Witness Name: Dr Susan Bewley
Statement No.: WITN6978001
Exhibits: WITN6978002 - WITN6978013
Dated: 16th February 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR SUSAN BEWLEY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 December 2021

I, Dr Susan Bewley, will say as follows: -

Section 1: Introduction

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

1. I am Susan Bewley. My personal address is GRO-C London GRO-C. My professional address is c/o Department of Women and Children's Health, 10th floor St Thomas' Hospital, Westminster Bridge Road, London SE1 7NH. My date of birth is GRO-C 1958. My professional qualifications are BA (Physiology) (Oxon), MB BS, MD (London), MA (Medical Law & Ethics), FRCOG.

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

2. My employment history is as follows:

Dates	Job Title	Employer
Aug 1982- Jan 1983	House Physician General Medicine	Kingston Hospital, Surrey
Feb 1983- Jul 1983	House Surgeon General Surgery/ENT	Middlesex Hospital, London
Aug 1983- Jul 1984	SHO O&G	Leicester Royal Infirmary, Leicester
Aug 1984- Jan 1985	SHO Neonatal Paediatrics	St Thomas' Hospital, London
Feb 1985- Jul 1985	SHO Venereology	Middlesex Hospital, London
Aug 1985- Jul 1986	SHO O&G	Kings College & Dulwich Hospitals, London
Sep 1986- Sep 1988	Research Registrar	Kings College Hospital, London
Oct 1988- Oct 1989	Registrar O&G	St Peters Hospital, Chertsey
Nov 1989- Oct 1990	Registrar O&G	St George's Hospital, London
Oct 1990- Sep 1991	Clinical Assistant Venereology / [Postgraduate student]	Middlesex Hospital, London [Kings College London, London]
Oct 1991- Sep 1994	Senior Registrar/ Subspecialty Trainee	University College Hospital, London
Oct 1994- Jun 2011	Consultant Obstetrician	Guy's and St Thomas' Hospitals NHS Trust
Oct 1994- Sep 2000	Director of Obstetrics	Guy's and St Thomas' Hospitals NHS Trust
Sep 2000- Apr 2004	Clinical Director	Guy's and St Thomas' Hospitals NHS Trust
Jun 2011-	Obstetric academic and	Self-employed

Oct 2014	expert	
Jun 2012-Jan 2015	Chair Intrapartum Care Guideline Group	National Institute of Clinical Excellence
Jun 2011-Feb 2018	Professor of Women's Health (honorary)	Kings College London
Nov 2014-Nov 2017	Chair Rapid Update Standing Committee	National Institute of Health & Care Excellence
Oct 2014-Feb 2018	Forensic Sexual Offences Examiner, Havens	Kings College Hospital, London
Jan 2016-Feb 2018	Research Lead, Havens	Kings College London, London
Sep 2016-Sep 2017	Interim consultant lead (job share), Havens	Kings College Hospital, London
Mar 2018-date	Professor Emeritus (honorary) in Obstetrics & Women's Health	Kings College London
Oct 2020-date	Chair Acute Covid-19 Treatment Living Guideline	National Institute of Health & Care Excellence

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.

3. I was the Chair of the Royal College of Obstetricians & Gynaecologists' Ethics Committee from 2004-2007. I was a Trustee of the Sophia Forum (the UK arm of the Global coalition of women living with HIV) from 2012-2017.

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, HBV and/or HCV in blood transfusions. Please provide details of your involvement and copies of any statements or reports which you provided.

4. I have not provided evidence to, nor have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to HIV, HBV and/or HCV in blood transfusions.

Section 2: Guys' & St Thomas' Hospital

General

5. Please describe:

a. Your role and responsibilities at Guys' & St Thomas' Hospital ("the Hospital") and how these changed over time.

5. My role and responsibilities at Guy's & St Thomas' Hospital were of a consultant obstetrician; antenatal clinics (in the community and high-risk), managing antenatal and postnatal ward patients, managing women in labour and emergencies on the labour ward and being available on call. There were also additional administrative, teaching and research roles. My work changed over time to having more managerial and research components, and sharing the complex antenatal patients with more colleagues. Although the obstetric on-call rota was less frequent, both the numbers and complexity of women in labour increased over time.

b. Your work at the Hospital insofar as it involves treating patients with blood transfusions.

6. My work at the hospital that involved treating patients with blood transfusions was largely related to women with serious obstetric haemorrhages (usually from the commoner conditions of placenta praevia, placental abruption and uterine atony as well as rarer conditions). For most of my employment, I was the antenatal lead/ liaison consultant for women with HIV, haemophilias and thrombosis and sickle cell disease.

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

7. My work that involved the care of patients who were infected with HIV, HBV or HCV and/or other diseases patients may have been exposed to as a result of receiving a 5 blood transfusion would have been in the high-risk antenatal clinic. I looked after occasional haemophilia patients (maybe one per annum), women living with HIV (approximately 30-70 per annum), and women with sickle cell disease (approximately 15-20 booking annually). Nevertheless, I cannot recall ever looking after a patient who had acquired these blood-borne diseases via transfusion.

6. Please:

a. Describe the roles, functions and responsibilities of the Obstetric Department ("the Department") at the Hospital during the time you worked there. Please also explain how the Department worked with other departments within the Hospital, such as critical care and anaesthetics 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.

8. The Women's Health Directorate was divided into Maternity (Obstetrics and Midwifery) and Gynaecology. The obstetric department was responsible for the safe antenatal, labour and postnatal care of women booked under our care (the majority living locally, but some referred for secondary and tertiary specialist services) and some unbooked emergencies. Blood transfusions were usually given in the emergency setting of active, and life-threatening, antenatal or postpartum bleeding. Sometimes they were given to women on the postnatal ward after late recognition of the size of a postnatal haemorrhage in the context of symptomatic anaemia and a low haemoglobin concentration (Hb level). In terms of responsibility of whether or not to transfuse, I would say that the decision to transfuse would usually be made by the obstetrician (especially for cases on the postnatal ward). In an acute labour ward emergency with bleeding, the obstetrician would initially concentrate on assessing

the volume of blood lost, determining its source, administering fluids and using both medical and surgical means to stop the bleeding. The anaesthetist would be called for larger haemorrhages, and concentrate on providing anaesthesia if required to control the bleeding, life support and resuscitation. If a patient were sicker, they might require to be transferred to theatre, an anaesthetic or later care on High Dependency Unit, or Intensive Care Unit. Thus, in these situations, primary responsibility for deciding whether or not to transfuse, the size of the transfusion and the type of blood products given in addition would move to the anaesthetist. As an approximate 'rule of thumb' I would say that in those situations where blood loss was over 2 litres or so, and a blood transfusion was over 2-4 units, such that further products were required (for example, fresh frozen plasma), then the responsibility would fully lie with the anaesthetic team. Another group of my patients who would occasionally require an exchange blood transfusion were women with sickle cell disease to prevent or overcome sickle crisis. Those decisions would lie with their haematologist.

