Witness Name: Professor Derek Manas
Statement No.: WITN7452001
Exhibits: WITN745002-13
Dated: 25 October 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR DEREK MANAS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 9 September 2022.

I, Professor Derek Manas, will say as follows:

Section 1: Introduction

1) **Please set out your name, address, date of birth and any relevant professional qualifications relevant to the role you currently discharge**.

1. I am Professor Derek Manas. My date of birth is GRO-C 1958 and my address is known to the Inquiry.

2. I am a Professor of Transplant Surgery and a Consultant Hepatobiliary and Transplant Surgeon at Newcastle upon Tyne Foundation Trust and Director of the Institute of Transplantation.

3. I was educated and trained in Cape Town, South Africa and completed fellowships at 'Johns Hopkins Hospital – USA' and 'Paul-Brousse Hospital - Paris', Japan, and Hamburg. I was the recipient of the 'CJ Adams/Sandoz Traveling Fellowship' to the UK in 1993 and joined the NHS at the Freeman Hospital in 1994.

4. Having attained a personal chair in Transplantation at Newcastle University in 2007, I was instrumental in developing three super-regionally funded transplant programmes in the Northeast of England – namely: Liver, Pancreas, and Islet transplantation – as well as establishing and managing Liver, Pancreas and Sarcoma cancer surgery in Newcastle. I established the Institute of Transplantation in 2008.

5. I have been a member of several national committees and societies including NICE MTA advisory committee and NHSE Liver Clinical Reference Group (vice chair). I was the deputy chair of NHSBT Liver Advisory Group (6 years) and member of the Pancreas and Islet Advisory Group for 10 years. I am a Past President of the British Transplant Society, and Past Chair of the British Liver Transplant Group (BLTG). I established the British Transplant Surgeons Chapter which I chaired for 6 years.

6. I was involved in the Organ Donation Task Force (ODTF) - re-designing the organ donor retrieval service to become a national service. I was part of the committee that designed the National Liver Offering Scheme (NLOS). I am a Trustee of Liver North (Liver patient support group) and a Trustee of the British Surgical Oncology Society (BASO) and Cholangiocarcinoma UK. I am a past councillor for the Association of Surgeons (ASGBI) and the British Association for Study of the Liver (BASL). I was the Associate Medical Director for Clinical Governance at NHSBT, and I am currently the Medical Director of Organs & Tissue Donation and Transplantation (OTDT). I have a well-established national and international research reputation in primary liver cancer (HCC), minimally invasive treatments of liver tumours and liver transplantation for malignancy with over 300 publications in peer review

journals. I have been awarded two lifetime achievement awards for services to liver transplantation and liver surgery.

7. In making this statement, I have had assistance from colleagues on the Liver Advisory Group - Professor Douglas Thorburn, Dr Stuart McPherson and Rhiannon Taylor.

8. Professor Thorburn is the Chair of the Liver Advisory Group and a Consultant hepatologist and clinical director for liver transplantation, hepatology, HPB and gastroenterology. Having trained in Glasgow and Canada, Professor Thorburn was appointed as a consultant hepatologist in the liver transplant unit in Birmingham in 2003, moving to the Royal Free in 2007. His clinical and research interests are in liver transplantation, autoimmune liver disease and biliary endoscopy (endoscopic ultrasound and ERCP). Since 2009 he has been involved in clinical management at the Royal Free and is currently clinical director for GI and liver services.

9. Dr Stuart McPherson is a Consultant hepatologist and clinical lead for liver medicine at Newcastle upon Tyne NHS Foundation Trust. He is the regional lead for management of Hepatitis C and DAA (direct-acting antivirals) implementation. He is the Clinical Research Network lead for research in liver disease and is past secretary of the British Society of Gastroenterology (BSG).

10. Rhiannon Taylor's role is in Statistics and Clinical Research for the Organ Donation and Transplantation Medical Team (OTDT). She is a Senior Statistician, working in Statistics and Clinical Research. She joined NHSBT in 2008 after graduating from Manchester University with an M.Math in Mathematics and Statistics. Since joining the Statistics and Clinical Research team in NHSBT, she has supported a number of organ specific areas in organ donation and transplantation and has been the lead statistician for liver transplantation since 2018. She has been involved in the development and implementation of the National Liver Offering Scheme

since 2014 (NLOS was implemented in March 2018) which is monitored on a regular basis.

11. The full membership of the Liver Advisory Group can be found here, as can a full set of minutes of the meetings of the group since 2016:

https://www.odt.nhs.uk/transplantation/liver/liver-advisory-group/

2) **Please describe, in broad terms, your role and responsibilities as Medical Director of Organ and Tissue Donation and Transplantation at NHSBT.**

12. My role is described on the NHSBT website, above and explained further below. I am the Medical Director for NHS Blood and Transplant's Organ Donation and Transplantation Medical Team (OTDT). I lead the clinical team and have oversight of all transplant activity across the UK, including clinical governance, organ and tissue retrieval, organ allocation, organ utilization and transplant outcomes in association with the UK commissioners.

13. The OTDT Clinical Team includes clinicians holding honorary contracts with NHS Blood and Transplant (NHSBT) to provide clinical leadership and input into NHSBT management.

14. There are seven Associate Medical Directors (AMD) who each have areas of responsibility including clinical governance, living donation, organ donation, organ retrieval, organ utilisation, clinical transplant development and research and development. The OTDT Medical Director attends the OTDT Senior Management Team meetings as well as the Change Programme Board (CPB). The AMD team are all members of relevant programme boards.

