INFECTED BLOOD INQUIRY

INITIAL WRITTEN SUBMISSIONS ON BEHALF OF NHSBT

AS TO POSSIBLE RECOMMENDATIONS TO BE MADE BY THE INQUIRY AND ANY ADDITIONAL EVIDENCE RELEVANT TO THEM THAT MAY BE REQUIRED

Introduction

1. This is the response of NHS Blood and Transplant (NHSBT) to the Inquiry's request for

   "*initial written submissions outlining any recommendations (not related to compensation) that they may invite the Chair to consider, for the purpose of enabling the Chair to decide whether there is any additional evidence that needs to be gathered relevant to the making of recommendations and if so to make the necessary arrangements to obtain that evidence.*"

2. The submissions in this document are provided solely on behalf of NHSBT and should only be considered as relevant to England given that health is a devolved function, and the position may be different between the four jurisdictions.

Background

3. NHSBT is a special health authority whose mission is to save and enhance the lives of others, as an essential part of the National Health Service. Its responsibilities are to:

   - Encourage people to donate organs, blood, stem cells and tissues.
   - Optimise the safety and supply of blood, organs, stem cells and tissues and match them to patients.
   - Help to raise the quality, effectiveness and clinical outcomes of blood and transplant services.
   - Provide expert advice to other NHS organisations, and the four UK health departments.
   - Provide and conduct research and development to improve outcomes for patients.
   - Implement relevant statutory frameworks and guidance.

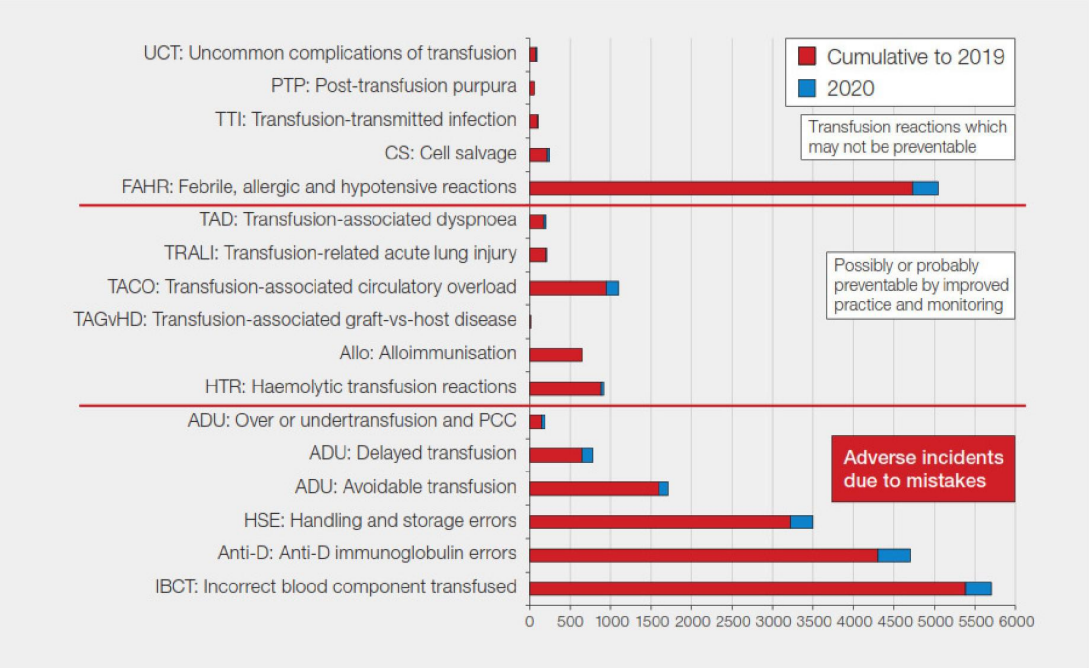
4. Dr Gail Miflin, Chief Medical Officer and Director of Clinical Services at NHSBT, has submitted an extensive statement covering historic and current arrangements and issues in blood safety and supply, dated 19 October 2021 [WITN0672006].