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

9. The facilities for blood transfusion were the ordinary ones on our wards which were staffed by trained midwives. Two units of O Negative blood were always kept in the blood fridge on the labour ward in case of emergency. Over time, blood transfusion would be more likely to take place in theatre or on the High Dependency Unit when this was developed.

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.

10. Every obstetrician, junior or senior, would be involved with the direct clinical care of pregnant and postpartum women undergoing blood transfusions. I was the consultant who looked after all pregnant women infected with HIV in a special

multidisciplinary antenatal clinic (at one point over 1% of our delivering population, and on average from 30-70 per year). I do not recall any patient, either before becoming a consultant nor over nearly two decades of being a consultant, who had acquired HIV from a blood transfusion, nor any cases of blood transfusion acquired HBV or HCV. Initially, I had a joint labour ward session with Professor Felicity Reynolds, obstetric anaesthetist and founding editor of the International Journal of Obstetric Anesthesia, and later with Dr Geraldine O'Sullivan (deceased), our senior obstetric anaesthetist, and also President of the Obstetric Anaesthetics Association 2002-2005. Dr O'Sullivan attended the hospital-wide Blood Transfusion Committee on our behalf. She would liaise between the departments, feed back any issues arising from Risk Monitoring, and keep us informed about Blood Transfusion developments, as well as contributing enormously to relevant departmental protocols and guidelines (such as the care of Jehovah's witnesses who refused blood and blood products as one example). She was a keen proponent of the judicious use of blood and products. I was confident in relying upon both of these anaesthetist's skills and up-to-date knowledge when formulating policy and introducing innovations and alternatives to blood products.

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

11. The practical steps taken when deciding on a blood transfusion:

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

12. Blood was requested from the hospital blood bank by electronic ordering, and by direct telephone request in emergencies, especially discussing additional products.

b. What the record keeping requirements were; and

13. I am not so sure about the exact record keeping requirements as this was done by anaesthetic and midwifery/ nursing staff. There were a series of double checks of the units before being administered and afterwards as used bags were returned.

c. What the patient was told before the transfusion.

14. Patients would be told the nature and purpose of the transfusion, that there were common minor side-effects and some serious risks, as well as unknown risks. They were reassured that blood was tested for hepatitis and HIV.

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

15. I did not have a direct relationship with the Regional Blood Transfusion Centre personally as a consultant, Director of Obstetrics or Clinical Director although I did have close working relationships with many of the hospitals' consultant haematologists. There was a devolved managerial relationship via Hospital-wide Committees. I was aware of their workings via my relationships with anaesthetic and haematology colleagues. For example, I vividly recall making a detailed multidisciplinary plan to perform a caesarean section on a patient with severe sickle cell disease anaemia who was severely anaemic and virtually untransfusable thanks to multiple antibody formation. There were only two compatible donors in the world left, and neither were located in the UK. Two frozen units of compatible blood existed, normally kept in Birmingham. These highly precious units were moved from Birmingham to the Tooting Regional Blood bank, in order to be closer to hand in the event we would make an urgent request for them to be moved, thawed and used. Dr O'Sullivan hydrated the patient and removed one or maybe two units worth of the patient's blood preoperatively. I operated in a field where blood was a watery light pink colour as the blood was so anaemic and dilute. The initial maternal blood was returned at the end of the operation. I don't remember the exact Hb levels but they were very similar before and after the operation (in the 3-4 g/dl range). This would have occurred sometime in the early 2000s. As another example, I recall being involved in robust discussions about hospital-wide policies to change the electronic pathway for cross-matching blood. The Obstetrics Department, and the UK profession, was well ahead of a national NHS effort to prevent 'hospital-acquired thrombosis'. New mandatory ordering policies in the Hospital required the person

ordering a Group and Save, or Crossmatch of blood to fill in a series of fields about thrombosis risk as a prelude which required searching for the information and approximately 17 computer 'clicks'. The was because we had safety concerns about adding additional time to an emergency request for information that duplicated information we already collected in hand-held notes about thrombosis risk to determine prophylactic anti-coagulation in pregnant and postpartum women.

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

16. I did not have a relationship with the National Blood Transfusion Service (see above).

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

17. I cannot recall how many patients a week would receive a transfusion under the care of our department although this information might be available from the Hospital. My approximate estimate would be somewhere between one per week and one per month.

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.

18. I am unaware of any patients subsequently developing HIV, HCV or HBV under the care of the department.

Research

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

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

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

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

19. I am unaware of any research being undertaken within the department regarding blood transfusion patients. We may have audited our use, or there may have been audits undertaken by anaesthetics or haematology. I have vague recollection of discussions over the years about single unit transfusions, but only in the sense of having been trained and agreeing that we 'disapprove' of such use. I enclose research papers I was involved in regarding postpartum haemorrhage, initially at University College London, then at St Thomas', within the whole South East Region, and in concert with Darent Valley Hospital. Transfusion was not the focus of any of the papers, but they do contain information that supports my recollections. They may also give a flavour of the quotidian work of Obstetrics in saving women's lives against a background where the background risks from major haemorrhage have been increasing. See exhibits.

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

20. There are no other research studies I was involved in that directly relate to the Inquiry's Terms of reference. However, I was involved in a number of studies with respect to severe maternal morbidity (the largest proportion being due to massive postpartum haemorrhage, PPH) that contain somewhat relevant findings for this Inquiry.

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

21. The studies were largely retrospective, patients were not informed of their involvement and their consent was not obtained. One postnatal study which followed women prospectively after a severely morbid event did invite participant to fill in a questionnaire and obtain consent. The case report of a woman with massive antenatal haemorrhage was written with her consent.

b. Your involvement in this research; and

22. My involvement was as an investigator.

c. Details of any publications relating to the research.

23. The publications are appended:

(i) WITN6978002: The 1997 publication relates to a study into 'near-misses' at University College Hospital performed when I was a senior registrar. I designed the study, did the data collection and wrote it up with a colleague. This was the first such study in the UK. It shows an emerging concept of learning from errors and moving from the lessons of the Confidential Enquiry into Maternal Death (which had seen a rise in PPH deaths). It can be seen that about 1 in 200 women had a life-threatening birth such that they ended up on the intensive care unit, with the commonest cause being massive postpartum haemorrhage of >2litres. There would have been many more smaller haemorrhages. The mean transfusion was 6.4 units (range 1-24). Although this does show a one unit transfusion was given on occasion, I'm afraid I know no more of the circumstance or the smaller PPHs. This single unit transfusion may have been planned larger transfusion that was stopped because of a reaction. It might be that one unit was the 'exception that proves the rule' that larger amounts were usually given.

