Witness Name: Dr Dafydd Thomas
Statement No.: WITN6973001
Exhibits: WITN6973002-WITN6973005
Dated: 9 February 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR DAFYDD THOMAS

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

I, Dr Dafydd Thomas, will say as follows: -

Section 1: Introduction

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

1. Dafydd Wyn Thomas

GRO-C

MBChB 1978, FRCA 1984

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. I was appointed as Consultant in Anaesthesia and Intensive Care in

February 1989 to the then West Glamorgan Health Board, my roles were based at Morriston and Singleton Hospitals.

3. College Tutor, Deputy Regional Educational Advisor (1999-2003) and Regional Advisor (2002-2005) for Royal College of Anaesthetists.
Secretary for Society of Anaesthetists Wales (3 year role)

Joint Founder of the South Wales Anaesthetic Course (SWAC) Inaugural Chair of Hospital Transfusion Committee (193-2003) Chair of the Patient Safety Board, National Welsh Informatics Service Examiner for Primary and Final FRCA Examination Royal College of Anaesthetists

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

4. Chair of the Rational Blood Committee (RBC) (Late 1990's until restructured by Welsh Government)

Chair of the Blood Implementation Group Welsh Assembly (from 2005)
Chair of the Clinical Advisory Group (from 2005)

Member of the Blood Policy Group 9 (from 2005)

Invited observer on National Blood Transfusion Committee (England) from 2001 Member of Appropriate Use of Blood Committee
Member of Autologous Transfusion Working Party

Member of Autologous Transfusion Special Interest Group British Blood Transfusion Society (BBTS)

Council Member BBTS

President of BBTS (2009-2012)
Board Member Network for the Advancement of Transfusion Alternatives (NATA) 2005-2018

Chair NATA 2013-2017

Chair Serious Hazards of Transfusion (SHOT) Steering Group 2012-2017 Co-opted member of International Society of Blood Transfusion (ISBT) Organising

Committee

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.

5. I have had no involvement in any such inquiries

Section 2: Morriston Hospital

5. Please describe:

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

6. I was initially appointed as a Consultant Anaesthetist with a special Interest in Intensive Care. My on-call duties related solely to covering the Intensive Care Unit (ICU). However, my working week also included my role as an anaesthetist to two all-day Vascular Surgery lists, one Trauma and Orthopaedic list, and two half days spent on the Obstetric delivery suite. Two half days were spent on ICU ward rounds. Over my career I concentrated on helping develop the ICU from an 8 bedded unit to a 26 bedded unit. During this period, I changed my clinical commitments to become entirely ICU-based.

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

7. My roles as described above often involved treating patients who were experiencing extensive blood loss, often requiring blood transfusions.

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

transfusion.

8. Patients admitted to Intensive Care or those presenting for elaborate surgery may coincidently have been diagnosed with HIV, HCV or HBV, but my care was not directly related to this diagnosis although clinical care of such cases required increased vigilance.

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

a. Describe the roles, functions and responsibilities of the Anaesthesia Department ("the Department") within 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, emergency, obstetrics/gynaecology, 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.

9. The department facilitated numerous specialists to perform their surgical interventions in an efficient and pain-free way. All roles with other departments could involve blood loss and the anaesthetist's role in deciding blood transfusion necessity was integral to the role. The decision to transfuse was often based on the circulating level of haemoglobin and the cardiovascular stability of the patient. In addition, the patient's age and co-morbidities were a consideration.

10. During my career, the transfusion decision became much more elaborate as infective risk from blood transfusion came to the fore, and various other physiological and pathological considerations were examined more closely to try and minimise the risk of transmitting infection by unnecessary transfusion. The department did not have a particular policy on transfusion, but individual anaesthetists made the decision when transfusion would be necessary. This decision varied between anaesthetists and depended on their grade of experience and patient need. It also needs to be appreciated that the role of

the anaesthetist at this time was developing into one of peri-operative clinician, but ongoing clinical follow-up was usually done by the operating surgeon if the patients were back on the ward, hence the decision for post-operative transfusion was often made by the surgical team.

11. Decisions for Intensive Care patients were instigated by the Intensive Care consultant, after discussion with the admitting consultant where possible. When I started my consultant career, there was no protocol or guidance in place to try and help guide transfusion practices. It was often the Medical Laboratory Scientific officers (MLSO), later known as BMS's (Biomedical Scientists), who were responsible for cross-matching and issuing the blood components and who questioned the requesting clinicians about the need for transfusion. There was great inconsistency in this and many clinicians were irritated by having their decision questioned. Around this time it was apparent that some more formal guidance and policies were required.

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

12. As described above, the decision to transfuse a patient undergoing a surgical procedure is often a dynamic one depending on the type of surgery, the decision to transfuse depending on the amount of blood loss and physiological response of the patient. At my hospital there was always a member of staff available to crossmatch and issue blood components from the blood bank, and of course by definition for operative surgical use, the presence of the surgeon and anaesthetists during the procedure and nursing staff during the recovery from surgery and anaesthesia.

13. During my time at Morriston Anaesthetic Department, I became the interested individual who took a role in advising the Department on blood transfusion policy in my early years as a consultant and developed the role instigating the formation of the Hospital Transfusion Committee (Chairing the Committee between 1993 and 2003). Apart from my own practice which

involved the use of autologous transfusion and the introduction of restrictive transfusion practices, I had no primary role, and neither did the department, in caring for patients who developed Hepatitis or HIV. Infected patients were only identified in retrospect when investigation of recipients of infected blood products was undertaken by the Regional Blood Service. There were protocols in place of course to ensure that patients who had been identified as infected would be treated carefully to minimise transmission to staff or other patients. Many things changed as a result and standard operating protocols changed e.g., wider availability of non-sterile gloves, visors to prevent blood hitting the faces of staff during an operation, and safe needle and sharps disposal etc.

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;

14. Blood was usually requested in advance by the surgical team depending on the historic need for the procedure being performed. A crossmatch sample was sent with a blood transfusion request form.

b. What the record keeping requirements were; and

15. Initially a record of blood issued was kept by the blood bank, a record of blood components transfused was written on the anaesthetic record and later the ward recorded on the patient's fluid balance chart. Over my career, the documentation and traceability improved tremendously in response to a clinical need to do so. Government involvement, Regional Blood Centres, the developing haemovigilance schemes and the European Blood Directive all played a significant role in this.

c. What the patient was told before the transfusion?

16. In my experience the information given to patients in the late 1980's and early 1990's was minimal, other than warning of the risk of needing a

transfusion during some more major procedures, and implicit in the consent they gave the surgeon to do whatever may become necessary.

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;

17. I interacted with the Medical Director and the Chief Executive of the Welsh Blood Service.

b. How frequently you interacted with them; and

18. I interacted with them on a regular basis.

c. What your interactions were primarily concerned with.

