Witness Name: Edward Colin Gordon-Smith

Statement No.: WITN6970001

Exhibits: 0

Dated: 26 January 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF EDWARD COLIN GORDON-SMITH

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

I, Edward Gordon-Smith, will say as follows:

Section 1: Introduction

1. Name and Qualifications

Edward Colin Gordon-Smith, dob GRO-C 1938.

GRO-C London, GRO-C

Qualifications:MA,BSc,BM,BCh,MSc,FRCPath,FRCP(UK),FRCP(Edin),FMed Sci.

2. Employment History

Current: Retired

Emeritus Professor of Haematology, St George's, University of London (SGUL).

Retired Honorary Consultant Haematologist (December 2013).

Previous Appointments:

2006 – 2011 locum Consultant Haematologist St George's Hospital.

2003-2004

Consultant Physician and Haematologist, St George's Healthcare NHS Trust

Professor (Emeritus) of Haematology, St George's, University of London (SGUL).

1987-2003

Professor of Haematology, St George's Hospital Medical School, later SGUL.

Hon Consultant in Haematology and Medicine, St George's Healthcare NHS Trust

1972-1986

Senior Lecturer, later Reader, in Haematology, Royal Postgraduate Medical School, University of London.

Honorary Consultant Physician and Haematologist, Hammersmith Hospital

1969-1972

Medical Research Council Clinical Research Fellow

Royal Postgraduate Medical School, London (Director JV Dacie)

Metabolic Unit, Oxford (Director Sir Hans Krebs)

1968-1969

Registrar in Haematology, Hammersmith Hospital, London (Professor JV Dacie)

1967-1968

Registrar in Medicine, St James' Hospital, Balham

1966-1967

Lecturer in Neurology, Churchill Hospital, Oxford (Professor Ritchie Russell)

1965-1966

Senior House Officer, Nuffield Department of Medicine, Radcliffe Infirmary, Oxford (Professor LJ Witts)

1964-1965

House Officer in Medicine and Surgery, Westminster Hospital, London

3. Committees and Administration

(I have indicated those international/national committees which I think may be of interest to the Inquiry in bold type.)

Chair, NCRI Subcommittee of Accredited Clinical Trials Units Heads (2000 – 2008)

Member, Expert Advisory Group, Haematology and Oncology, Medicines and Healthcare Products Regulatory Authority (MHRA)

Member, CHM/GTAC Advisory Committee on gene therapy

Member, MRC Advisory Committee on Transmissible Spongiform Encephalopathy (1996-1999).

Chair, Council of International Society of Haematology (2000-2005)

Member, (previously Chair), MRC Leukaemia Trials Steering Committee (1990 – 2006)

Member, Subcommittee on Transplantation Biology, American Society of Hematology

President, International Society for Experimental Haematology

President, EBMT Group

President, British Society for Haematology

Vice-President, Royal College of Pathologists

Chairman, UK Aplastic Anaemia Study

Chairman, Intercollegiate Committee on Haematology

Special Advisory Committee, Haematology: Member, Joint Committee on Higher Medical Training

Chairman, Joint Committee on Higher Medical Training

Member, National Cancer Services Forum

Member, Referral Guidelines Steering Group for Cancer

Member, Committee of Safety of Medicines (1990 – 2001)

National Blood Users Group (Chair) 1995-1997

Member, Medical Advisory Committee, Joint British Bone Marrow Transplant Registries

Councillor, Pathology Section, Royal Society of Medicine

Local

Chair, Medical Service Centre, St George's NHS Trust

Chair, Academic Board, SGHMS

Member of Council and Executive Committee, SGUL

SDU (Service Delivery Unit) Leader, Clinical Haematology

Chairman, Residence Committee, SGHMS

Chairman, Validation Committee, SGHMS

St George's Special Trustee

4. I confirm I have not provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to HIV, Hepatitis C ("HCV"), Hepatitis B ("HBV") in blood transfusions. I provided as requested details of transfused patients in my care to the look back inquiry into hepatitis C infections.

<u>Section 2: St George's Hospital</u>

General

5. Professional roles at St George's Hospital 1987 – 2003

I was appointed Professor to the newly established University Department of Haematology at St George's Hospital Medical School, SGHMS, (later St George's, University of London, SGUL) in 1986 and took up the post on January 1st, 1987. On behalf of Wandsworth Health Authority, I was appointed honorary Consultant in Haematology at St George's Hospital during the tenure of my appointment as Professor of Haematology at SGHMS.

It was understood at the time of my appointment that I would develop a Clinical Haematology Service to complement the excellent laboratory service bequeathed by my predecessor Professor Peter Flute. I was expected to develop a bone marrow transplant unit at St George's Hospital for the treatment of patients with bone marrow failure, including patients with aplastic anaemia (AA). I had already established such a unit at Hammersmith Hospital. The laboratory service was directed by Dr John Parker Williams in charge of the diagnostic, blood transfusion and quality control aspects of the Service and Dr David Bevan in charge of laboratory, and in practice the clinical, aspects of hemostasis and thrombosis.

Clinical haematology care was provided either as outpatient care or courtesy of the Department of Medicine which provided provision for in-patient care as required. The Haemophilia Service was run by Dr David Bevan who took it over when Professor Flute retired. Dr Parker Williams provided the major liaison service for haematology for the other surgical and medical departments of the hospital, including provision and, if requested, advice on blood provision. Dr Parker Williams at that time was also director of the National Quality External Assessment Services (NEQAS) for laboratory haematology. Between 1987 and 1988 arrangements were continuing to transfer services from St James' Hospital Balham to a newly built St James Wing at St George's and close the former. Transfer of the haematology laboratories was managed by Dr Parker Williams and Dr Bevan. Consultant cover at St James' Hospital had been provided by a locum consultant (covering long term sick leave) and the post became available at St George's following the merger. It was quite clear to me that the laboratory services provided by Haematology at that time were of the highest order and that both Dr Bevan and Dr Parker Williams were held in high esteem by haematologists nationally and I did not interfere.

I would like to add a few comments at this stage on the nomenclature of haematology service delivery to try and avoid confusion. The University (SGUL) referred to major groups of research and teaching as Departments – eg Medicine, Pathology, Pharmacology. As more subspecialties arose the departmental name was applied more widely, eg Microbiology, Cardiology, Infectious Diseases and Haematology, each headed by a professor. The remit of these Departments did not necessarily correspond to similarly titled units in the hospital service and to avoid

confusion various alternative names were used by the NHS teams. For haematology there was generally concordance between the University research aspects of the specialty and the Service delivery through the NHS. Initially at St George's Hospital "Haematology" tended to be used to include both laboratory and clinical aspects. Subsequently, following further reorganisation nationally, laboratory and clinical services were separated into Clinical and Laboratory "Service Delivery Units" (SDU), administerially and financially separate. I will try to use "Haematology Unit" when referring to all service haematology, "Department" when talking about the University and "SDU" when referring to the administrative structure.

1987-1990.

