thomas H, Eve J, Ord J, Lister TA & Waters AH. Use of leucocyte-poor blood	WITN7001056

	components and HLA-matched platelet donors to prevent HLA alloimmunisation. Br J Haematol. 1986; 62: 529-534	
01/01/1997	'Survey of the information given to patients about blood transfusion and the need for consent before transfusion', by Murphy, M. F. et al, vol. 7, Journal of Transfusion Medicine, p. 287-28	NHBT0017564
11/02/1999	Hébert PC, Wells G, Blajchman MA, Marshall J, Martin C, Pagliarello G, Tweeddale M, Schweitzer I, Yetisir E. A multicentre, randomized, controlled clinical trial of transfusion requirements in critical care. Transfusion Requirements in Critical Care Investigators, Canadian Critical Care Trials Group. N Engl J Med. 1999;340:409-417	WITN7001057
03/01/2015	'Do liberal blood transfusions cause more harm than good?', written by Lawrence Tim Goodnough and Michael Murphy, BMJ. 2015; 350: 13-15	WITN7001058
12/10/2016	Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic	WITN7001059

	red blood cell transfusion. Cochrane Database Syst Rev. 2016 Oct 12;10(10): CD002042	
12/10/2016	The plain language summary version of academic paper: Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database Syst Rev. 2016 Oct 12;10(10):CD002042	WITN7001060
16/08/1996	Job description: Consultant Haematologist NBS and the Oxford Radcliffe Hospitals	WITN7001005
06/11/2003	A letter from Dr Tim Wallington to Dr Murphy with an invitation to apply for a Clinical Director post and the job description.	WITN7001006
19/11/2003	Covering letter to Dr Angela Robinson (NBS Medical Director) in application for the post of NBS Clinical Director (Patients)	WITN7001007
01/11/2003	Dr Murphy's application for the post of NBS Clinical Director (Patients).	WITN7001008
01/05/2000	Covering letter from Dr Murphy to Mr T Male (NBS Director of Transition) in application for the post of National Medical Lead for Hospital Liaison in 2000.	WITN7001009

16/11/2000	Job description for Regional Leads for Hospital Liaison.	WITN7001010
11/12/1998	Health Service Circular, 'Better Blood Transfusion', containing action steps for implementing HMG's plans to modernise the NHS and its application to blood transfusion practices	NHBT0083701_002
04/07/2002	Health Service Circular, Better Blood Transfusion, Appropiate Use of Blood, Public Health, Department of Health (DH), 04 July 2002	AHCH0000055
01/11/2007	Department of Health, Health Service Circular, titled 'Better Blood Transfusion, Safe and Appropriate Use of Blood', 2007	WITN7001011
19/02/2003	Journal article by M. F. Murphy and others, National Blood Service, Transfusion Medicine, Better Blood Transfusion, entitled: Survey of the implementation of the recommendations in the Health Services Circular 1998/224 'Better Blood Transfusion', published in 2003	DHSC0004261_012
2009	Proposal by Dr M Murphy on NHS Quality and Productivity Electronic blood transfusion systems, provided by Oxford Radcliffe Hospitals.	DHSC0004233_041

01/09/2003	Journal article published in 'Transfusion practice' 2003; 43:1200-1209 titled 'Barcode technology: its role in increasing the safety of blood transfusion' by C.L. Turner, A.C. Casbard.and M.F. Murphy	WITN7001012
01/03/2006	Transfusion Service, 'End to end electronic control of the hospital transfusion process to increase the safety of blood transfusion: strengths and weaknesses, by Davies a, Staves J, Kay J, Casbard A & Murphy M. F., 2006	DHSC0004261_017
01/03/2008	Journal article published in 'Transfusion Practice' 2008; 48:415-424 titled 'Electronic remote blood issue: a combination of remote blood issue with a system for end-to-end electronic control of transfusion to provide a "total solution" for a safe and timely hospital blood transfusion service' by Julie Staves, Amanda Davies, Jonathan Kay, Oliver Pearson, Tony Johnson, and Michael F. Murphy	WITN7001013
01/05/2009	Murphy MF, Staves J, Davies A, Fraser E, Parker R, Cripps B, Kay J & Vincent C, 'How do we approach a major change program using the example of the	WITN7001014

