SUBMISSIONS
ON
RECOMMENDATIONS
on behalf of
NHS SCOTLAND TERRITORIAL HEALTH BOARDS
in the matter of
THE UK INFECTED BLOOD INQUIRY

PART 1: INTRODUCTION

1. It has often been said that a fundamental purpose of a Public Inquiry should be to enable real and enduring learning from the events of the past.[1] The current NHS Scotland Territorial Health Boards ("the Scottish Health Boards") wish to affirm the importance of that purpose in relation to this Inquiry. From their perspective, that is not only so as to prevent any future recurrence of the infected blood tragedy, but also to encourage improvements in the care and treatment which patients and families receive from the NHS in Scotland today. They, therefore, welcome the opportunity to contribute to the discussion about the making of recommendations and approach it in that spirit.

2. In the remainder of this document, the Scottish Health Boards:
   - set out their approach to these Submissions;
   - identify several substantive recommendations for consideration by the Chair and core participants;
   - make some comments on the issue of additional evidence[2];
   - and, finally, offer their concluding remarks.

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[1] See, for example, the type of discussion in the 2017 Report for Institute for Government: *"How Public Inquiries Can Lead to Change"*

[2] It is recognised that the Chair has not specifically asked Core Participants to make a submission in relation to the matter of additional evidence. However, in giving their full consideration to the issue of outline recommendations, the Scottish Health Boards have inevitably had cause to reflect on the related issue of further evidence. Our comments are the product of those reflections. It is hoped that they are helpful and assist the Chair in reaching his decision about what additional evidence, if any, is needed.

PART 2: THE APPROACH TO THESE SUBMISSIONS

3. At the outset, we wish to record that the Scottish Health Boards will engage in this discussion about recommendations sincerely and with an open mind. They recognise, of course, that such an attitude might be said to go without saying of any responsible public body participating in a public inquiry process. However, as they continue to reflect on all that has gone before, today's Scottish Health Boards consider it is important for them to state this intention clearly and in this public forum.

4. The Scottish Health Boards place great value on their relationship with all current patients from the infected and affected community. Strengthening that relationship is a paramount objective to them in participating in this Inquiry. Actively listening to what their patients say about what needs to change and how things can be improved is an important part of that. The Scottish Health Boards acknowledge that they have not always been successful in this regard, including at the Penrose Inquiry. That is something they intend to address and rectify in their approach to these submissions, before this Inquiry.

5. The Scottish Health Boards see the recommendations by this Inquiry as being of particular importance in large measure because a substantial number of infected and affected core participants are current patients of the NHS in Scotland. Many of those patients, or their family members, have given evidence to the Inquiry. All have contributed in other ways by their involvement as core participants. This group of core participants – as individuals and collectively - has brought to the Inquiry a unique perspective and body of knowledge and insight, particularly in relation to the Scottish dimension of the Inquiry. In many cases, such expertise will have been acquired not only from decades of experience as NHS patients, but also through campaigning work on behalf of the infected and affected community; and indeed their previous involvement as core participants or interested observers at the Penrose Inquiry. It is therefore not at all

surprising that the evidence of the infected and affected from Scotland has been amongst the most valuable heard by the Inquiry to date.

6. Given their experiences as current patients of the Scottish Health Boards in particular, the Scottish infected and affected are very well-placed to respond to the Chair's invitation for submissions as to recommendations. For their part, the Scottish Health Boards look forward to giving these submissions their most careful consideration and attention in due course – including by assisting in providing such additional evidence as may be necessary to enable the Inquiry to do justice to the Scottish dimension of its remit when making its recommendations.

7. Finally, it is axiomatic that recommendations by their nature are forward looking. In that regard, the utmost priority for the Scottish Health Boards going forward is to win and retain the confidence of their patients and the public by the provision of high quality health services. That being so, there is undoubtedly a substantial community of interest between the Scottish Health Boards and the Scottish infected and affected core participants in assisting the Inquiry to identify and formulate pertinent and deliverable recommendations for change, with a view to encouraging genuine improvements. The Scottish Health Boards think it likely there will be areas where views and ideas converge. However, at the same time, it may be only realistic to anticipate the potential for honestly held difference of opinion that may give rise to scope for reasonable disagreement between core participants in relation to proposed recommendations. Be that as it may, the Scottish Health Boards undertake at all times to engage in this dialogue constructively and in a spirit of good faith and respect.

8. We hope that this submission will constitute a meaningful contribution to the Chair's deliberations on the subject of recommendations.