During the first years following my appointment as Professor/Hon Consultant in Haematology, I was responsible for establishing a research group dedicated to studies in AA. Haematology was allocated 5 inpatient beds within Medicine, including two side rooms for managing immune-depressed patients. Sickle cell patients continued to be managed within Medicine under the direction of Dr Bevan. Some patients with aplastic anaemia whom I had been treating at Hammersmith Hospital followed me to St George's and new patients with this rare disease were referred from elsewhere nationally to our service as it became established. Currently, I was de facto head of clinical haematology service and overall representative of both clinical and laboratory services. As such I was responsible for the arrangements for the training program for junior doctors both within St George's and within a wider rotation to local District General Hospitals and the Royal Marsden Hospital (Sutton branch). Within St George's, I taught clinical aspects of haematology to undergraduates. I was given an honorary consultant appointment at the Royal Marsden, in part so that I could be involved in the continuing care of patients with aplastic anaemia that we referred there for transplant until such time as we opened our own unit.

Much of my work involved liaising with the St George's Hospital management executive as we planned a dedicated bone marrow transplant/clinical haematology unit within the new St James' Wing and with fund raising through a charity devoted to improving understanding and treatment of AA – the Aplastic Anaemia Trust (AAT).

I was aware of, and sometimes involved in, the transfer of the laboratory services from St James' to St George's Hospital. At St George's, laboratory space for haematology had been allocated in the newly built Hunter wing of SGHMS. The bulk of the hard work including establishing an up-to-date automated haematology laboratory and rationalising laboratory protocols was overseen by Dr Parker Williams and Dr Bevan. I initiated weekly consultant meetings to keep senior staff informed of progress in all aspects of haematology service. These were informal and were not

minuted. I was also part of the consultant rota which covered both clinical and laboratory services at night etc.

1990 – 2003

From about this time, the management structure of the Hospital began to change with the introduction of the Service Delivery Units (SDU). Initially, I was appointed Chair of SDU for both clinical and laboratory services, at least as far as financial controls were concerned. There were regular meetings of the SDU which I chaired and which included representatives from management and the finance office.

With the opening in 1989 of the Ruth Myles Haematology Ward (named after a patient), with 13 isolation rooms including 4 HEPA filtered transplant rooms, I was able to introduce bone marrow transplantation as therapy for appropriate blood disorders. These included my own special interest group of patients with non-malignant bone marrow failure and locally referred patients with various types of acute leukaemia. Most of the aplastic anaemia patients were tertiary referrals from within the UK, occasionally from overseas. Virtually all such patients had been transfused with red blood cells and often platelets before they arrived and if not rapidly became transfusion dependent until treatment was completed, often a period of two months or more. Patient information leaflets, printed initially by the AAT and later by the Leukaemia Research Fund (LRF), were available to explain AA and or Bone Marrow Transplant. Much of the care of these patients required considerable time on the part of all staff, nursing and medical, devoted to explaining procedures and answering their and their families' questions.

I did not have any direct responsibility for patients who had been infected with HIV, HCV or HBV. The Infectious Disease Unit at St George's had responsibility for HIV infections and HCV infected patients were mostly referred to the specialist unit at King's College Hospital. I was of course responsible for the care of patients who had become infected because of blood transfusions given under my direction. There were two patients whom I saw at St George's; one an otherwise successful transplant from the Hammersmith Unit, transplanted in 1984 who had received an HIV infected red blood cell unit, and the other, a patient who had been infected with HCV following red cell transfusion for bone marrow failure. The former was identified as having received a red blood cell transfusion from an infected donor from NBTS records and received the no-fault compensation which was available at the time. The other was still being managed at the King's College Hospital Liver Unit at the time I retired from St George's.

Further facilities for specialist care became available when the dedicated Haematology Day Care Unit opened in 1995 for outpatient transfusions and chemotherapy together with an apheresis unit for plasmapheresis treatments and peripheral blood stem cell collections.

I considered it part of my role as "head" of service haematology to try to ensure that the functions of the service were properly delivered to the highest possible standard. This did not mean that I expected to deliver these services myself but that I was to be satisfied that such standards were delivered by those members of the department directly responsible for those aspects of the service.

6. The Haematology Service "Department"

a. I don't recall having a formal document describing the role, functions and responsibilities of Haematology service delivery but understood them to require the provision of a comprehensive laboratory and clinical service as follows:

- Provide prompt and effective laboratory service for all departments at St George's Hospital. This would include blood counts, diagnostic services, coagulation tests and where required interpretation thereof. Develop new diagnostic services as they became available nationally.
- Maintain a hospital blood transfusion unit to provide safe and appropriate blood components for transfusion. To ensure that there were standard operating procedures in place so that the correct blood component for the right patient was available and identifiable as requested.
- To provide clinical outpatient and inpatient services for the local population served by St George's catchment area. This included patients with Sickle Cell Diseases (SCD) and haemophilia syndromes.
- To establish a tertiary referral service for patients with bone marrow failure.
- To provide appropriate education for doctors in training in haematology as required by the Joint Committee on Higher Medical Training (later replaced by that from the Postgraduate Deans and GMC).
- To ensure appropriate staff were available to provide the haematology service at all times.

b. The hospital blood bank service was under the direction of Dr Parker Williams. He had been the main liaison link with other blood user units throughout the hospital since before I was appointed. I was very pleased for this arrangement to continue throughout my time at St George's.

For planned surgical procedures where transfusion might be needed, a request would be made in advance of the operation for an estimated number of red blood cell units to be provided in case required. The crossmatched units would then be delivered to the surgical storage transfusion fridge. The decision on their use would be taken in surgery. Unused units would be returned to the blood bank. Around 1990, this somewhat wasteful process. For example, two units might be requested

and stored in the surgical theatre blood fridge, not used but not returned to the blood bank before the units went out of date. This was replaced by a procedure where the blood was grouped for the patient but only cross-matched and released from the blood bank if needed. Generally, the decision to transfuse was taken by the surgical team.

A&E staff requested blood for transfusion as considered necessary. Clinical Haematology personnel were not involved unless there were requests for specialist blood products or need for blood to cover major haemorrhage.

In cardiothoracic surgery transfusion requirements and protocols for open heart surgery were determined by the surgical unit. Blood salvage techniques became standard.

Obstetric unit protocols were in place and updated as appropriate for major peripartum haemorrhages. There was usually close collaboration between the attending obstetrician, clinical haematology team and the hospital blood bank when the emergency code was activated.

Paediatric transfusion was arranged directly by that department, usually determined by the paediatric haematology or oncology team.

The clinical haematology service was a major user of blood products particularly once the bone marrow transplant unit was fully operational. Decisions about transfusion were usually made by the transplant team, whenever possible in advance of the need. There was close liaison with the hospital blood bank in determining the type of transfusion product required.

c. Facilities and Staffing arrangements for care of patients receiving transfusion.

Out with the facilities and staffing provided by Haematology and to some extent Oncology, there were no separate arrangements for in-patient transfusions other than the standard nursing protocols and medical training provided across the hospital. Transfusions in intensive care were usually requested by the ITU teams, in consultation with Haematology if needed.