5. In that statement she explains some of the significant changes that have taken place within the blood services, and the development of various systems and practices since the events that are the subject of the Inquiry. This includes the extensive work that has been done on donor selection and donation testing, the 'joining up' of the system (both in terms of the formal organisation of the blood services and more widely across the NHS); the introduction of surveillance systems including haemovigilance systems; close working with public health and MSBTO/SaBTO; the use of risk-based decision-making frameworks and the Better Blood Transfusion, hospital transfusion committees and other initiatives working with NHS bodies and healthcare professionals who administer transfusions. Evidence has also been provided by Professor Murphy on consent and the use of electronic systems to improve transfusion safety.

6. Statements have also been submitted to the Inquiry on behalf of the Scottish, Welsh and Northern Ireland blood services.

7. The suggestions which follow are not confined to transfusion-transmitted infections (TTIs), the incidence of which is thankfully now relatively rare, as the cumulative data summary for 1996 to 2020 in figure 3.7 from the most recent SHOT report shows (see third bar down):

Figure 3.7: Cumulative data for SHOT categories 1996-2020 (n=25218)



8. The Inquiry provides an opportunity to consider recommendations going beyond TTIs as to a range of transfusion practice in relation to which progress has been made, but where it is hoped some fresh impetus might advance the safety of transfusion.

9. As a matter of principle, it seems to NHSBT that there are two main categories of possible recommendation:

    - Recommendations relating to changes to present practice, or that will assist in securing improvements that are already in train.

    - Recommendations aimed at putting right historical matters (to the extent that they have not already have been addressed, or the need superseded by subsequent events).

    All of the matters addressed below, save for the last, fall within the former category.

10. Section A below sets out NHSBT's positive suggestions (at A1-A8) for recommendations for the future. All of these relate to Transfusion Medicine, save A2 which relates to Future Lookback Exercises.

11. NHSBT recognises in making these submissions that in practical terms some of these recommendations will be easier to implement than others. We have attempted, in formulating them, to reflect considerations of proportionality.

12. NHSBT is one NHS organisation of many which interact. The Chair has heard evidence from Professor Murphy in relation to the difficulty there can be in establishing where accountability may lie.

13. The single item at Section B below relates specifically to further HCV tracing. In this area NHSBT does not invite any recommendation for consideration. Rather it wishes to suggest sources of further evidence likely to be of assistance if the Inquiry wishes to consider making any such recommendation.

A. Suggestions for Recommendations: Transfusion Issues and Future Lookback Exercises

14. As stated above, these possible recommendations all relate to Transfusion Medicine.

A1. Risk-based decision-making

Suggested Recommendation for Consideration

> **That the approach to risk tolerability for complications of blood transfusion in the UK by those concerned in blood policy is based on risk-based decision-making in accordance with international practice.**
>
> **That the levels of appropriate risk tolerability and cost effectiveness parameters are defined for transfusion safety policy making.**

Rationale

15. The risk-based approach is premised on the basis that not all risk can be eliminated, even in the case of activities that are in the public interest and societally valuable.

16. Formal processes to assess risk are well established in numerous areas of society including the environment, transportation, energy and food production sectors as well as some areas of health care such as new drugs or other therapeutic goods. These processes and their associated frameworks have only recently come to be used to make decisions in blood transfusion practice or in blood system policy development, as addressed by Dr Gail Miflin in her statement at paragraph 1466.

17. NHSBT employs a risk-based decision-making framework for blood safety. This approach, developed by the Alliance of Blood Operators (ABO), is embedded into the risk management framework and comprises two elements: Policy Foundations and Decision-Making Framework [WITN672100]. This framework has also been adopted by both JPAC and SaBTO.

18. The Risk-Based Decision-Making Framework for Blood Safety was created under the auspices of the ABO. It grew out of a series of activities that began with the International Consensus Conference on Risk-Based Decision-Making for Blood Safety in Toronto in 2010.

19. The consensus statement that emerged from these discussions acknowledged that:

- though blood transfusion is an integral component of medical practice, risk is inherent from 'vein-to-vein'
- achieving zero risk is unattainable, and the well-being of transfusion recipients is central to any recommendation to improve blood safety decision-making.
- product safety and supply responsibilities reside with blood operators.

