INFECTED BLOOD INQUIRY

INTERIM SUBMISSIONS ON NON-FINANCIAL RECOMMENDATIONS

ON BEHALF OF THE HAEMOPHILIA SOCIETY

INTRODUCTION

1. This submission is made by the Haemophilia Society ("The Society") on its own behalf, and on behalf of its members, to include those designated with Core Participant status in the Inquiry and represented by Eversheds Sutherland (International) LLP. It is an interim submission made in accordance with the Statement of Approach issued and updated by the Chair of the Infected Blood Inquiry ("this Inquiry") most recently on 30 May 2022. It is made for the limited purposes set out in that Statement of Approach, and is without prejudice to fuller and wider submissions to be made on or before 24 October 2022. It is made in brief format only to identify relevant topics upon which the Chair is asked to consider making appropriate recommendations.

2. This submission is informed by the responses of 251 of The Society's members to a survey asking for the membership's views on non-financial recommendations and considerable correspondence with its membership and former trustees over the past years. A summary of the responses will be provided to the Inquiry.

PUBLIC INQUIRY REFORM

3. Section 1 of the Inquiries Act 2005 contains the power to establish a Public Inquiry. The power is solely exercisable by a Minister. Save in the event of a successful judicial review resulting in an order requiring the Minister to establish an inquiry, the public, or affected sections of the public, are frequently denied justice or have justice delayed. This Inquiry is a paradigm example: decades of delay have resulted in many dying without answers or compensation, whilst evidence is lost or destroyed, memories fade and witnesses become unavailable.

4. Under current legislation, the public find themselves disenfranchised, and unable to bring matters of public concern to light. This (and previous) legislation, has therefore resulted in meritorious groupings repeatedly seeking the establishment of public inquiries on matters of public concern to no avail, with such concerns eventually leading to the establishment of a belated public inquiry – often after many decades of waiting. By then, it may be too late for those that have been affected by the concerns forming the basis of the original demand, and the public will have been wrongly deprived of recommendations by the eventual public inquiry which should have been available far earlier. There can be surely no greater example of this than this Inquiry, where the scandalous issues of concern have been overlooked by successive governments of different political persuasions, with the eventual establishment of a public inquiry decades too late, and when many of those affected are no longer with us.

5. The Society and its members feel strongly that reform of the Inquiries Act is the only way to ensure that others caused avoidable harm by the State, and who thereby find themselves in poverty and poor health, do not have to expend energy lobbying Ministers/Governments who may have an interest in refusing a statutory inquiry or non-statutory review.

6. The Chair is therefore asked to consider recommendations so that meritorious seekers after a public inquiry have a better means to seek the establishment of a public inquiry. This could be by the recommendation of an amendment to the Inquiries Act, whereby a Minister would be required to consider the establishment of a public inquiry if a certain percentage of members of parliament demanded it. Alternatively, a recommendation could be made to establish an independent body who would have the power either to convene a public inquiry (which would require an amendment to the Inquiries Act), or to recommend to the relevant Minister that a public inquiry be held. There is precedent for such an independent voice. Canadian Judge Cory was asked, as an independent figure, to consider whether various matters of concern in Northern Ireland merited the establishment of a public inquiry, and to make recommendations to government. The Chair could consider formalising such an ad hoc arrangement to an independently constituted body for such a purpose.

7. Such an independent body could be charged with applying transparent criteria to assess the circumstances in which statutory and non-statutory inquires/reviews must be held. Such a body could also collate inquiries and reviews (so that there is a central repository of recommendations), monitor recommendation implementation and, in appropriate circumstances, require inquiry Chairs to review implementation.

8. The Society notes that announcement of the appointment of the first Patient Safety Commissioner (following the Government's acceptance of the Cumberlege Review's Recommendation 2) is overdue and, it is hoped, imminent. References in this submission to "the Cumberlege Review" refer to the report of the Independent Medicines and Medical Devices Safety Review (titled 'First Do No Harm'), published on 8 July 2020. The Cumberlege Review is addressed further later on in this submission.

REDRESS FOR AVOIDABLE HARM

9. The Inquiry's work has laid bare the fact that the contaminated whole blood and blood products infected and affected community has suffered avoidable harm as a result of patient safety systems failures. Whilst believing that negligence actions for damages for infection with HIV/AIDS were likely to fail, the Government still required sufferers to litigate. Litigation takes years which, the Government knew, people with haemophilia infected with HIV/AIDS did not have. Almost 40 years on, people with haemophilia are still dying of infected Factor VIII and IX products without adequate recompense and, as Sir Robert Francis QC's Infected Blood Compensation Study highlights, without being able to put their affairs in order. On 7 June 2022, Sir Robert published his study, 'Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework', that looks at options for a framework for compensation for the victims of the infected blood tragedy.[1] This report is referred throughout this submission as "Sir Robert's Infected Blood Compensation Study report".

