Witness Name: Anthony Goldstone

Statement No.: WITN6971001

Exhibits: 0

Dated: 24 January 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR ANTHONY GOLDSTONE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 10 December 2021.

I, Professor Anthony Goldstone, will say as follows:

Section 1: Introduction

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

Name: Professor Anthony Goldstone
Address: GRO-C Herts GRO-C
Qualification: MA (Oxon), BM BCh, FRCP (London), FRCP (Edin), FRCPath
Date of birth: GRO-C 1944

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

House Physician: Medicine
Chase Farm Hospital, Enfield — Feb 1969 – Aug 1969

House Surgeon: Surgery
Edgware General Hospital — Aug 1969 – Feb 1970

Resident Clinical Pathologist
Guy's Hospital — Feb 1970 – Aug 1970

Registrar in Haematology Western General Infirmary, Edinburgh	Feb 1971 - June 1973
Cancer Research Campaign Research Fellow in Clinical Immunology Edinburgh Royal Infirmary	June 1972 – June 1973
Senior Registrar in Haematology Addenbrooke's Hospital, Cambridge	Oct 1973 - Mar 1976
Consultant Haematologist University College London Hospital and UCLH NHS Trust	1976 - 2011
Chair Royal National Orthopaedic Hospital NHS Trust	2011 – 2019
Chair HCA Cancer Department	2017 – present

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

Member of the British Society of Haematology	1975 to present
Medical Director and Chairman of Clinical Directors Group UCLH NHS Trust	1992-2000
Chairman of North East Thames Regional Haematologists	1988 to 1992
President and co-founder of British Society for Blood and Bone Marrow Transplantation	December 1998 to December 2000
President of British Society for Haematology	2001

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

No involvement

Section 2: University College Hospital

General

5. Please describe:

a. Your role and responsibilities at the University College Hospital ("UCH") and how these changed over time.

I was initially appointed Consultant in Haematology with some interest in Blood Transfusion. I looked after patients with blood cancers and deputised for Professor Prankerd, and shared routine haematology laboratory responsibilities with Dr Richards. I did medical admissions "take" with and for Professor Prankerd. The only other consultant was Professor Huehns – who worked in the research red cell lab and did one clinic in sickle cell disease and thalassaemia and looked after no inpatients.

b. Your work at UCH as a Consultant Haematologist.

I initially did general clinical Haematology, medical take and lab advice. I went to the USA in 1977 to train in bone marrow transplants and came back to build up an adult leukaemia and transplant unit at UCH, soon giving up "general medical admissions". I began to reduce my involvement in the routine haematology laboratory before ceasing completely. From 1980 Professor (then Dr.) Machin took over the care of patients with haemophilia and later Dr Keith Patterson joined as an additional consultant with laboratory and clinical responsibilities. I developed autologous and allogeneic transplantation at UCH; and David Linch and myself developed a high profile in the BNLI (British National Lymphoma Investigation), the MRC Leukaemia Trials adult AML and ALL and the EBMTG (European Bone Marrow Transplantation Group). I subsequently did not have responsibility in the routine haematology laboratory.

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

I had no specific responsibility for HIV, HCV and HBV-infected patients from transfusion or the Haemophilia service. If patients with Leukaemia or those undergoing bone marrow transplant patients developed these problems, I looked after them clinically with advice from the laboratory-based haematologists and from infectious disease colleagues.

6. Please:

a. Describe the roles, functions and responsibilities of the Haematology department ("the Department") within UCH during the time you worked there. Please also explain how the Department worked with other departments within the Hospital, such as critical care, emergency, birth or surgical units in so far as it related to blood transfusions. In particular, please explain which Department took primary responsibility for deciding whether or not to transfuse a patient and/or the type of transfusion to give.

When I got there in 1976, Professor Tom Prankerd in the Department of Medicine was the main Haematology clinician. He played a national role in bringing Clinical and Laboratory Haematology together and basically defined a new combined Speciality in which haematologists had both a clinical and laboratory role. Professor Prankerd became Dean of the Medical School and did less and less clinical work. I took it over increasingly and therefore spent less and less time in the laboratory as the clinical practice increased. Professor Prankerd was Director of the Haemophilia service when I arrived.