Clinical haematology facilities developed to include the Ruth Myles Haematology Ward, a dedicated Haematology Day-Care Unit, and specialist facilities for haemophilia patients (see Dr David Bevan's evidence). The Haematology facilities were staffed by haematology trained nurses under the direction of a Senior Sister. Staffing levels were determined by national or international guidelines for transplant units. An apheresis unit was developed originally sited within the Haematology Day Care Unit (see below).

We also developed a nurse led venous access team for insertion of central venous lines, available for transfusion patients in the Day Care unit with difficult venous access.

d. Senior Staff whose roles and responsibilities included transfusion of blood products:

- Professor Edward Gordon-Smith (myself), honorary consultant haematologist, responsible for care of patients referred to my service and admitted to the haematology facilities for their management. Overall responsibility for the delivery of services by Haematology.
- Dr John Parker Williams. Haematology consultant. Director of general haematology laboratory including hospital blood transfusion service. Main liaison consultant for Surgical Unis.
- Dr David Bevan. Haematology consultant. Director of coagulation service including haemophilia service. Haematology consultant liaising with general medicine teams over patients with haematological disorders admitted to the medical beds before dedicated facilities were available. (See Dr Bevan's evidence to the Inquiry).
- Dr Sarah Ball. Consultant haematology and paediatric physician from 1989. Director of the haematology service to the Paediatric Department.
- Dr Judith Marsh. Senior Clinical Fellow, later Senior Lecturer, honorary consultant. From 1989. Appointed initially to a research post for the study of AA. Became second consultant to Haematology clinical service including joint director of the bone marrow transplant service.
- Dr Fenella Willis. Haematology consultant from 1990. Expanded and developed clinical

Since that time there have been several new senior appointments as the clinical demands on Haematology increased over the years. Their roles mainly supplemented and expanded those outlined above.

7. Determining need for and requesting blood for transfusion

Most patients under my care had bone marrow failure of one sort or another. Most were severely pancytopenic and needed repeated transfusion of red blood cells and/or platelets. For new patients who had not had transfusions before being seen at St George's, detailed discussion of the diagnosis and treatment for their blood disorder included *inter alia* the need for blood transfusions. I usually tried to keep the haemoglobin of the patient around 100g/L and the platelet count around $20x10^3$ /ml. When possible, a schedule of repeat transfusions was developed for individual

patients. Many patients required specialist blood products, for example irradiated and/or leucodepleted products for transplant patients.

a. The way in which requests for transfusion blood products were made evolved over the years I was at St George's but usually involved an initial request for detailed blood grouping to uncover any specific problems for future transfusions. Paper blood transfusion request forms were sent from the ward or day care to the hospital blood bank, mostly signed by the haematology SHO from the ward and duty haematology registrar from Day Care. The form showed the type and unit of blood product required. When there was likely to be a need for individualised products, I would have a discussion with the hospital blood bank about their provision. By the time I retired from haematology management, electronic ordering had been introduced but the close relationship between the clinical units and the hospital blood bank remained.

One of the great advantages for Haematoloy and the patients at St George's was the geographical proximity of the main units. The offices of the consultants and trainee staff, both laboratory and clinical, were in the same corridor of the Medical School within which was also the service laboratory. Personal contact between medical staff and technical laboratory staff was easy and encouraged. Thus, for patients receiving regular transfusions, discussion with blood bank technical staff about which blood product or component was most appropriate, often led to the order being placed without a formal paper request. Record keeping of blood components in and out of the hospital blood bank was immaculate, as demonstrated by the success of the HCV look back conducted by Dr Parker Williams.

b. The initial requests for transfusion products and the reason for the requests were documented in the patients' hospital records, both in the medical notes and the nursing records. This would be done as part of the first treatment plan. Once a plan was in place, the requests might not have been so regularly registered in the medical notes - nursing notes often being more reliable. However, when the products arrived for the patients, they were accompanied by identification information which was entered in the hospital record. Nursing notes recorded the delivery of the products and any immediate adverse reactions. Details of the origin of the product from the regional transfusion centre were kept in the hospital blood bank.

c. For patients whose condition warranted transfusion of red cells for the first time, there were discussions with each about the reason for the suggested transfusion and risks and reactions inherent in the procedure. Infection risks were usually given as those published by SHOT, namely about 1 in a million for HIV and 1 in

30 thousand for HCV. Warnings about febrile reactions, sensitization and where appropriate, iron overload were also discussed. When a patient declined transfusion, usually on grounds of faith, their views were respected and alternative measures of support discussed. Consent for transfusion was not obtained in written form, at least in the first few years I was director, in line with decisions nationally from the transfusion service.

8. Relations with the Regional Blood Transfusion Centre

a. I had no direct or formal relationship with the Regional Transfusion Centre (RTC) on behalf of Haematology or the Hospital. These essential interactions were conducted by Dr Parker Williams.

b. I did have irregular informal contacts and discussions with Dr Ne Win, director of the Tooting Regional Transfusion Centre (RTC), particularly in the first few years when I was setting up the bone marrow transplant service. Such contacts were easy because the Centre is within the area of St George's Hospital. Informal meetings were arranged as appropriate to discuss the demands a transplant unit might make on the transfusion service.

c. An example of such interaction was the need for irradiated blood components for transplant patients. At first, Tooting was unable to provide such a supply and I was able to set it up at St George's by getting a cobalt blood irradiator and installing it in the Haematology Laboratory. Subsequently it became clear that the Regional Transfusion Centre could provide such service and improve the logistics of getting irradiated blood to the patients if the irradiator was transferred to the Tooting site. Thereafter irradiated blood components could be ordered directly from the RTC.

Another example was the need for leucodepleted blood products and their supply for haematology patients.

9. Relations with the National Blood Transfusion Service (NBTS)

I had no formal relationship with the NBTS on behalf of St George's Hospital. Again, as Director of the Hospital Blood Bank, Dr Parker Williams conducted any necessary interactions with the NBTS. On the other hand, I had considerable interactions with NBTS following my appointment to the National Blood Users Group (see below).

10. Weekly transfusions numbers

The number of transfusions given to patients under the care of the Haematology team clearly changed over the years as the specialist Transplant Service was established. When the Haematology Unit facilities became fully operational, some 10 - 12 inpatients each week would receive transfusions, each of 2 or 3 units of packed red blood cells and 2 to 4 units of platelets. Up to 30 outpatients would receive packed red cell transfusions each week, usually 3 units each and much less often platelet transfusions. Peak transfusions would be between 85 and 100 units of packed red cells and about 30 units of platelets. In the early stages, pooled platelet transfusions would be used. Later, single donor apheresis platelets from the RTC would be available. Many of these blood products would be specially modified. In addition, there would be donations of bone marrow and donor lymphocyte transfusions for transplant patients.

a. Sickle Cell Disease (SCD) patients. From 1987 to about 1992, the patients with SCD were under the care of Dr David Bevan who had been looking after them when the service was part of general medicine. I think there were some 20-25 SCD patients in the Tooting catchment area of whom a minority, perhaps 6 or 7, required frequent inpatient care. Children were under the care of the Paediatric Department, initially in partnership with Dr Bevan, later with Dr Sarah Ball following her appointment to both Paediatric and Haematology services.