19. Mostly about educational issues and clinical blood use auditing. It was obvious to me at the time that many clinicians continued to use blood as they always had. Of course, since the inception of a blood transfusion service in the UK the lifesaving availability of a regular blood supply to hospitals had saved many lives and enabled more complicated surgical procedures which often led to significant blood loss. The replacement of this blood loss had been for decades seen as an effective way of ensuring better survival and quicker recovery from surgery. The realisation that Hepatitis B and C as well as HIV could be transmitted via blood transfusion altered the balance of risk to patients and made a re-examination of alternatives an appropriate and sensible course.

20. In addition, as blood components have a finite shelf-life, Blood Services are constantly at the mercy of donor behaviour and availability, which on occasion may lead to supply and demand issues.

21. Promotion of alternatives to allogeneic transfusion, e,g. Cell salvage autotransfusion became a talking point at our meetings. Clinical use of blood and the use of intravenous iron were also topics that were discussed, to help

lessen demand on allogeneic supplies. We were concerned that all new suggestions did not impose a greater risk and felt the further education of the clinicians about the risk of both allogeneic transfusion and the alternatives was needed.

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

22. The situation in Wales meant that the Regional Blood Transfusion Centre was also the National Transfusion Service. However, due to my interest and interaction with Welsh Blood Service (WBS), I met several medical directors of other Regional and National Transfusion Centres in England, Scotland and Ireland. These were not formal relationships and often depended on them wanting me to contribute to educational meetings they were running. Eventually, of course I did have a relationship with the National Blood Transfusion Service and an invited member of a number of Committees Chaired by Angela Robinson, Medical Director of NBTS, but this was not a formal relationship on behalf of the Anaesthetic Department.

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

23. I do not have data on this and due to my retired status am unable to gain access to records. I have some audit data related to clinical use which may be of interest. I need to explain that the computer systems that were in place during the 1990's were unable to give precise data on many issues we needed to assess. They would be unable to calculate how many transfusions were instigated by the Anaesthetic Department for example; only how many units of blood were issued to each department or specialty in the hospital. Lookback audits required painstaking work by an individual to trace the identity of each blood component and its destination and recipient. The other problem was, and still is in many hospitals, the state of the clinical notes which at the time were completely paper-based and often incomplete.

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.

24. I was not aware of any patients who subsequently developed HIV, HCV or HBV under the care of the department. I am sure there must have been some, particularly in the 1980's prior to my appointment.

Research

25. I will refer to exhibit **WITN6973002**, slide 11.

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.

26. The research undertaken supervised by myself was in the area of evaluating the use of cell salvage autotransfusion in orthopaedic surgery, running two RCT's with the School of Postgraduate Studies based at Morriston Hospital at the time.

27. (Shenolikar A, Wareham K, Newington D, Thomas D, Hughes J, Downes M. Cell salvage auto-transfusion in total knee replacement surgery. Transfus. Med 1997;7:277-80.

28. Thomas D, Wareham K, Cohen D, Hutchings H. Autologous blood transfusion in total knee replacement surgery. Br J Anaes 2001;86:669- 73.) Please see exhibit **WITN6973006**.

29. My colleague Sue Catling undertook a research project of use of leucocyte depletion filters with cell salvaged blood in Obstetrics.

30. (Catling, S.J., Williams S., Fielding, A.M. (1999). Cell salvage in obstetrics: an evaluation of the ability of cell salvage combined with leucocyte depletion filter to remove amniotic fluid from operative blood loss at caesarean section. International Journal of Obstetrics and Gynaecology, 112(2), 131-132.)

31. I also undertook research into the effect of leucoreduced red blood cells with a grant awarded by the Welsh Office for Research and Development. The report was completed but collection of data occurred during the late 1990's and the decision to leucoreduce blood components in the UK in 1999 meant that we could not continue our randomisation to receive non-leucoreduced blood or leucoreduced blood. As a consequence, our study became observational and not published as an RCT.

32. The Hospital became involved in several National Comparative Audits on clinical use of blood run by John Grant Casey.

13. Please list all research studies that you were involved with in any other relevant positions of employment (including any of the committees listed in your answer to question 3) insofar as relevant to the Inquiry's Terms of Reference, ensuring your answer addresses:

33. I will refer to exhibit **WITN6973002**, slide 2 when answering the following questions.

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;

34. The research referenced above was randomised controlled studies run in conjunction with the Postgraduate School at the time based at Morriston Hospital. Full informed consent was obtained prior to randomisation. The

hypothesis was that the implementation of intraoperative cell salvage techniques during their knee replacement surgery would not impact on their allogeneic blood use. The final analysis showed an impressive reduction in allogeneic red cell transfusion. The analysis of the second larger study showed that even without ICS, allogeneic blood transfusion can be dramatically reduced with educational provision and withholding blood transfusion, using a trigger for transfusion of 90g/L

b. Your involvement in this research; and

35. I designed the trial and acted as clinical lead and main grant applicant.

c. Details of any publications relating to the research.

36. Detailed above.

14. The Inquiry understands that you have made significant contributions to the field of autologous blood transfusion. 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.

37. Please see slide 3 of **WITN6973002**.

38. My involvement with autologous transfusion commenced almost as soon as I was appointed to my consultant position. One of my responsibilities was to anaesthetise patients undergoing infra-renal aortic aneurysm surgery. At the time the request for blood to be crossmatched, in an anticipation of large blood loss, was typically for 6 to 10 units. An anaesthetic department assistant working with me at the time had also trained as a perfusionist to assist during heart lung by-pass in a previous hospital and he was offered a temporary loan of a cell salvage autotransfusion device. We reviewed the literature and noted its use in vascular surgery, mainly in the US. After discussion with the vascular

surgeon, I worked alongside, we decided to start using the machine during infra-renal aortic surgery.

39. Over the ensuing 3 years we audited the use of such a device and noted it could contribute to a decrease in the volume of red cell transfusion administered to these patients.

40. A business case was made to theatre management to purchase our own cell salvage machines and starting in 1992 we prospectively audited blood use in this type of surgery. At the same time our success with its use was presented to other relevant surgical specialties and we agreed to conduct an RCT in knee replacement surgery to assess its effectiveness and safety in this type of surgery (both studies mentioned above). At the time I was unaware how little this technique was being used across the UK, and I was introduced to three other clinicians using the devices.

41. (Dr Michael Desmond Anaesthetist Liverpool Cardiothoracic Centre, Mr John Thompson Consultant Vascular Surgeon, Royal Exeter and Devon Hospital and Mr Bob Jeffries Cardiothoracic Surgeon, Aberdeen Hospital.)
We all became members of the Autologous Transfusion Special Interest Group of the BBTS and tried to promote increased use of such devices throughout the UK starting with a Consensus Conference held at the Royal College of Physicians, Edinburgh in 1995. A repeat consensus assessing the uptake of such techniques was repeated at the same venue in 1998.