(ii) WITN6978003: The 2001 publication was of a funded regional population based study of all severe maternal morbidities. It was inspired by my previous work, but led by Charles Wolfe, a research supervisor, and conducted by Dr Mark Waterstone. It was population based and all 19 hospitals in the South East Region took part. Severe Maternal morbidity is now established as an important measure of maternity care, and the work was commended by Sir Goerge Godbur, the retired Chief Medical Officer who had set up the Confidential Enquiry into Maternal Deaths. It can be seen that the definition of a severe haemorrhage that we used at the time: an estimated blood loss > 1500 ml, a peripartum fall in haemoglobin concentration >4 g/dl or an acute transfusion of 4 or more units of blood. There isn't much other information that is helpful to the Enquiry.

(iii) WITN6978004.: The 2003 publication was a prospective postnatal recovery study (performed as part of the regional study) showing that over half of the women followed as a severe morbidity had experienced severe haemorrhage. Despite transfusion, as a group these women suffered higher event rates than controls (that included moderate morbidity) for poorer general health, with more readmission to hospital and follow up appointments and lower resumption of sexual relations.

(iv) WITN6978005: A paper about hysterectomy was written up as part of the regional study. Rarely, if bleeding cannot be stopped, a hysterectomy is performed as a last resort. It can be too late and the patient still dies. This paper showed that 22 women out of 48,765 in our study had hysterectomy (4.5/1000 deliveries) and there was one maternal death. The range of their blood loss was 2-10 litres, and the range of blood replacement was 6-68 units (the much higher values reflecting the loss of ability to clot and intravascular coagulopathy).

(v) WITN6978006: This paper was the major output of a funded PhD (the STOP study) involving every woman delivering over a year 2008-2009 in a two-hospital population study. All estimates of blood loss from 10,213 women were noted, and samples of notes were reviewed in each blood loss category. We found higher rates of PPH in the handwritten notes than recorded electronically and other errors. We were able to make novel findings regarding the background drivers of haemorrhage,

and what was associated with the largest haemorrhages. The paper reports the highest rates of PPH ever and also provides an explanation for rising haemorrhage in the modern era.

(vi) WITN6978007: This is a qualitative paper from the STOP study analysing narratives from staff and patients involved in the kinds of cases where blood transfusion 13 decisions are made. The interviews took place near the end of the study, i.e. in the first half of 2009. The patients, partners and staff are not representative. Five women who received blood transfusions were interviewed: two received 2 units of blood following 2.5 and 4.0 litre estimated blood losses; one received 3 units after 1.5 litre loss; one received 4 units after 2.0 litre loss; and one received 21 units after a 14 litre blood loss - this patient also received cell salvage). It demonstrates the kinds of experiences in an evolving emergency and conversations between patients and health professionals.

(vii) WITN6978008: This conference abstract from the STOP study shows how large haemorrhages were increasing over the years (1998-2010 from our two units at Guys' & St Thomas' and Darent Valley). This rising rate of severe PPH mirrored the Scotland wide Audit (both shown in the graph). It illustrates the fact that the loss of blood at birth was increasing, likely due to patient factors (of age, previous caesarean etc) all over the UK for part of the period the Inquiry covers. Thus it is likely that the need and demand for blood and products from obstetric units was also increasing at a time we were encouraged to use blood more sparingly, even if more women would have taken longer to recover from anaemia.

(viii) WITN6978009: This was a highly unusual single case report of a massive antenatal haemorrhage showing the place of antenatal 'top-ups'. It was a case we had managed at St Thomas' several years before and drawn to our IVF unit's attention as an avoidable complication of twins following elective multiple blastocyst transfer in a young woman. This was around the time that the Human Fertilisation and Embryology Authority began a campaign to cut the multiple pregnancy rate [see exhibit WITN6978010].

(vi) WITN6978011: This was a collection of case reports written with a colleague from a district hospital regarding management of abnormal placental adherence. It showed that maternal threats can occur in any kind of setting and cannot all be transferred to tertiary hospitals with more facilities. It also demonstrates the shift in obstetric thinking to trying to predict massive haemorrhage in advance (more likely with 14 multiple caesareans and abnormally adherent placenta), in order to prepare, and thus minimise morbidity, including the size of blood transfusions.

14. The Inquiry understands that you have made significant contributions to the field of women's reproductive health. Insofar as relevant to the Inquiry's Terms of Reference, please provide an overview of your research, including the creation of any guidelines, policies, studies or reports implemented as a result.

24. The majority of my contributions to the field of women's reproductive health are not relevant to the Inquiry's Terms of Reference, barring the publications above. They have been cited many times, including in the Confidential Enquiry into Maternal Deaths, but I do not think they led to any specific guidelines.

Section 3: Policies and practices regarding blood transfusions

15. To the best of your knowledge, was guidance provided to you and/or other medical professionals by the Hospital as regards transfusion policies and practises during your employment? If so, please outline in as much detail as possible the policies in place which would prompt you to transfuse obstetric or gynaecology patients and how those policies changed over time.

If possible, please refer to how many units of blood would be used, alternative treatments, autologous transfusions, applicable haemoglobin threshold levels for transfusion, as well as any other considerations, such as when not to transfuse, adverse reactions or infection risk, or resource and cost considerations.

25. I do not recall much guidance being provided to me by the Hospital as regards transfusion policies although many emails were circulated to consultants about clinical matters. Over time, I was aware that there were increasing restrictions on the use of blood and products, that there was increasing pressure to avoid blood transfusions coming from haematology. I was unaware whether this was to do with 15 conserving stock rather than a danger from the blood itself. Generally the amount of blood that would be used would relate solely to the individual patient's needs, bearing in mind that, as a general rule, we would always prefer to avoid a blood transfusion with its inherent risks of adverse reactions and infection risk. We were also aware that blood and products were costly and constrained resources. Many patients are reluctant to have a blood transfusion. A few patients refuse blood (for example Jehovah's witnesses) which is associated with an approximately 100 fold risk of maternal death. We tried to avoid small blood transfusions; it was generally felt that a one unit transfusion represented poor clinical practice. I only recall one case of autologous transfusion (during a caesarean, not taken in advance, see below) during my time at the Hospital. I recall discussing cell savers, that were used in other situations, but there was a reluctance to try this, given worries about blood mixed with amniotic fluid and baby vernix (the waxy covering on babies' skin at birth).