   Transfusions of red cells for anaemia or pain crises were infrequent. Exchange transfusions were sometimes needed for life threatening organ crises particularly for paediatric patients. Most patients with SCD were genotyped for blood group, at least from about 1998 onwards, when exchange transfusions using blood collected by apheresis (provided by the RTC) became standard. From about 2000, prophylactic exchange transfusions were offered to SCD patients who had very frequent crises requiring hospital admission using apheresis technology provided by the Haematology service.

b. Thalassaemia was much less common in Tooting than SCD, reflecting the ethnic mix of the population. I recall only 2 thalassaemia patients on regular transfusions (approximately 4 units of red cells per month). They also received treatment to relieve iron overload. The haemoglobinopathy service initiated by Dr Bevan was taken on by new consultant teams as the St George's workforce expanded.

11. Patients who became infected with viruses from transfusions given under the care of the Haematology team

I recall two patients who had become infected as result of blood transfusion and were seriously ill and whom I saw at St George's.

The first was a patient from overseas with severe AA whom I had transplanted using a sibling donor when I was at Hammersmith Hospital in 1984. He presented with AIDS to my service at St George's in 1992. HIV infection was discovered after he had returned home. He had been transfused before he was first referred but a reverse look back showed he had been infected with HIV from a single red blood cell transfusion from a donor in the UK. He received support from the "no fault compensation scheme" then in place in the UK. He was managed jointly with the Infectious Disease Unit at St George's Hospital but sadly died from the complications of AIDS.

The second was a patient with bone marrow failure who had received red cell transfusions from childhood. HCV infection was discovered. He developed chronic liver damage and was referred to the liver unit at King's College Hospital where he received treatment with interferon (IFN) inter alia. Unfortunately, IFN, which controlled his liver disease and was greatly reducing the HCV load also reactivated his bone marrow depression.

I also learned of two other patients who had been under my care at Hammersmith Hospital who became HCV positive but they were not referred on to my service at St George's. I do not know any more details.

12 - 13. Research

A research study was initiated by Dr Judith Marsh and me. It was led by Dr Sally Killick into which platelet preparations were most effective for the management of AA patients who required repeated transfusions. (Killick SB, Win N, Marsh JCW, Kaye T, Yandle A, Gordon-Smith EC (1997) Pilot study of HLA alloimmunization after transfusion with pre-storage leucodepleted blood products in aplastic anaemia. *British Journal of Haematology* **97;** 677-684) (RLIT0000845). Patients with AA who had not received any transfusions were given blood components, platelets or red cells, which had had leucocytes removed pre-storage and the rate of alloimmunization, which can increase refractoriness to future transfusions, compared to previous patients who had received standard transfusions. The pilot study suggested that PLDP products decreased the rate incidence of alloimmunization and should be considered the better option for patients with AA.

In another study of platelet characteristics in AA and paroxysmal nocturnal haemoglobinuria (PNH) with abnormalities arising from GPI -linked deficiency we found there were subtle differences between AA and those with haemolytic PNH (Jin J-Y, Tooze JA, Marsh JCW, Gordon-Smith EC (1997) Glycosylphosphatidyl-inositol (GPI)-linked protein deficiency on the platelets of patients with aplastic anaemia and paroxysmal nocturnal haemoglobinuria: two

distinct patterns correlating with expression on neutrophils. *British Journal of Haematology* **96;** 493-496) (RLIT0000844).

In both studies blood was taken from patients when it was required for treatment and only a part used for research. Patients were asked by the relevant clinician if they objected to such research use and the reason for the research explained but no written consent was obtained in these early studies.

My academic research was aimed towards better understanding the nature and causes of AA. In studies requiring bone marrow, samples taken for diagnostic reasons were used for the studies. Initially patients were asked for consent to that use but after 1999, written consent was obtained. Patients whose details were entered into national or international research databases gave oral consent. Those who were entered into international trials gave written consent. I don't think these studies are within the remit of the Inquiry.

My role in these research studies sometimes involved direct interaction with the patients but more often discussion and advice on the set up of the study and the running thereof.

Section 3. Policies and practices related to blood transfusion.

14. This question of guidance on transfusion policies and practices provided by St George's Hospital requires a complicated answer. St George's Hospital, if by that is meant a central management organisation, did not provide such services. Guidance in such matters came from professional bodies both within St George's and more widely in the national specialist societies. Furthermore, guidance changed remarkably over the time I was at St George's. Surgical teams had their own guidelines and opinions, influenced no doubt by advice from Dr Parker Williams from Haematology. Cardiothoracic surgery had national guidelines for open heart surgery, modified by local demands. Intra-operative blood salvage techniques became the norm. Haematology and Obstetrics and Gynaecology combined to provide guidelines and protocols to cover major peripartum haemorrhage. These protocols were regularly updated whilst I was at St George's. These protocols were provided by the hospital transfusion service and modified as national guidelines changed. I did not write the protocols myself and don't recall specific dates. Protocols to cover major acute haemorrhages were also developed with input from Haematology and national standard bodies. They evolved from rather basic schemes in the earliest days to more complex, monitored responses as techniques evolved to manage haemorrhage aggravated by clotting factor consumption responsive to the availability of new replacement strategies. It would be naïve to suppose guidelines were always used

and followed in detail in all cases but as far as I could see, there were no gross excesses in blood demands when I first joined St George's. There had been a Hospital Transfusion Committee (HTC) chaired by Professor George Griffin from the Infectious Disease Unit to advise on these matters, but it had ceased to function. (Information from Dr Parker Williams, I don't know the dates).

Units of blood used. The common surgical practice in 1987 at St George's, as at other hospitals, was to arrange for blood to be made available pre-operatively if it was deemed probable that transfusion might be needed during surgery. This was based on previous surgical experience. This was understandable when response to an urgent request for blood from the operating theatre might be slow because of delay in laboratory response and perhaps blood supply problems. This meant that there was always a significant amount of blood stored in the Hospital Blood Bank or surgical transfusion fridges which was unavailable for other reasons and often not used. The introduction of group and save, where surgical patients' blood group details were established pre-operatively and appropriate blood group donations were available in the Bank and could be supplied after rapid cross match if required, greatly reduced such wastage. The minimum amount of blood requested for this prophylactic event was 2 units. If more than two units might be needed arrangements between surgical unit and hospital blood bank were made.

Although I did not have direct interaction with surgical teams when first at St George's, I was aware that there was considerable variation in the triggers for transfusion. Some surgeons (and/or anaesthetists) seemed to like their patients to have a haemoglobin level close to 130g/L whereas others were happy to operate at levels even below 100g/L. This is not surprising since there was no universal agreement for such recommendations until randomised studies could be conducted. Even with such trials, there is no clear agreement about the effects of pre-operative anaemia and the risks of blood transfusion (eg. Abeysiria S, Chaua M, Highton D, Richards T, (2019) Management of the patient presenting with anaemia in the preoperative setting. *Transfusion and apheresis Science.* **58;** 392-396) (RLIT0000846).