Dr John Richards followed Professor Prankerd as Director of the Haemophilia service around 1977. He was head of the Laboratory and worked in several honorary positions with the Royal College of Pathologists. He did a modest amount of clinical work. He supervised the senior registrars who ran the Haemophilia Service on a day to day basis.

Professor Ernie Huehns ran the Red Cell Service for Sickle cell and Thalassaemia patients, headed the Research Department and did clinics for red cell patients.

Initially all general enquiries from clinicians to the lab were handled by Dr Richards and to a minor extent myself and later, when he arrived, Dr Keith Patterson. The clinical departments of the hospital – critical care, maternity and surgery took their own decisions at that time of which patients to transfuse, but were encouraged to discuss with the laboratory staff which products they should order. This was my experience from 1976 onwards.

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

For inpatients in all specialities the arrangements for transfusions were made by the specific clinical teams on the ward after reviewing the patient's blood count and taking into account their clinical needs. Sometimes, in complex cases, there was discussion with the haematology clinicians. As I remember, we also had a physical

facility in the haematology laboratory block to transfuse outpatients. This was arranged by the laboratory.

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.

Professor Prankerd was Director of the Haemophilia Centre when I arrived. Dr Richards later took over. As I recall, from around 1980 Dr Machin (and, under his supervision) the senior registrars had responsibility for caring for these patients, along with Dr Richards, and later (? 1987 and beyond Dr Patterson).

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

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

We had specific paper forms to request blood products - these were used on the wards and in outpatients.

b. What the record keeping requirements were; and

There were "standard" paper records kept in the Haematology laboratory department. I was not involved in planning record keeping and I am both unfamiliar with and do not remember the details. There were four senior members of the UCLH lab technical staff in charge of these aspects and they were known to be very meticulous in adhering to the standards of the day:

Fred Fellingham - Chief Technician
Mary Reavley - In charge of the routine haematology laboratory
Maddy Barlow - Head of Transfusion
Linda Wilkinson - Head of Coagulation

c. What the patient was told before the transfusion.

As far as I recall all patients were counselled about known risks which was updated as information came through. The patients that I cared for with blood cancers were extremely unwell and without blood products, they would not have survived either their diseases or their treatments. At the start of my job, I do not recollect any meetings in the hospital, in general, as to what was or should be said to patients

regarding risks of transfusion. Later when certain risks became more apparent - I don't know the date - we established a hospital "Transfusion Committee". I think the Hospital Transfusion Committee was established after the Trust SHOT report in 1996. I did not attend that regularly, but suspect it dealt with what was counselled to patients.

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

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

When I interacted at all it was with the Head of the Regional BTC.

b. How frequently you interacted with them; and

Less than once every 6 months.

c. What your interactions were primarily concerned with

My interaction related to standing in for others – Professor Prankerd or Dr Richards, at routine meetings.

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

No. I recall we used to get juniors sent there for training (Brentwood or Colindale) and we used to order blood products from there.

10. Approximately how many patients per week would receive a transfusion under the care of the Department? If it is possible to indicate the number of patients in relation to each circumstance identified in question 14 below, please do so.

I would not have known this at the time and cannot recollect sufficiently to give a useful estimate. There is no way now of tracking the actual data on this question. The answer also depends on whether the question refers to patients belonging to the haematology department itself – i.e. patients with haemophilia, sickle cell disease, leukaemias, those undergoing bone marrow transplant etc or whether to other departments of the Hospital.

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

A few patients developed viral infections as a result of transfusions, as I remember - I think perhaps fewer than 5. As I remember, these were mostly patients with haemophilia.