	development, evaluation, and implementation of an electronic transfusion management system' published in 'Transfusion' 2009; 49:829-837	
01/12/2012	Journal article published in 'TRANSFUSION' 2012; 52:2502-2512 titled 'HOW DO I ...? How do we monitor hospital transfusion practice using an end-to-end electronic transfusion management system?' by Michael F. Murphy, Edward Fraser, David Miles, Simon Noel, Julie Staves, Barbara Cripps, and Jonathan Kay	WITN7001015
01/08/2020	Journal article published in 'TRANSFUSION' 2020; 60:1658-1665 titled 'HOW DO I? How do we use electronic clinical decision support and feedback to promote good transfusion practice' by Sophie Staples, Richard A. Salisbury, Andrew J. King, Paolo Polzella, Gardash Bakhishli, Julie Staves, and Michael F. Murphy	WITN7001016
18/10/2011	Report, re: National Health Service Blood and Transplant commercial review	DHSC0041309_035
31/08/2019	Journal article published in 'Transfusion' 2019; 9999:1-7 titled 'Original Research', 'Electronic identification systems reduced the	WITN7001017

	number of wrong components transfused' by Michael F. Murphy, J Jayne Addison, Debbi Poles, Paula Dhiman, and Paula Bolton-Maggs	
05/06/2001	Journal article published in 'Transfusion Medicine' 2001; 11:363-370 titled 'National audit of the blood transfusion process in the UK' by M.F. Murphy, J. Wilkinson, D. Lowe and M. Pearson	WITN7001018
01/01/2011	Journal article published in 'Transfusion Medicine Reviews' 2011; 25:12-23 titled 'Blood Transfusion Safety: The Potential Role of the Patient' by Rachel E. Davis, Charles A. Vincent, and Michael F. Murphy	WITN7001019
27/02/2012	Journal article published in 'Transfusion Medicine' 2012; 22:167-172 titled 'Consent to transfusion: patients' and healthcare professionals' attitudes towards the provision of blood transfusion information' by R. Davis, C. Vincent, A. Sud, S. Noel, R. Moss, M. Asgheddi, I. Abdur-Rahman & M. Murphy	WITN7001020
01/09/2019	'Wrong Patient Details on Blood Sample', Healthcare Safety Investigation I2019/003,	WITN7001021

	September 2019 Edition	
04/02/2021	Journal article published in 'Transfusion' 2021; 61:1333-1335 titled 'Hemovigilance drives improved transfusion safety' by Michael F. Murphy	WITN7001022
01/01/2017	ISBT Science Series, Congress Review, 2017; 12:410-417 'The role of the National Blood Transfusion Committee' by M.F. Murphy & K. Pendry	WITN7001023
	Guidance produced by the World Health Organization (WHO) Blood Safety Unit Geneva, titled, 'Developing a National Policy and Guidelines on the Clinical Use of Blood'.	NHBT0035417
17/11/21	Interim National Transfusion Committee, Minutes of the first meeting which was held at the Institute of Materials, 1 Carlton house Terrace on 7th September 2000	WITN7001024
Undated	The Regional and National Transfusion Committees, Terms of Reference	WITN7001025
01/09/2002	Terms of reference of the CMO's National Blood Transfusion Committee and Regional Transfusion Committees (revised September 2002)	WITN7001026

03/12/2001	Minutes of the First meeting of the CMO's National Blood Transfusion Committee, at Royal College of Pathologists	DHSC0038528_050
19/02/2003	Journal article by M. F. Murphy and others, National Blood Service, Transfusion Medicine, Better Blood Transfusion, entitled: Survey of the implementation of the recommendations in the Health Services Circular 1998/224 'Better Blood Transfusion'	DHSC0004261_012
26/06/2014	National Blood Transfusion Committee 'Patient Blood Management'; 'An evidence-based approach to patient care' 2014 by Professor JE Martin	WITN7001027
21/01/2002	Minutes of meeting of the Executive Working Group of the National Blood Transfusion Committee, 21st January 2002 by videoconference	WITN7001028
16/10/2015	'The Choosing Wisely campaign to reduce harmful medical overuse: its close association with Patient Blood Management initiatives', written by M.F. Murphy, published in Transfusion Medicine 2015; 25:287–292	WITN7001029
2018	'2018 Survey of Patient Blood Management' produced by the	WITN7001030