Terms of Reference

15. The Terms of Reference for Organ Specific Advisory Groups, including the Liver Advisory Group (LAG), are available on the NHSBT website and are as described below.

16. The major role of the organ advisory groups is to advise NHSBT on all aspects of organ transplantation and ensure equity of access and best outcomes for all patients.

17. The Membership consists of:

    a. **The Chair** who is appointed in a competitive interview process by NHSBT after consultation with the relevant Advisory Group members following applications by invitation from transplant health care professionals. The appointment is for 3 years in the first instance, with the possibility of renewal for a subsequent term.

    b. The Membership also includes:

    - Advisory Group Chair
    - Medical Director OTDT
    - Relevant NHSBT Statisticians
    - Voting members: Two clinicians (surgeon and physician) from each Liver Transplant Centre and 1 representative for paediatric recipients.
    - Non-voting members: Representative from Commissioning (NHSE) and representatives of other organ advisory groups.
    - Representatives from the national Departments of Health
    - 2 lay members and 2 patient representatives
    - National representative for recipient specialist nurses in liver transplantation and the National representative for specialist nurses in organ donation (SNOD).

    c. Others who may attend:

    - Representatives from the Republic of Ireland
    - Director of Organ Donation and Transplantation (OTDT)

- Associate Director for Statistics and Clinical Studies
- Assistant Directors, Organ Donation (OTDT)
- National Clinical Leads for Retrieval and for Donation
- Member of the support services for minute taking
- The Chair, in discussion with voting members of the Group, may include other representatives from relevant professional bodies, societies and Colleges when required.

18. Members will be responsible for discussing and voting on changes in policy and responding to statistical analysis of standing agenda items. In addition, members are responsible for bringing to the Advisory Group any relevant concerns or suggestions from the transplant centres they represent and items for the agenda.

19. The main Advisory Group meets twice a year. There are several sub-committees and working groups that meet more regularly. Two standing groups include the LAG 'core' group which is a policy review committee and monitors non-compliance. They meet 3-monthly. The centre directors' group meets monthly and is an operational group managing mainly individual unit issues and specific organ allocation and utilisation issues as well as engaging with unit collaboration processes and any clinical issues for patients. The Chair in conjunction with the core group will establish short life fixed time working groups to address specific aspects or topics that need to be reviewed or revised within the practice of liver transplantation. The chair of LAG will appoint a chair of the sub-committees, they will be supported by NHSBT statisticians and will report formally to the Advisory Group.

20. The Liver Selection and Allocation Working Group (LSAWP) was the predecessor working group to what became the National Liver Offering Scheme (NLOS). Over a 5-year period the NLOS working group developed the offering and allocation scheme we use today. The scheme is monitored by a specifically appointed monitoring committee chaired by a specialist consultant in liver transplantation (surgeon or physician) and will usually

convene twice per year with each transplant centre represented. Statistical support is from NHSBT statistical services. They report to the chair of LAG and all their recommendations are ratified by the LAG.

21. The Chair of LAG, Associate Director of Statistics and Clinical Audit and Medical Director of OTDT will meet at least every 6 months to agree the agenda, new projects to be agreed and to assign priorities. With regard to the NLOS monitoring committee, if there is a need for change in parameters, they will meet at 3 months after implementation to ensure any problems are identified early. A standardised report from NHSBT statistics has been designed to try to identify signals where the national offering scheme is not working for groups of patients. There is also a forum for feedback from centres and other stakeholders where issues or concerns can be raised.

22. The hepatocellular carcinoma (HCC) group of patients is the best example of how this works. When an issue was identified, this led to a revision in the scheme and the change in parameters. It may take some time to go from identification of an issue to implementation of a solution and that is a function of the support that is provided for development and IT implementation timelines.

Role of Advisory group

23. The Advisory Group as well as the LAG sub-committees will consider and advise NHSBT on operational aspects of transplantation at their 6 monthly meetings - including:
    - organ retrieval
    - recipient selection criteria
    - issues of organ allocation
    - data analysis with respect to activity and outcome
    - Recommend, as necessary, promote and implement changes to the nationally agreed policies

- Advise NHSBT and other bodies on appropriate methods of monitoring outcomes and interpretation of findings
- Monitor and report on clinical governance with special reference to:
  - Outcomes and deviations from expected outcome
  - Deviation from agreed protocols in selection and/or allocation
  - Equity of access of patients to transplantation throughout the UK
  - Evaluation and comments on issues raised by investigations into triggers from outcomes analysis, investigations, and other issues
  - To identify and promote areas of audit and research.
  - Remit to OTDT matters of practice or policy that require consideration within a broader framework.
  - Liaise as necessary with the British Transplantation Society, BTLG and other professional bodies in the development of national standards
  - Provide 6 monthly reports of clinical governance
  - Respond to and advise on implementation of aspects of donation and transplant policy that arise from legal and/or policy developments both within the UK and more widely
  - Review the 6 monthly NLOS report

2) 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.