42. As I became more involved in promoting the use of such devices I collaborated with the Chief Medical Officer for the Welsh Office and later the Welsh Assembly and a number of Medical Directors of the Welsh Blood Service and Medical Director of the NBS. I was involved in all three Better Blood Transfusion meetings instigated initially by the CMO (England) by Kenneth Calman.

43. I approached the Association of Anaesthetists, suggesting the production of one of their guidance documents about red cell blood transfusion to

educate the membership about issues surrounding appropriate use of blood and subsequently chaired a committee writing this booklet. Further involvement with guidance about Blood Component (2005) use and Intraoperative Cell Salvage and Massive Haemorrhage was undertaken. All these guidelines have more recently been updated and amalgamated by a new writing group at the AAGBI. Representing the Royal College of Anaesthetists, I sat on a number of writing groups for the British Committee for Standards in Haematology (BCSH) and contributed to NICE guidance (exhibit **WITN6973004**). Some examples are contained within (exhibit **WITN6973005**)

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 practices during your employment? If so, please outline in as much detail as possible the policies in place which would prompt you to transfuse in the course of surgery or critical care, and how those policies changed over time.

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

44. As stated above, my initial involvement in blood transfusion issues was confined to my own practice between 1989 and 1992. Apart from introducing cell salvage autotransfusion to Morriston Hospital, it appeared safe practice in Intensive care to try and limit transfusion of blood components strictly according to clinical need, particularly as all patients were monitored closely and with the aid of regular arterial blood gas assessments which not only allowed assessment of haemoglobin levels but also adequacy of global oxygen delivery and acid base balance. Generally 90gm/L was accepted as

a safe level in almost all patients and transfusion of red cell transfusion was limited in these patients if their haemoglobin was above this level. It was not until 1999 that Hebert published the TRICC study confirming this type of transfusion principle was safe.

45. Please refer to slide 4 of **WITN6973002**.

46. In 1993 I was involved with the then Senior Haematologist and Chief Blood Bank MLSO in setting up a Hospital Transfusion Committee to monitor and audit clinical blood use, to introduce a minimal blood ordering schedule, to monitor the developments in autotransfusion and to disseminate articles and information on best transfusion practice. In this venture we received support from the then Medical Director of WBS Dr Tony Napier, particularly keen to start understanding how blood transfusion was being used in the clinical setting as there was very little data available at the time.

47. We introduced a simple guidance on which to base our transfusion of red blood cells for all patients in the hospital. This was guidance and not a protocol.

i. Red cells transfusion ideally be requested for patients whose Hb was lower that 90gm/L
ii. To this end a recent assessment of Hb should have been undertaken
iii. The clinician had the right to over-rule the questioning of the Blood bank MLSO if the clinician deemed the clinical necessity urgent. All such instances would subsequently be followed up to investigate if the actions of the clinician was justified.

48. Please refer to slide 5 in exhibit **WITN6973002**.

49. The multi-disciplinary membership of the HTC received regular reports on appropriate use, and of course inappropriate clinical instances, to enable them to feedback hospital policy to their team members.

50. In general, unless the patient was suffering from massive bleeding, red cell units were released one at a time.

51. Considerations for the time of transfusion, risk of infection and cost considerations were relayed to hospital departments via the HTC as they were developed and the data became available. As mentioned earlier, there was very little data around in the early 1990's on clinical usage and that predated the SHOT initiative, which only occurred after 1996. At this time,testing of all blood components was at a very advanced stage, and donor questionnaires led to a significant decrease in risk. Prior to this, clinicians and patients were aware that HIV and Hepatitis B and C could be transmitted via blood component therapy but exact risk was difficult to quantify.

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

52. Involvement of Anaesthetists and Intensive Care consultants in transfusion mostly involved packed red cell transfusion, in ITU patients and acute haemorrhage, fresh frozen plasma and platelet transfusion were common.

53. The use of FFP to reverse coumarin effects, e.g. warfarin, was altered gradually in part due to the availability of PCC's and the introduction of other oral anticoagulants such as Newer Oral anticoagulant drugs (NOADS) which required less monitoring and once daily administration due to shorter half-lives.

17. How, if at all, did policies for blood transfusion differ for paediatric patients? Please explain in as much detail as you are able to, and with respect to different types of blood transfusion.

54. My experience with paediatric patients was limited due to the relocation of paediatric intensive care to Cardiff.

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 how the level at which transfusion was deemed necessary may have changed over time.

55. As described above we quite early on introduced a haemoglobin level of 90gm/L to trigger the need for transfusion. In stable and younger intensive care patients without co-morbidities this trigger was often lower, perhaps as low as 7gm/L

56. The practice had become more commonplace but we did not feel we needed a more aggressive policy of withholding transfusion, and opinion over the years has tended to come to the same conclusion in published research and guidance.

19. 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.

57. I would agree entirely with the document but although not dated I would consider that it was produced in the early 90's from its appearance and content.

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

58. At this stage at Morriston Hospital we were already discouraging single unit transfusions.

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?

59. The implementation of the guideline to only transfuse if the patient's

haemoglobin was below 90g/L meant that we had to actively encourage the use of single unit transfusion, as we were trying to reduce patient exposure to allogenic components

60. Effectively a two-unit transfusion doubled the perceived risk. As we had a policy introduced to avoid unnecessary transfusion already, monitoring and audit of its implementation gave us more information and understanding about clinical transfusion practice and allowed us to educate clinicians on the principle of withholding transfusion according to clinical need.

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

61. There were many instances where patients were over-transfused in my clinical opinion. However, it needs to be taken in the context of what was the clinical practice of the majority of clinicians at the time. Patients were often transfused to the level of haemoglobin they had pre-operatively. Some clinicians said that in Total Knee Replacement surgery they always transfused 2-3 units and our audit confirmed this. Over time with the production of our two RCT's in this area and the 90g/L transfusion trigger, we managed to reduce the incidence of allogeneic red cell transfusion in TKR surgery from 82% to 27% and then to 7%. This occurred due to the introduction of a transfusion trigger and the use of cell salvage autotransfusion.

62. Please refer to slides 6-8 of **WITN6973002**.

20. The enclosed document reports on a study conducted by Mallet et al (2000) titled 'Reducing red blood cell transfusion in elective surgical patients: the role of audit and practice guidelines', published in *Anaesthesia*

[NHBT0086594_003]. The study found that 'haemoglobin was measured infrequently prior to transfusion' (p1). With respect to your experience at Morriston Hospital, please explain the process of measuring a patient's haemoglobin count, including the frequency with which it was monitored.