	National Blood Transfusion Committee by Jayne Addison, Brian Hockley and Louise Sherliker	
10/10/2021	Journal article in 'Transfusion Medicine' 2021; 1-9 titled 'Transfusion 2024: A 5-year plan for clinical and laboratory transfusion in England' by Shubha Allard, Jon Cort, Catherine Howell, Louise Sherliker, Gail Miflin and Cheng Hock Toh	WITN7001031
16/08/2005	Journal article published in 'Transfusion Medicine' 2005; 15:453-460 titled 'Survey of the implementation of the recommendations in the Health Service Circular 2002/009 ‘Better Blood Transfusion’' by M.F. Murphy and C. Howell on behalf of the National Blood Transfusion Committee in England	WITN7001032
27/05/1997	Journal article published in 'Transfusion Medicine' 1997; 7:287-288 titled 'Survey of the information given to patients about blood transfusion and the need for consent before transfusion' by M.F. Murphy, S. Doherty and P. Greenfield Department of Haematology, St Bartholomew's and the Royal London School of Medicine and Dentistry	WITN7001033

12/03/2019	Journal article published in 'JAMA, Clinical Review & Education, Special Communication' 2019; 321(10):983-997 titled 'Patient Blood Management Recommendations From the 2018 Frankfurt Consensus Conference', Markus M. Mueller, MD; Hans Van Remoortel, PhD; Patrick Meybohm, MD, PhD; Kari Aranko, MD, PhD; Cécile Aubron, MD, PhD; Reinhard Burger, PhD; Jeffrey L. Carson, MD, PhD; Klaus Cichutek, PhD; Emmy De Buck, PhD; Dana Devine, PhD; Dean Fergusson, PhD; Gilles Folléa, MD, PhD; Craig French, MB, BS; Kathrine P. Frey, MD; Richard Gammon, MD; Jerrold H. Levy, MD; Michael F. Murphy, MD, MBBS; Yves Ozier, MD; Katerina Pavenski, MD; Cynthia So-Osman, MD, PhD; Pierre Tiberghien, MD, PhD; Jimmy Volmink, DPhil; Jonathan H. Waters, MD; Erica M. Wood, MB, BS; Erhard Seifried, MD, PhD; for the ICC PBM Frankfurt 2018 Group	WITN7001034
14/12/2006	Journal article published in 'Transfusion Medicine' 2007; 17:354-365 titled 'Guidelines for policies on alternatives to allogeneic blood transfusion.	WITN7001035

	1.Predeposit autologous blood donation and transfusion' by British Committee for Standards in Haematology, Transfusion Task Force, F.E. Boulton National Blood Service, Southampton & V.James National Blood Service, Sheffield, UK	
01/09/2004	Paper titled 'Blood Conservation Strategies', Summary of Recommendations from the Working Particles on Autologous Transfusion and Alternatives to Transfusion of the Appropriate Use of Blood Sub-Group of the NBS Blood and Tissue Safety Assurance Group, compiled by Virge James, submitted to the National Blood Transfusion Committee - September 2004 Meeting, The full backup report will be available by November 2003?	WITN7001036
01/01/1997	Serious Hazards of Transfusion (SHOT) Annual Report 1996 - 1997	NHBT0000113_023
01/01/2020	Annual SHOT report 2020, titled 'Reporting organisations in 2020'	WITN7001037
07/02/2004	The Lancet (Vol 363) 'Possible transmission of variant Creutzfeldt-Jakob disease by blood transfusion', by C A Llewelyn, et al 2004	NHBT0008743_013

04/07/2005	Transfusion safety, Oxford Radcliffe Hospitals, executive board, subject 'Trust-side rollout of a comprehensive electronic transfusion safety programme' for Decision from Julie Hartley-Jones, Chief Nurse	WITN7001038
01/01/1998	Pergamon, Potential clinical benefits and cost savings of universal leucocyte-depletion of blood components, by M. F. Murphy, 1998	NCRU0000281_097
01/04/1999	Transfusion Medicine Reviews, New Variant Creutzfeldt-Jakob Disease: The Risk of Transmission by Blood Transfusion and the Potential Benefit of Leukocyte-Reduction of Blood Components, by Murphy M. F, 1999	NCRU0000281_054
01/04/2004	Journal article from Transfusion, April 2004; 44:489-500 titled 'Transfusion practice', 'The effect of universal leukoreduction on postoperative infections and length of hospital stay in elective orthopedic and cardiac surgery' by Charlotte A. Llewelyn, Rod S.Taylor, Audrey A.M. Todd, Warren Stevens, Mike F. Murphy, and Lorna M. Williamson for the Leucodepletion Study Group	WITN7001039
19/06/2007	Journal article published in Vox	WITN7001040