26. After drafting this report, I checked my recollections with standard textbooks I owned that I used during my time as a consultant. These reflect standards of the time, and may help the Inquiry.

(i) WITN6978012: The pages come from the then leading 1989 textbook "Obstetrics" that I used when training in maternal-fetal medicine 1991-93. On page 451, reference is made to autotransfusion, which I knew about in theory but never saw in practice. On pages 562 onwards the management of haemorrhage is described. It is clearly described that whole blood was "not generally available in the UK" due to insufficient time to check it for blood-borne viruses, and the well-established risks of infection associated with different plasma products are described.

(ii) WITN6978013: The pages come from an entirely new book on obstetric haematology published in 2010, which demonstrates the 'leading edge' of practice. I have enclosed our chapter on managing haemorrhage as well as the anaesthetic chapter. The routines are described. It demonstrates that even in 2010 cell salvage was only being "now increasingly considered" in obstetrics because of concerns to do with amniotic fluid embolism and alloimmunization.

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

27. The types of blood and blood products most commonly given to patient under my care were transfused packed cells and fresh frozen plasma. Initially, fresh frozen plasma would be used. Over time, other blood products such as cryoprecipitate, fibrinogen or factors were given, but only in larger haemorrhages with ongoing massive bleeding, often complicated by disseminated intravascular coagulopathy or to avert it. The decisions and details would be the responsibility and decision of the anaesthetist in discussion with on-call haematology and in response to changing clinical findings and blood clotting parameters.

17. With respect to your experience at Guys' & St Thomas' Hospital, please explain the process of measuring a patient's haemoglobin count, including the frequency with which it was monitored. Please outline at which level generally a patient's haemoglobin count would be considered low and thus require a blood transfusion.

28. The process of measuring a patient's haemoglobin (Hb) concentration would involve sending a blood test to the laboratory. In latter years, bedside testing became available for use in the obstetric theatre. However, during an active emergency, the Hb level might be an unreliable measure of the haemorrhage if fluid replacement had not kept up with the loss. Hb would be measured frequently, maybe 1-2 hourly at the height of the worst uncontrolled haemorrhages. Once bleeding was controlled, or settling, or the replacement overtook continuing loss, it might be measured at 4-6hrly

intervals, and then daily. Hb under 10.5 g/dl would be considered slightly low during pregnancy (and was the level at which we would usually recommend iron supplementation). A blood transfusion would not be given at a specific count, but relating to the amount of loss, the fall from pre-haemorrhage levels and the mother's 17 vital signs and symptoms. Thirst, fatigue, feeling faint or short of breath and a tachycardia (fast heart beat) would be particularly concerning.

18. With respect to your experience at Guys' & St Thomas' Hospital, please explain the process of measuring a patient's haemoglobin count, including the frequency with which it was monitored. Please outline at which level generally a patient's haemoglobin count would be considered low and thus require a blood transfusion.

29. In terms of how the level at which transfusion was deemed 'necessary' may have changed over time, I think the 'rule of thumb', when I was first training in Obstetrics and Gynaecology in the mid 1980s, was that blood transfusion might be considered and discussed with a patient if Hb fell below 8g/dl, and this probably moved closer to 7g/dl by the time I left St Thomas' Hospital in 2011. The level at which transfusion was considered 'vital' (in the sense of using more persuasion or not discharging for safety reasons) would probably be 5-6g/dl, in conjunction with symptoms and the whole clinical picture. Factors that would be different for pre- and post-natal patients would relate to the risks of bleeding from impending labour. For example, with a normal multiparous antenatal patient who had not had a previous PPH, there would be little worry. The increased red cell mass, physiological dilution of Hb in pregnancy and an expected normal blood loss of less than 300 mls would not lead to any extra pressure to transfuse. A woman with recurrent antepartum haemorrhages due to placenta praevia might not need blood acutely, but she might not be able to replace her own blood fast enough with iron therapy by the time of delivery and anticipated greater haemorrhage. As we would anticipate needing a potentially difficult caesarean (or even caesarean-hysterectomy) and likely out of hours, she might be given 'top-ups' of blood to keep her level around 10g/dl. Another situation would be of a patient having multiple severe sickle cell crises (which have a high mortality). These women are more used to very low Hb levels (I recall one patient whose 'usual'

level was about 3-4 g/dl). Transfusion would be more likely to be determined by symptoms than specific Hb level

19. The enclosed guidelines for the use of blood components in obstetrics state that 'In the absence of acute blood loss, antenatal and postnatal patients should only be transfused in exceptional circumstances, where the haemoglobin is low and associated with symptoms' [page 61 of DHNI0000013_065]. Please describe the main circumstances in which patients under the care of the Department would require a blood transfusion.
In relation to each different circumstance, please also describe the type of blood component given and broadly the usual amount required. Please explain how the position changed over time.

30. I have read the enclosure DHNI0000013_065 (Better use of blood products in Northern Ireland, Jan 2001) and page 61 in particular. I believe the obstetric profession was always in agreement with the overall sentiment that blood should only be used when "essential" (page 3). In 2001, this group of physicians is starting to consider alternatives ("examining the feasibility") (page 3) such as cell salvage, autologous transfusion and acute normovolaemic haemodilution. The main circumstance in which patients under the care of the department would require a blood transfusion would be in the face of acute blood loss. Outside that, transfusions were only given in exceptional circumstances to antenatal and postnatal patients. Over time, the threshold below which transfusion was deemed necessary to offer fell slightly, from about 8g/dl to 7g/dl. We would have used more persuasive pressure when Hb was <6g/dl. I recall one patient who initially refused a transfusion postnatally, when her Hb was found to be somewhere around 4-5g/dl after an unrecognised large PPH. She was kept in hospital as she was very unwell. Eventually she accepted a 2 unit transfusion and went home with her baby still weak but managing better.

20. Other than acute blood loss, blood transfusion would only be given in exceptional circumstances (eg, as above, severe anaemia, antenatal placenta praevia with recurrent antepartum haemorrhage and sickle cell crises). I have

explained the symptoms of concern in paragraph 17, and agree with the principles elucidated on page 58 of enclosure DHNI0000013_065.

31. See above.

21. 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 Guys' & St Thomas' Hospital and in any other relevant roles, please outline in what circumstances single-unit and two-unit transfusions were administered to patients. Please describe how, if at all, the position changed over time.

32. I have considered the document on the use of single unit transfusions of blood in the UK [DHSC0035471]. I have not seen this document previously.