63. I remember Sue Mallet's paper well but as you may have gathered, we had implemented our policy about seven years earlier and tried to facilitate and encourage contemporary haemoglobin assessments. Depending on the urgency of the need for the blood, e.g. major haemorrhage, haemoglobin assessment may have been accepted on an arterial blood gas sample or later on by the use of point of care machines such as Haemocue.

21. The enclosed document contains guidance on red cell transfusion published by the Association of Anaesthetists of Great Britain and Ireland in 2001 [DHSC0020813_059]. Page 5 of the booklet (page 6 of DHSC0020813_059) notes that 'patients should not be transfused to achieve a *normal* haemoglobin concentration'. Please comment on this in light of your experience of practising during your tenure at Morriston Hospital, ensuring your answer addresses the considerations that are taken into account when deciding to transfuse a patient other than haemoglobin concentration.

64. I have already partly addressed what I considered inappropriate peri-operative transfusion. In patients that are cardiovascularly stable, i.e. a normal or acceptable pulse and blood pressure, who are adequately hydrated, oxygen delivery to the tissues is not compromised to a dangerous level, and withholding transfusion minimises exposure to allogeneic blood components. Often patients regain their haemoglobin level relatively quickly over the post-operative weeks following surgery providing the patient is not iron deficient. Dynamic physical activity may be difficult due to the lower haemoglobin level but is rarely an issue in the period directly after surgery.

65. The production of the AAGBI booklet allowed the spread of these principles across the members of the AAGBI. It was published in 2001. In fairness, practice did change and the NHSBT blood stocks management scheme monitored a decrease in red cell use in the subsequent years in part

due to these guidelines on transfusion. - or I would like to believe so.

66. Please see slides 9 and 10 of exhibit WITN6973002.

22. In the enclosed publication titled 'Usage in Anaesthesia', you state that 'clinicians suddenly realised that there was an easy alternative to allogeneic blood in elective situations, which was, accepting a lower postoperative haemoglobin level in our patients... avoiding unnecessary transfusion remains a practice that many UK practitioners have yet to adopt' [NHBT0015709_004].

a. At what date did a 'lower postoperative haemoglobin level in patients' become generally accepted within the anaesthesia profession?

67. There is no doubt that the AAGBI guidelines meant that anaesthetists had a publication on which to base their practice and if necessary, defend their actions to their surgical colleagues, many of whom remained sceptical.

b. With reference to your experience at Morriston Hospital and your knowledge more generally, please explain the relationship between haemoglobin levels and the unnecessary administration of blood transfusions to patients.

68. More recently, up until retirement in March 2020 I still had to debate the merits of allogeneic transfusion even when they had haemoglobins in excess of 90g/L. Hebert in his paper in 1999 NEJM found that transfused patients with non-leucoreduced blood seemed to have detrimental effects probably related to a degree of immune modulation when compared to those on a restrictive transfusion policy. Also there continued to be inappropriate ordering and wastage of un-transfused blood components which were ordered in haste and not kept in a temperature-controlled manner.

23. The enclosed paper titled 'Lack of haematological and biochemical consequences following autologous blood transfusion' states that a primary benefit of autologous transfusion is it may 'diminish the risk of viral cross

infection' [NHBT0040771_001]. Please explain:

69. This paper pre-dates my appointment as a consultant but fuelled my enthusiasm to use such devices outside the surgical area of liver transplantation and cardiothoracic surgery.

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

70. The use of autotransfusion was very limited at the time of this publication and this lack of experience with its use meant that it could not be suddenly employed and clinicians had to be persuaded that it was not detrimental to their patients. The necessity was the risk of infection from the use of allogeneic blood, but clinicians needed to be persuaded that it could be beneficial. This required education and active promotion of the techniques.

b. Approximately how often this practice occurred;

71. Prior to 1989 this practice did not occur at Morriston Hospital. I include the uptake of cases after the purchase of two cell salvage devices in April 1992.

c. The perceived benefits and risks of autologous transfusions;

72. The perceived benefits primarily were the avoidance of allogeneic risk. However, there was reluctance by many clinicians and transfusion haematologists because they questioned the quality of the autologous blood, which was untested and not cross matched. In addition, they rumoured that free Hb may be present and other biochemical differences such as the effects of haemolysed blood cells leading to altered potassium levels. Gilbert Park's short paper alluded to the apparent safety of such devices and this has been confirmed by more widespread use over the last 30 years.

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

73. All patients were verbally informed that autotransfusion may be required

prior to consenting for surgery, and further explanation given during the anaesthetist's pre-operative visit. Initially it would be fair to say that informed consent was rarely given in a way expected today. In my experience I never saw any patient harmed due to cell salvage autotransfusion and saw many massively bleeding patients benefit greatly from its use.

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

74. As I was appointed as a consultant after the introduction of more rigorous testing for these viruses, I did not perceive that any one component carried a higher risk. It became apparent later in my career and through my involvement with SHOT, that viral risk became a very low risk compared to the dangers and pitfalls of clinical transfusion practice e.g. positive patient identification, traceability, labelling of blood samples for cross match procedures etc.

25. Please consider the enclosed minutes of a meeting of the CRAG (Clinical Resource and Audit Group) Blood Transfusion Working Party held on 1 July 1992 [SBTS0003883_090]. Page 3 of the minutes contains discussion about the use of whole blood to treat paediatric patients.

75. My experience in paediatric practice is limited and now long ago.

a. With reference to your experience and the considerations mentioned in the meeting minutes, please explain why treatment policies regarding whole blood transfusion may differ in the context of paediatric patients.

76. My interpretation of these minutes leads me to believe that in smaller weight patients circulatory overload can occur more easily and there seemed to be a reluctance to overload the paediatric patients with an excess of OAS.

b. The minutes state that anaesthetic staff had expressed concerns 'regarding the difficulties of administering OAS and standard RCC through paediatric

cannulae'. Please explain the difficulties referred to in this statement.

77. To avoid circulatory overload red cell concentrates would seem a sensible solution, however in small children venous access can be very difficult and gauge of the canula used may be very narrow. Thus, flow via the canula would be slow if red cell concentrate was used due to its increased viscosity.

26. Please consider the enclosed document on minimising the perioperative use of blood which you wrote for the 2004 Sensible Use of Blood Conference [HSSG0000133_147].

a. You wrote that 'improved surgical technique...has played a major part in minimising operative blood loss.' Please provide an overview of the relationship between surgical technique and the need to administer blood transfusions.

78. The changes have been mostly behavioural, with many surgeons considering haemostasis to be more important. Methodical use of diathermy and attention to all bleeding vessels have decreased operative blood loss and decreased the need for transfusion. Other developments in surgical aids, e.g. harmonic scalpels, ligasure devices and laparoscopic techniques have all decreased the trauma of access and tissue damage leading to decreased blood loss.

b. You further stated that 'the clinical decision to prescribe a blood transfusion has also evolved over the last 25 years...there has been a need to evaluate the risk/benefit of such a decision in each patient'. 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.