I am not able to give any information concerning the implementation of guidelines such as Patient Blood Management (PBM) schemes by surgical or medical units at St George's. Since PBM is a multidisciplined approach to pre-operative anaemia management this would most likely have been raised at the appropriate multidisciplinary team meeting (MTD).

The above comments refer to my recall of the use of blood transfusion requests, mainly whole blood units and less often packed red cells. Requests for fresh frozen

plasma, initiated by surgical or medical teams faced with patients with massive haemorrhage were usually only granted after discussion with haematology.

Questions to be considered concerning avoidance of transfusions and effects of cost constraints are also somewhat complex and answers must consider changes over time. My comments are my recollection (maybe inaccurate) of how things were at different times. Before I went to St George's, blood supplied from the RTC had been free to the hospitals. There had sometimes been supply problems. Until the advent of HIV infected blood became realised, the most concern about infection had been centred on questions of hepatitis and a slowly emerging realisation that sero-negative "transfusion" hepatitis was not as harmless as often portrayed. By 1987 when I joined St George's, the risks of HIV contaminated blood from infected donors were fully realised and the efforts of the NBTS to mitigate the risks were appreciated. The tragedy undoubtedly affected the practice in haematology departments and would have had some consequences on general medical and surgical usage, but I don't think there was an internal memo about these risks.

When hospitals had to pay for blood provided for transfusion (I forget the dates but I suspect it was following some reorganisation of the internal market and the creation of the NBTS as a special health authority, see (see NHBT0005943_001, para 3.2(b) for reference) there was a much greater awareness of how precious such products were but it did not significantly change practice, it merely led to internal wrangling over to which department budget the cost should be charged.

The challenges presented by these changes would have been taken on board by the HTC which had existed at St George's before I arrived with the purpose of disseminating the information.

15. Types of blood and blood products commonly transfused to patients under my care

I am taking the request for information concerning patients "under your care" to mean all patients managed in the haematology facilities even though they may have been directly under the care of other consultants, who subsequently joined the team. I was, throughout much of my time, director of the bone marrow transplant programme and chair of the clinical haematology SDU. Even when others took over these roles, practice remained pretty much the same. Care of haemophilia patients and other disorders of haemostasis and thrombosis was directed by Dr David Bevan, whose evidence you have already heard and I am not competent to discuss blood products used in that service.

- Red Blood Cells.

The most common request was for packed red blood cells. Whole blood was very rarely requested. The usual request was for packed red cells obtained from whole blood donations after the plasma was removed. For patients who received bone marrow transplants, modified product was needed, for example irradiated packed red cells or pre-packaged leucodepleted depleted (PLD) red cells. Many frequently transfused patients developed antibodies to rare blood group antigens and they had to receive extended crossmatch donations or even donations from genotyped donors.

- Platelets.
  Many patients also received platelet transfusions. Platelet concentrates from up to 4 donors in a single pack were the usual presentation of platelets in the first years. Single donor platelets using cytopheresis separation at the RTC became available for sensitised patients or when special preparations were required including PLD platelets.

- Fresh Frozen Plasma and other coagulation products.
  These were very infrequently required in the general and transplant haematology service.

- Bone marrow stem cells and donor lymphocyte transfusions.
  These products obtained from HLA matched donors for bone marrow transplant patients were obtained in the haematology facility from donor bone marrow or by cytopheresis as appropriate. Collection and processing quality control followed the protocols required for international licensing (JACIE registration by EBMT).

16. Risk of viral infection from different products

We all had an understanding that pooled products carried a higher risk of virus transmission than single donor products but that part of the risk had been mitigated by intensive screening of donors and donations by the NBTS. I don't remember that we issued particular warnings over the use of red cells or platelets depending on the product used.

17. Excessive use of Blood - [NHBT0117504]

I agree with Dr Hewitt's opinion expressed in her letter to Mr Peeler that it was not possible to exclude the possibility of excessive use of transfusion in some places, though I rather suspect that much of the excess was in fact wastage. I have touched

on the impact of the HIV tragedy in answer to question 14 above and agree that it put a stop to any likelihood of excess use.

18. Haemoglobin level triggering recommendation for transfusion

Here is another question which looks straight forward but which should elicit a very circumspect reply.

- Bleeding.
  I will not consider the bleeding patient where the need for transfusion is related to the speed and volume of blood loss and the haemoglobin level is irrelevant.

- Anaemia identified pre-operatively.
  There is a balance between the risk of operating on a patient with anaemia and the risk of peri-operative transfusion. What level of haemoglobin below which a preoperative patient is considered anaemic is also debated – a common figure is 130gL for men. This level does not warrant transfusion. Furthermore the haemoglobin level is only relevant once the cause of the anaemia has been identified and where possible corrected, if necessary delaying the surgery. When delay is not feasible, decisions have been based on a haemoglobin level but there is still not a universal standard. For a patient with no other morbidities other than that for which surgery is indicated, transfusion should not usually be considered with a haemoglobin level of 100g/L or above, especially when there is scope post operatively for corrective measures not involving transfusion.

- The infected blood tragedy
  It may be that advice from the formation of the Blood Users Group and the work of the anaesthetic and surgical community worldwide in developing Patient Blood Management (PBM) algorithms certainly concentrated attention on the need for preoperative transfusion and made acceptance of a lower threshold for peri operative transfusion pretty much universal. Changes in attitude have taken place over the last 40 years or so.

- Anaemia presenting de novo or in a medical setting.
  There is a lot that could be discussed under this heading but perhaps several obvious principles could be stated.
    - The cause of the anaemia and its correction must be considered before transfusion.

- Patients with slowly developing chronic anaemia tolerate much lower haemoglobin levels than those with rapid onset anaemia, to which transfusion must be used with extreme caution.
- For conditions where moderate anaemia cannot be corrected (cancers, rheumatoid arthritis and other chronic inflammatory diseases, renal failure) guidelines concerning transfusion, quality of life and alternative therapies (e.g. erythropoietin) have been widely published and debated.

19. Use of alternative treatments

I was not employed at St George's before 1987. For most of my employment there, liaison with surgical, general medical and obstetric units was conducted by Dr Parker Williams. There had also been a Hospital Transfusion Committee. Exactly how much discussion of potential alternatives to transfusion went on, I do not know but I expect that it would have been used appropriately

a. In the practice of the Haematology Units with which I was concerned, discussion about alternatives centred mainly on treatment options, one of which involved repeated transfusions and the management of adverse effects. Where alternative treatments were available (eg Steroids for chronic autoimmune anaemias) transfusion was usually offered as a less satisfactory alternative.

b. I don't think that the doctor/patient relationship had any influence on the outcome over the use of transfusions in most cases. In occasional instances, where transfusion was considered as a "one off" treatment, there may have been inadvertent bias in one way or the other from the doctor's presentation.

c. I don't think the relationship changed whilst I was at St George's.

d. Transfusion was regarded as an essential and irreplaceable part of the treatment of our patients. The potential hazards were well understood. The clinical team felt great admiration for the hospital blood bank for its unfailingly excellent service.

e. In our service, it is difficult to see any way that we users could have changed practice to reduce infection risk. At each introduction of new products, whether initiated by us or by the Transfusion Service, infection risk would have been discussed. For nearly all patients, transfusion was the life sustaining option.