	Sanguinis 2007; 93:196-207 titled 'Why have meta-analyses of randomized controlled trials of the association between non-while-blood-cell-reduced allogeneic blood transfusion and postoperative infection produced discordant results?' by E.C.Vamvakas Department of Pathology and Laboratory Medicine, Faculty of Medicine, University of Ottawa, Ottawa, ON, Canada	
06/04/2005	Letter from Dr. J. Witcher, National Blood Service, to Dr. Mike Murphy, John Radcliffe Hospital, re: transfusion medicine epidemiology review: blood component for tracing	NHBT0047525_005
Undated	Email from Mike Murphy to James Morris cc Jenny Turner titled 'Transfusion of blood from a donor with probable vCJD to ORH patients'	WITN7001041
01/10/2011	Report on Patient Consent for Blood Transfusion by SaBTO Advisory Committee on the Safety of Blood, Tissues and Organs, 2011	ASPT0000170
01/01/2014	Royal College of Physicians, NHS Blood and Transplant, 'National	WITN7001042

	Comparative Audit of Blood Transfusion', 2014 Audit of Patient Information & Consent	
11/03/2015	The Supreme Court Judgment, On appeal from: [2013] CSIH 3; [2010] CSIH 104, Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) before Lord Neuberger, Present; Lady Hale, Deputy President; Lord Kerr; Lord Clarke; Lord Wilson; Lord Reed; Lord Hodge. Judgment given on 11 March 2015; Heard on 22 and 23 July 2014	WITN7001043
17/12/2020	Gov.uk, Independent report, 'Guidelines from the expert advisory committee on the Safety of Blood, Tissues and Organs (SaBTO) on patient consent for blood transfusion	WITN7001044
01/01/2021	Journal article published in 'Clinical Medicine' 2021; 21(3):201-3, concise guidance, titled 'Consent for blood transfusion: summary of recommendations from the Advisory Committee for the Safety of Blood, Tissues and Organs (SaBTO) by Michael F Murphy, Andrea Harris and James Neuberger, on behalf of the SaBTO Consent for Transfusion Working Group	WITN7001045

01/01/2015	National Clinical Guideline Centre 2015 'Transfusion, Patient information; 20.1 Review question: What is the information and support patients under consideration for a blood transfusion and their family members or carers would value and how would they prefer to receive it?'	WITN7001046
15/12/2016	NICE, National Institute for Health and Care Excellence, 2016 publication titled 'Blood Transfusion' Quality statements.	WITN7001047
Undated	Choosing Wisely UK, 'Royal College of Pathologists section', recommendation, evidence/guidance, patient information\decision aids, patient information\decision aids	WITN7001048
01/02/2019	Journal article published in 'Transfusion', 2019; 59:574-581 titled 'Blood Donors and Blood Collection; Setting priorities for research in blood donation and transfusion: outcome of the James Lind Alliance priority-setting partnership' by Stephen P.Hibbs, Susan J. Brunskill, Graham C. Donald, Heather D. Saunders and Michael F. Murphy	WITN7001049
Undated	NICE GUIDELINES ON BLOOD	WITN7001050

	TRANSFUSION Summary of section on Patient information	
09/07/2021	UK Blood Services, 'Receiving a Blood Transfusion: Information for patients and their families, carers and guardians'	WITN7001051
12/02/2013	Journal Article titled 'Has incentive payment improved venous thrombo-embolism risk assessment and treatment of hospital in-patients?' published in F1000Research 2013, 2:41, written by Sue Child, Rod Sheaff, Olga Boiko, Alice Bateman, Christian A Gericke	WITN7001052
19/07/2019	Journal Article titled 'Pay for performance for specialised care in England: Strengths and weaknesses' published in Health Policy 2019;123:1036-1041, written by Yan Feng, Søren Rud Kristensen, Paula Lorgelly, Rachel Meacocke, Marina Rodes Sanchez, Luigi Sicilian, and Matt Sutton	WITN7001053
Undated	Patient consent form for transfusion, Dartmouth-Hitchcock, United States	WITN7001054
N/A	Screenshot of the electronic process for confirming consent to	WITN7001055

	transfusion both at the point of blood ordering and blood transfusion in the United States	