24. List of memberships
    a) NICE Technology appraisal committee (5 years)
    b) NHSE Liver Clinical Research Group (6 years)
    c) Past President of British Transplant Society (2014-2016)
    d) Chair of the British Liver Transplant Group (2017-2019)
    e) Committee member of the NLOS implementation group (2013 – 2018)
    f) Co-chair of the NHSBT Liver advisory Group (2012-2017)
    g) Associate Medical Director for clinical governance (2018-2021)

h) Councillor for ASGBI (2013-2017)
i) Councillor for BASL (2008 -2018)
j) Trustee for BASO (2015 – Present)
k) Secretary for Cholangiocarcinoma UK (2016 – present)

3. **Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations or criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports which you provided.**

25. I have not provided any such evidence.

Section 2: The Systems and Criteria for Liver Transplants

5) **Please set out what the current prioritisation criteria is for those with hepatitis C and hepatitis B for a liver transplant**.

26. I hope it will assist if I explain the process by which livers for transplantation are currently allocated. The basic provision is in the NHS Blood and Transplant Regulations of 2005, which came into force on 1 October 2005. Regulation 4 directs NHSBT that the allocation of organs shall be in accordance with the schemes and given equal priority (see further below).

27. There are Guidance and Policies which describe how clinicians, scientists and others work to deliver the service. The policies are usually developed by the appropriate Advisory Group in discussion with other patient and lay groups and professional organisations. When agreed, these are reviewed and approved by the Senior Management Team and Change Programme Board as well as Clinical Audit Research and Effectiveness committee

(CARE), which acts on behalf of the Board of NHSBT where the statutory responsibility lies.

28. When appropriate, guidelines are issued in conjunction with appropriate professional or statutory bodies. These policies are regularly reviewed and revised. The policies are available on the NHSBT website as set out below:

https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/

Selection, registration and allocation policies:

- Introduction to Patient Selection and Organ Allocation Policies - POL200 (WITN7452002)
- Assessment of allocation policies for organs from deceased donors - POL187 (WITN7452003)
- Non-compliance with selection and allocation policies - POL198 (WITN7452004)
- Patient Selection and Organ Allocation Policies Review and Approval (Organs) - POL223 (WITN7452005)
- Patient Registration for Transplantation POL247 (WITN7452006)
- Registering a Patient for Transplantation MPD1211 (WITN7452007)
- Management of Mass Activations or Suspensions of Potential Transplant Recipients (WITN7452008)

29. Policy POL200/4 (WITN7452002) is an **Introduction to Patient Selection and Organ Allocation Policies**. This notes that organ transplantation is a highly successful form of therapy in selected patients either as a form of lifesaving or life-enhancing treatment. Following the recommendations of the Organ Donation Taskforce in 2008, many changes were made to the provision of organ donation and, although this resulted in achieving the target of increasing the number of deceased organ donors by 50% in the subsequent 5 years and the donor numbers are continuing to increase, the

number of patients eligible for consideration of liver transplantation has also increased and as a result there remains a shortfall between the number of people who would benefit from an organ transplant and the availability of suitable organs.

30. An estimated 3 people die each day because of organ shortage and up to 1 in 6 of those listed for a heart, lung or liver transplant dies or becomes too sick to receive a graft.

31. All clinicians will act in the best interest of the patient. However, transplantation poses a particular problem as the clinician will usually be responsible for several patients all of whom might benefit from the use of the same donated organ.

32. Furthermore, all liver grafts donated from Deceased Brain-dead donors (DBD) are allocated to named liver recipients via NLOS. This is based on the national registration process and as a result, all registered /listed patients are considered in the decision as to who will receive the donated organ on a particular day. NHSBT is required, amongst other duties, to ensure that within the UK there is a fair, transparent, and equitable approach to patient selection and organ allocation as approved by LAG and the board. Currently for donors after circulatory death (DCD), centre-based offering is still in place.

33. For Living Kidney donors, two options are in place. 1) Local management of donor/recipient pairs (both related and un-related but directed), is centre based and 2) Donor/recipient pairs registered into the Living Donor Kidney Sharing Scheme (LDKSS) which is a UK wide scheme are managed on a UK wide basis by NHSBT. Living donor liver transplantation still only accounts for 3% of activity and is centre based.

34. The policy document outlines how patients are selected and organs allocated across the UK. The organs and tissues included in this policy are the heart, lung, kidney, liver, bowel, pancreas (including islets) and cornea.

NHSBT supports the principles on organ donation and transplantation from the World Health Organisation outlined in the Resolution on Human Organ and Tissue Transplantation of May 2010 (WITN7452009) and is a signatory to the Declaration of Istanbul on Organ Trafficking and Transplant Tourism http://www.declarationofistanbul.org/.

35. Responsibility for the development, review and dissemination of the policy lies with the Board of NHSBT. However, for policies to have credibility, there needs to be full support from all the healthcare professionals involved in transplantation, potential recipients and their families, donors (including potential donors) and their families, relevant patient groups and the general public.

36. To achieve these goals, each Advisory Group is asked by NHSBT to propose the policies for patient selection and organ allocation for that organ. I have described the membership above, but each Advisory Group consists of clinical representatives from designated centres and other relevant healthcare professionals, scientists and lay members and is chaired by a clinician who is independent of NHSBT.

37. In addition, the Medical Director for OTDT and the Chair of each Advisory Group meet with patients and patient groups on an annual basis to discuss, amongst other issues, selection, and allocation to ensure that patients are involved in developing these policies. The membership and minutes of each Advisory Group meeting are published on the ODT website (https://www.odt.nhs.uk/odt-structures-and-standards/clinical-leadership/advisory-groups/)

Selection criteria for adult elective liver transplantation

38. Selection will be based primarily on risk of death without a transplant. Patients can be considered for elective transplantation if they have an anticipated length of life or survival in the absence of transplantation that is less than that obtained with a liver transplant.