Red cell Concentrates

20. Red cell concentrates are the preferred vehicle for providing oxygen carrying capacity to the anaemic patient. They are the standard product supplied by the NBTS for red cell transfusion. In the excellent document [BWCT0000120_001], the guidelines mean red cell concentrates when they refer to transfusions. Whole blood is no longer supplied by the NBTS except on special request.

a. Red blood cell concentrates (packed red blood cells) were used almost exclusively in Haematology practice where the aim was to correct anaemia and maintain an adequate tissue oxygen supply with minimum effect on blood volume.

b. Packed red blood cells are preferable when the anaemia has occurred because of a failure of production of red blood cells. They cause less fluid overload problems than whole blood. There might be a theoretical increased risk of bacterial (not viral) infection because of the extra handling process but I don't know of any evidence for this.

c. Post transfusion testing on any blood product was conducted in the event of any patient collapsing during a transfusion. The most common causes were immunological reactions or shock due to wrong blood to patient, wrong grouped blood, undetected antibody, but very occasionally activated complement present due to bacterial contamination. Further post-transfusion tests would be carried out if the patient sero-converted with viral antibodies, discovered during follow-up standard investigations, including a reverse lookback search for an infected donor instituted by the NBTS.

d. Information on the risks and benefits of transfusion were included in all discussions where it was part of the therapeutic management. Written consent was not required (except when it was part of a surgical consent form).

e. One unit (bag) of packed red cells raises the haemoglobin by about 0.2g/L. The number of units given depended on the ultimate level required. The aimed level did not need to be the level aimed for within the non-anaemic population. Adults did not receive less than 2 units or more than 4 units in one session.

21. These guidelines (BWCT0000120_001) issued by the Midlands and South West Zone Policy Group of the NBS in 1999 would have been distributed in some way or another to RTCs and perhaps to Hospital blood transfusion departments in the Region. They reflect the measures discussed nationally, designed to rationalise the use of red cell transfusions at a time of potential shortage. I don't remember guidelines being sent out to all hospital departments, for example by the CMOs or by NBS. As mentioned before, specific guidelines on the use of transfusions are difficult to set out because of the very different circumstances when they might be required. There were certainly widespread discussions nationally on how to limit transfusions, often involving hospital transfusion committees. The need to reduce blood transfusions nationally was disseminated via RTCs and hospital transfusion centres

locally following extensive discussions such as those in the above document. There was a general awareness that such a need existed within the surgical community and anaesthetists, in part informed by the NBSUG and its zonal subsections.

Platelets

22. Document [NHBT0113679_002] is an Appendix presumably attached to minutes from a Manchester RHA or RTC meeting. It highlights local concerns around 1984 about testing for HIV (HTLVIII) being available in an emergency. Similar concerns may have been raised in other RTCs but this is surmise on my part.

At that time, I was a consultant in Haematology and Medicine at Hammersmith Hospital. Any concerns over testing of platelets would have been considered by the Blood Transfusion Department at Hammersmith and the relevant RTC. I don't recall having been advised that a request for platelets could only be met by receiving untested platelets, but there were occasions when a specific product could not be supplied, to which there would be discussion with the clinician on whether the product should be used. (This occasionally happened when I was at St George's, but usually over compatibility testing, not for viruses).

a. I used platelet concentrates to treat patients with bone marrow failure from about 1972 when I was appointed Consultant at Hammersmith Hospital and until my retirement from St George's in 2006.

b. Some patients needed platelet transfusion once a week or more. Others might require daily platelets if they became refractory.

c. Full screening and testing were provided by the RTC, a specialist service to identify specific platelet antigen incompatibilities was provided by the Cambridge RTC under Professor William Ouerhand, but this was withdrawn when it was perceived not to help in patient management. No further testing was done locally. Any adverse reactions were recorded and reported to the RTC and to the Serious Hazards of Transfusion (SHOT) database.

d. Like most clinicians, I relied on the screening and testing procedures in place at the Transfusion Centres. I expected to be informed by the hospital blood transfusion unit and I had confidence that that would be so.

e. Risks and benefits of platelet transfusions were regularly discussed for each individual patient at the daily consultant led group meeting. The risks considered mainly concerned refractoriness or febrile reactions.

f. Patients who needed platelet transfusions were usually given 2 units. Significant bleeding in a thrombocytopenic patient,possible causes and whether the bleeding could be controlled by the transfusion were always considered. For prophylactic transfusions, the aim was to keep the platelet count above $10x10^9$/L. The excellent guidelines drafted by Dr Murphy and others in 1992 (BSHA0000031] cover the indications in more detail.

g. The supply of platelets for transfusion improved enormously from the early days in the 1970s to the present time. My letter to Ms Corrigan (DHSC0006850_111) at the NHS executive reports the rather minor concerns raised during the rationalisation of the Transfusion service. The reasons for the potential delays in supply have long gone with the introduction of technologies such as cytopheresis.

Fresh Frozen Plasma

23

a) Very little FFP was used in my haematology practice. Most FFP released from St George's blood transfusion unit was to medical or obstetrical departments or trauma with massive haemorrhage. Its use was mainly to reverse coagulation defects.

Large volumes of fresh plasma were used in the plasmapheresis treatment of thrombotic thrombocytopenic purpura and some autoantibody mediated neurological disorders.

The correspondence in [DHSC0017189] and my letter to Dr Machin at the British Committee for Standards in Haematology (BCSH), relates to the very important debate on the safety of FFP and how viral or vCJD contamination was best negated. The statement on the future provision of FFP in England and Wales [DHSC0017189]. It was a closed and informal meeting organised by Dr Machin and funded by a pharmacological company Octapharma. The conclusion that virally inactive product only, should be provided, was incontrovertible. I was at the meeting and thought that the commercial influence on the conclusions might be misconstrued in the absence of a representative from the NBS, and that all stakeholders should be consulted. I left the meeting without voting, not from disagreement with the conclusions but that the debate should be wider. I expressed my view in my letter [NHBT0091964], perhaps wrongly, that my abstention meant the report was accepted *nem con* (I was indeed not *con*) rather than unanimous.

b) The risks of infection from the use of pooled transfusion products were known within Haematology. The perceived benefit of replacing coagulation factor was known to be erroneous.

c) The clinical Haematology service did not use FFP. Follow-up of transfused patients in that service included tests for infection. I do not know if other hospital units carried out regular tests on patients who had received FFP.

d) I don't recall ordering FFP myself. Consent would have been obtained verbally.

e) This information would have been available from the hospital blood bank records of from the coagulation unit.

