SUBMISSIONS

ON

RECOMMENDATIONS

on behalf of

NATIONAL SERVICES SCOTLAND
THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

in the matter of

THE UK INFECTED BLOOD INQUIRY

PART 1: INTRODUCTION

1. National Services Scotland (NSS) Scottish National Blood Transfusion Service (SNBTS) would like to thank the Inquiry for the opportunity to provide initial written submissions outlining any recommendations that we may want to invite the Chair to consider.

PART 2: PROPOSALS FOR RECOMMENDATIONS

2. NSS SNBTS invites the Chair to consider the following recommendations, as set out in outline below.

Recommendations 1 – Risk tolerability

3. (i) *Background* – All medical interventions involve a balance of potential benefit and risk. The current residual risk of missing an infection with current donor selection and screening procedures in the UK is generally low as evidenced by the UK Serious Hazards of Transfusion (SHOT) haemovigilance system, however the risk of transmission of infection by substances of human origin cannot be completely eliminated because of limitations to the sensitivity of assays, the emergence of new infections and continuing genetic evolution of established infectious agents - as we have seen in the emergence of SARS-CoV-2 and its variants over the past 2 years. Moreover, the risk of transfusion or transplantation transmission of infection is contingent on the prevalence and transmission of infection in the general population (such as, for example, the food-borne transmission of BSE/vCJD and hepatitis E).

Furthermore, the healthcare system is financially and operationally constrained and all commitments of resources therefore elicit opportunity costs in terms of other health benefits foregone. There are therefore broader societal considerations around the extent to which society wishes to accept a risk and/or assume the costs of mitigation. (ii) *Recommendations* - We would invite the Chair to consider the nature and appropriate level of tolerability of risk in regard to transfusion / transplantation transmitted infection compared to that associated with other medicinal interventions, the extent to which conventional cost effectiveness calculations can or should be applied in the area of transfusion / transplantation safety and the broader societal responsibility to mitigate the prevalence of serious infections.

Recommendations 2 – Lookback

4. (i) *Background* – The Inquiry has investigated the performance of lookback in the context of introduction of HIV and Hepatitis C testing in depth. Whilst limited lookback is not unusual in the context of individual donors who develop evidence of a new infection or a previously unknown risk, large scale national lookback such as may be required following introduction of a new assay is more unusual. Lookbacks need to be considered from the perspective of the healthcare system as a whole involving (*inter alia*) Blood Services, hospital blood banks, primary and secondary care, public health services and the Government. The need or otherwise for lookback is not captured in the European Blood or Tissue Directives or related UK legislation. The decision as to how far a lookback should extend is a difficult balance of the ethical, legal and medical imperative to inform a person who may have been put at risk of infection, against the diminishing practicality and cost benefit as one goes back in time. (ii) *Recommendations* - We would invite the Chair to consider the circumstances under which a lookback should be done, the extent to which cost effectiveness should be considered, and whether or to what extent the duty to perform lookback could or should be included in relevant legislation.

Recommendations 3 – Clinical transfusion practice

5. (i) *Background* – The measures taken to reduce the risk of transmission of infection by Blood Services have greatly changed the risk-profile of blood transfusion. The majority (>80%) of reports to SHOT are now due to errors or mistakes in the clinical transfusion process. The biggest risks are receiving the wrong blood (either wrong component transfused or specific requirements not met), receiving too much blood too quickly and developing transfusion associated circulatory overload (TACO) or not receiving blood quickly enough (blood delays). Shared decision making and consent in clinical transfusion practice was recommended by SaBTO, by NICE in their blood transfusion guidance and supported, in Scotland, by Realistic Medicine, yet successive audits, including a recent audit against the NICE Quality Standards, has demonstrated less than universal compliance. NHS hospitals and staff continue to be under exceptional pressure, perhaps never more so than over the past few years, however most of these systems errors are preventable with the right processes, knowledge and training as well as implementation of enhanced electronic clinical systems which promote and support best practice in the laboratory and at the bedside.

   (ii) *Recommendations* - We would invite the Chair to consider the extent to which blood sufficiency, quality and safety are functions of the healthcare system as a whole and the ways in which intelligence from appropriate blood usage and patient safety data from local and UK haemovigilance systems, can be better used to inform changes in healthcare systems, policies, and practices.

PART 3: COMMENT ON ADDITIONAL EVIDENCE

6. We are mindful that the primary focus of the Inquiry has been on events which occurred in the past and would ask the Chair to consider the need to take cognisance of contemporary information when considering those of his recommendations which may relate to current practice. Whilst the fundamental challenges in managing a Blood Service in respect of ensuring the sufficiency, quality and safety of blood components and other substances of human origin (tissues, cells and organs) persist over the long term, science and technology, clinical and operational practice, quality management and the regulatory environment have evolved significantly over the past 50 years and

continue to do so. Some contemporary information has been captured in the written evidence provided by SNBTS in its responses to the Inquiry's Rule 9 requests and we are aware that similar written evidence has been provided by the other UK Blood Services. SNBTS would be happy to provide any additional information or clarification required by the Chair to assist him in considering his factual determinations and any recommendations he considers it appropriate to make.

PART 4: CONCLUSIONS

7. With regard to the nature of the recommendations the Inquiry may choose to make with regard to the sufficiency and safety of the blood supply in Scotland, we would request that these are practical, deliverable and effective.

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