39. All patients selected for the elective adult liver transplant list must have a projected 5-year survival after transplantation of >50%. That figure may change in the future if/when donor numbers alter.

40. Selection will be assessed secondarily on ability of transplantation to improve quality of life. All patients will need to be regularly reviewed to ensure that they continue to meet criteria and have not improved or become too sick to benefit from transplantation. When the clinical situation alters such that a patient no longer meets these criteria, the patient's name must be removed from the national list.

41. Patients can be selected if they fulfil one of the following criteria:

    - Projected 1-year liver disease mortality without transplantation of >9%, predicted by a United Kingdom Model for End-Stage Liver Disease (UKELD) score of ≥49. The UKELD score is derived from the patient's serum sodium, creatinine and bilirubin and International Normalised Ratio (INR) of the prothrombin time.

    - Patients with porto-pulmonary hypertension (mean PAP >25 mmHg, <50 mmHg; PVR >120 dynes/s/cm-5; PCWP <15 mmHg) should have had a clinically significant response to one of long-acting prostacyclin (or analogues), Sildenafil, or Bosentan.

42. Organs may be retrieved from deceased or living donors. Deceased donation may occur after circulatory death (DCD) or brain death (DBD).

43. Worldwide, different healthcare administrations have adopted different approaches to patient selection and organ allocation. There are broadly two approaches to selection:
    a) List everyone who might benefit from the transplant procedure
    b) Restrict the list so that those who are listed will have a reasonable expectation that they will receive a transplant.

44. The first approach allows all those who might benefit to have a chance of receiving an organ and will give a more accurate reflection of the need for transplantation. It will highlight the extent and impact of the organ shortage. However, with this approach many listed patients will have no realistic chance of receiving a transplant and may never achieve the required 50% 5-year survival.

45. Eligibility to the list is usually controlled by minimum listing criteria. A large and variable list may lead to problems in fair allocation especially if units are listing different patients. Ensuring that all units list patients with similar indications and risk ensures equity and fairness. Restricting the list to acceptable indications and need reduces futility and better matches the availability of organs. The availability of liver grafts may lead to challenges in determining listing criteria – but these are reviewed regularly to reflect the need of the chronic liver disease population.

46. Discussions with patient groups have indicated that the great majority prefer the second approach of restricting access to the list. The selection policies for each organ have therefore been developed balancing equal access to the waiting list with the benefit that donation of a scarce resource will provide to individual patients.

47. Allocation policies need to balance several factors, some of which may be conflicting. Factors to be considered include **clinical compatibility, need, equity, utility, benefit, and fairness.**

Access to the NHS Transplant list

48. The Directions (available at: https://www.odt.nhs.uk/odt-structures-and-standards/regulation/ and WITN7452011 set out who is eligible to receive a donated organ in the UK, categorised as Group 1 and Group 2 patients. Eligibility status should be determined by the transplant centre before NHSBT is asked to list the potential recipient on the NHS Transplant list. If in doubt, hospitals should

seek advice on a patient's eligibility status from the relevant National Health Department.

49. Group 1 includes those who are ordinarily resident in the UK; members of UK HM Forces serving abroad, their spouse, civil partner and children under the age of 19 years; persons entitled under EU Regulations and reciprocal health agreements. Group 2 patients are all those who are not included as Group 1. Full details of the categories can be found within the Directions and in the accompanying guidance, available on the website www.odt.nhs.uk

50. As set out in the Directions, organs donated by deceased donors should first be allocated to Group 1 patients and then only to Group 2 patients if there is no suitable Group 1 patient in the UK.

51. Organs from DCD and DBD donors may require different processes for allocation as these organs are associated with different factors that predict outcome.

National and local allocation

52. Allocation may be on a national basis where there is a defined evidence base for the allocation process (as seen with kidney transplantation, for example). Alternatively, for the liver or heart, for example, organs may be allocated to a centre where the receiving clinician will select the most appropriate recipient on the transplant list of that centre. When centre-based allocation was the UK practice, all transplant centres were required to publish their own policies and processes to ensure transparency. Centre-based allocation is subjective and does not always consider a national view of patient need.

The current basis of allocation of livers for transplant

53. The system changed in 2018 when it became a national rather than a centre-based scheme for **DBD** liver grafts, which is more equitable.

54. A transplant benefit score (TBS) is used to allocate a specific organ to a specific recipient (named patient offering and allocation system) based on the recipient's clinical parameters and the 'matchability' to the specific donor liver being offered. This only applies to organs from brain dead donors (**DBD**) as opposed to DCD (about 30% - 40% of livers) which are still offered to centres to allocate. The 70% of organs that are from **DBD** donors are offered nationally according to the TBS. Every patient on the national waiting list has a score calculated each time an organ is available because the nature of the donor organ changes all the time. The person with the highest score receives the organ.

Review while on the transplant list

55. The transplant candidate will normally remain under clinical review; this is for many reasons, including the need to ensure that transplantation is still indicated. Rarely, some patients may unexpectedly improve to such an extent that transplantation is no longer indicated, but, more commonly, the disease may progress so that transplantation becomes futile, and the patient should be suspended or removed from the transplant list. Any decision around suspension or removal will be taken using the criteria laid down in the selection policy current at that time and following discussion with the patient and their family/advocate.