24. FFP Guidelines

Advice on the use of FFP was mainly given by Dr David Bevan, including the risks and benefits and quantities needed. Dr Bevan certainly agreed with the views of Hannah Cohen in her BMJ leader [NHBT0004335_004] and did his best to dissuade clinicians from using it.

Single Unit Transfusions

25. Other than in paediatric practice, single unit transfusions were not requested at St George's for the reasons set out in [DHSC0035471]. As the document suggests, two-unit transfusions are the minimum below which risks outweigh benefits.

Two-unit transfusions were common, particularly in outpatient clinics though perhaps 3 units were the standard. One unit raises the haemoglobin by 2.0g/L. It takes about one and a half hours to give one unit safely. For patients with bone marrow failure, 2 – 3 units weekly would keep a level of haemoglobin at a level for good quality of life.

Autologous transfusions

26. I am not competent to discuss autologous transfusions as a method used in blood salvage or isovolaemic conditions. These are specialised surgical techniques.

There are few, if any, indications for pre-donation autologous blood collection as is argued in [BSHA0000017_021]. At St George's, we had a discussion on such and decided not to encourage its use, mainly on logistical grounds.

Fresh Warm Blood

27. There were no requests for fresh warm blood for transfusion for patients under my care. There were requests for donation from specific donors when blood group or tissue antigen matching issues were complex.

28. Blood transfusion policies

The National Blood User Group (NBUG) was established in 1995 as an advisory body to the Secretary of State for Health via the National Health Executive (NHE). Its remit, in light of challenges which might arise following reorganisation of blood transfusion services from the regional autonomous arrangements to a centralized national model, was to monitor standards in the use of blood transfusion (RCPH0000138_002 para 11.2).

More detail about the NBUG is given in the answers to question 44. Briefly, the NBUG was involved in some way with a. awareness of national guidelines for promotion of good transfusion practices, e. promotion of new information regarding transfusion matters and i. assessment of transfusion practices in light of product usage.

29. I have indicated how my role at St George's impacted on transfusion practice. Briefly, in my role as SDU leader and director of the Bone Marrow Transplant unit, I was responsible for b,e,f,h and j as they applied to my own practice. As far as these applied more widely in the Hospital, they were undertaken by the Hospital blood transfusion service directed by Dr Parker Williams.

Consent for blood transfusion. Dr Rejman's response (RCPH0000138_002, 11.3) highlights the general concern over transfusions which might be given during surgery without the patient knowing. It must have been after this discussion, that potential use of blood transfusion was included in surgical consent forms.

30. Transfusion Policies created by committees on which I served in relation to general and specific clinical services.

> **a.** Obstetrics. Protocols for haematological events in obstetrics were developed in conjunction with the O&G department by Dr David Bevan and Dr Parker Williams with the Laboratory Haematology SDU.
>
> **b.** Trauma and emergency care. St George's became a designated Trauma Centre just as I retired. I know that there was considerable work done on transfusion policy and practice but I was not part of that.

c. Surgery. Policies for surgical practice were developed for specific procedures by the appropriate surgical team considering national guidelines aided when needed by Dr Parker Williams.

d. Haematological cancer treatment. Transfusion policy was determined by the malignant haematology teams. Dr Bevan, at first, followed by Dr Fenella Willis for adult patients and Dr Sarah Ball for paediatric patients.

e. Thalassaemia and f. Sickle cell disease. The haemoglobinopathy service developed greatly between 1987 and 2006 with the introduction of counsellors, exchange transfusions and prophylactic exchange programs. Policy developed along with the changes but the needs of each patient were always considered paramount.

31. Hospital Transfusion Committee (HTC)

I have already referred to an HTC which existed before I joined St George's. Following recommendations from NBUG, a new HTC was established at St George's in about 1999, chaired by Dr Judith Marsh with representatives from surgery and anaesthetics/intensive care as well as the hospital blood transfusion unit. It was hoped that it would monitor and influence general transfusion practice across the hospital departments. I'm not sure how influential it was, partly because I had demitted most of my director roles by then and partly because the liaisons in place already meant it did not have much to do.

Likewise relationships between the users, the hospital transfusion service and the RTC were already excellent.

32. Potential blood shortages and red cell imports from the USA

The Secretary of State for Social Services in answer to questions about imported blood clearly indicated the red blood donations were not imported at that time, 1985, and that the concern was with Factor VIII preparations and the HTLV III (HIV) virus transmission [HSOC0018830]. I was a consultant at the Hammersmith Hospital then. Discussions on this matter were led by the haemostasis department and the hospital blood transfusion unit. There was not any discussion about red cell transfusions from abroad that I recall.

In 1998, Dr Angela Robinson reported to the NBSUG on potential red blood cell shortages. The reasons for her concerns are indicated in the minute [NHBT0005943_001, para 3.1(a)]. Fortunately the reorganised NBS under her watch managed to avoid the need for red cell imports. I don't remember that the issue was raised whilst I was at St George's. There was concern about the importation of

plasma from the USA after the response to perceived risk of vCJD transmission from plasma transfusions but these worries were allayed by the reports of the efficacy of heat treatment and leucodepletion.

Section 4: Knowledge of Risk

General

33. When I joined St George's in January 1987, I had been in Haematology, mainly clinical haematology for over twenty years. I had a better than average knowledge of the risks of transfusion than those which students acquire during medical training. This was courtesy of the training and later collaboration provided by the blood transfusion department of the Royal Postgraduate Medical School (RPMS) and Hammersmith Hospital, directed by Dr Sheila Worlledge until her death in 1980.

New risks were identified over time including those highlighted by the HIV and HCV tragedies. The major risks which had to be addressed were giving the wrong blood group or the wrong blood to the wrong patient. These remain major risk factors. I was also aware of the risk of sensitisation and refractoriness in multiply transfused patients.

Hepatitis

34. When I started at the RPMS in 1968, the risks associated with HBV were recognised and the measures taken to screen for the virus known. The risk of "transfusion" of non-A, non-B hepatitis was known and accepted until the potential seriousness of the infection with HCV gradually dawned and screening became possible. By 1987, the dangers inherent in HCV were still being debated. Screening for HCV was instituted and the HCV look-back initiated in 1990.

HIV and AIDS

35. When I began at St George's, my knowledge and understanding of HIV/AIDS was derived from publications and discussions around the discovery of the virus and recognition of transfusion transmission in the period 1982 -1984 and beyond. At St George's, the Infectious Disease department had expertise in AIDS which was readily communicated to me when required.

Other

36. Decisions and actions in response to all matters related to haematological practice were taken collectively by the Haematology consultant/Senior Nursing staff. We met regularly once a week in informal sessions to keep us all up to date with what happened in each section. I was convener and "Head" and accepted responsibility for the decisions taken by other senior members (Dr Bevan, Dr Parker Williams and Dr Judith Marsh). The expertise of these colleagues directed any actions which were required. Dr Parker Williams addressed the questions of infection in the US. He conducted the HCV look back with great thoroughness.

We also had once a week a "grand teaching" round at which all consultants, registrars, senior ward nursing staff and representatives from microbiology radiology were present to discuss management of all in-patients, including those with SCD and haemophilia.