PART 3: PROPOSALS FOR RECOMMENDATIONS

9. The Scottish Health Boards invite the Chair to consider the following recommendations, as set out in outline below.

Recommendations 1 – Reporting of Adverse Events

10. (i) *Background* – For treatment of bleeding disorders, Health Boards in Scotland report via the MHRA yellow card scheme but also have regular adverse event reporting to the UK National Haemophilia Database (NHD) which itself then reports on (in an anonymised manner) to EUHASS (European Haemophilia Safety Surveillance). EUHASS prospectively monitors for adverse events related to treatment. It is not known whether all haemophilia centres in the UK report in this manner. Furthermore, where they do, it is our experience in Scotland that staffing pressures (both clinical and administrative) can on occasion lead to delays and potentially incomplete reporting.

    (ii) *Recommendations* - Alongside routine pharmacovigilance measures, the reporting of adverse events to the National Haemophilia Database (NHD) with onward anonymised reporting to European Haemophilia Safety Surveillance (EUHASS) should be encouraged or mandated in line with appropriate consent practices. The clinical and administrative staffing necessary to facilitate a consistently high standard of adverse event reporting should also be ensured at all UK haemophilia centres. These measures would ensure continuation of the current enhanced surveillance for any emerging issues relating to historical, or current, treatments for people with bleeding disorders.

Recommendations 2 – Psychological Support for the Infected & Affected

11. (i) *Background* - NHS Scotland currently provides vital, dedicated psychology support for the infected and affected, as well as to other patients and families affected by bleeding disorders. This support is provided via the Scottish Haemophilia Psychology Support Service and the Scottish Infected Blood Psychology Service. In terms of the Haemophilia Psychology Support Service, funding has not been assured beyond 2024. So far as elsewhere in the UK is concerned, it is understood that access to dedicated psychology support services is currently variable.

    (ii) *Recommendations* – The Scottish Health Boards recommend that specialist psychology support should be directly available via all haemophilia centres for infected and affected members of the bleeding disorders community. In addition, easily accessible specialist support services should be available for

those infected and affected by blood transfusion associated infections. To ensure ongoing provision and avoid geographical inequality, either local service commissioners should be recommended to provide long-term funding for these specialist psychology services or centralised funding should be recommended.

Recommendations 3 – Specialist Bleeding Disorders Physiotherapy Services

12. (i) *Background* – Joint damage with associated pain and loss of function is a major cause of physical morbidity for people with bleeding disorders. It also has an adverse impact upon the psychological health of a patient group already badly affected by the consequences of treatment-associated infection. Specialist physiotherapy is recognised as a core part of haemophilia care with respect to assessment and optimisation of joint health. Availability of access to this varies greatly across Scotland and the rest of the UK and, where unavailable, this is recognised as a significant clinical need.
(ii) *Recommendation* – In order to optimise joint health for patients with bleeding disorders, and to reduce regional inequality in this regard, either local service commissioners should be recommended to provide funding for specialist bleeding disorders physiotherapy services or centralised funding should be recommended.

Recommendations 4 – Regional Networks of Haemophilia Clinicians

13. *(i) Background* – As bleeding disorders are rare, most haemophilia centres only have a small number of dedicated specialists.
(ii) *Recommendations* – In order to help clinicians with decisions regarding complex cases, and to assist in policy decisions at individual centres, service commissioners should support the setting up (if appropriate) and the running of, regional networks of clinicians. These networks should provide regular forums for case and policy discussion for clinicians. The necessary administrative and clinical resources should be provided. A forum for patient involvement in policy decisions should be available within such networks. The Scottish Haemophilia Centre Directors' Meeting (which is held on a bi-monthly basis) is an example of such a network which is

already in operation; in relation to it, patient input comes via the Scottish Inherited Bleeding Disorder Network (SIBDN).

Recommendations 5 – Developing Clinical Guidelines

14. (i) *Background* – The UKHCDO and British Society for Haematology currently provide guidance on optimal treatment for people with bleeding disorders. Those organisations and the National Haemophilia Database also raise awareness of developments in patient safety concerns. This work is of great value in terms of both keeping clinicians up to date on best practice and enabling rapid identification of new safety concerns.
(ii) *Recommendation* – These national organisations should be supported with the resourcing necessary to carry out their roles in producing guidance on the optimal treatment of people with bleeding disorders and raising awareness of any developments or patient safety concerns amongst clinicians. They should be encouraged to continue with their valuable work, in broadening the scope of their guidelines and updating these as practice changes.