[1] Sir Robert Francis, 'Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework' dated 7 June 2022 ('Infected Blood Compensation Study Report'), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1081007/Compensation_and_Redress_for_the_Victims_of_Infected_Blood_-_Recommendations_for_a_Framework_-_Sir_Robert_Francis__Final_.pdf

10. In the 1980s and 90s, The Society decided that fairness and equality for all its members, and the community as a whole, required that there be some level of immediate financial relief for all those infected and for families and the bereaved. The only means of securing that was to mount successive campaigns based on moral, not legal, rights. As Sir Robert observes in his Infected Blood Compensation Study report, those successive campaigns resulted in a *'"patchwork" of support"* which has been wholly inadequate for the reasons explained by the APPG, which he sets out[2].

11. The support monies made available are considered by the current Government to be *ex gratia* payments[3] but even here there is confusion: in March 1995, speaking about the Macfarlane Trust, Baroness Cumberlege told the House of Lords, *"the majority of the payments made were not ex gratia since an undertaking had to be made not to take the matter to the courts"*[4].

12. As set out below, history appears to be repeating itself. Mr Hancock told the Infected Blood Inquiry that he accepted that the Government has a moral responsibility to address the impact of what has happened to those infected and affected[5]. But that acceptance has been arrived at without there being any clear or coherent approach to Government decision making about those sections of the public caused avoidable harm by patient safety systems failures Government owes a moral responsibility, and those which it owes no moral responsibility at all.

13. The Society seeks a recommendation that there be publicly available, clear and coherent criteria setting out the circumstances in which the State will pay financial redress to members, or a section, of the public suffering avoidable harm as a result of patient safety systems failures.

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[2] See page 43 of the Infected Blood Compensation Study Report at paragraphs 4.10 to 4.12, in particular.
[3] See for example Mr Hancock's transcript of evidence to the Infected Blood Inquiry, 21 May 2021 at page 148 lines 17-21. And also the Government's Response to the Cumberlege Review dated 26 July 2021, which described the Infected Blood Support Scheme as providing "ex-gratia support" (page 22 paragraph 3.2).
[4] See BWCT0000017 at 0008, which is a letter dated 3 May1995 from F.G.H Hill (Consultant Haematologist) to 'Maggie', enclosing a photocopy of the proceedings of a debate in the House of Lords dated 15 March 1995. One notes that this statement preceded Lord Clarke's views about the Government's thinking in 1989 highlighted by Sir Robert in his Infected Blood Compensation Study Report at page 44 paragraph 4.17.
[5] Transcript of evidence of Matt Hancock to the Infected Blood Inquiry, 21 May 2021 page 126 lines 15-19.

14. Further, the Society seeks a recommendation that this Inquiry support the Cumberlege Review's recommendation 3 that there be a new, independent Redress Agency (see below). This may be an appropriate body to determine when such criteria are met.

15. In its response to the Cumberlege Review, dated 26 July 2021, when giving reasons for declining to accept the Redress Agency recommendation, the Government, through the Department of Health and Social Care ('DHSC'), prayed in aid its ability to set up support schemes. It referred to the 'Infected Blood Support Scheme' (sic).[6] The only inference that can sensibly be drawn from that reference is that the current Government believes that the EIBSS (one presumes) and various other infected blood support schemes (and possibly trusts) provided/provide an example of redress done well.

16. The Government representation to other sections of the public who have suffered avoidable harm as a result of NHS patient safety systems failures, that the infected blood support schemes evidenced its ability to set up vehicles for providing financial support that were/are fit for purpose, is of concern for two main reasons.

17. First, that suggestion flies in the face of all the evidence heard in this Inquiry by those who utilise the schemes. This part of the Government's response to the Cumberlege Review suggests that it (and the authors of the DHSC response) were either ignorant of, or paid no heed to, the evidence of trust and scheme users to this Inquiry about the adverse effect on them of: the lack of any financial assessment of their losses or their needs; the psychological harm caused by different treatment of infected and affected in each of the devolved nations; divisive means testing; needless complexity and opacity; onerous requirements for evidence before even small sums would be paid out; unexplained exclusion of bereaved parents in financial need; the lack of any proper voice of the infected and affected within the trust and scheme administration; the conflict between users in dire need and trust/scheme administrators who held back large reserves of monies intended by Government to be paid out to those infected; and the end result for the large majority of infected people which was that the trusts and schemes demeaned them because they were constantly required to hold out a begging bowl.