There was a specific incident that I do clearly recollect from within the department in the early 1990s wherein hepatitis B was transmitted to 6 multiply-transfused patients undergoing bone marrow transplants after contamination of marrow stored within cryopreservation tanks. This was the first report of such an incident, the source of which was only identified after extensive work together with the hospital virology department. Our department completely changed the cryopreservation methods and reported this incident widely including publication of the data, in order to warn other units of this previously unidentified danger (SBTS0000463_131).

Research

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

Yes.

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

The research involved looking at multiple transfused patients and the efficacy of donor screening for Hepatitis C and the characteristics of acute Hepatitis C infections that developed in patients undergoing therapy for haematological malignancies.

b. What, if any, involvement you had in the research; and

I was the Director of the Clinical Leukaemia and Transplant service, and some of the patients enrolled into this and any other trials would have been my own patients.

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

1. Brink et al. – Efficacy of donor screening for Hepatitis C antibodies in preventing Hepatitis C infection in multiply transfused patients - Transfusion Medicine 1993.3. 291-294 (NHBT0083834).

2. Brink et al. – Acute Hepatitis C infection in patients undergoing therapy for Haematological Malignancies: a clinical and virological study. Brit. J. Haem. 1993 83 498-503 (RLIT0000842).

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

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

As above for blood transfusion trials, which was not my area of expertise.

I was an investigator on numerous other trials of treatments for patients with blood cancers as this was my own area of expertise. I do know that all trials carried out in our unit were carefully conducted according to the legal and ethical frameworks of the time.

b. Your involvement in this research; and

For any transfusion trials my involvement was limited to taking care of patients clinically as needed. To the best of my knowledge, all patients were appropriately informed as relevant and consent was obtained as relevant to the best standards of the time.

c. Details of any publications relating to the research.

The high incidence of CMV after non-myeloablative stem cell transplantation: potential role of Campah– 1H in delaying immunity constitution. Authors: Chakrabarti et al. Blood 100 (13) 4310-4316. 2002 (RLIT0000885).

My involvement was to clinically look after some of the patients.

Section 3: Policies and practices regarding blood transfusions

14. To the best of your knowledge, was guidance provided to you and/or other medical professionals by UCH as to transfusion policies and practices during the time of your employment? If so, please outline in as much detail as possible, the policies in place which would prompt you to transfuse haematological malignancy patients, including but not limited to the following: If possible, please refer to how many units of blood would be used, alternative treatments that would be considered, the impact of chemotherapy and/or radiotherapy on the need for transfusions and the use of autologous transfusion. Please also refer to any other considerations such as when not to transfuse and adverse reactions. Please also explain how these policies changed over time.

I do not recall any written policies with regards to transfusion of patients with blood cancers when I arrived in 1976.

a. Leukaemia

Leukaemia – we transfused whole blood or red cell concentrates to the elderly and those at risk of heart failure, usually to keep the haemoglobin above 90-100g/L or to control symptomatic anaemia. We transfused platelet concentrates to control any bleeding associated with thrombocytopenia and electively when counts fell below around $30x10^9$ per litre. Both of these transfusion thresholds fell successively, over the years – i.e. prophylactic platelet transfusion was left later until the platelet count was even lower. We worked towards the guidelines produced by Murphy et al. 1992 – guidelines for platelet transfusion (BSHA0000031). Transfusion Medicine 1992 311-318. And towards guidelines of BCSH for administration of Blood and Blood products. Murphy et al. Transfusion Medicine 1999 (AHCH0000049).

b. Lymphoma

Patients with lymphoma needed much less blood transfusion as there was less marrow involvement by disease unless the patients were receiving aggressive chemotherapy. Patients therefore needed fewer red cell and platelet transfusions.

c. Multiple myeloma

Myeloma patients were often anaemic because of marrow infiltration and expanded plasma volume. They frequently required red cells. They rarely required platelets.

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

Red cells
Packed red cells
Platelets concentrates
Platelets from a single donor
FFP
Cryoprecipitate
Factor 8 concentrate

Over time, we began to transfuse later and didn't attempt any longer to get the lab haemoglobin over 90-100g/L. We later transfused prophylactic platelets only at a lower level of $20x10^9$ per litre and sometimes not even then. We used FFP in haematology patients less and less often. There has been a very appropriate and increasing tendency over the past 30 years to think twice about the administration of any blood product on grounds of risk.