20. From this consensus statement, it was decided that an integrated risk framework must be developed to improve decision-making, facilitate proportional responses to risk, ensure decisions are evidence-based, increase trust in investment decisions, and allow for the re-direction of resources to improve effectiveness.

21. Following the identification and characterization of the risk, a structured process is undertaken to assess the magnitude of the risk and the level of risk reduction that can reasonably be achieved in the context of the complexity of the risk management action proposed and its cost.

22. Inputs must be sought from appropriate subject matter experts, but also from those who can consider issues of ethics and social values. Engagement with the public is an essential step. Proposed interventions should be assessed for their likelihood of mitigating the risk and the proportional resource allocation in comparison with similar risks to the blood system or health system.

23. For policy decisions the following must be defined: (i) the appropriate level of the risk tolerability (ii) the cost effectiveness parameters; given this will be applied within a resource constrained system

Possible Further Evidence

24. The ABO risk- based decision-making framework is referenced in the statement of Dr Gail Miflin and described here: Risk-based decision making in transfusion medicine - Leach Bennett - 2018 - Vox Sanguinis. Document available here.

A2. Future Lookback Exercises

Suggested Recommendation for Consideration

That there be recommendations on how to perform a large-scale national lookback in the face of a new pathogen or test that is consistent across the UK.

25. This is an area for consideration being suggested at this stage on a topic currently being explored by SaBTO (see below). It would need to include consideration of the different circumstances of the different UK jurisdictions and might cover for example issues such as for how long samples are kept and whether or not lapsed donors are traced.

Rationale

26. The Inquiry has the oral and written evidence of NHSBT clinicians relating to lookback.

27. In the UK there are differences between the four constituent nations of the UK in the performance of lookback, as they have different systems in place and health is a devolved function.

Possible Further Evidence

28. SaBTO are setting up a working group to review lookback including overview, ethics and responsibilities. The minutes of the meeting from October 2021 can be accessed here. The Chair may wish to consider these discussions in evidence.

29. If the Chair is minded to make recommendations in respect of future lookbacks, he will be assisted by evidence on this issue. This might include:

- The international experience of lookback, including success rates of such lookback and factors which may improve prospects of success.
- The relevance of electronic systems which might assist the process.
- Ethics, data protection, and the rights of individual recipients and donors.
- The work of SaBTO.
- Resource implications.

A3. Consent to Transfusion

Suggested Recommendation for Consideration

Patients receiving blood transfusions are properly consented in compliance with NICE and SaBTO guidance

Rationale

30. Consent is a necessary part of the transfusion process. The Inquiry has heard evidence of the shortcomings of the consenting process.

31. Professor Murphy has given evidence in writing and orally as to the findings of the recent audit: 2021 National Comparative Audit of NICE Quality Standard QS138; National Comparative Audit of Blood Transfusion [WITN7001061], which included that 64% of transfused patients had evidence of receiving written or verbal (i.e. oral only) information about the risks, benefits and alternatives to transfusion, and only 26% received both written and verbal information. The recommendations include that Hospitals should examine their procedures for implementing the NICE Quality Statements for Blood Transfusion and explore the barriers to their implementation, work to overcome them and take advantage of regular repeats of this audit to monitor effectiveness of interventions.

32. Professor Murphy also referred to the CQUINS scheme. NHS England administers that scheme, and such further evidence as to its implementation and successes may be relevant evidence that the Chair should consider.

33. Patient consent to blood transfusion has also been a focus of the work of the Committee on the Safety of Blood, Tissues and Organs (SaBTO). On 17 December

2020 the Committee issued updated recommendations to NHS Trusts and Health Boards on patient consent to blood transfusion. Those recommendations are available here. They include a shift of emphasis on healthcare organisations employing mechanisms to self-monitor compliance with these recommendations, with subsequent improvement plans, rather than specifically recommending external monitoring and regulation.

Possible further evidence

34. Those recommendations are, in and of themselves, important evidence for the Inquiry. Insofar as further evidence is thought to be needed on this matter, evidence from SaBTO or regulatory bodies – CQC and MHRA - might assist.