There was no specific forum to discuss blood transmitted infection but if any new information from NBTS or our clinical practice arose, this and its consequences would be introduced at these meetings. I should say that in and amongst all the decisions that needed to be taken in the running of the Unit, blood infection occupied a small proportion of discussion time but, when concerns were raised, they were addressed in depth and the importance recognised.

37. Regular audits were carried out on many aspects of hospital practice. I don't recall any audits on blood usage – one may have been arranged by the hospital transfusion unit. I think there may have been one on the use of FFP, which was overseen by Dr Bevan.

38. Reporting of Adverse Reactions to Transfusions

a. Hospital procedures. I don't think there was a hospital wide policy on reporting adverse reactions to transfusions given for surgery etc, other than those in place for reporting immediate and/or severe reactions around the time of the transfusion itself. I don't know if there were any longer term follow up protocols. As regards patients cared for by clinical haematology, immediate reactions such as fever/rigors, anaphylaxis, haemolysis, haemoglobinuria and so on were recorded, the hospital transfusion service informed and relevant blood product saved for further testing.

b. There was no general protocol for longer term reporting.

c. Haematology patients would be warned about the rare complication of delayed haemolysis but follow-up concerning infection was managed by repeat testing for HCV during routine visits.

d. Adverse reactions or symptoms were reported by clinicians to the hospital transfusion service and if necessary, to Dr Parker Williams. Severe adverse reactions were reported to SHOT.

e. There was excellent communication between the hospital transfusion service and the RTC at Tooting.
f. If the blood transfusion was directly involved in the death this would be recorded. Patients who died from hepatitis or AIDS should have had transfusion mentioned on the death certificate but I don't know if this was the practice in the relevant departments.

Section 5: Treatment of patients

Provision of Information to patients

39. The risk of infection, including the observed frequency, was made available to haematologists in training and nurses in the training programs. The information was included in booklets provided for transplant patients and for those attending Day Care but the most important route was through discussion with appropriate staff. I can't remember if there was a specific booklet produced by the NBA as suggested in the NBSUG minutes [DHSC0042264_106, page 4, section 5.3].

40. Later, possibly in 2000, the dangers of incompatible or wrong blood transfusions were emphasised and patients were encouraged to know their own blood group and check that group on the blood product they were about to receive.

41. I can only comment on my practice. I have already mentioned the two cases with which I was directly involved. The link with transfusion was clearly explained. The HCV look back was not particularly useful in that the GP, not the doctor responsible for the transfusion, was informed by the NBTS. It was the GPs' role to discuss the result with the patient and their family.

Consent

42. Lots of blood samples were taken from many patients under the care of St George's Hospital for various reasons. There was/ is a large phlebotomy service. Usually the person taking the blood would inform the patient what the sample was for though the fact the patient accepted the procedure was taken as consent. There were some reasons for taking blood samples for which informed consent, written or verbal, had to be obtained and recorded before taking the sample, for example for HIV testing, genotyping or research.

43. Consent for transfusion was obtained from haematology patients during the setting up of a treatment programme, mostly as part of that program. Written consent was not deemed necessary, except in exceptional circumstances. Consent was

assumed from patients who had repeat transfusions when they submitted to the procedure. Before the inclusion of possible transfusion on written surgical consent forms, there must have been many instances of transfusions given without consent. Likewise, unconscious trauma patients or those with massive peripartum bleeding must have been given transfusion without consent.

Section 6: National Blood Service User Group (NBSUG)

44a. The Users Group was created and announced in a Parliamentary debate in 1995 by the Secretary for State for Health, Stephen Dorrell. My appointment as Chair was announced at the same time. The group was set up because of the political turmoil the reorganisation of transfusion services was causing in the country. One of the aims was to ensure standards were maintained after the changes. The aim of improving communication was part of this overall strategy.

b. To improve and maintain communication, the NBSUG recruited membership from surgery, anaesthetic/intensive care, hospital transfusion directors and the RTCs. Observers from the new NBA (Dr Angela Robinson), the Welsh Office and the NHSE were recruited. Three zonal users groups were established with similar mixed membership to liaise with interested stakeholders locally.

c. My letter to Dr Winyard of 1998 [DHSC0041280_035], indicates the poor relationship between blood users and the transfusion service. The creation of a National Blood Authority (NBA) from the regional arrangements in place, as suggested by the Cash report, was perhaps pushed with a lack of sensitivity concerning staff who would be affected by the changes. There was a huge reaction by unions, local transfusion service and in the media over what was thought to be a money saving operation which would close Centres, disrupt supply and endanger life.

d. I'm not quite sure what is expected regarding comments on this point. The processes used in this relationship at that time included picket lines, disruption of meetings and a major media campaign. Fortunately the zonal user groups were able to gather concrete evidence about disruption to service and the NBSUG was able to reassure, at least in the main, the NHSE and more widely blood users on the blood supply.

e. It was a slow process to get the trust of users in the NBA and it was not complete by the time my Chairmanship ended in 1998. Now there is total confidence

in the ability of the NBA to deliver an excellent, innovative and safe transfusion service.

Section 7: vCJD

45. In April 1996 the UK National CJD Research and Surveillance Unit reported possible transmission of variant CJD by blood transfusion (tissue transmission of congenital CJD was already known). The MRC set up a group to examine and monitor this further. I was invited to attend these meetings. Measures taken by NBA in the face of evidence for such transmission included leucodepletion, not accepting blood donations from donors transfused after 1980 and refusing donations from people who might have been exposed to vCJD. These measures were also discussed at NBSUG. In the event, these and other measures taken over animal feed limited infection to 5 probable cases, though there may still be a latent risk.

46. We did not have to address this problem. Advice from the Ministry of Health would probably have been followed.

47. Measures from the public health perspective re possible vCJD transmission. We accepted the effectiveness of the measures adopted by the NHSBT.

48. vCJD risk assessment. NBSUG, RCPath committees, MRC Advisory Committee on TSE and indeed any other committees where blood transfusion was an important topic such as Bone Marrow Transplant groups all had an input or interest in vCJD transmission.

49. Dr Angela Robinson's letter [NHBT0007028]

I interpret the phrase "rapidly changing circumstances that are affecting the Blood Transfusion Services in the UK" to refer to the ongoing restructuring of the transfusion services as well as measures to be taken over vCJD.

a. The "Blood Matters" seminar took place at the RCPath in the summer of 1998. I forget the exact date and do not have a copy of the agenda. The topics mentioned in Dr Robinson's letter would certainly have been on the agenda but as I recall, it was a lively meeting with much heckling over the stages of the reorganisation.

Section 8: Immunotech Holdings Limited

50 - 51. This is a Biotech Company based in China involved in cellular therapy for malignant disease. Its operations would not be relevant to the Inquiry. I quit my formal association some 5 years ago.

Section 9: Other Issues

52. I have not had any complaints made against me to my employers, the GMC, the Health Service Ombudsman or any other body whether relevant to the Inquiry's terms of reference or any other relevance.

Statement of Truth

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

Signed GRO-C

Dated 26 January 2022