6) Please explain the following:

a) Who is currently responsible for setting the criteria for liver transplant prioritisation.

56. The prioritisation is set by the clinical community who are subject matter experts for Liver Transplantation, via the Liver Advisory Group, which is led by the Chair and me, as Medical Lead. The current system of liver transplant prioritisation is through the National Liver Offering Scheme (NLOS):

https://www.odt.nhs.uk/odt-structures-and-standards/odt-hub-programme/national-liver-offering-scheme/

57. In 2018 NHS Blood and Transplant (NHSBT) introduced this new way of matching livers from brain dead deceased donors to adult patients on the liver transplant waiting list. The new scheme matches livers on a national, rather than a centre basis and helps to place the organ with the patient most likely to benefit from it. This is expected to increase the number of life-years gained from transplanted livers and decrease the number of people who die on the waiting list. It computes the patient's survival with the particular liver being offered as compared to their survival on the waiting list if the liver is not offered. The first stage of development of the new system was an open forum as to what should be included in the scheme. At the outset it was community developed and following that an expert working group was formed.

58. The scheme looks at the characteristics of the donor and the liver patient and matches the donated liver to the patient in a more specific way; helping to make sure the liver is allocated to the patient who will receive the most benefit from it. The new scheme uses the Transplant Benefit Score system (TBS).

59. ODT Hub Operations are responsible for all liver offering. https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/

b) How the criteria for liver transplant prioritisation is decided;

60. Matching runs are carried out by NLOS. The process is described in WITN7452010.

- The Specialist Nurse Organ Donation (SNOD) registers the donor with Hub Operations
- Hub Operations initiates a matching run

- The matching run is based on the 7 donor characteristics and 21 recipient characteristics, described below
- Liver offers are made for a named patient at one of the 7 liver transplant centres by Hub Operations.
- If it is a donor after circulatory dead (DCD) the organ is offered as a 'Fast-Track' offer to the centres

61. Matching runs are carried out whenever there are DBD donor livers on offer and include 7 tiers:
    i- Super urgent
    ii- Hepatoblastoma
    iii- Intestinal
    iv- Liver and cardiothoracic
    v- Split liver
    vi- Elective liver patients – eg everyone on the liver transplant list offered by the transplant benefit score TBS for either chronic liver disease and hepatocellular carcinoma (CDL/HCC) or variant syndrome
    vii- Fast track

62. Priority is always given to those on the 'super urgent' list (those who will die within 72 hours without a transplant, patients with hepatoblastoma and those waiting for a multi-organ transplant (intestinal/liver and cardiothoracic).

63. The liver is then offered to patients with the highest transplant benefit score (TBS).

64. The highest ranked patient with the best match will be the first to be offered the liver. If the offer is accepted and the transplant proceeds, the patient will be removed from the list within 24 hours.

65. Transplant benefit scores are computed using the 21 recipient criteria and the 7 donor criteria.

Donor Criteria

- Age
- Cause of death
- BMI (height and weight)
- Diabetes
- Donor type
- Blood group
- Split liver criteria

Recipient Criteria

• Age • Gender • Hepatitis C • Disease Group • Creatinine • Bilirubin • INR • Sodium • Potassium • Albumin • Renal support	• Inpatient status • Previous abdominal surgery • Encephalopathy • Ascites • Time on waiting list • Diabetes • Maximum AFP level • Maximum tumour size • Two tumours • Three or more tumours

66. I **attach** the National Liver Offering Scheme document at WITN7452012. The changes to the policy are set out in paragraph 1.

67. This explains at Appendix E, the Transplant Benefit Score (page 46) that in November 2014, the Fixed Term Working Unit (FTWU) of the Liver Advisory Group (LAG) on Organ Allocation presented to LAG members a document that investigated three ways of offering liver donors to patients on the liver waiting list; offering on the basis of *need* (priority given to the patient with the greatest risk of dying on the transplant list), on the basis of *utility* (priority given to the patient with the greatest chance of surviving the longest after transplantation) and on the basis of *transplant benefit* (priority given to the

patient with the greatest difference between expected survival with and without a transplant). After careful consideration of these three alternatives, the FTWU recommended that the LAG should consider transplant benefit-based offering as the optimum. Full details of the investigations are available at WITN7452013.

68. The LAG endorsed the recommendation and tasked NHSBT with the implementation of the Transplant Benefit Score (TBS) as the rule to offer livers from donors after brainstem death (DBD) to adult, small adults and large paediatrics on the elective waiting list with an indication for transplantation in the chronic liver disease or hepatocellular carcinoma groups. The LAG agreed that offering of donors after circulatory death (DCD) would remain unchanged for the first 6 months of the new scheme, to understand fully the implications and put in place any arrangements that are deemed necessary for effective and efficient DCD offering. Super-urgent and hepatoblastoma liver patients, patients who require multiple organs – except those who require liver and kidney transplantation – and patients with indications for transplantation not in the groups above, will not be offered via the TBS.