[6] See the Government's Response to the Cumberlege Review dated 26 July 2021 at paragraph 3.2, page 22.

18. Second, the Government's July 2021 response failed to acknowledge, or even refer to, the oral evidence of Mr Hancock. Speaking to the Inquiry on 21 May 2021, the then Secretary of State for Health and Social Care accepted that the trusts and schemes had been run without there being a *"proper process around coming to a fair and just way of ensuring that people are supported"*[7].

19. As the Government's July 2021 response to requests for financial support by other harmed sections of the public appears uninformed by its own former[8] Minister's acceptance, just two months earlier, that the infected blood support trusts and schemes were inadequate and unfair, it is hardly surprising that Sir Robert Francis records[9] that trust is so low on the part of some, that doubts were expressed about the authenticity of the Government's intention to pay compensation[10].

20. The Society was also astonished to see from the blog written by lawyers representing families harmed by sodium valproate[11], that the Government recommends, just as did the Governments of the 1980 and 1990s in relation to infected blood, that those families litigate. Nothing, it seems, has changed. When presented with an NHS tragedy that should never have happened, Government's knee jerk reaction is to deny financial support, pray in aid the need to protect the principle of no fault compensation, state that the priority must be improvement of health services, and invite those harmed to litigate.

21. The Society notes from the Cumberlege Review and the Select Committee's report on NHS Litigation, that there is now a significant body of authoritative work which has found that not only does the current adversarial clinical negligence system fail those who have suffered avoidable harm, but, importantly for the public at large, the adversarial system is an obstacle to improving patient safety.

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[7] Transcript of evidence of Matt Hancock to the Infected Blood Inquiry, 21 May 2021 page 125 lines 10-16.
[8] Mr Hancock resigned on 26 June 2021.
[9] Infected Blood Compensation Study Report page 10 paragraph 1.11.
[10] That commitment having been made expressly by Mr Hancock: "*...if the Inquiry points to compensation, as opposed to a support scheme, in the future then the Government will pay compensation*" [see transcript of evidence of Matt Hancock to the Infected Blood Inquiry, 21 May 2021 page 151 line17-19),
[11] Leigh Day blog, 'Lawyers look forward to the implementation of redress schemes recommended by Baroness Cumberlege', dated 27 May 2022, https://www.leighday.co.uk/latest-updates/blog/2022-blogs/lawyers-look-forward-to-the-implementation-of-redress-schemes-recommended-by-baroness-cumberlege/

22. The Society considers that formulation of workable recommendations in relation to redress for avoidable harm would be assisted by evidence. In considering whether further evidence is required to inform workable recommendations on this topic, the Chair may wish to have regard to written evidence that has recently become available, set out in Annex 1.

CONSENT

23. Improvements have been made to the way healthcare professionals go about seeking patient agreement to treatment (ie consent) in the decades since the NHS first started prescribing US Factor VIII and the General Medical Council's guidance was revised recently[12]. However, the Cumberlege Review provides a significant body of evidence which demonstrates that there is still a great deal going wrong. Doctors remain too ready to make assumptions about what patients want, or to adopt the position that they know what is in their patients' best interests. They are still overselling possible benefits, underselling possible burdens, and not being clear enough about what is uncertain and unknown.

24. The Cumberlege Review records that women treated with pelvic mesh in the twenty first century faced not only an arrogant attitude, but also that the Review was told of *"missing or altered medical records"* and *"concerns about deliberate cover ups"*. Further that some hospital Trusts routinely destroy medical notes which is concerning for long latency adverse events where harm may not become apparent for many years[13]. In Annexe A to the Government's Response to the Cumberlege Review and in relation to pelvic mesh, it is said that *"Dismissive, defensive attitudes by surgeons are a cultural issue that needs to be addressed by the medical profession, its professional bodies and regulators."*[14] And the response refers to the fact that the GMC is currently reviewing its guidance *Good Medical Practice* which came into effect in April 2013. But no conclusions are reached as to why this cultural issue of dismissive, defensive attitudes persisted into the twenty first century, and after April 2013.

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[12] See General Medical Council, 'Decision making and consent: Guidance on professional standards and ethics for doctors'. published on 30 September 2020, https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf.

[13] The Independent Medicines and Medical Devices Safety Review (aka First Do No Harm, referred to herein as "the Cumberlege Review"), published on 8 July 2020, see paragraphs 5.43-5.44 at pages 152-153.

[14] Government Response to the Cumberlege Review dated 26 July 2021, page 98 at item 50, and page 43.