33. With reference to my training and experience at Guy's and St Thomas', single-unit transfusions were not ever given. I cannot remember instances where patients were intended to have such a small transfusion (although I do note that there was one example of this in our regional paper). Some transfusions might end up being smaller than intended (eg. if they were not completed following some transfusion reaction or side-effects). I recall two-unit transfusions being given which would be considered closer to the borderline for prescribing. Correspondingly, it would still be relatively unusual to administer two-unit blood transfusions to obstetric patients. Sometimes, even if it was felt that more blood was needed, just two units would be given (on the logic of the risks being additive - whether it was the first, third or fifth unit that might cause a problem, it was always better to be parsimonious).

b. In light of the above, and if applicable, how often did this practice occur under the care of the Hospital? Please describe how, if at all, the position changed over time.

34. I do not think the practice of small blood transfusions occurred frequently in the hospital, and if anything would have become less common with time

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

35. I understood the risks of a single unit of blood greatly outweighed the benefits. It was seen as poor practice to want to give a single unit of blood.

d. Do you recall any instances or periods of time in which you or others raised concerns about unnecessary single unit blood transfusions? If so, please explain in as much detail as you are able to.

36. I do not recall any instances or periods of time in which I or others raised concerns about unnecessary single unit blood transfusions.

22. Do you recall any instances or periods of time in which you or others raised concerns about unnecessary or excessive blood transfusions of any kind? If so, please explain in as much detail as you are able to, including why this may have occurred and how, if at all, this changed over time.

37. I do not recall any instances or periods of time in which I or others raised concerns about unnecessary or excessive blood transfusions of any kind. I recall discussing blood transfusion with my anaesthetic colleagues on many occasions. We tried to judge the replacement of fluids and blood cautiously and remain on the judicious side. I only recall one case in my career where too much blood was given. The transfusion volume had been misjudged and 'overshot' the aimed target (8-10g/l max). The patient had a remarkably high Hb postnatally relative to normal postnatal patients. Maybe it was around 13g/dl or so, but it was still not enough to consider phlebotomy as a response. On reflection at the time, we thought that there was a combination of not appreciating the slightness of the patient while unconscious on the operating table, excessive fluid dilution during the resuscitation giving a falsely low Hb result

and overestimating the extent of blood loss during the emergency (a notoriously difficult task, especially at delivery when blood is mixed with liquor). During my 21 training, and when teaching, I had an understanding that blood was risky and should only be used for life-saving, not for 'soft' or 'slight' indications.

23. In your experience at Guys' & St Thomas' Hospital, did any particular blood products or transfusion methods carry a higher risk of viral infection?

38. In my experience at Guy's and St Thomas', I recall that both non-heat treated blood products or products that were pooled were consider riskier and having a higher risk of viral infection.

24. Where applicable, were any alternative treatments made available to patients under the care of the Hospital throughout the time of your employment? If applicable, please ensure your answer addresses treatments throughout the 1970s and 1980s at any institution.

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

39. Throughout the time of my training and employment, alternatives to blood transfusion were always made available to antenatal patients with anaemia, whether oral or parenteral iron (I think we used erythropoietin on rare occasions in renal patients). I believe the advantages and disadvantages of having a transfusion or not, was always explained to patients with anaemia. Both patients and doctors were reluctant to use blood. The advantages and disadvantages of alternative treatments were not always discussed in the way they might be for elective procedures because pregnancy was considered differently.

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

40. The doctor / patient relationship does have an effect on the way in which agreement is reached with patients. Due to a prior relationship with a particular doctor, training, experience, personality, busyness and time of day, there is a range in the way 22 individual doctors will exude trust and confidence, or give detailed information, encourage questioning or empower more timid patients to speak about their concerns.

c. Referencing your answer to 24(b), did any aspect of this change over time?

41. Patient demographics and expectations have changed with time - we would rarely be without interpreters now, and are used to being asked direct questions. Communication skills training has also improved over time. I believe the change from assumed deference/'paternalism' (or an expectation that patients would do as advised without question) towards shared decision making with full and frank conversation (between 'equals' exchanging medical information with patients' values and preferences) occurred earlier in Women's Health Services than many other medical specialities. This is partly because the patients are young and mostly healthy.

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

42. Generally, I would say that transfusions were regarded as a "necessary evil" within the Department of Obstetrics and speciality in general. We did not like giving them, partly because of the frightening precipitating emergencies, and partly as they were not risk-free. However, our main business of 'life-saving' relies on blood (and occasional hysterectomy) in PPH, antibiotics in sepsis, and prompt delivery in preeclampsia. These lessons are drummed into juniors. Examples of delayed recognition and under-treatment appear regularly in Confidential Enquiries into Maternal Death.

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

43. I am not sure what alternatives could have been used in preference to blood transfusions so as to reduce the risk of infection. We knew about the use of cell 23 savers but I only saw this used occasionally after 2000. I never saw blood collected for autotransfusion.

25. Please explain your knowledge and experience of autologous blood transfusion, including: the circumstances in which it was considered appropriate and any benefits or risks as compared to other methods of transfusion. You may be assisted by the enclosed document [NHBT0110350].

44. I have read NHBT01103560. I do not think I had much knowledge, and no experience, of autologous blood transfusion as a serious consideration in obstetrics before the 2000s.

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

45. The circumstances when it was considered appropriate I knew were for elective surgical operations.

b. Approximately how often this practice occurred;

46. I do not recall this being used in a pregnant women during my training or at the Hospital, or hearing about it through colleagues elsewhere. This is despite the fact that I worked in teaching hospitals in Central London with diverse multiethnic populations. Guy's and St Thomas' had a special Jehovah's witness committee, we had policies for such patients, and any who would refuse transfusion would be referred to the anaesthetists after booking for discussion of their options.

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

47. The benefit would be particularly for Jehovah's witnesses who would refuse homologous blood. However, the practice was generally considered less appropriate and riskier in pregnancy. Although red cell mass is increased, the Hb is usually lower thanks to haemodiluation, the increased cell mass is needed for fetal nutrition and respiration; and lastly, even if a small number of units might be collected within a suitable timeframe for use, this would be unlikely to be enough in a serious PPH, and the woman might be more endangered if she had recently been venesected. PPH is rarely predictable (except maybe for placenta praevia and difficult caesarean sections) and autologous blood collection was rarely discussed.

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

48. Thus I cannot answer about the process of informing patients about risks.

26. Please consider the enclosed letter from Dr F. A. Ala of the National Blood Transfusion Service dated 19 January 1987 [NHBT0045785].
a. Did you/the Department at Guys' & St Thomas' Hospital ever receive guidance from the NBTS regarding autologous transfusions?