Calculation of the transplant benefit score

69. The TBS is calculated on the basis of mathematical equations which are set out in the document. $M1_i$ is the patient's expected survival without a transplant (i.e. survival on the list) and $M2_i$ is the patient's expected survival with a transplant (i.e. survival post transplantation) over a five-year interval. From **equation (1)**, a patient with low expected survival on the list and high expected survival post transplantation will produce a high TBS, whereas a patient with every other possible combination of $M1$ and $M2$ will produce a relatively lower TBS.

70. In practice, there are two versions of equation (1), depending on whether the patient has cancer or not.

71. A working example of the liver TBS calculation for a specific non-cancer patient and a specific donor is implemented in File 4 at Appendix F, section 15.7.

72. The liver TBS calculator updated in 2022 is found at WITN7452014.

73. The UK End-stage Liver Disease score (UKELD) represents a patient's sickness or risk of death without a transplant. It is calculated for elective patients only using the equation - based on the most recent laboratory values reported either at registration or at sequential data submissions. The higher the TBS the greater the net benefit.

c) The extent to which this issue is kept under review and the process for altering the liver transplant prioritisation.

74. Since NLOS was introduced in 2018, it was originally reviewed 3 monthly. After about 24 months it moved to 6 monthly monitoring – fed back to LAG which meets 6 monthly. I have noted the membership of LAG above, but it includes lay and expert members and patient representation. The liver patients' transplant alliance – now UK Liver Alliance Patient Forum - has representatives of all groups with liver diseases and nominates individuals for the monitoring and working groups.

75. NLOS was updated in 2021 and IT changes are being updated now based on the advice of the group which included lay and patient members. The adjustments made reflected that the original prediction of survival of patients with primary liver cancer was overestimated; there was removal of non-statistically significant variables; and as the TBS introduced in 2018 – was based on data up to 2016 – the parameters were updated based on

data up to 2020 from five year follow up of registrations and transplants from 2016 (so up to 2021).

7) Are the criteria for liver transplant prioritisation uniform across the United Kingdom, or, are the criteria set locally? If the latter, please address the following:

76. The criteria are uniform for DBD donors through the NLOS. DCD donors are offered to the transplant centre and allocated by the centre clinicians based on agreed minimal listing criteria, nationally agreed protocols and clinical circumstances. These organs are a good resource for patients with HCC and diseases that may not affect the TBS as much as other diseases. These decisions have to be documented and transparent and monitored through the Directors sub-committee which meets monthly.

i) Are there any differences in the criteria in different regions. If so:

(1) What do you understand to be the differences and the reasons for these differences.

(2) What are the effects of these differences?

(3) What are the advantages and disadvantages of having regional criteria rather than National criteria?

77. NHSBT is a Special Health Authority for England and Wales and part of its remit is to facilitate, provide and secure the provision of services to assist tissue and organ transplantation, which it does across the UK. NHSBT's accountabilities for providing organ donation and transplantation services in Scotland and Northern Ireland are governed via its Board arrangements and through Income Generation Agreements with the Scottish Government and the Department of Health, Social Services and Public Safety in Northern Ireland.

78. NHSBT is directed by the NHS Blood and Transplant (England) Directions 2005, and the NHS Blood and Transplant (Wales) Directions 2005, as amended (the Directions) which govern the arrangements in relation to

organ donation and transplantation services. These sets of Directions are identical regarding who is eligible to receive a donated organ in the UK.

79. NHSBT, and the Transplant Centres, have to comply with the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006, as amended, and the Human Transplantation (Wales) Act 2013, and are regulated by the Human Tissue Authority (HTA). NHSBT is designated by the HTA as the body in the UK that can lawfully allocate and supply organs to NHS hospitals. In addition, NHSBT is regulated by the Care Quality Commission.

80. Offering of all livers to recipients for transplantation is based on a national waiting list / register. No patient can be transplanted without being registered with NHSBT HUB operations. When a suitable DBD liver becomes available for transplantation anywhere in the country on any given day/night all patients who are registered with NHSBT for a liver transplant are matched with the donor liver via the NLOS algorithm and the liver is offered to the patient who has the highest score (TBS scoring system) – irrespective of where they are in the country (one of 7 units).

81. If the clinical team (MDT) treating the patient is unhappy with the patient's (recipient) clinical condition at the time (may be too ill) or feels the liver being offered for the named patient is not suitable, the liver is offered to the next highest TBS scoring patient on the waiting list (register). On occasion the liver is deemed 'marginal' (unsuitable; high risk) and the recipient's clinical team feel it is not in the interest of their recipient to accept the liver or the patient themself is unhappy. The liver is then offered to the next highest TBS scoring registered patient. When the liver has been turned down by 3 centres as not being suitable for a TBS scoring patient as deemed by the recipients' clinical teams it will be 'Fast-tracked' to all centres for the clinical teams to consider for any of their other registered recipients.

82. At this point there may be some degree of regional or unit variation in terms of utilisation - for 2 reasons – i) Larger units have more patients waiting and have a larger pool of recipient to choose from to facilitate accepting a

'marginal' liver or ii) logistically there may be more resources in larger centres to do simultaneous liver transplants - something that smaller units could not do.

83. It is important to state that all units follow minimal listing criteria, and all patients are registered according to these nationally agreed policies, which are audited 6 monthly, so variation is only around utilization. This is monitored by LAG, LAG core group, the centre directors, the NHSBT stats team and ultimately the MD of OTDT to ensure that patients are NOT unduly disadvantaged.