Recommendations 6 – Clinical Audit

15. (i) *Background* – West Midlands Quality Review Service (WMQRS) audited both Edinburgh and Glasgow Comprehensive Care Centres (CCCs) on behalf of the UKHCDO against the UKHCDO standards in 2019.[3] The expectation thereafter was that further auditing would be "rolled out" across Scotland to include all of the Scottish Haemophilia Centres. Unfortunately, WMQRS went out of business during the pandemic. Prior to the UKHCDO audits, there had been regular (approximately every 3 years) peer review audits of Scottish Haemophilia Centres and this process was paused when the UKHCDO peer review began. There are currently discussions amongst the Scottish Haemophilia Centre Directors about restarting this process if there remains a lack of clarity in relation to when the UKHCDO process will restart.
(ii) *Recommendations* - Regular audit of standards of care should be performed in centres treating people with bleeding disorders. Peer review

[3] An Edinburgh visit took place on 22nd January 2019; the report date was May 2019. The Glasgow visit took place on 15th and 16th May 2019; the report date was September 2019.

with patient representation, such as performed by the UKHCDO or else the Scottish Haemophilia Centres provides the optimal model in this regard. Subject to interruptions imposed by the pandemic, it is suggested that the optimal time interval for audits might be not less than once every five years.

Recommendation 7 – Prescription of Recombinant Coagulation Factors

16. *(i) Background* – Multiple measures have been put in place over time to improve the safety of coagulation factor concentrates. One of the greatest improvements has been the transition from plasma derived products to recombinant factor products. In the UK, recombinant factor is now almost universally prescribed where appropriate licensed products are available.
(ii) Recommendations - Recombinant coagulation factor products should be offered in favour of plasma derived ones where clinically appropriate. Service commissioners should ensure that such treatment decisions are funded accordingly.

PART 4: COMMENT ON ADDITIONAL EVIDENCE

17. The Scottish Health Boards are pleased that the Chair intends to consider, at this stage, whether there is any additional evidence that needs to be gathered relevant to the making of recommendations. We take this opportunity to offer some general observations from the perspective of the NHS in Scotland, which we hope may assist with that task.

18. In offering our proposed recommendations to the Inquiry, we acknowledge that the Chair may not, as yet, be in possession of sufficient evidence to adjudicate on the merits of all our suggestions. While the evidence heard at the Inquiry has formed an essential context for our discussions, it is also fair to say that our proposed recommendations are, in large part, the product of deliberation within the Scottish Health Boards[4] in relation to the state of affairs within the NHS in Scotland today. For reasons which we expand

[4] We have also sought input from Public Health Scotland (PHS) and Healthcare Improvement Scotland (HIS). In relation to adverse reporting work carried out by HIS see footnote 13. PHS has been involved in working with the SNBTS in its blood donor hepatitis core testing related lookback. They have not given evidence to the Inquiry about these matters. (Public Health Scotland has provided a Rule 9 statement to this Inquiry in relation to the specific issue of vCJD.)

upon below, we accept that the Inquiry may consider that it requires to be furnished with further evidence as to the current position (whether by rule 9 statement, or otherwise) in order to evaluate properly our proposals. In a similar vein, it seems reasonable to anticipate that other core participants may suggest recommendations in areas where the Inquiry has yet to examine in detail the contemporary position within the NHS in Scotland.

19. In our submission, this is an issue which raises some important considerations in relation to deciding what further evidence may yet be required in order for the Inquiry to decide upon recommendations.

20. While recommendations relate to the future, a defining feature of this Inquiry is that many of the most significant and controversial events under investigation occurred more than 30 years ago. Without presuming to predict the conclusions of the Chair's final report, it may be that a number of these events will ultimately be found to be associated with failings and other deficiencies relating to the NHS. Where such problems are identified, the question of corresponding recommendations for improvement may then arise, by way of natural corollary.

21. However, the Inquiry has also heard at least something of the far reaching changes which have already occurred in the NHS and medical profession during the intervening period.[5] These changes are particularly evident across many of the themes and issues where the Inquiry may ultimately offer criticisms. For example, paternalism in the health service has given way to an ethos which aspires to shared-decision making between clinician and patient working in partnership.[6] The autonomous medical consultant paradigm has been replaced by a multi-disciplinary approach to clinical care in the majority of healthcare settings in the UK.[7] In Scotland, treatment

[5] It is perhaps unsurprising that there may have been fundamental changes in practice in the NHS given the significant period of time that has elapsed since the material events.