79. I meant by this statement that as the medical profession and the public became more aware of the viral risks of transfusion, there developed a situation where patients wanted to avoid transfusion and doctors realised that withholding transfusion following even moderate blood loss was not detrimental to the patient.

c. Please explain the safety concerns associated with red blood cell use in 2004.

80. By 2004 I considered the use of red cells to be very safe from a viral perspective but as SHOT shows it continues to be hazardous. We had learnt by this stage to find safe alternatives where possible.

27. Please consider the enclosed report regarding an audit of blood transfusion in Wales in 2004 [HSSG0000133_002]. At page 4, the report states that 'safer blood transfusion practice, which includes the avoidance of unnecessary transfusion, is now a clinical governance requirement.' Do you recall any instances or periods of time in which you or others raised concerns about unnecessary or excessive blood transfusions? If so, please explain in as much detail as you are able to recall, including why this may have occurred and how, if at all, this changed over time.

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

81. I appreciate the statement in the NCA audit of Blood Transfusion in Wales referred to unnecessary transfusion as a Clinical Governance issue. In my experience no clinician was ever specifically reported to the Clinical Governance Committee for unnecessary transfusion. Most instances where perhaps a patient received over transfusion, achieving a higher Hb than recommended by the HTC, there was usually clinical debate on the issue between myself, the hematologist and the clinician concerned to perhaps understand the clinical situation and the process

28. In light of Question 15, where applicable, were any alternative treatments made available to patients under the care of Morriston Hospital throughout the time of your employment?

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

82. There were several alternatives used to a varying degree throughout my time of employment. As described earlier I was the clinical lead for the introduction of cell salvage autotransfusion, when used during surgery this was explained verbally initially. In time, I was involved with the formation of a UK cell salvage action group (UKCSAG) which produced a booklet outlining cell salvage procedures. Each section could be printed and used as a data sheet on various aspects of cell salvage. Included in these data sheets was information about business case development, correct labelling of cell salvaged blood and information sheets which could be used to provide informed consent.

83.https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/technical-factsheets-and-frequently-asked-questions-faq

84. Other treatments possible were preoperative autologous donation until this fell out of favour. The use of preoperative erythropoietin and intravenous iron infusions, particularly for Jehovah's witnesses, and the practice of isovolaemic haemodilution per-operatively.

85. As they became available, the use of fibrin glues were introduced, prothrombin complex use, recombinant factor VIII, plus increased use of tranexamic acid and the provision of near patient clotting assessment of whole blood using ROTEM and TEG thromboelastography.

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.

c. Referencing your answer to 28(b), did any aspect of this change over time?

86. The most elaborate discussions took place between patients who refused or preferred not to receive allogeneic blood products. Some (particularly Jehovah's Witnesses) patients had good knowledge of alternatives and a very

informed discussion could take place.

87. Other patients less informed initially accepted a broad overview of the alternative therapies offered and we were very accepting of the suggested therapies offered to minimise allogeneic transfusion. There remained a great deal of trust in the medical advice.

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

88. Over the last 20/30 years attitudes have changed to transfusion and consideration about the need assessed carefully. However, many operations require significant blood transfusion still and can obviously be life-saving. Also during this time, the testing of allogeneic blood components has improved. The ongoing message to clinicians is that blood transfusion is very safe BUT not without its own risk as highlighted by various haemovigilance reporting schemes. In addition, newer infective risks may develop which we are not currently aware of, as was the case with HIV and new variant CJD.

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?

89. The development of new alternative technologies and behaviours often takes time to be evaluated properly. The implementation of these changes often takes time to educate clinicians about the benefits. It must be remembered we are in a completely different environment these days with the availability of the internet and digital information. Back in the late 1980's and for much of the 1990's as NHS practitioners most information and communication was via paper based journals and letters, with virtually no access to e-mail for many. Please refer to slide 12 of **WITN6973002.**

29. 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;

90. As far as I can remember we rarely received whole blood as a red cell transfusion product following my appointment. Some of my colleagues had used whole fresh blood during their career and valued the effect this had on their patients, improving clotting ability as well as restoring red cell mass. The use of fresh blood was impossible due to the logistics of testing for HIV, HBC and HBV.

b. Approximately how often this practice occurred;

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

91. By the time of my consultancy the regional blood transfusion centres had changed to issuing blood components.

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

92. Post-transfusion testing did not routinely occur. Testing of recipients of infected blood would be targeted specifically. In my view, immediate and routine post-transfusion testing would have been a waste of resources as testing would not have identified infection at this stage.

30. Were there any circumstances where platelet transfusions would be used instead of whole blood? Please explain:

a. The circumstances in which platelet transfusions were considered necessary, and preferable to other types of transfusion;

93. Platelet transfusions and the need for them in general surgical practice is usually in situations of large blood loss. By far the greatest use for platelet transfusion is in patients with haematological conditions, or as an adjunct to

correct low platelet counts following chemotherapy.

94. Surgical and ICU use is often associated with blood loss and so often given alongside red cell transfusion and the use of fresh frozen plasma. Historically whole blood would have been given, but since the decision to provide blood components by regional blood centres there has been a need to give separate red cell concentrate, platelet transfusions and fresh frozen plasma to mimic whole blood.

b. Approximately how often this practice occurred;

95. The use of platelet transfusion probably occurs at least daily at Morriston Hospital particularly in cardiothoracic surgery. Other specialties may also experience the need for platelet transfusion but dependant on presentation of trauma victims and type of planned surgical procedures, or unexpected surgical difficulties.

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

96. The benefit of platelet transfusion is the need to maintain a certain level of circulating platelets to achieve the formation of a strong clot. The activity of circulation platelets as well as the absolute numbers are important. For example, a patient may have an adequate number of platelets but they may have been rendered ineffective due to the patient's medication e.g. the effect of antiplatelet drugs (e.g. clopidogrel) taken to prevent the formation of platelet clumping and clot formation within coronary stents.

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

97. All platelet issues were fully tested as with red cell concentrates. Platelets for transfusion have a limited shelf life and are stored at room temperature so there is always a risk of bacterial infection as identified in the SHOT reports. Post-transfusion testing is not routinely undertaken.

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

98. The process of taking informed consent in the context of today's practice rarely occurred. Patients would have been informed verbally of the need for their use.