A4. The Serious Hazards of Transfusion (SHOT) scheme

Suggested Recommendation for Consideration

That all NHS organisations have a mechanism for implementing recommendations of SHOT reports and for assuring themselves that this has been done.

Rationale

35. The recommendations considered in this section relate to a range of transfusion issues. They are not confined to transfusion-transmitted infections (TTIs), the incidence of which is thankfully now rare (see the graph at paragraph 7 above). The Inquiry provides an opportunity to consider recommendations going beyond TTIs to a range of other relevant aspects of transfusion practice.

36. Since the inception of the SHOT haemovigilance scheme in 1996, reports have been received of serious adverse events[1], serious adverse reactions[2] and near misses (mild/moderate transfusion reactions are not reportable). Reporting criteria are reviewed annually and are mostly aligned with International Society of Blood Transfusion 2022 SHOT definitions. Reporting criteria can be found here.

37. For completeness, the 2022 SHOT definitions reporting criteria also note:

> *SHOT does not accept reports on adverse reactions or events related to manufactured blood products except those relating to anti-D Ig, prothrombin complex concentrates (PCC), solvent detergent fresh frozen plasma (Octaplas) and lyophilised plasma (LyoPlas). All serious adverse reactions and adverse*

[1] MHRA Definition of SAE: Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to death or life threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity. (Definition provided here).

[2] MHRA Definition of SAR: an unintended response in a patient that is associated with the transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating or which results in or prolongs hospitalisation or morbidity. All transfusion transmitted infections (TTI) must be reported to MHRA. (Definition provided here).

events related to manufactured blood products should be reported on the Yellow Card scheme. (https://yellowcard.mhra.gov.uk/).

38. SHOT is a professionally mandated scheme rather than being statutorily mandated. This means there is no legal basis to compel reporting, although there is currently 100% participation from across the UK. However, there is awareness of current under-reporting in certain categories.

39. Haemovigilance in the UK is covered by both SHOT and MHRA and reporting to MHRA is mandatory. The reporting requirements for MHRA and SHOT are similar but not the same. The latest joint reporting guide can be found here.

40. Annual reports from 1996 have been produced by SHOT and are in evidence before the Inquiry. These reports contain recommendations which are of relevance to the Inquiry and relate to the wider landscape of safety in transfusion practices. SHOT reports can be accessed here. The most recent such report is the 2020 report. The 2021 SHOT Annual Report is due to be published in July 2022 and should be accessible at that link.

41. As well as the reports themselves, the Chair will also be assisted by 2020 recommendations included in the GAP analysis tool, which can be accessed here. The collated recommendations for the period 2002-2019 can be accessed here.

Possible further evidence

42. The Chair may wish to consider whether he needs to hear further evidence relating to these findings, how they are implemented and who is responsible for implementation.

43. The remainder of this section concerns some of the recommendations in the SHOT reports and other evidence that has been heard by the Inquiry.

A5. Staffing levels in clinical haematology and laboratory areas within NHS Trusts

Suggested Recommendation for Consideration

That transfusion laboratories are staffed (and resourced) adequately

Rationale:

44. Clinical and laboratory teams can function optimally only if adequately staffed and resourced. Staffing levels have been a common feature of other inquiries into NHS incidents including: the Mid-Staffordshire Inquiry, the Paterson Inquiry, the Ockenden Review, and '*No One's Listening*' (an Inquiry into avoidable deaths and failures of care in sickle cell patients – further information is available here).

45. The SHOT Adverse Incident Reporting Scheme has consistently reported an unacceptably high level of errors originating in the laboratory setting. In 2006 an initiative was launched in conjunction with the IBMS, SHOT, RCPath, BBTS, UK NEQAS, the NHSE NBTC and the equivalents in Scotland, Wales and Northern Ireland that led to the formation of the UK Transfusion Laboratory Collaborative (UKTLC).