25. It is difficult for those harmed by new medicines and new medical products and devices to succeed in a claim for damages for personal injury based on negligent failure to provide information. That may be for a variety of reasons including the fact that "consent" appointments are not audio or video recorded, and the difficulty for patients in proving that they would have acted differently if complete or differently presented information had been provided.

26. The Society invites the Chair to consider the "Informed Consent" section of the Government's Response to the Cumberlege Review[15], where it accepted the "Actions for Improvement", and consider whether those go far enough. Publication of this Inquiry's report may also provide an opportunity to monitor implementation of, for example, the National Institute for Health and Care Excellence's shared decision making guideline and the extent to which patients are routinely made aware that they have the right to record a discussion with a doctor if they wish to do so. The Chair may feel that the infected and affected would derive particular benefit from hearing evidence to assist with consideration of recommendations addressing cultural attitudes in the NHS, particularly to believing patients as well as listening to them.

CONTINUING SCRUTINY OF RECOMMENDATION IMPLEMENTATION

27. The Society and its members are aware that this Inquiry's recommendations to Government are no guarantee of their ultimate implementation for the benefit of current and future people infected and affected by infected blood products. However, The Society asks the Chair to make recommendations to enhance the scrutiny and implementation of his recommendations. It is submitted that this might be achieved in a number of ways, including:
    a. the adjourning of the Inquiry, post its report, with a recommendation that the Chair review implementation of recommendations within a given time period, with the possibility of a supplemental report commenting on the success or otherwise of the implementation of the final recommendations in the interim; and/ or

[15] Government Response to the Cumberlege Review dated 26 July 2021, paragraphs 2.23 to 2.24 on page 15-18.

b. a recommendation that the implementation of the recommendations in the final report be reviewed by the cross-party Health and Social Care Committee on a regular basis, with consequent reports to Parliament.

THE IRISH EXPERIENCE AND BRIAN O'MAHONY

28. The Society submits that the Chair may be assisted in hearing evidence from Brian O'Mahony.

29. Mr O'Mahony is well known to the Inquiry. He is the Chief Executive of the Irish Haemophilia Society, former President of the European Haemophilia Consortium and a former President of the World Federation of Haemophilia. He is also an assistant adjunct Professor in Health Service Management at Trinity College, Dublin.

30. On 22 April 2022, he kindly gave a talk to legal representatives of infected and affected Core Participants where he presented slides and answered questions. This talk was extremely helpful and informative. The Society (and, it believes, all infected and affected Core Participants) are strongly of the view that the Inquiry, and all those infected and affected, would benefit from hearing from Mr O'Mahony.

31. As noted in this submission, The Society seeks recommendations in the areas of:
    a. Case managers;
    b. NHS care and treatment passporting;

32. Mr O'Mahony can speak directly to how recommendations in these areas were implemented in Ireland, which have proved most valuable over time as infected people age and their needs change, and the important role played by knowledgeable and experienced case managers in ensuring that infected and affected people gain the maximum benefit from non-financial areas of redress.

ACCESS TO CURRENT TREATMENT AND UP TO DATE INFORMATION

33. The Chair is asked to make a recommendation that all those affected by bleeding disorders, contaminated blood products and all related infections are afforded the

following due to current services not providing the necessary level of support and care as is clear from evidence provided to this Inquiry:

a. access to all knowledge of new treatments and information relating to their condition, to be provided through Haemophilia Centres
b. guaranteed access for all with bleeding disorders to recombinant (non plasma) products
c. the choice of treatment to suit people's lifestyles and guaranteed access for all sufferers to new therapies, to include gene therapy
d. guaranteed access to care that would include psychological services, pain management and physiotherapy for all of those identified with the current service specification[16]
e. equality of access to all care to include dental treatment and endoscopies.

34. The Society and its members are conscious that all patients will require prompt access to appropriate NHS treatments for a full range of ailments, and that such access for many will be problematic, particularly in the post Covid era. A recommendation is not sought that by virtue of their condition, people with bleeding disorders/ infected with contaminated blood/ HIV/ Hepatitis B/ C should be able to "queue jump" in relation to NHS waiting lists. A recommendation is however sought, given the extensive delays that such sufferers have endured, that in relation to their conditions and issues associated with such conditions only, they be afforded a facilitated and expedited access to NHS services to avoid future delays and to avail themselves of prompt treatment. This could be facilitated through an NHS care and treatment passport, which would be a record designed to help communicate their needs to doctors, nurses and other healthcare professionals.