Transfusion of red cells in malignant haematology is to restore Hb levels produced by the disease or the treatment to levels at which the patient has a functional Hb of 80-100g/L. This maintains organ function and allows the treatment to be tolerated. For acute leukaemia in particular the platelet levels were often very low from the disease or its treatment and the patient required prophylactic platelet transfusion sometimes 2-3X/week to maintain safe levels & prevent bleeding.

Acute leukaemia is a disease of stem cells in the bone marrow and these abnormal stem cells need to be removed by chemotherapy to allow the few residual normal stem cells to regrow and put the patient into a remission with normal red cell, white cell and platelet counts. This frequently takes several weeks. Aggressive chemotherapy is frequently used to achieve this result. This results in severe anaemia & thrombocytopenia (low platelet count). The increasing use and success of aggressive chemotherapy from the late 1970s onwards escalated the need for red cell and platelet transfusion. In later decades some patients achieved successful bone marrow transplantation which even for patients going into the procedure in remission with normal blood counts required several more weeks of red cell and platelet support to cover the procedure.

Lymphoma, Hodgkin and Non-Hodgkin, is predominantly a disease of the lymph glands but infrequently has infiltration of the bone marrow with abnormal cells. The disease itself is often associated with anaemia and accompanying infiltration of the marrow can exacerbate this and produce thrombocytopenia as well. Again, treatment

has progressively improved since the 1970s and 80s. Sometimes local radiotherapy can put limited local site lymphoma into remission but emerging stronger chemotherapies have succeeded in curing both Hodgkin and non-Hodgkin lymphoma and some of these patients have required red cell and occasionally platelet transfusion as treatment has become more intensive. In general, blood product replacement is used much less intensively in lymphoma than leukaemia.

In some patients with both leukaemia and lymphoma in recent years, more specifically targeted drugs and antibodies have maintained outcome success with overall less aggressive therapy which has required less blood product support.

In the period of my own Consultant tenure, blood products largely represented "supportive care" which relieved symptoms and allowed potentially toxic therapy to eliminate the underlying disease. For both leukaemia and lymphoma during my tenure it was standard for many patients to give 6 courses or so of chemotherapy on an intermittent basis over several months at regular intervals to produce the desired long term remission/cure, the need for blood product replacement usually being greatest during the first 1-3 treatments.

16. In your experience at UCH, did any particular blood products or transfusion methods carry a higher risk of viral infection?

Product from multiple donors.
Product from paid donors.
Commercial factor 8.

17. The Inquiry has received evidence that clinicians were concerned regarding excessive use of transfusions. Please see [NHBT0117504]. With reference to your experience at UCH and in any other relevant roles, please outline if you believe that blood transfusions were provided excessively?

I have reviewed the reference NHSBT0117504. I agree with the comments of Dr Pat Hewitt. Even at the time of my appointment as a Consultant at UCH in 1976, blood transfusions were only given after careful and detailed consideration of the benefits and known risks at that time and of course in consideration that supply of products was not unlimited and should be reserved for those most in need. It was not uncommon to seek blood products such as platelets for patients with significant bleeding and find them lacking in availability. I do not recall that blood transfusions were administered excessively then, nor at any time later, at UCH.

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

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

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

Now, from trials and better evidence, we have realised many patients can manage with haemoglobin levels of 70-80g/L, whereas in the early days of my career, we transfused up to what we considered would be "normal" levels even as high as 110-120g/L.

19. Were alternative treatments made available to patients under the care of the Department throughout the time of your employment but specifically in the 1970s and 1980s? If so, please explain:

a. What alternative treatments were available for haematological malignancy patients?

Supportive care only
Palliative care only
Red Cell transfusion only
Platelets occasionally
Oral mildly Leukaemia suppressive therapy

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

Yes, they were.