46. The UKTLC, in considering the nature and spread of the errors documented by SHOT, concluded that a significant proportion of these errors were most likely to be related to either the use of information technology or staff education, staffing levels, skill mix, training and competency issues. In the absence of any formal guidance on these matters, the UKTLC developed a series of recommendations using the results of two laboratory surveys conducted in 2007 and 2008. The most recent survey, undertaken in 2019, is available here. A link to all the surveys and related documents is available here. In addition, the RCPath haemotology workforce survey is available here

47. Compliance with the UK TLC standards has been accepted by both the United Kingdom Accreditation Service (UKAS) / Clinical Pathology Accreditation (UK) Ltd (CPA) and the Medicines and Healthcare products Regulatory Agency (MHRA) as evidence to support their inspection programmes for laboratories. Further information can be accessed here.

Possible further evidence

48. If the Chair is minded to make recommendations on practical operation of the NHS, such as in the realm of staffing levels, he may find it helpful to seek evidence from the relevant bodies including UKTLC, UKAS, and the MHRA.

A6. Education of healthcare professionals in the field of transfusion medicine

Suggested Recommendation for Consideration

That people working in the NHS are adequately trained in transfusion and that accountability for this is defined

Rationale

49. All staff involved in blood transfusions need to have basic knowledge of blood components, indications for use, alternative options where available, risks, benefits, possible reactions, and management but also of the need to improve patient outcomes and reduce health inequalities by involving patients in their care and ensuring that any care takes into account the individual needs of the patient.

50. Transfusion is practised across the NHS. The Inquiry has received evidence covering various specialities. However, transfusion is often ordered by junior doctors and nursing staff. As a result of this evidence, the Chair may consider that recommendations should be made in respect of undergraduate and postgraduate

medical education to include haematology training, transfusion training, or education on the Better Blood Transfusion initiative.

51. Dr Gail Miflin has described in her statement at paragraphs 1480-1488 some of the work in this area by NHSBT. This is primarily at post-graduate level.

Possible further evidence

52. The Chair may consider that it would assist to have evidence of training provided at undergraduate level to relevant healthcare professionals and possibly from relevant Royal Colleges.

A7. Transfusion and Governance

Suggested Recommendation for Consideration

That NHS Trusts have appropriate governance structures including in relation to hospital transfusion committees as outlined in Health Service Circular 2002/009 Better Blood transfusion

Rationale

53. It is important that appropriate governance structures are in place to ensure that hospital transfusion committees are functioning, effective, report into the patient safety group or equivalent, and are reviewed at Board level. This is covered by Health Service Circular 2002/009 (Health Services Circular, Better Blood Transfusion, Appropriate Use of Blood, Public Health, Department of Health (DH), 4 July 2002).

54. Various recommendations which may further transfusion practice in this respect are open to the Inquiry, including:

- Continuing training for healthcare professionals in transfusion medicine.
- Proper dissemination of transfusion guidelines.
- Appropriate routes for reporting matters of patient safety to committees.
- Protected learning time for clinical leads with sufficient funding.
- Representation of all relevant clinical specialities on hospital transfusion committees.
- Monitoring of hospital transfusion committees to ensure they are operational and effective.
- Board level responsibility for the implementation of these structures.
- Audit by an appropriate authority to ensure compliance.

Possible further evidence

55. If the Chair is minded to make these, or similar such recommendations, he may be assisted by evidence from NHS bodies involved in transfusion practice including acute trusts and relevant regulatory bodies – Care Quality Commission (CQC) and MHRA.

A8. Information Technology

Suggested Recommendation for Consideration

> **That information technology is adopted where it has been shown to improve patient safety in relation to transfusion, including that relevant NHS bodies implement electronic systems for identification, blood sample collection and labelling.**

Rationale

56. The Inquiry has heard evidence on the use of IT in the transfusion context from Professor Mike Murphy and Dr Jonathan Wallis. Such evidence has related to the use of electronic blood ordering, and the use of electronic records to include prescribing blood and components.

57. In his statement Professor Murphy exhibited a journal article from the 2021 volume of Transfusion Medicine pp.1-9 titled: *'Transfusion 2024: A 5-year plan for clinical and laboratory transfusion in England'* (Shubha Allard, Jon Cort, Catherine Howell, Louise Sherliker, Gail Miflin and Cheng Hock Toh) [WITN7001031].