49. I have considered the letter from Dr Ala [NHBT0045785]. I do not recall ever receiving guidance from the NBTS regarding autologous transfusions.

b. Please comment on the concerns raised regarding the risks associated with first and third trimester pre-deposit of autologous blood. What did you understand the risks to be?

50. I can't think of the logic about worrying about risks associated with pre-deposit in the first and third trimester, but not the second. Giving blood would be different. In both the first and second trimesters, a mother with a transfusion reaction becoming ill might miscarry. There might be a concern that if a woman had a reaction and pyrexia that could cause developmental damage in the first trimester. In the third trimester, a reaction might lead to premature labour and a permanently damaged

infant. But taking blood for a pre-deposit would only risk anaemia and maternal symptoms in all trimesters.

c. Did you/the Department at the Hospital ever receive guidance from the NBTS regarding the risks associated with first and third trimester pre-deposit of autologous blood?

51. I do not believe I or the department at the hospital received guidance from the NBTS regarding the risks associated with first and third trimester pre-deposit of autologous blood.

d. Did any patients under your care raise concerns about first and third trimester pre-deposit of autologous blood? If so, what steps, if any, were taken to address these concerns?

52. No patient under my care ever raised concerns about pre-deposit of blood, in any trimester.

27. The enclosed guidelines for autologous transfusion state that 'in pregnancy, the haemoglobin should exceed 10g/dl' [page 3 of NHBT0110350]. Was this guidance different to the usual guidance that applied to when a patient would receive a transfusion?

53. I have read NHBT01103560 where it states that in pregnancy the Hb should exceed 10g/dl. I take this to mean that it would not be safe to remove blood for storage from a woman under this level, rather than it being compared to guidance that applies when a patient would receive a transfusion.

28. Were there any circumstances where red blood cell concentrate transfusions would be used instead of whole blood? Please explain:
a. The circumstances in which red blood cell concentrate transfusions were considered necessary, and preferable to other types of transfusion;
b. Approximately how often this practice occurred;

c. The perceived benefits and risks of red blood cell concentrate transfusions;

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

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

54. I do not understand this question. Red cell concentrates were normally used, rather than whole blood. I recall a traditional idea from senior consultants when I was training in the early 1980s that they preferred fresh and whole blood as they felt it clotted better and ongoing post partum haemorrhages would end earlier (ad see Exhibit 10). At the time I would have understood and believed this. My understanding is that change came from the Blood Banks in terms of what they would supply, which became red cell concentrate rather than whole blood although I do not recall the timescale.

29. The enclosed guidelines for the clinical use of red cell transfusions state that 'there is no universal trigger for red cell transfusions i.e. a given level of haemoglobin at which transfusion of red cells is appropriate for all patients,' and that 'clinical judgement plays a vital role in the decision to transfuse red cells or not' [page 2 of NHBT0006696_002]. With reference to your knowledge and experience at Guys' & St Thomas' Hospital, please comment on the factors taken into consideration when choosing to transfuse red blood cells to patients, other than a patient's haemoglobin level, and whether those factors changed over time.

55. With respect to a trigger for red cell transfusions, I agree there is no universal trigger and that the factors taken into consideration are those suggested in NHBT0006696. These did not change over time, and would relate most to the size of acute blood loss, maternal clinical condition (symptoms and signs), the size of the fall in Hb from the third trimester blood sample (i.e. a fall from 10.0 g/dl to 8g/dl would be less worrying than a fall from 12.5g/dl to 7.5 g/d).

30. Were there any circumstances in which plasma transfusions (including fresh frozen plasma) would be administered to patients under the care of the Obstetrics Department at Guys' & St Thomas' Hospital? Please explain:

56. There were no circumstances I can recall where a patient under the care of the Obstetrics department was administered a plasma transfusion alone.

a. The circumstances in which plasma transfusions were considered necessary, and preferable to other types of transfusion and whether the position changed over time;

57. Fresh frozen plasma would be administered to prevent and correct the consumption of clotting factors in large haemorrhages. See exhibit WITN6978011.

b. Approximately how often this practice occurred;

58. This practice occurred with most transfusions over 4 units in size.

c. The perceived benefits and risks of plasma transfusions;

59. The perceived benefits were that stopping life threatening haemorrhage. Plasma would be particularly necessary and beneficial in large, concealed abruptions (where a large clot forms in the uterus). The risks would have included infection.

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

60. I do not know what measures were taken to minimise infection

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

61. I do not believe patients and relatives would have had the opportunity to get information and give informed consent in most cases, due to the urgency to control bleeding, and the decision making about use of blood products taking place when most were unconscious under general anaesthetic. If they were having spinal or epidural anaesthesia, they would be informed in general terms what was going on.

31. The Inquiry has received evidence 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 Guys' & St Thomas' Hospital? If so, please explain in as much detail as you are able to, ensuring your answer addresses:

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

b. Approximately how often this practice occurred;

c. The perceived benefits and risks of fresh warm blood transfusions;

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

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

In answering this question you may be assisted by the enclosed guidelines on transfusion for massive blood loss by the British Committee for Standardisation in Haematology Blood Transfusion Task Force [NHBT0000037_013].

62. I have read NHBT0000037_013. Throughout my entire medical career, from being a medical student in 1976 onwards, I have never heard of fresh warm blood being donated by hospital staff and being donated to patients in any emergency. It would obviously be dangerous for the risk of incompatibility, let alone a reaction or infection risk. The only (theoretical) circumstance I ever heard of giving fresh blood was of taking a sample and giving a small transfusion from a mother to a fetus if there was blood loss from fetal cord blood sampling causing fetal bradycardia. Even so, I never heard of it actually happening.

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

63. The groups in question 3 did not create any policies relevant to the Inquiry's Terms of Reference.

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

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

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

c. Transfusion policy induction procedure for new staff;

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

e. Promotion of new information regarding transfusion matters;

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

g. Blood transfusion record keeping and documentation;

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

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

j. Consent for blood transfusion

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

64. The committees in question 3 did not discuss matters to do with blood transfusion.

34. 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 obstetrics and gynaecology.

65. These committees did not create any specific transfusion policies.

35. Was there a Hospital Transfusion Committee at Guys' & St Thomas' Hospital? If so:
Please provide a brief overview of the Committee, including when the Committee was created, its roles and responsibilities at Guys' & St Thomas' Hospital, and its relationship with the Obstetric Department.

With reference to any of the matters identified in Questions 27 and 28 of this request, please outline any significant policies or practices related to blood transfusion established by the Committee.