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

The better the relationship, the easier the possibility of agreeing a strategy which was informed. We often developed long and close relationships with our patients, as a team and we tended to know them and their families personally.

d. Referencing your answer to 19(c), did any aspect of this change over time?

Yes. At UCH, when I arrived in 1976, there was a view that leukaemia induction therapy usually didn't work and that the vast majority of patients died without achieving a remission. Treatment was essentially 'half-hearted'. I changed all that within 2-3 years, pushing hard at remission induction and starting autologous stem cell transplant in 1979. This required a significant increase in use of blood products particularly red cells and platelets.

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

Transfusions were regarded as "routine" issues when I first arrived at UCH in 1976, albeit done with great care as the main concerns at the time were incompatibility reactions and the main cause of those was felt to be human error. All of our staff (nurses, junior doctors, technical staff etc.) were taught about and familiar with the safe transfusion practices of the time. Thinking more cautiously and selectively about blood product use evolved in subsequent years.

f. 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?

In some instances, i.e. the substitution of desmopressin for factor 8 products and the better use of colloids, yes, but mostly not. There was not a culture of "let's look for an alternative" when I arrived at UCH, but that did evolve later.

Red cell concentrates

20. What considerations were made by the Department for the use of red blood cell concentrate transfusions? In particular:

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

For bleeding when there was significant loss and reduced blood pressure and blood volume. For blood loss during some surgery. For anaemia produced by chemotherapy.

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

In 1976 the benefits of red cell transfusion were considered widespread and there was little thought of disbenefits, risks etc. beyond transfusion reactions. However, within 10 years there was much more consideration of real indications and cessation of unnecessary transfusion, peri-operative and post-operative, in chronic anaemias for some low haemoglobins etc.

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

Limit the use of blood and blood products. We joined early with the Virology Department at UCL led by Richard Tedder to publish on Hep-C infections etc (see above), and to work with them on viral associations overall with blood transfusion.

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

I don't recollect initially that this was led from or emanated from the Department of Haematology of UCH but this came later (not sure of the year) with the Hospital Transfusion Committee.

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

I think usually no more than 2-3. Main issues being return of the Hb levels, BP, circulating volume and a wish later not to over-transfuse because of the risks of iron overload.

21.Were guidelines circulated to clinicians concerning the use of red cell concentrate? If so, did the usage pattern of red cell concentrate change as a result of these guidelines? If not, why were guidelines not provided? You may wish to consider [BWCT0000120_001] when answering questions about red cell concentrates.

We followed national guidelines and instituted a Transfusion Committee. The SHOT programme actually started in UCH in 1996 led by Professors Hannah Cohen and Paula Bolton-Maggs. The usage pattern of red cell transfusion did change with the guidelines in that the guidelines emphasised the need for making sure there was a definite need to transfuse an individual patient and discouraged transfusion of mild anaemia. The guidelines emphasised more circumspection in decisions about transfusion.

Platelets

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

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

For thrombocytopenic bleeding and prophylaxis. All other indications much less. Occasionally platelets were used to 'cover' massive red cell transfusion in a previously thrombocytopenic patient.

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

In the mid-1970s the benefits were thought to be mainly in prophylaxis. Awareness of risk increased over the next few years.

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

Rationalise usage by increasing awareness between 1975-85 of the risk of blood products. Testing for HBV, Hep-C was introduced when available.

d. The process for obtaining informed consent and informing patients or their relatives of the risks associated with platelet transfusions. You may wish to consider [BSHA0000031] when answering questions regarding platelets.

We counselled and obtained informed consent regarding platelet transfusions but I cannot be sure of the date we started.

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

a. Why leukaemia patients specifically required transfusion with platelets over other blood components (you may wish to refer to NHBT0010755_001 page 4);

The disease itself and the chemotherapy both can make the platelet count very low.

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

Sometimes 2-3 times per week during chemotherapy but often less frequently.

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

4-6 units for an adult – depends on size of patients, count and yield of platelets. This is the current equivalent of 'one pool' of platelets.