ONGOING LONGER TERM ASSISTANCE

35. A recommendation is sought that public funding be provided to The Society, and other Haemophilia Societies in the UK and other charities supporting the infected, to provide advice and advocacy services to those affected in relation to the report, its implementation, and any scrutiny of that report in pursuance of the proposed

[16] The current service specification is available online: https://www.england.nhs.uk/wp-content/uploads/2013/06/b05-haemophilia.pdf

recommendation above, and generally. Public funding should also be recommended to ensure that the Haemophilia Societies, and charities working in this sector, have an ongoing ability to assist those affected by the issues covered by this Inquiry.

36. What is clear is that those affected by the conditions considered by this Inquiry will need ongoing assistance and care from the health and social care systems, customised to individual need. A specific recommendation is therefore sought that the Social Care system is geared to accommodate these individual needs, and to properly fund them. Such a recommendation may need to encompass appropriate swift mechanisms to challenge any refusal of such identified needs to ensure that any difficulties are quickly addressed, and resolved, without the need for litigation. For example, a Case Manager could assist individuals from a financial perspective and support them in making claims for benefits and support generally.

37. In relation to litigation and dispute resolution more generally, a recommendation is sought prohibiting the use of non disclosure agreements, and/or waivers of rights by government/public bodies as a part of any settlement agreements reached.

RESEARCH ON FUTURE CARE AND PALLIATIVE CARE

38. The Society seeks recommendations that there be research into the needs of those infected by contaminated blood and blood products with particular reference to changing needs and health risks as those infected age, the specific needs of people with bleeding disorders who are dually infected, the long term effects of treatment for AIDS and Hepatitis C and the needs of infected women as they age particularly in relation to bone density.

39. Public funding should also be made available to consider and analyse the as yet unknown long term impacts of living with bleeding disorders/ HIV/ AIDS/ Hepatitis, to include the social impact as well as the clinical needs and to report onwards to government.

TRAINING AND EDUCATION

40. On the basis of past patient experience, a recommendation is sought that all relevant medical professionals, to include doctors, nurses and dentists, should have included in their mandatory training:
    a. advanced patient communication skills, to include direction as to how to liaise with patients to avoid them feeling that they are a burden on the NHS due to their condition
    b. ethical training, to include obligations of confidentiality, and restrictions on use of patient information
    c. the ability of patients to demand, and be provided with, full access to their medical records

    on the lessons to be learned from the contaminated blood scandal, as outlined in this Inquiry's final report (addressed further below).

EDUCATION ABOUT THE CONTAMINATED BLOOD SCANDAL

41. The Society seeks a recommendation that the contaminated blood scandal is part of core teaching of all healthcare professionals, all NHS managers, all non-medical staff in NHS leadership roles and all civil servants in leadership roles at the Department of Health so that the lessons to be learned from this Inquiry, not only in relation to delay in implementation of the patient safety centred Government policy of self-sufficiency with its many catastrophic consequences, but also subsequent lack of communication with patients and patient advocacy groups, lack of candour and cover-up within the NHS, the civil service and Government are embedded now and in the future.

APOLOGY / MEMORIAL

42. There can be no doubt that the issues encompassed by this Inquiry, and the approach of successive governments to them, has been one of the most disgraceful scandals of recent years. A recommendation is sought that this be acknowledged by Government; first in its acceptance and implementation of this Inquiry's eventual recommendations; secondly by appropriate apology, and thirdly a permanent memorial to those so tragically affected .

INTERIM PAYMENTS FOR COMPENSATION

43. Sir Brian's request for interim submissions that focus solely on non-financial recommendations is at the forefront of The Society's mind. However, in fairness to its members, The Society cannot pass up this opportunity to communicate its strong support for Sir Robert Francis' recommendation that there be immediate, interim payments of £100,000 to each person.

44. The Society and its members suggest that the delay in establishing this Inquiry, and the inevitable delay in preparing and publishing its report, should lead the Chair to consider the issue of compensation in the interim period. The Inquiry will of course be mindful of the numbers of those who have died from their illnesses whilst awaiting justice, and the situation whereby those affected continue to pass away whilst awaiting the outcome of this Inquiry. It must surely be right that interim payments be recommended without delay pending this Inquiry's full report.

45. The Inquiry is due to hear from Sir Robert on 11 and 12 July 2022. The Society seeks from the Inquiry an interim recommendation that the Government makes payments of £100,000, to all those currently registered on schemes across the UK. Whilst Sir Robert's Infected Blood Compensation Study report primarily deals with matters of financial compensation (which these submissions do not necessarily address in line with the Chair's direction), at Annex 2 we have set out certain of Sir Robert's recommendations endorsed by The Society . These recommendations are not solely 'financial' in nature and support what is proposed above.