66. I believe there was a Hospital Transfusion Committee at Guys' and St Thomas' Hospital that my obstetric anaesthetic colleague, Dr Geraldine O'Sullivan attended. I am unable to give any more information.

36. Please consider the enclosed guidelines for blood transfusion and the management of transfused patients produced in 1999 in collaboration with the Royal College of Surgeons of England [AHCH0000049]. Were any of these recommendations implemented during your time at Guys' & St Thomas' Hospital, or any other institution at which you have worked, either before or after the publication of this document?

67. I have read the attachment AHCH0000049. The vast majority of the recommendations (for example, the request form, patient identity check, storage and transfer requirements and prescription) look like the usual good care that was implemented in hospitals I worked in before and after the document was published.

37. Please consider the enclosed letter dated 17 September 1987 from Dr Harold Gunson to Professor V R Tindall regarding the viral safety of blood transfusions. Dr Gunson states that the advent of testing and improved quality assurance measures means that 'the risk involved with the transfusion is far less than the dangers associated with the clinical risks of the condition for which the transfusion is given' which he believed was particularly applicable to obstetric and gynaecology patients [NHBT0203709]. Please explain how the need to balance the risks of not transfusing against the risks of infection has influenced your approach to transfusing patients and how, if at all, this changed over time.

68. I have considered the letter [HNBT0203709]. The need to balance the risk of not transfusing against the risks of infection has always influenced my practice and this has not particularly changed with time. With seniority I would have known more on both sides of the equation. I would have seen more 'near-misses' and maternal deaths on the one hand, and become more adept at not acting as well. But, on balance, I'd agree that the risks of not transfusion would be 'particularly applicable for obstetric patients'.

38. 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 Guys' & St Thomas' Hospital, 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?

69. I have seen Mr Hayhoe's statement [HSOC0018830]. I was unaware of patients being given blood transfusions with red blood cells imported from the USA during my tenure at Guy's and St Thomas' (or anywhere I worked after 1985). I would have been worried about this had I known it, given my understanding that the UK supply (from altruistic sources) was much safer than products sourced from the USA. I would have worried about imported and pooled products.

Section 4: Knowledge of risk

General

39. When you began working as an obstetrician, 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?

70. I began working as an obstetrician in 1983. My sources of knowledge about blood products were the general basic knowledge gained from medical school, supplemented by what I read in obstetric textbooks (e.g Dewhurst), and medical journals. I knew about the German HCV outbreak in the late 1970s from anti-D that was given to prevent rhesus isoimmunisation as that was specific to obstetric care. I'd have been particularly sensitive to information in both directions of risk from bleeding, and risk of infected blood. My mother's life was probably saved in the 1950s following a PPH. two returns to theatre and a blood transfusion after my own birth in 1950s. I lost two childhood friends, brothers with Christmas (Factor X) disease, who died of AIDS contracted by their use of blood factors before HIV became treatable with anti-virals. One died of a 'mysterious' infection in 1981, the other was identified infected as HIV soon afterwards, and he died of AIDS in the late 1980s before antivirals were developed. My knowledge and understanding developed over time reading journals, discussions with colleagues.

Hepatitis

40. 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?

71. My sources of knowledge were similar as above. My understanding about HBV and HCV were that they were being tested for once identified. Even if the risk of known blood borne viruses was small (or eliminated by testing), new and unknown pathogens might exist and be transmitted. Every woman receiving a transfusion should be reassured it was tested, but warned that it could not be guaranteed infection free.

HIV and AIDS

41. When you began work as an obstetrician, 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?

72. When I began working as an obstetrician, very little was known about HIV and AIDS. I remember working as a house officer at the Middlesex in 1982 and picking up an early case of a homosexual man with generalised lymphadenopathy during the preoperative surgical review for varicose vein surgery. The operation was cancelled as he was investigated by Genito-Urinary Medicine. My interest and understanding of HIV and AIDS was further developed whilst working in GUM. I was very alert to the risks of blood transfusion in the earliest days because of my friends with haemophilia. In the early days I would have been greatly reassured about UK blood donor practices and heat-treated products and as a junior doctor I would have reassured patients about the quality of the blood.

Other

42. If you were responsible for making decisions and actions on behalf of the Obstetric Department or any other departments 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.

73. I do not recall being involved in making decisions or actions on behalf of the Obstetric Department in response to known or suspected risks of blood borne infection.

43. Were any audits or surveillance programmes regarding the use of blood transfusions for obstetric/gynaecology patients conducted at Guys' & St Thomas' Hospital? If so, please explain these processes and the impact they had on blood transfusion standards and practice.

74. I do not recall any audits or surveillance programmes. It is possible that Dr Geraldine O'Sullivan, obstetric anaesthetist, performed these, and would have fed the results and recommendations back to the Obstetric Department, as I clearly remember her being up-to-date and keen to discuss developments in medicine. She was a voice of caution, and keen to keep blood transfusions down.

44. At Guys' & St Thomas' Hospital, were any efforts made to monitor the incidence of transfusion-transmitted infections in obstetric/gynaecology patients? If so, please explain these processes, the findings, and the impact they had on blood transfusion standards and practice.

75. I do not recall any efforts made to monitor the incidence of transfusion-transmitted infections in O&G patients. The senior consultants in the Department were also sensitised to the question of infecting patients as a junior obstetrician working at St Thomas' had been the unwitting source of operation-transmission with Hepatitis B in late 1980s and had to stop working as a surgeon.

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

a. What procedure did the Hospital have in place?

76. My understanding of the usual procedures in place to report adverse reactions or symptoms were as follows:
Regular monitoring of the patient observations & symptoms.

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

77. This procedure was not extended after discharge.

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

78. I do not think patients were asked to report any adverse reactions of symptoms within a certain timeframe.

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?

79. If clinicians were involved in cases with any adverse incident, they were required to report this via Risk Reporting. Maternity and gynaecology were early adopters of incident reporting and ahead of procedures in most of the rest of the hospital. In the mid-1990s and soon after my appointment as a consultant, we appointed a senior midwife as Risk Manager. She instituted formal risk reporting via a simple A4 form which would be posted and collected from cardboard boxes in staff handover rooms which she would collate, investigate, analyse and turn into appropriate actions (individual clinician and supervisor feedback, guideline development, education programmes, liaison with other departments etc.). Then we used a hospital wide triplicate form which was devised for internal departmental and hospital oversight. Eventually the hospital moved to the Datix electronic reporting system. The Blood bank had its own system for reporting incidents.