[6] In terms of current work to further improve clinical practice in Scotland, the principles of Realistic Medicine emphasise the importance of people using healthcare services and their families feeling empowered to discuss their treatment fully with healthcare professionals, in language and using information that is appropriate to help their understanding and enable genuine shared-decision making. Realistic Medicine explicitly emphasises a number of opportunities for improvement including managing risk better. For further information on this initiative see the *Realistic Medicine website*; and also *Chief Medical Officer's Annual report 2014-15*.

[7] See, for example the Academy of Medical Royal Colleges (2020): *"Developing professional identity in multi-professional teams"*

of Hepatitis C has been improved by the availability of Direct Acting Antiviral Therapies and a strategy for rapid elimination of the disease now forms part of current Scottish government policy.[8] In relation to informed consent, clinical practice looks very different today as compared to the 1980s.[9] Health and care professionals working within the NHS have a professional duty of candour in their communications with patients.[10] Health, care and social work services in Scotland are also subject to an organisational statutory duty of candour.[11] The way in which doctors are educated and supervised has also evolved substantially over the years.[12]

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[8] *Scotland's Hepatitis C Action Plan: Achievements of the First Decade and Proposals for a Scottish Government Strategy (2019) for the Elimination of both Infection and Disease - Taking Advantage of Outstanding New Therapies* (The Action Plan was accepted as Scottish Government policy in 2019). As part of the Scottish Government's approval of the elimination strategy, Public Health Scotland (PHS) was instructed to set up an Elimination Working Group to support health boards in the delivery of elimination. This meets regularly. It produced a short life working group report summarising best practice for detection diagnosis and cure of HCV for use in a Scottish Context. The group also produced targets for HCV elimination by 2024 at a national level and was in the process of generating these targets in an annualised form for each health board when the pandemic intervened. In response, to the pandemic the clinical teams associated with HCV treatment were deployed to Covid wards and the epidemiologists in PHS were directed to Covid modelling work. It is only in the last two months that some of the epidemiologists have returned to working on HCV. One of their first tasks will be to estimate what Scotland has to do to get back on track for elimination. The Elimination Working Group is also working with the Government to explore utilising some of the newly recruited vaccinating workforce to deliver dried spot testing to the at risk population for HCV infection. The HCV clinical treatment teams are now also returning to HCV work. In relation to the progress of the elimination of HCV infection in NHS Tayside, the Board has now moved to the implementation phase. As such, all patients with known HCV infection have been offered treatment, and all those who accepted the treatment have been cured. The Board has achieved WHO HCV elimination targets 10 years ahead of global schedule. It has also conducted multiple look back exercises related to blood products from available records to identify as many patients as is possible who might be at risk of infection. All of those patients have been contacted and tested, with treatment provided where needed. Using "*intelligent Liver Function Testing*" all those with abnormal liver tests have an automatic HCV test, the best remaining way of finding those who may have been infected by blood products in the UK or abroad.

[9] See for example, the General Medical Council (2020) *"Guidance on professional standards and ethics for doctors: Decision Making and consent"*

[10] See for example, the General Medical Council (2022) *"Openness and honesty when things go wrong: The professional duty of candour"* .

[11] See The Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and The Duty of Candour Procedure (Scotland) Regulations 2018.

[12] For discussion of which, see the report of Professor Philip Cachia submitted to the Inquiry in June 2020, *"Medical Education, Training and Supervision in 2020: Response to issues raised in oral evidence from the Psychosocial Expert Group, Infected Blood Inquiry, February 2020"*

Systems for clinical governance and adverse event reporting have been transformed.[13]

22. These are but a few obvious examples illustrating what is perhaps an obvious point: that while the evidence before the Inquiry has hitherto principally focussed on events many years in the past, a proper consideration of recommendations is likely to require evidence as to the current position today. That is not, of course, to say that events from the 1970's and 80's do not contain lessons of continuing relevance for the NHS in Scotland today. However, it is equally the case that for recommendations to gain traction and achieve their objective, they should be grounded in an informed assessment and understanding of the position "here and now"[14]. Otherwise, there would, for example, be a risk that a recommendation might turn out to be superfluous (such as where the historical failing to which it relates has since been remedied[15]) or futile (if it fails to take account of the current position or contemporary context such that its implementation becomes in some way impracticable).