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Serjeants' Inn Chambers

EVERSHEDS SUTHERLAND (INTERNATIONAL) LLP

20 June 2022

Annex 1: Evidence available to the Chair in deciding whether further evidence on intended recommendations is required

Recently published documents

46. The Society wishes to draw to the Inquiry's attention some recently published documents relevant to recommendations addressed in this submission. These resources, which are publicly available, may assist the Chair with consideration of any further evidence required in relation to non-financial recommendation, and with formulation of workable such recommendations.

47. This (almost) chronological list of documents starts with the Cumberlege Review and the Inquiry will, of course, be well aware that in the 1990s, she was the Parliamentary Under Secretary in the House of Lords with responsibility for HIV and Hepatitis C:
    a. The Independent Medicines and Medical Devices Safety Review (titled "First Do No Harm" and referred to herein as "the Cumberlege Review") published on 8 July 2020;[17]
    b. General Medical Council's revised 'Decision making and consent: Guidance on professional standards and ethics for doctors', published on 30 September 2020;[18]
    c. The Government's Response to the Cumberlege Review dated 26 July 2021;[19]
    d. The First Do No Harm APPG's letter to the Minister for Patient Safety and Primary Care, dated 18 May 2022;[20]
    e. Leigh Day's blog "Lawyers look forward to the implementation of redress schemes recommended by Baroness Cumberlege" dated 27 May 2022;[21]

[17] https://www.webarchive.org.uk/wayback/archive/20200805110914/https://www.immdsreview.org.uk/Report.html.
[18] https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf.
[19] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1005847/IMMDS_Review_-_Government_response_-_220721.pdf
[20] http://firstdonoharmappg.org.uk/wp-content/uploads/2022/05/Letter-to-Maria-Caulfield-MP-May-2022-FINAL.pdf
[21] https://www.leighday.co.uk/latest-updates/blog/2022-blogs/lawyers-look-forward-to-the-implementation-of-redress-schemes-recommended-by-baroness-cumberlege/

f. The Health and Social Care Select Committee's Report titled NHS Litigation Reform ("the Select Committee Report") published on 28 April 2022 (the Government response to which is due on or before 28 June 2022); [22]

g. The report, Mind the Implementation Gap: the persistence of avoidable harm in the NHS, published on 7 April 2022 by the charity Patient Safety Learning ("Mind the Implementation Gap"); [23]

h. The Review into Health and Social Care Leadership undertaken by General Sir Gordon Messenger (Vice Chief of Defence Staff) and Dame Linda Pollard (Chair of Leeds Teaching Hospital Trust) published on 8 June 2022 ("the Messenger Review").[24]

48. The Society draws to the Chair's attention the following matters in particular, though the Inquiry may feel that its work is furthered by looking at the entirety of these documents:

a. The Cumberlege Review:

Recommendation 3: that "*a new independent Redress Agency for those harmed by medicines and medical devices should be created based on models operating effectively in other countries. The Redress Agency will administer decisions using a non-adversarial process with determinations based on avoidable harm looking at systemic failings, rather than blaming individuals*" and

Recommendation 4: that redress schemes be set up for each of the three medicines/medical devices considered "*to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim*";

b. As to the recommended Redress Agency, Government said (paragraph 3.2 on page 22) that (emphasis added):

[22] https://committees.parliament.uk/publications/22039/documents/163739/default/
[23] https://www.pslhub.org/learn/patient-safety-learning/patient-safety-learning-documents/patient-safety-learning-mind-the-implementation-gap-the-persistence-of-avoidable-harm-in-the-nhs-7-april-2022-r6564/
[24] https://www.gov.uk/government/publications/health-and-social-care-review-leadership-for-a-collaborative-and-inclusive-future/leadership-for-a-collaborative-and-inclusive-future

> *"We do not believe it is necessary to create a new agency for redress as it is already possible for the government and others to provide redress for specific issues where that is considered necessary (for example, the ex-gratia support through the Infected Blood Support Scheme). If, as the recommendation proposes, existing redress schemes were relocated behind a single front door of a new agency, we do not see that would necessarily improve patient's redress experience."*

c. The Government rejected the recommendation that it (or others) make redress through ex gratia schemes where there was no legal liability to do so. It said that it was crucial that it focused government funds on improving patient safety, including specialist mesh centres and support for families affected by medicines in pregnancy (paragraphs 3.5-3.8 on page 23).

d. Baroness Cumberlege expressed dismay at this Government recommendation, in the letter dated 18 May 2022 to Maria Caulfield MP from the First Do No Harm APPG she co-chairs with Jeremy Hunt MP:

> *"We were particularly disappointed to read in your letter dated 30 March that the Government continues to advocate the litigation route. This is an adversarial process that has not served affected individuals and their families well. Having seen the avoidable harm people have suffered and continue to suffer, we are firmly of the view is that there is a strong ethical responsibility to provide redress."*

e. Since publishing its response, the Government has recommended that those suffering harm from sodium valproate should seek to meet their needs by pursuing litigation, despite the fact that litigation commenced in 2004 had to be withdrawn in 2010 when Legal Aid funding was terminated, as explained in Leigh Day's blog of 27 May 2022;

f. The Select Committee's report proposes a move away from an adversarial system, wherein negligence must be proved before compensation can be made, and towards an administrative system where there is access to compensation

based on an agreement that correct procedures were not followed and the system failed to perform. The administrative system proposed would be no less generous in its awards than the courts but it would be simpler and much quicker. It is notable that the Select Committee took evidence from individuals in those countries about how compensation is managed in the different systems in operation in New Zealand, Sweden, Virginia USA and Japan (see paragraph 28 of the report). The Select Committee's prime reason for advocating a change to an administrative system is the need to *move "from a blame culture to a learning culture"* (paragraph 8 of the Executive Summary).

g. Further, the Executive Summary to this report says:

> "*adversarial litigation makes learning from mistakes harder not easier. Rather than reviewing cases in a way which accounts for context and system failure, a system focused on clinical negligence by definition seeks out individual failings*". (paragraph 4)
>
> "*Maintaining a costly and adversarial litigation system is evermore at odds with our understanding of how the NHS should respond to failures in care. England's system of clinical negligence stands in stark contrast to international best practice in terms of patient safety.*" (paragraph 6)
>
> "*We urgently need a system where the biggest priority is the prevention of future harm.*" (paragraph 7)

h. Mind the Implementation Gap provides a definition of patient safety (page 8) and sets the concept of avoidable harm in a national and international context.

i. In section 1, *"public inquiries and reviews"*, it reviews the many inquiries and reviews touching on patient safety that there have been over the last 22 years. It notes difficulties in implementation of recommendations and the fact that there is no easy way to assess what recommendations have and have not been implemented, describing this as *"an affront"* to patients and families who are assured that *"lessons have been learned"* (page 12).

j. It notes the persistence of an NHS blame culture, which is inimical to patient safety, over the course of two decades starting with Sir Liam Donaldson's 2000 report Organisation with a Memory, and continuing through the Bristol Royal Infirmary Inquiry which reported in 2001, the Mid Staffordshire NHS Foundation Trust Inquiry which reported in 2013, the Cumberlege Review in 2020 and the Ockenden Review in 2022. It ends this section by recommending that patient safety inquiries and reviews need "*effective and transparent performance monitoring to ensure that the accepted recommendations translate into action and improvement*". And under the heading "common themes" (page 23), notes how Government and NHS respond to reports about patient safety in isolation, without looking at other reports that highlight similar systemic problems. It says that: "*it is far from clear that inquiries and reviews where there are overlapping patient safety themes are being looked at in a coordinated fashion*".

k. The Executive Summary to the Messenger Review refers to two problem areas: cultures and behaviours, and NHS management. In relation to the former, it speaks of an institutional instinct in the healthcare sector "*to look upwards to furnish the needs of the hierarchy rather than downwards to the needs of the service-user*". In relation to the latter, there is a "*focus on the current absence of accepted standards and structures for the managerial cohort within the NHS.*"

l. Echoing the Cumberlege Review which described "*a fragmented healthcare system, despite numerous initiatives*" (paragraph 2.128), the Messenger Review speaks of "*a system which still relies heavily on siloed personal and organisational accountability.*"

m. This Review made 7 recommendations all of which have been accepted by Government. They include:

1 – "*A new, national entry-level induction for all who join health and social care. A new, national mid-career programme for managers across health and social care.*" And Recommendation 3: "*A single set of unified, core leadership*

and management standards for managers. Training and development bundles to meet these standards."

n. The final section of the Messenger Review deals with implementation. It proposes a Review Implementation Office which should have a direct mandate from the Secretary of State.

49. Lord John Horam's statement to the Infected Blood Inquiry dated 13 May 2022 [WITN5294001] illustrates Government's determination to hang onto the no-fault principle even if that meant allowing those caused avoidable harm by the State to suffer poverty. Although the costs of making payments were estimated, no work was done on the extent to which early support payments could save money in the long term. Early payments would have allowed people to maximise health, return to work, and prevented family members from having to give up work to provide care to sick and dying relatives. (These are matters which may be considered by the health economics panel in due course.) Attachment to the no-fault principle without consideration of health economics is not necessarily value for money. Further, had this Inquiry been established 25 years ago, as it should have been, it would have been cheaper and quicker.