31. Were there any circumstances where Fresh Frozen Plasma ("FFP") transfusions would be used instead of whole blood? Please explain:

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

99. The use of FFP is usually associated with other component therapy. A few instances where FFP may be given to correct the effect of drugs e,g. warfarin reversal prior to invasive procedures, although this is no longer considered good practice since the introduction of prothrombin complex concentrates which are virally inactivated. FFP was used prior to a liver biopsy due to the suspected low level of clotting factors associated with liver disease.

b. Approximately how often this practice occurred;

100. Again FFP was frequently used during liver and heart surgery.

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

101. It is used primarily to either treat or prevent excessive bleeding.

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

102. Practice concentrates on judicious use of FFP as the best way to minimise risk. Post-transfusion testing is not routinely undertaken.

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

103. The process of taking informed consent in the context of today's practice rarely occurred. Patients would have been informed verbally of the need for their use.

32. With reference to any of the groups outlined in question 3, please identify any significant policies relating to blood transfusion practice 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.

104. I have never witnessed the use of fresh whole blood at Morriston Hospital or elsewhere.

33. With reference to any of the groups outlined in question 3, please identify any significant policies relating to blood transfusion practice 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.

105. During my early career my involvement in trying to audit clinical blood use and promote cell salvage autotransfusion was limited to my role within Morriston Hospital. As Hospital Transfusion Chair I tried to disseminate information about clinical use and also tried to update my colleagues about any latest national guidance.

106. I represented the Royal College of Anaesthetists on a number of BCSH guidelines for the use of red cell components, platelets, fresh frozen plasma

and cryoprecipitate, the treatment of anaemia, and transfusion in critical care. I also persuaded the AAGBI to help formulate their own guidelines to reach more anaesthetists directly. The writing group had invited haematologists, surgeons and transfusion specialists to validate the guidance. Booklets were produced on Red Cell Transfusion, Blood Component Transfusion, Massive haemorrhage, and Intra -operative cell salvage autotransfusion.

107. It is my belief that these guidelines influenced a change in practice across the UK. The National Blood Stocks Management Scheme noted a significant decline in the use of red cell transfusions which coincided with the publication of these guidelines but also must have been as a result of the three Better Blood Transfusion Conferences and the ensuing publications.

108. At the same time, I lectured widely across the UK at National Meetings, International Conferences and to individual hospital educational meetings. My involvement with the UKCSAG resulted in the production of the various data sheets helping the safe spread of this practice throughout the UK.

34. 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

109. As alluded to earlier, digital versions of national guidance were not initially available, so promoting their existence required great effort and attendance at various educational meetings.

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

110. My role as HTC chair, combined with the Chief MLSO's help, promoted best practice guidelines locally.

c. Transfusion policy induction procedure for new staff

111. I successfully prepared a job description for a hospital transfusion practitioner and appointed a helpful and dynamic midwife to the post who was able to produce a scheme for induction of all newly appointed medical staff, ensuring competencies for the correct requesting and sample provision for cross-matching as well as the administration of blood according to national guidance.

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

112. The transfusion practitioner took a lead role in promoting correct nursing procedures for nursing staff.

e. Promotion of new information regarding transfusion matters

113. The transfusion practitioner tried to ensure adequate promotion by attending departmental meetings.

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

114. Informed consent and examples of how to implement this was promoted via the HTC

g. Blood transfusion record keeping and documentation

115. Our transfusion practitioner was instrumental in devising a transfusion record chart very like a prescription chart. This proved very successful in aiding record keeping and enhancing the traceability of transfused components aiding compliance with the European Blood Directive. The chart

was eventually adopted on an all-Wales basis.

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

a. Obstetrics;

b. Trauma and emergency care;

c. Surgery;

d. Haematological cancer treatment;

e. Thalassaemia;

f. Sickle Cell Anemia;

116. Bleeding disorders (Haemophilia A, Haemophilia B, or von Willebrand's disease) I mentioned earlier my efforts to include cell salvage autotransfusion in Obstetric practice were supported by NICE guidance. In time the RCOG adopted the guidance into one of their Green top guidelines. (**WITN6973004**). In terms of surgical use we relied on an internal voice at RCS to promote best practice.

117. In relation to committees regarding d,e,f,g, (I had no involvement)

36. With reference to the committees named in your answer to question 3, please provide details of any publications (including but not limited to guidelines, studies or articles) produced by those committees insofar as relevant to the Inquiry's Terms of Reference. For instance, please see the enclosed guidelines for the use of platelet transfusions produced by the British Committee for Standards in Haematology [BSHA0000016_013].

118. I was involved with the writing of these guidelines. Unfortunately, none of the clinicians I worked with had ever read them. Until my retirement I was frequently involved in debates on the merits of using platelet transfusion when a patient's platelet level was low and below the normal recorded number in a

fit individual. The patients were not bleeding and there were no invasive procedures planned. I often performed the procedure of percutaneous tracheostomy on patients on the ICU with platelet numbers lower than the normal range. I always ensured there were platelets
reserved for the patient should a bleeding issue develop. To my knowledge these were never used. I was in my practice following Nationally published guidelines which were not being followed by my colleagues.

37. Was there a Hospital Transfusion Committee at Morriston Hospital? If so:

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

119. The committee was set up in 1993 in response to the various suggestions amongst the colleagues I had met in the Blood Transfusion community. I was not aware of any official guidance distributed to us at the time. The desire to establish HTC was due to my relationship with the Chief MLSO of the blood bank and my interest in cell salvage autotransfusion and not at the request of the Anaesthetic Department.

120. My role as HTC chairperson it was my role to liaise with all departments in the hospital to encourage audits of blood use and to ensure transfusion safety and standards were upheld.

121. Obviously, as an anaesthetist working in Intensive Care, I ensured that I kept these departments informed of developments.

b. With reference to any of the matters identified in Questions 32 and 33 of this request, please outline any significant policies or practices established by the Committee.

122. Clinical audit of use of blood was the mainstay initially but later with the introduction of the European Blood Directive there were many policies to

implement. The transfusion practitioner became a member when the post was created and was responsible for traceability, blood audit, and education of new staff on transfusion issues. Over time the committee supported the introduction of near patient testing thromboelastography, policies on reversal of warfarin with PCC, the introduction of a transfusion chart, correct labelling of cell salvage blood, safe track transfusion process and automatic issue blood fridges and the removal of satellite blood storage fridges.

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

123. The local HTC had a very good relationship with the Regional Transfusion Centre. A senior member attended our transfusion committee meetings; usually the Medical Director.

124. In time the Chief Executive at the Regional Centre was persuaded to support the roll-out of Cell Salvage at all Welsh hospitals, reimbursing trusts the cost of the disposable materials needed to run the machines. A better Blood Transfusion Team was set up and based at the Regional Centre.