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

Single donor platelets were sometimes chosen for people with severe allergic reactions, antiplatelet antibodies or those who were refractory to platelet transfusion from multiple donors.

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

a. If you are aware whether patients under the care of the Department where transfused with platelets that had not undergone full testing; and

I was never aware that this might be the case.

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

See above. I do not recollect an "in house" policy in the 70's and I do not recollect ever being asked the question "shall we transfuse this patient even if we haven't done that particular test"?.

Fresh Frozen Plasma

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

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

Liver disease (recommended by GI and Liver Physicians), Disseminated Intravascular Coagulation (decided by Haematology, with massive transfusion (usually decided by physician in-charge of the patient)).

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

In the mid-1970s the Haem Department was not worried enough to regulate its use.

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

I do not recollect anything specific but others may have had input – Dr Richards, Dr Patterson, Senior Registrars and Hannah Cohen when she began work in the department. In the later years after I joined we became more and more aware of the risks of blood products.

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

I do not recollect how that was done.

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

Usually, two units were standard. This may have been less for small patients with liver disease – usually not more.

26. Were guidelines circulated to clinicians concerning the use of FFP? If so, did the usage pattern of FFP change as a result of these guidelines? If not, why were guidelines not provided? You may wish to consider [NHBT0004335_004] when answering questions about FFP.

We followed BSH and WHO guidelines.

Single Unit Transfusions

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

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

The standard was 2 units. We may have used single units for children and very small adults – it was rare. One of the things I remember being taught was "The recipient of a one-unit transfusion is in no greater need of it than the donor".

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

Single units became used less and less. Risks of infection were still there before standard testing but the benefit achieved was limited.

c. Approximately how often single unit transfusions would be administered and/or whether single-unit transfusions were suitable for patients with haematological malignancies? Please explain your answer.

*This is d*ifficult to recollect but I think very rarely in Haematological malignancy. This is because anaemia and thrombocytopenia were common, significant and recurrent.

Fresh Warm Blood

28. It has come to the Inquiry's attention that on rare occasions, when a blood transfusion was needed urgently, fresh warm blood donated by hospital staff was administered to patients. To your knowledge, did this practice occur at UCH? If so, please explain in as much detail as you are able to, ensuring your answer addresses:

I don't recollect any occasion when this occurred but cannot say with certainty that it did not occur.

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

I don't recollect a case and cannot think of any circumstances.

b. Approximately how often this practice occurred;

I don't recollect a case.

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

In theory, a very rapid fall of blood volume, oxygen - carrying potential and clotting factors. I have not seen this done.

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

I do not recall any such case and therefore cannot comment.

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

I do not recall any such case and therefore cannot comment.

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

I was not involved in drafting or developing any blood transfusion or blood product practises with these groups, but helped shape thresholds for platelet transfusion re UCH blood cancer therapy activity and from leadership of MRC Trials in Leukaemia.

30. With reference to all of the committees named in your answer to question 3, please outline the extent to which any of those committees were involved in the following matters:

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

The British Society of Haematology, North East Thames Regional Haematologists, BSBMT were all aware of national guidelines and the UCH hospital fed by the Department of Haematology.

b. Development of local hospital guidelines in relation to transfusion practice;

The UCH hospital and the North East Thames Regional Haematologists would have been aware of/involved in the development of local protocols. An Edinburgh meeting regarding platelet transport in 1997 describes a presentation by me of a change in prophylactic transfusion of platelets practice at UCH where we shifted the threshold for platelet transfusion down from 20 to 15x 109/litre showing a 20% overall reduction in platelet usage but the incident of major haemorrhage reducing 12% to 10% (p=NS) saving costs £10,000 - £18,000 per month lowering the risk of infection.

c. Transfusion policy induction procedure for new staff;

The UCH hospital and its Department of Haematology.

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

The UCH hospital, Regional Haematologists and UCH Nursing Directorate would have been involved.

e. Promotion of new information regarding transfusion matters;

All bodies.