84. When a DCD donor liver becomes available, all units receive the offer and need to respond in 60 minutes to accept the organ for a registered patient on their unit waiting list. It is allocated on a rotational basis by HUB operations. Each unit must clearly and transparently identify on their waiting list, recipients who could potentially be suitable for a DCD Liver.

85. Some DCD livers and livers denoted 'marginal' can carry increased risk for some recipients and both NLOS and centre-based allocation allow for clinical decision making in the best interest of the patient.

86. During the development phase of NLOS, following public and patient engagement, there was a clear steer to clinicians that clinical decision making should remain part of the allocation process.

87. The disadvantage of a purely Artificial Intelligence (AI) algorithm-based allocation system is the exclusion of clinical decision making, which could affect patient outcome. Therefore, within NLOS there is 'space' for clinical acumen.

88. The ultimate aim of NLOS is to factor in Need, Utility, Equity and Benefit in conjunction with clinical decision making but to prevent random subjective decisions which is the danger with a purely centre-based allocation process.

8) To what extent would the fact that a patient has a bleeding disorder such as haemophilia, impact on their likely prioritisation for a liver transplant?

89. The processes described above would apply in relation to registration of the patient on the transplant list, review of the patient and allocation of a liver on a matching run. Haemophilia because it is a co-morbidity would have no impact on the TBS. A patient with haemophilia and liver disease who is stable with no evidence of decompensation, would be unlikely to benefit from a transplant (subject to a point discussed further below at paragraph 103). The mortality from a liver transplant is 9% within 12 months which would be a far higher risk of death than with their existing condition. If, however, the patient with a bleeding disorder decompensated and developed fulminant or end stage liver disease, then as with anyone else on the list, they would exhibit criteria such as encephalopathy, worsening ascites etc which are included in the 21 recipient criteria used to calculate the TB score.

9) To what extent would the fact that a patient is co-infected with hepatitis B and/or C and HIV, impact on their likely prioritisation for a liver transplant?

90. Hepatitis C is one of the specific recipient criteria factored into the Transplant Benefit Score. For those co-infected with hepatitis B and C – Hepatitis C would score higher; HIV would be a co-morbidity. Factors outside the 21 criteria relevant to calculating the TBS would be considered in listing but would not impact on the TBS. The situation would be as described above. If the situation worsens and the patient decompensates and suffers from conditions listed in the recipient criteria, these would be factors included in calculating the TBS score.

10) The Inquiry has received evidence from its expert group on blood and bleeding disorders [EXPG0000002 page 29 and the oral evidence given by the group on 28 February 2022 at pages 15 - 23] that the complications of hepatitis C infection can cause enhanced bleeding for those with bleeding disorders, and such patients have a higher risk of developing liver

cirrhosis and hepatic carcinoma and dying from these complications. To what extent are these factors reflected in the prioritisation criteria for liver transplant for those with bleeding disorders?

91. Patients co-infected with HCV, HBV and HIV may develop fibrosis at a more aggressive rate but with the ability now to control the viral load, the rapid progress we saw 20 years ago is no longer an issue. Having a bleeding disorder does not add to the rapid progression but bleeding and coagulopathy is a common associated co-morbidity and worsening coagulation will be reflected in the UKELD and TBS.

11) The following submission has been made to the Inquiry:

"The UK Health Departments should adapt the criteria for organ transplants so that: (i) persons infected by blood or blood products are able to receive a liver transplant after the age of 70; (ii) prioritisation criteria which disproportionately affect persons infected by blood and blood products should be identified and disapplied in their cases; and (iii) the fact that a person was infected by blood or blood products should be a criterion which is adopted so that it leads to greater prioritisation (bearing in mind that liver failure develops more quickly in persons infected with Hepatitis C than other causes and they have been infected for decades)"

Please consider this proposal and set out:

(i) whether this could be achieved and if so. how it could be achieved.

92. These patients could be prioritised other than in the manner described above, probably by what we describe as variant listing and the use of centre-based DCD offers, but essentially the situation would be as described. In relation to whether liver failure develops more quickly in those with Hepatitis C, the vast majority of patients with this condition have been given highly effective treatment and have had a sustained virological

response. Because of that, we see very few patients on the list whose liver disease is caused by Hepatitis C. Livers are not allocated according to chronological age, but physiological age and there would be no benefit in allocating purely on the basis of age if a patient has a stable condition, and has no signs of decompensation, for the reasons already described.

93. We did at one point consider whether HIV and hepatitis C together should be given priority but with the modern treatments for both, survival prospects are better than they would be with a transplant unless as mentioned before the patient decompensates, and this would then be reflected in their UKELD score and ultimately TBS score.

94. We have also discussed at considerable length the possibility of awarding exception points for various conditions, but we were ultimately not in favour because you can end up awarding so many exception points that you come back to the same place. In America they do use a system of exception points, but for conditions like cancer where the patient does not have long to live and not for anything else.

(ii) the advantages and disadvantages of making these changes to the criteria.

95. I hope I have covered this above. We have the best treatment for this condition and have rarely seen a patient requiring transplant for the effects of hepatitis B since that treatment became available in 1993. The only time it occurs is on very rare occasions of fulminant disease in the acute phase. These patients would qualify as super urgent.

12) Does a Hepatitis C or Hepatitis B diagnosis have an impact on liver transplant prioritisation? If it does not, please explain why it does not. Should it have such an impact?

96. I have discussed the position in relation to Hepatitis C. We see very few patients on the transplant list with hepatitis B.