58. That five-year strategy includes various recommendations on IT and the development of a blueprint for hospitals to improve the safety of laboratory IT. It also includes development of a system of '*vein-to-vein*' tracking. The plan notes that implementation of these significant schemes would be subject to finding a funding solution.

59. The five-year strategy paper notes that, despite the evidence of the effectiveness of IT in clinical settings, NHS Trusts have been slow to implement new technology to support clinical transfusion practice. Investment has been lacking. In the paper there is a reference to the Healthcare Safety Investigation Branch's (HSIB) recommendation that NHSX (now the NHS Transformation Directorate) take steps to ensure the adoption and ongoing use of electronic systems for identification, blood sample collection, and labelling.

60. Evidence is already available to the Inquiry on various IT systems which are in place, or could be implemented, to assist transfusion practice. It is acknowledged that where resources are not unlimited and there are many competing priorities, some of the possible IT solutions are longer term aims, whilst others may be achievable more quickly. Current systems include:

- Blood stocks management: different aspects include management of delivery of stocks to hospitals, management of stocks within hospitals, and management of stocks outgoing from hospitals. Further information is available here.
- Patient blood management: information on the use and implementation of an electronic transfusion management system is available in [WITN7001014].
- Electronic clinical decision support: information on the use and implementation of such support is discussed by Professor Murphy and exhibited to his statement at [WITN7001016].
- Systems allowing full electronic traceability from donor to recipient ('*vein-to-vein tracking*'): the Inquiry's attention is drawn to the following documents which address such schemes: [WITN7001013], [WITN7001015], and [DHSC0004261_017].

Possible further evidence

61. These various forms of IT support for blood transfusion would entail significant cost and practical change. As such, the Chair might be assisted by evidence on the present position of funding for this in the NHS in England, and the cost and practicality of implementation of these schemes from, for example the NHS Transformation Directorate (formerly NHSX). The ambition of NHSX is for every NHS trust to use digital systems to maximise the quality and safety of care. See for example the wrong blood in tube (WBIT) investigation response from NHSX here , and information on the acute global digital exemplars here .

62. The adoption of electronic patient records in healthcare has not been straightforward. The Secretary of State for Health and Social Care has stated that he wants 90% of NHS trusts to have an electronic patient record (EPR) in place by December 2023. He set out his priorities for health care by harnessing the power of technology at the Health Service Journal Digital Transformation Summit. The Chair may consider that further evidence would be required of the wider picture before considering recommendations relating to this complex issue which has significant resource implications. See the comments of the Secretary of State here.

63. The Chair may be assisted by evidence on the work currently being done in this area that could be built upon.

B. Other Matters: Tracing of additional recipients infected with Hepatitis C

Context and Possible Recommendations

64. NHSBT advances no suggestions for recommendation on this topic. However, the Inquiry has heard evidence on the tracing work done historically in respect of the recipients of blood and blood products infected with Hepatitis C, and NHSBT recognises that it is possible that the Chair may be considering a recommendation in this area.

Possible Further Evidence

65. If the Chair does consider that he may wish to make recommendations in this area, he will be assisted by considering the work of the UK Health Security Agency (UKHSA) in pursuit of the World Health Organisation recommendations on such testing and target of elimination of hepatitis C.

66. The UKHSA's work is reported annually and can be accessed here and the short report here.

67. This is the subject of CQUIN PSS1 - Co-ordination of Operational Delivery Networks to work towards Hepatitis C elimination by delivering an out of hospital-based HCV Programme, liaising with stakeholders such as prisons, probation services, community pharmacies, drug and alcohol services, GPs and patient groups to identify, test and engage people living with HCV. This can be accessed here.

Conclusion

68. These suggestions are advanced in the hope of assisting the Inquiry generally, and NHSBT remains committed to providing whatever assistance and whatever further evidence it can in order to achieve this end. If there are any areas in respect of which the Chair considers NHSBT might be able to provide or suggest further evidence, it will be happy to assist to the best of its ability.

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