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

80. I am unaware of the details of any mechanism for the Hospital to report adverse reactions externally. The responsibility for investigating and learning from transfusion reactions or accidents (for example, blood group incompatibility) lay with Haematology and the Blood Bank laboratory. For example, I do recall one detailed investigation after a wrong blood group transfusion on one of our patients, as our department had to provide appropriate support for staff. The incident had started with a mislabelling mistake made by a medical student who had taken blood from a postnatal patient over a bank holiday weekend, but had also involved errors in the laboratory and when double checking the patient details. My learning was that there were something like over 50 points of vulnerability in the overall pathway where errors could occur that automation and barcoding of labels were trying to cut down in number.

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.

81. I was never involved in any efforts to trace potentially infected donors or recipients.

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

82. See previous answers.

Section 5: Treatment of patients

Provision of information to patients

47. Were you involved in discussions with patients regarding risks of infection by blood transfusion? If so, what information did you provide or cause to be provided to patients under your care at Guys' & St Thomas' Hospital about those risks prior to treatment commencing?

83. I would have been involved in discussions with patients about the indication for blood transfusion and its risks, mostly for inpatients, but some outpatients (eg: Jehovah's witnesses).

48. If the nature of provision of information changed over time during your employment as an obstetrician at Guys' & St Thomas' Hospital, please explain what changes occurred, and the reasons for any such change/s.

84. With respect to the provision of information, it did not change substantially over time with respect to infection

49. Did Guys' & St Thomas' Hospital have a process of informing patients that they had been, or might have received infected blood through a transfusion? If so, how were patients and/or their relatives informed? What, if any, involvement did you have in this process?

85. I do not think that Guy's and St Thomas' had a process of informing patients or their relatives that they had or might have received infected blood through a transfusion.

Response to risk

50. When you began working as an obstetrician/gynaecologist, what policies were in place regarding treatment for patients who suffered complications or adverse reactions following blood transfusion? How, if at all, did this change over time?

86. When I began working as an obstetrician/ gynaecologist, I was unaware that there were any policies in place regarding treatment for patients who suffered complications or adverse reactions following blood transfusion or polices for complications of blood transfusion.

51. How, if at all, did a patient's infectious status (including HIV, HBV and HCV) affect treatment decisions relating to future obstetric and/or gynaecological treatment?

87. A patient's infectious status should not have affected treatment decisions relating to future obstetric or gynaecological treatment. It was amazing to see the changes and improvements in the care of the infections (especially HIV) over time, but the specifics of obstetric and gynaecological care should otherwise have been the same as their peers. I was aware that there was fear of contagion, and some prejudice against patients which is why I took a leading role in setting up a multidisciplinary HIV clinic, and would always perform the caesarean sections myself, using universal precautions.

Consent

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

88. I am not aware that any patients under the care of Guy's and St Thomas' hospital were treated without their express or informed consent. We were aware of legal cases involving Jehovah's witnesses and the need to respect autonomy. The only time it

might have happened was in massive haemorrhage under anaesthetic when it would not have been possible to ask, blood being given using the doctrine of necessity.

Section 6: vCJD

53. 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.

89. I do not recall when I first became aware of vCJD or its possible transmission via blood transfusion, but likely it was at the same time as any other doctor who read the British Medical Journal and Lancet (which I subscribed to), who was aware of the news and who prescribed blood.

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

90. I do not know what measures were put in place at Guy's and St Thomas' Hospitals in respect of the risk of vCJD transmission by blood transfusion.

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

91. None of the committees mentioned in question 3 were involved in assessing or managing the risk of vCJD transmission.

Section 7: Other issues

56. 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.

92. I have had no complaints made about me to my employer, GMC or Ombudsman insofar as relevant to the Inquiry's terms of reference.

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

93. I have no further professional comments for the Inquiry. I have reflected on matters whilst preparing this statement as I am also personally connected to the matters in hand. Undoubtedly, all front-line clinicians in the NHS rely upon the National Blood Transfusion Service as we change individual practices in the face of new information (some of us being leaders or laggards at various times), and all of which have opportunity costs even when automated. In the 1970s I was trained to be proud of the NHS and especially of the 'Gift Relationship' as described by Richard Titmuss. We believed this example of collective altruism was the first, and most powerful, bulwark in ensuring a safe blood supply and protecting patients from infection and harm. I have been a regular blood donor since being a medical student, and have witnessed many beneficial changes at the donation centres. I delight in seeing research and randomised controlled trials being used to change practices such as what we drink or the chairs we lie in as this gives me confidence in the scientific approach of 'self-correction' and continued learning. Clinicians were, and largely remain, unaware of the buying and selling and international trading of products that we give freely as donors. We trusted the NBTS to 'do the right thing' in terms of risk aversion, balancing risks, developing policies, learning and putting matters right, even after various disasters, such as the outbreak of HCV from anti-D and the HIV acquisition by haemophilia sufferers. If the Inquiry finds mistakes were made, I hope that an 'Appreciative Enquiry' approach will be taken (alongside any 'name, shame, blame, defame game' if it proves necessary for any egregious individual behaviour). This considers what 'works' and goes right, as well as any

underlying driving forces (for example, the cutting of corners driven by financial or other pressures), as few people are deliberately reckless or negligent. Albeit, it is far too late for many including my two childhood friends who died of haemophilia and AIDS in the 1980s, I am grateful for the effort being put into learning and retribution.

58. 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.

94. I do not have any other potentially relevant documents.

Statement of Truth

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

Signed: GRO-C

Dated: 16th February 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
01/01/1997	Journal of Obstetrics and Gynaecology, 'Near-miss' obstetric enquiry	WITN6978002
05/05/2001	BMJ 'Incidence and predictors of severe maternal morbidity: case-control study'	WITN6978003
01/02/2003	BJOG: An International Journal of	WITN6978004

	Obstetrics and Gynaecology, 'Postnatal morbidity after childbirth and severe obstetric morbidity'	
01/02/2006	Journal of Obstetrics and Gynaecology, 'Obstetric hysterectomy in a population of South England'	WITN6978005
01/01/2005	Journal of Obstetrics and Gynaecology, 'Coping with placenta praevia in a DGH setting and words of caution'	WITN6978006
18/04/2012	Abstract. 'Unprecedented rates of PPH: a prospective observational cohort study of blood loss in childbirth (The Stop Study)'	WITN6978007
29/01/2010	Human Reproduction. 'A complicated IVF twin pregnancy'	WITN6978008
Undated	Our campaign to reduce multiple births, https://www.hfea.gov.uk/about-us/our-campaign-to-reduce-multiple-births/	WITN6978009
12/02/2014	BJOG, An International Journal of Obstetrics and Gynaecology, STOP study, 'Reporting errors, incidence and risk factors for postpartum haemorrhage and progression to severe PPH: a prospective observational study'	WITN6978010
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