13) What, in your view, are the arguments for and against the following cohorts of patients having greater prioritisation on transplant lists?

a. Those infected with hepatitis B and/or C through NHS treatment.

b. Those co-infected with hepatitis B and/or C and HIV through NHS treatment.

c. Those infected with hepatitis B and/or C through NHS treatment and who also have a bleeding disorder.

d. Those co-infected with hepatitis B and/or C and HIV through NHS treatment and who also have a bleeding disorder

97. I can understand and sympathise with the proposal that NHS treatment provided for these patients has caused or contributed to their potential need for a transplant, but we do believe that the system we have is fair and produces the most benefit for the most people and the best use of the organ. There would be little point in prioritising someone for a transplant that carried more risk of death than their current situation. A decision to prioritise those infected with Hepatitis B or C or HIV through NHS treatment and/or those for whom their NHS treatment has caused or contributed to the need for transplant would need a change in policy to be agreed by LAG, CARE and the Senior Management Team.

98. The main argument against this is that it goes against the current principle of making the maximum use of the insufficient number of livers available to offer transplant to all those who would benefit from transplant by prioritising those who will receive the most benefit from the organ to maximise its use and the gift of the donor.

99. The system by which patients are prioritized was designed to maximise patient survival. It is always possible to change the system but if you elevate access for a certain group, the consequence is fewer donor organs for those in greater need which may increase deaths on the waiting list. One of the aims was to make the system open, transparent, and equitable.

100. There are many situations where NHS treatment may result in liver injury leading to the need for liver transplantation. Examples include antibiotic treatments that result in acute cholestatic liver failure, Methotrexate liver failure for the treatment of rheumatoid arthritis, chemotherapy for breast cancer, and post-surgical misadventure to name a few. The NLOS is designed to consider the need and utility of the organ and the best outcome for the patient. Most Hepatitis C patients have now had access to Direct Acting antivirals (DAAs - anti-HCV drugs) with a 99% sustained viral response and in most cases a stabilization or reversal of their Chronic Liver Disease. As a result, the need for transplantation in these patients has essentially stopped or remains very low and the current indication for HCV transplantation is usually due to the development of a hepatocellular cancer (HCC) or associated alcohol abuse.

101. NLOS has recently been modified to improve access for HCC patients to liver transplantation and so this group of patients has been well catered for. Transplanting patients with HCC requires adherence to strict internationally agreed criteria (Milan Criteria) which all centres adhere too. Acute HCV is extremely rare. HBV is again largely a historical condition with respect to transplantation due to the extremely effective anti-viral treatment which has been accessible now for many years – and again requirement for transplantation is due mainly to HCC associated with HBV and they are well catered for as previously mentioned. HIV is a co-morbidity in most cases and there are well developed protocols for these patients to be transplanted – but this does require experience when it comes to managing immunosuppression. Again, prioritising these patients above others more in need would not seem to be the most efficient and equitable use of the organ.

102. In addition, the patient registration form does not record whether patients are still viraemic at the time of going onto the list, so it is likely to be difficult to know precisely the scale of the remaining problem.

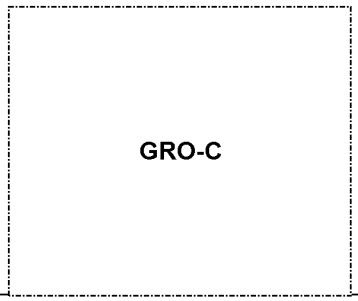
103. We have considered Haemophilia previously, as the transplant may cure the condition and the numbers nationally are small. We have as a clinical community discussed this option and decided against it, especially with the new gene therapies and viral vector treatments coming on board. I believe that the current system remains the fairest and most appropriate and do not think there has been a material change since the last review, but we could consider a further review if that was likely to be helpful, notwithstanding my explanations above as to the need for and value of transplant.

104. I understand the reason for the request to which I am responding and have great sympathy for those who have been infected by blood or blood products.

105. For the reasons I have tried to explain, it is my belief that the current system is the fairest we can provide overall and makes the best use of the limited organs available. LAG monitors and reviews allocation on a regular basis and changes to the system will be made as necessary to ensure fairness to all.

Statement of Truth

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

Signed 

Dated _____25/10/2022_____

Table of exhibits:

Date	Notes/ Description	Exhibit number
31/05/2022	Introduction to Patient Selection and Organ Allocation Policies - POL200	WITN7452002
02/08/2022	Assessment of allocation policies for organs from deceased donors - POL187	WITN7452003
05/08/2022	Non-compliance with selection and allocation policies - POL198	WITN7452004
05/08/2022	Patient Selection and Organ Allocation Policies Review and Approval (Organs) - POL223	WITN7452005
23/06/2020	Patient Registration for Transplantation POL247	WITN7452006
09/07/2020	Registering a Patient for Transplantation MPD1211	WITN7452007
21/07/2021	Management of Mass Activations or Suspensions of Potential Transplant Recipients	WITN7452008
21/05/2010	World Health Organisation Resolution on Human Organ and Tissue Transplantation of May 2010	WITN7452009
N/A	National Offering Scheme outline	WITN7452010

2005	NHS Blood and Transplant Directions 2005	WITN7452011
23/03/2011	National Liver Offering Scheme document	WITN7452012
2022	TBS calculator updated in 2022	WITN7452013