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

The UCH Hospital, The Medical Committee, and individual clinicians.

g. Blood transfusion record keeping and documentation;

The UCH hospital and its lab. North East Thames Regional Haematologists.

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

The UCH hospital, its Department of Haematology, Regional Haematologists – passing data nationally.

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

The Department of Haematology, North East Thames Regional Haematologists (BCHDO – I wasn't involved).

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

Hospital protocols, Department of Haematology UCH, Medical Committee.

31. With reference to all of the committees named in your answer to question 3 above, please outline any specific transfusion policies created by those committees in relation to haematological malignancies.

British Society of Haematology – guidelines on Hospital Blood Bank documentation and procedures 1984.

32. Was there a Hospital Transfusion Committee at UCH? If so, insofar as you are able:

a. Please provide an overview of the Committee, including when the Committee was created, its roles, functions and responsibilities at UCH, and its relationship with the Department at UCH.

As far I can recollect, this was instituted after 1996 and after being called for by SHOT. I have enquired of UCLH itself and was told there were no available records from that time and I also had a discussion with Professor Hannah Cohen who suggested they were brought in in general after the first SHOT report in 1996. It would have been led by the Department of Haematology I suspect and reported to the hospital Board and the Medical Director and liaised with the local Transfusion Centres.

b. With reference to any of the matters identified in Questions 30 and 31 of this request, please outline any significant policies or practices established by the Committee.

I do not specifically recollect but since the Edinburgh Platelet Consensus Conference of 1997 reports a piece regarding transfusion threshold from myself, I suspect we worked through the local protocol in the Department of Haematology and the Hospital Transfusion Committee.

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

As described above in section 32a.

33. During Parliamentary questions on 10th December 1985, Mr Hayhoe stated that 'supplies of whole blood are not imported since the United Kingdom is self-sufficient in its needs for blood for transfusions; it is only certain blood products which are imported' [HSOC0018830]. To your knowledge, during your tenure at UCH were you aware of patients being given blood transfusions with red blood cells imported from the USA? If so, was there any concern about its use at the time?

I was aware of that the UK need for product for patients with haemophilia was insufficient and this was "topped up" with imported product.

Section 4: Knowledge of risk

General

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

I knew the potential risk of infection of Hepatitis B from my training in haematology, my reading and attending conferences. My knowledge of the risks improved in subsequent 10 years by working with colleagues in an academically – oriented Department working in teaching and research, attending conferences and reading, Grand Rounds, and from subsequent juniors in training who had been exposed to units elsewhere.

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

I learned about risks with Hep-B during my training as senior registrar in Cambridge and my first years as a consultant in UCH from 1976. Donor blood was required to be antigen tested from around 1972. Hep-C was identified in 1989. We learned about the risks of both in training, lectures, academic meetings, interactions with the regional national transfusion doctors and the academic research lab.

HIV and AIDS

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

I knew nothing about HIV/ AIDS when I started working in the UCH in the Haematology Department in 1976. We became aware of issues from 1982 and our knowledge rapidly accelerated. We followed Regional and National recommendations and those of the BSH.

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

I was not responsible for leading the management of these risks. Dr Richards and Prof Machin were, but we all discussed. We followed regional and national practice. Our decisions for change were implemented quicker than most in the UK because we worked directly with Richard Tedder's Research Virology laboratory which was at the forefront of research into these issues in the UK.

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

These audits came following commencement at the hospital transfusion committee but I cannot recollect when that began.

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

UCH instigated them but I do not remember the dates.

a. What procedure did the Hospital have in place?

Lab records in hospital transfusion committee.

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

It did later but not initially.

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

Not that I recall but it was not managed by me.

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

Not sure – probably Dr Richards, Professor Machin or Dr Bolton-Maggs.

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

Yes. Our Director of Haemophilia or deputy attended meetings on a regular basis at the Regional Transfusion Centre and also a Committee of Regional Haematologists. I was Chair at one time of the Regional Haematology Committee but I do not recollect specifically these topics during my tenure but I suspect there will have been.