38. The Inquiry understands that you previously held the position of Chair of the Hospital Transfusion Committee Chairmen. Please:

a. Outline the dates during which you held this position;

125. I held the position as inaugural Chair for just over 10 years between 1993 and 2003.

b. Explain what this role entailed and the remit of this group; and

126. At the time the whole concept of an HTC was very new and in a way the role developed as a result of my discussions with the Regional Centre,which was WBS, and discussions with the Welsh Government to try and promote an understanding of firstly what was happening in clinical transfusion practice, secondly to audit this practice and to try and change practice with the help of

national guidelines, some of which I helped write. The production of nationally agreed practice in the light of available research and safety analysis helped me, and certainly other hospitals behind the curve of this implementation of best practice, to have some documents to go and show their Medical Directors and Chief Executives when applying for staff and funding to aid implementation of various clinical changes.

c. Identify any policies or practices implemented by this group insofar as relevant to the Inquiry's Terms of Reference.

127. Probably the most important contribution to a decrease in allogeneic red cell use during elective and emergency service was the support given to the purchase of two Haemonetics Cell Saver machines and the support for a 24/7 cell salvage autotransfusion team to run the machines. The policies and audit put in place by the RTC, supported by clinical representatives and haematologists and the blood bank staff, meant that changes to clinical practice had some traction when introduced. The trust placed in the HTC and later the educational role provided to the hospital by the transfusion practitioners became central to the success of the implementation of new policies and behaviour e.g. the blood transfusion record, educational scheme in transfusion for all new staff, traceability and follow up etc. All of these measures led to a decrease in allogeneic blood use and also enhanced the safety of blood transfusion at a time when the major risk had been decreased by the measures put in place by the national blood services.

39. 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]. During your tenure at Morriston 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?

128. I was unaware of such use of imported blood during my tenure, but was

very keen that all measures be safely introduced to clinical practice to decrease our reliance on allogeneic transfusion wherever possible. Of course at the time we were unaware of the existence of nvCJD. West Nile Virus, Hepatitis E, etc.

40. Please consider the enclosed letter from Deputy Chief Medical Officer J S Metters to Colonel M J G Thomas dated 5 February 1998, which refers to a meeting held on 2 February 1998 between these individuals, Dr Michael Desmond, and yourself regarding intraoperative cell salvage [DHSC0004055_013]. Please explain the extent of your involvement with the Department of Health both on this issue and in respect of any other matters relating to blood transfusion.

129. Following the consensus conferences organised by Colonel M.G.Thomas, one prior to our meeting with DCMO JS Metters and the one following our meeting, I had the impression that the DoH had understood why our campaigning for greater use of ICS made sense. I had no further direct contact with the DoH but was invited to join the Appropriate Use of Blood Group chaired by the late Angela Robinson. The year after our meeting with JS Metters the Welsh Public voted in favour of a Welsh Assembly. Probably as a result my contact with the Government was restricted to personnel at Cardiff. However, I continued to contribute to committees based in Wales and to the Appropriate Use of Blood Group, The National Blood Transfusion Committee as a Welsh Observer and meetings involved in setting up a structure to implement the European Blood Directive.

41. Please consider the enclosed letter from Dr Angela Robinson to Dr Mike McGovern dated 8 April 1998 regarding the Chief Medical Officer's Initiative on Appropriate Blood Usage [NHBT0003557_002]. Regarding autologous transfusions, Robinson states that you 'would be interested in any national initiative that might be considered on this front'. Did you have any involvement in the development or implementation of a national initiative on autologous transfusion? If so, please explain the extent of your involvement and the aims and outcomes of the initiative.

130. My membership of the Appropriate Use of Blood Group allowed me to share my experience of developing a successful service for Intraoperative cell salvage and the development of hospital audit of the service and its conversion to an all-Wales Data Base held and organised by the Better Blood Transfusion Team based at the Welsh Blood Service. I was also a member of the group preparing the document on autologous transfusion Chaired by Virge James as a sub-group of the Appropriate Blood Use Group.

Section 4: Knowledge of risk

General

42. When you began working as an anaesthetist, 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?

131. In all honesty, most of my appreciation of the risks of infection associated from blood transfusion came from media coverage and very little in my undergraduate or postgraduate education helped very much in this regard. As an undergraduate I received six tutorials on haematology which covered haemato-oncology, the various anaemias and little else. The tutorials took place on a Wednesday afternoon and as Captain of the University 1st XV I believe I attended less than 50% of these, receiving a reprimand from the Dean of The Medical School. Over time my postgraduate experience led me to an interest in oxygen delivery and adequate circulating volumes of my patient and the physiology of oxygen delivery fascinated me. This led to an interest in the value of transfusion and the more I read the more I understood that probably less transfusion could be achieved with a successful outcome whilst also decreasing viral risk.

132. I was aware that transfusion of contaminated blood products could lead to transmission of HBV and HIV. At the time, HBC was referred to as Non A Non B hepatitis. Clearly once I trained as an anaesthetist the value of

avoiding unnecessary exposure to staff and patients was vital, and care of products transfused, and care regarding safely disposing of needles and blades became paramount.

Hepatitis

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

133. My understanding of HIV transmission was similar to what I have described above. *HIV and AIDS.*

44. When you began work as an anaesthetist, 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?

134. My role, which in fact can be seen in retrospect as self-appointed, meant that I tried to implement national guidance when issued. I believe that this was the best way of distributing good transfusion policy to a large group of busy clinicians, distilling the essence of these guidelines in an easily understood manner. Many clinicians are unable to keep abreast of all clinical developments and sub-specialty information is best given in easily understood and manageable aliquots.

Other

45. If you were responsible for making decisions and actions on behalf of the Anaesthesiology 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.

135. We continually monitored blood use by speciality and by operation. These audits were published anonymously in regard to clinical teams and surgeon but eventually the competitiveness of the individual surgeons meant that they did not mind open publication of these audits. This 'No Blame' culture helped encourage better blood transfusion practice. The hospital helped collect data for several National Comparative Audits on blood component use.

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

136. Known infections which occurred as a result of transfusion on infected components usually were initiated by the Regional Centre when they became aware of infected components.

47. 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?

137. Adverse reactions to transfusion can be divided into two types, Acute and delayed. The acute reactions are usually allergic or due to bacterial contamination, and result in cardiovascular collapse. This sort of reaction is dealt with in the usual way, often well-rehearsed by medical staff and involves the use of oxygen, fluid resuscitation and adrenaline, sometimes followed with steroid treatment. Delayed transfusion reactions were often identified by the haematologists alerted to abnormal blood results in the post-operative period by laboratory staff or by the regional centre when they became aware of an infected component having been issued. These policies all worked well in my

experience.

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

138. A follow-up of these patients affected was often undertaken by the local haematologist involved in the episode.

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

139. Patients tend to report symptoms of how they are feeling and do not report adverse reactions. No timeframe is ever placed on the investigation of a patient's reported symptoms.

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?