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[13] By way of example in relation to Adverse Events Reporting in Scotland: Healthcare Improvement Scotland has developed a national framework to support Scottish health boards to standardise processes for managing and learning from adverse events *(Learning from adverse events through reporting and review - A national framework for Scotland: December 2019) (healthcareimprovementscotland.org)*); HIS has implemented an Adverse Events Notification System which receives information from all NHS boards regarding all commissioned Significant Adverse Event Reviews, (SAERs.) Work is underway for a "Once for Scotland" approach to standardise all levels of adverse event data reporting in collaboration with the Adverse Events Network where all NHS boards are represented. Included in this work is standardisation of events which lead to a SAER which will ensure a consistent approach across Scotland. Work on a revised adverse events framework will commence in autumn 2022. Improved alignment with SAER's and Duty of Candour will also be addressed. An update report on the adverse events work of HIS can be found at *Adverse Events Notification System: Update Report: January 2022 (healthcareimprovementscotland.org)*. In terms of ongoing research work, the "Adverse Event Reviews in healthcare: what matters to patients and family?" was completed by members of the joint commission team and was recently published in the British Medical Journal (*Adverse event reviews in healthcare: what matters to patients and their family? A qualitative study exploring the perspective of patients and family)*. For developments in Scotland in relation to: "Qualify Management Systems" (see, for example, Quality Management System.aspx); and in relation to "Quality Improvement Methodologies" see *Safety is at the heart of our work*, *Value Management* and *Quality Improvement Zone*.

[14] In this regard, the Scottish infected and affected helpfully bring to the discussion their experiences as "users" of the current NHS is Scotland. Their perspectives are very valuable in informing issues in relation to recommendations. However, for the purpose of properly assessing recommendations, in many cases, we think it will also be necessary to consider evidence from the NHS organisations in Scotland as service "providers".

[15] Or which is in the process of being remedied. Such information would presumably be helpful for the Chair to know.

23. Depending on its nature, the implementation of a recommendation may have a profound impact upon the organisations to whom it is directed - and properly so. For example, it might require difficult decisions involving reallocation of staffing resources or scarce public funds away from other areas of health care spending. The issues involved may be complex, inter-related and multi-factorial – and go beyond the matter of resourcing. In our submission, at least as a matter of general principle, identifying the correct solution to a particular 'problem' will therefore usually require a sufficient understanding of the full context within which the issue is said to exist. For these reasons, we recognise that the Inquiry obtaining sufficient evidence as to the present-day position is generally a prerequisite for (and, indeed, logically anterior to) reaching an informed decision as to what recommendations to make.[16]

24. Finally, this is a public inquiry for the whole United Kingdom. As such, there may be areas in which the Inquiry has already obtained evidence in relation to England, Wales and/ or Northern Ireland but has yet to conduct an examination of the position in Scotland. Particularly in the era of devolution, it cannot be assumed that a recommendation which may be right for one nation of the United Kingdom is necessarily suitable for all of the others. It therefore seems to us that any recommendation which applies to the whole of the United Kingdom should only be made on a correspondingly comprehensive evidential basis, including (where applicable) relevant evidence as to the current position as regards the NHS in Scotland. The same observation would, of course, equally apply in respect of any recommendation which is proposed specifically in relation to Scotland.

25. In this regard, we would of course be glad to assist the Inquiry in identifying potential witnesses from within NHS Scotland who may be able to provide

[16] For the avoidance of doubt, we do not suggest the Inquiry requires to review all aspects of current practice relevant to its terms of reference, beyond the areas where potential recommendations fall to be considered. Insofar as there may turn out to be areas where no potential recommendations arise, in our submission the Inquiry may reasonably infer that any historical shortcomings identified have since been remedied.

relevant evidence[17] in relation to the subject matter of proposed recommendations.

PART 5: CONCLUSIONS

26. The evidence heard at this Inquiry has caused the Scottish Health Boards to engage in a process of reflection upon their own role in the infected blood tragedy. Much of that process has naturally included evaluating our involvement in the events which led to the tragedy occurring, and during the years of its immediate aftermath. However, we consider it is also essential for us to be able to reflect upon the position within the NHS in Scotland today in 2022, and seek to identify areas where there may yet be work still to be done. The recommendations which we propose in this submission are the result of our process of reflection, though by no means an end to it.

27. We look forward to participating constructively in the discussion about recommendations which lies ahead. In accordance with our approach throughout the duration of the Inquiry, we undertake to provide any further assistance as may be required in producing, or facilitating access to, such additional evidence as the Inquiry may require in order to determine its recommendations.

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[17] We do not consider that there would be any need for oral evidence from any such witnesses if written evidence by way of appropriately focussed rule 9 statements can be obtained.