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

In terms of the death certificates, matters were much more likely to be recorded of a death following an acute abnormal response to the transfusion – anaphylaxis, massive sepsis or massive haemolysis. I have no recollection of specific circumstances relating to certification of death at UCH following Hep-B, Hep-C or HIV. Others were involved at that time, in transfusion – related matters so there may have been some.

Section 5: Treatment of patients

Provision of information to patients

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

Initially when I arrived, as I remember, it was about bacterial sepsis and Hepatitis B and transfusion reactions, then later Hep B, Hep C and HIV. I do not recollect any written advice for the malignant patients. I was not seeing haemophiliac and coagulation patients myself then.

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

As above, information about Hep-C and HIV came later. I do not recollect details.

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

I believe Dr Richards and later Dr Machin supervised this but I was not involved. I don't know whether they called them,wrote to them or brought them to the clinic.

This UCH department was orientated to academic inquiry with Dr Machin and then Dr Tedder regarding Virology and then Dr Hannah Cohen introducing the SHOT concept. I've inquired through UCLH NHSFT regarding archiving and past documents and seen statements/ information to the IBI inquiry from Victoria Hiscock who has some material sent to the IBI but they cannot locate the documentation of the 1970s and 1980s.

Consent

43. Were blood samples taken from patients under the care of the Department and if so, for what purposes? How frequently were blood samples taken? Was this information shared with patients? Was patient consent recorded and if so how and where?

Blood samples were taken for Hepatitis and HIV research evaluation. I don't know how frequently they were taken. I believe the information was shared with the patient for that but I cannot confirm. I believe consent was recorded but I can't confirm.

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

I am not aware of patients under the care of the Department being treated with blood transfusion without their informed consent.

NANB Hepatitis/Hepatitis C

45. Are you aware if the Department tested patients for HCV? If so, please describe the Department's process for HCV testing, including pre-test and post-test counselling. What was your involvement in this process? Was it effective in preventing HCV infection? You may wish to consider [NHBT0083834] in your answer

The department tested patients for Hep-C under the guidance of Professor (then Dr) Richard Tedder. I was the consultant in-charge of the clinical care of some of the patients with blood cancers.

46. When testing for HCV became available, what, if any, steps were taken by the Department to ensure that all patients who had received a blood transfusion were traced and invited to be tested? You may wish to consider [NHBT0025819_009]

UCLH was my institution. We led the way with Professor Machin and Dr Patterson leading.

47. In light of the above, were patients infected with Hepatitis C informed of their infection and if so, how and by whom? What information was provided to patients about each infection, specifically their significance, prognosis, treatment options and management? What, if any, involvement did you have in this process?

See NHBT0025819_009 as to how we did it. I had no direct involvement in the process of informing the patient. This was done by the Lab Haematologist but I followed the patients up on the ward and in the clinic. I was also the Medical Director of the hospital at the time and therefore copied into much correspondence.

48. How was the care and treatment of patients with HCV managed within the department? In particular:

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

b. What follow-up and/or ongoing monitoring

See UCLH details as in NHBT0025819_009. All appropriate patients were referred to the specialist GI Hep C clinic – Dr Brink, Dr Gilson, Dr Sarner. Other alternatives were the consultant's own clinic or to be seen at a specific NBA national clinic.

Section 6: vCJD

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

After 2003 I don't recall a local case but heard from meeting presentations and publications.

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

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

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

No personal involvement.

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

As far I can recall we kept in touch with Dr Pat Hewitt and took advice on leucodepletion, geographically – based donor deferrals and deferral of transfusion recipients.

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

I suspect that the North East Thames Regional Haematologist and the BSH both considered the issues regularly but I have no recollection of the meetings.

Section 7: Other Issues

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

No complaints of which I am aware.

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

No additional comments.

55. In addition to any documents exhibited in support of your statement, the Inquiry would be grateful to receive copies of any potentially relevant documents you possess relating to the issues addressed in this letter.

I don't have any further material.

Statement of Truth

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

Signed: GRO-C

Dated: 24.01.2022