140. Usually clinicians contacted the chair of the HTC or the on-duty haematologist or transfusion practitioner.

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

141. The adverse transfusion reactions were (since 1996) always reported to SHOT. Episodes that seemed related to blood component causes were also reported by the haematologist to the Regional Centre.

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.

142. All deaths that seemed to be related in any way to transfusion were related to SHOT and further investigation was undertaken by a SHOT representative together with the locally-based transfusion practitioner and with the support of the local HTC and haematologist. The exercises were conducted in a clear and open manner cooperating fully with the vigilance provided by our HTC members and later once introduced the HTT (Hospital Transfusion Team) in conjunction with Welsh Blood Service support.

Section 5: Treatment of patients

Provision of information to patients

50. 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 the Hospital about those risks prior to treatment commencing?

143. The inquiry is probably well aware of the paucity of information given to patients in the late 1980's and early 1990's. As the risks of transfusion became more known, some patients would question more particularly but many just wanted to not receive a blood transfusion. Even up until my recent retirement the standardised consent for surgical intervention included a catch-all phrase about bleeding and possible need for "blood transfusion".

The various types of blood component required may have been mentioned by the individual surgeon but this varied, with some giving adequate and easily understood guidance of the treatment and others very cursory and verbal information if asked. Personally, I provided a clear and detailed explanation of ICS. As I had developed the service, I was at pains to ensure it had to be as safe if not safer than allogeneic transfusion which it was trying to replace. This was usually given the previous evening prior to surgery but with time as we developed anaesthetic pre-assessment clinics,written guidance could often be provided some time before surgery allowing correct informed consent

to be provided.

51. If the nature of provision of information changed over time during your employment as an anaesthetist at the Hospital, please explain what changes occurred, and the reasons for any such change/s.

144. I have mentioned the information with regard to ICS provided on the JPAC website. This is the most standardised way of providing information, although over the years local practice and experience provided examples of best practice to be incorporated into national guidance.

Response to risk

52. How, if at all, did a patient's infectious status (including HIV, HBV and HCV) affect their treatment and care as regards blood transfusion?

145. If a patient's HIV, HBV or HCV status was known certain precautions were put in place. The care as regards to transfusion did not differ to any other patient if they required transfusion. Clinical practice developed to try and put precautionary measures in place for all patients with regard to transmitted infection due to blood contamination whether it be component therapy or needle-stitch injury.

Consent

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

146. Many patients are admitted to hospital unconscious with no accompanying relatives. In these circumstances if blood transfusion is required informed consent cannot be obtained. Many patients, if bleeding and conscious, often do not worry about giving consent as they believe that life-

saving measures come first and verbally accept the risk.

Section 6: vCJD

54. 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.

147. I only became aware of the transmission of vCJD via blood transfusion following discussion with the Medical Director of the Welsh Blood Service. Clearly there was much debate amongst the blood transfusion community about prion transmission and how it could be identified.

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

148. There were measures put in place which assumed that anyone who had eaten affected meat could possibly transmit prion related disease. This included the universal leucoreduction of all blood components in the UK in 1999. The use of only imported plasma or methylene blue treated plasma for children under the age of 16. These were all measures put in place by the blood transfusion service. From my point of view, all the measures put in place for decreasing reliance on allogeneic component use applied equally to any new infective threat to blood component contamination. In this regard the policies to use intra-operative cell salvage, and the withholding of blood transfusion until physiologically necessary became even more valid.

56. 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.

148. The Blood Safety committees within Wales tried to implement whatever safety measures were suggested by SABTO and The National Blood Transfusion Committee and guidance from the MHRA which was the responsible body implementing the European Blood Directive.

57. The enclosed letter from Dr V James to you and others dated 18 June 2001 discusses the merits of autologous transfusion in light of the emerging risk of vCJD transmission through blood transfusion [JPAC0000152_070].

a. Please explain the benefits of autologous transfusion in this context.

149. The benefits of autologous transfusion means that no person-to- person transfusion-transmitted disease can occur.

b. As far as you can recall, to what extent was autologous transfusion promoted as a safer alternative to allogeneic transfusion during this time? What, if any, involvement did you have in this?

150. The promotion of autologous transfusion continued but closer scrutiny occurred about the quality of the product used and the cost-effectiveness. As a result of this and the need for all institutions involved in the storage and issuing of blood components needed to meet the EBD standards. Also, as a result many individual hospitals stopped the practice of pre-operative collection of pre-deposited blood. Intraoperative cell salvage became the one method of autologous transfusion predominantly used.

151. Guidance for the setting up and use of cell salvage was devised to help individual hospitals develop such a service, In the main it was left to individual trusts to set up and finance this service. I spent many days and weeks promoting cell salvage autotransfusion and contributed to several textbooks about appropriate and sensible use of blood. I played a role in developing the UKCSAG data sheets to promote safe use of intraoperative cell salvage.

58. Please consider the enclosed 2003 Strategy Report from the Working Party on Autologous Transfusion and the Working Party on Alternatives to Transfusion of the NBS Sub-Group on the Appropriate Use of Blood [NHBT0062673]. The report outlines various proposals for improving the safety of blood transfusion practice and conserving blood supplies.

a. With reference to your experience at Morriston Hospital, were any of these proposals implemented?

152. The main proposals were already implemented at Morriston Hospital by the time I was invited to join the working party looking at autologous transfusion. Of course, the policies continued following the published report.

b. In your view, what was the impact of this group and the recommendations it created on the safety of blood transfusion practice?

153. It was a significant help in promoting more widespread good practice involving the use of alternatives and increasing the use of intra-operative cell salvage across the UK.

154. As I mentioned earlier, having a nationally agreed document to refer to when preparing a business case and appealing for funding from the Executive Board of your Trust.

155. A great number of patients at Morriston underwent complex surgery without the need for allogeneic transfusion at all. Regarding transfusion safety, these patients avoided any transfusion-transmitted infections.

Section 7: Other Issues

59. 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.

156. I have never been the subject of any complaints about my clinical practice.

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

157. I have been fortunate not to have been knowingly involved in any incidents of infective blood transmission during my transfusion practice.

61. 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

158. I attach a short PowerPoint presentation as an example of the locally conducted audits we carried out and have referred to relevant slides in the text of my responses.

Statement of Truth

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

Signed GRO-C

Dated : 9 February 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number

Undated	Powerpoint	WITN6973002
2010	Article, titled 'Blood transfusion and the anaesthetist: management of massive haemorrhage'	WITN6973003
May 2015	Guideline 47, titled 'Blood Transfusion in Orthopedic'	WITN6973004
Undated	List of contributions towards guidance provided by the British Standards of Haemotology	WITN6973005
01/01/2001	Thomas D, Wareham K, Cohen D, Hutchings H. Autologous blood transfusion in total knee replacement surgery. Br J Anaes 2001;86:669- 73.)	WITN6973006