Annex 2: Non-financial recommendations made by Sir Robert Francis in his report, 'Compensation and Redress for the Victims of Infected Blood – Recommendations for a framework', published 7 June 2022

Support services - Pages 134-135

11.15 ***Advice and advocacy:*** *As indicated above, it is desirable that the scheme and its applicants are supported by an advice and advocacy service. This should be a commissioned service acting independently of the scheme management, to assist all applicants navigate the process and ensure that their needs and claims were fully and effectively articulated and understood.*

11.16 In cases of particular complexity or sensitivity, the scheme should have the discretion to fund legal representation to address the particular needs of the case.

11.17 In the case of award recipients who lack the capacity to manage their property and affairs, it may be necessary on a discretionary basis to fund the costs of guardians, attorneys and Court of Protection proceedings.

11.18 ***Financial and associated advice:*** *Such advice may be required to mitigate losses such as difficulties in obtaining finance or insurance services, or simply advice on the management of the award. The management of the sums involved will be outside the experience of many applicants, and they will be disadvantaged if independent and impartial advice is not available to them. One example, from the experience of the support schemes, is the facility to write on behalf of an infected or affected person to a prospective financial lender to confirm the nature, extent and security of funding arrangements under a support or compensation scheme.*

11.19 ***Access to health and care services:*** *Some of the schemes described have a facility to expedite or facilitate access to the health and care services, and also financial services relevant to the infected or affected person. The management of support schemes in the UK have often made efforts to do that here, which has been welcomed by the beneficiaries of the schemes.*

11.20 In a country where healthcare is free to all at the point of need, the issue may not be the theoretical availability of - and entitlement to - a service, but the ease of access to it. Insofar as it is an issue for the infected and affected, the scheme should be resourced to offer advice and referral to appropriate services. For example, if an applicant has experienced difficulties in accessing appropriate counselling, the scheme should be equipped to offer them a referral to such a service, or where there is a common unmet need, to take steps with the NHS to ensure that specialised counselling is available.

11.21 Likewise, if - as must be hoped - the support schemes' efforts to engage the financial and insurance sectors are continued and improved on, either by the support schemes or the compensation scheme, the compensation scheme may have a role to play in signalling or certifying entitlement to access any special arrangements made for this cohort.

11.22 In addition to this body, the scheme should seek and report on the views and feedback on their experience of all applicants whether they are successful or not in their application.

User Involvement in the Scheme – Page 137

11.31 Whatever form the scheme takes, it will be novel, and there will inevitably be opportunities to learn from claims experience. It is important that victims' groups are consistently involved in offering feedback to the scheme on applicants' experience. Therefore, there should be an advisory forum or committee with a membership representative of those infected with all the relevant conditions and also of all nations. The scheme should be obliged to have regard to the views of this body in the management of the scheme and any changes proposed to be made to it.

Non-Financial Support – Page 137

11.32 The scheme should have a support unit which is available to provide or arrange the provision of medical, psychological and social support to infected

and affected persons appropriate to the needs caused by the consequences of the infection. The Archer Inquiry recommended that the infected should be issued with a card entitling them to benefits not freely available under the NHS, including free prescriptions, counselling, physiotherapy and support services. This recommendation should be revisited and consideration given to whether such a scheme or comparable facility should be provided via the administration of the compensation scheme or otherwise.

The standard of such provision should be in accordance with recognised contemporary standards.

Recommendation 17 – Page 138

I recommend that the scheme should include provision of the following support services:

a) an advice and advocacy service, supplemented where necessary by discretionary access to independent legal advice and representation, to assist and advise applicants;

b) a financial advice and support service to assist recipient in the management of awards and in accessing financial services; and

c) facilitation of access to appropriate health, care and counselling services.

Legal Support – Page 139

12.1 It is inevitable that the scheme will be complex for many applicants to understand, to prepare their case for compensation and to respond to an offer or assessment of compensation. If, as they did, the Home Affairs Committee considered the Windrush scandal victims required legal support, it is difficult to see how the same conclusion cannot be reached for the victims of the infected blood scandal. While no doubt there were cases of complexity among the Windrush victims, the period of time during which the impact of the deficiencies in administration were operative are likely to have been

considerably shorter than will apply in most cases in an infected blood scheme, and the issues - medical, psychological and social - cover a much wider range of circumstances. Potential claimants will have to understand into which, if any, of the categories of eligibility their case falls, and except in the simplest of cases they will have to articulate and explain the impact of the infection on them. To consider and describe the losses they have incurred within the categories of loss recognised by the scheme, and to prepare their best case. Even if potentially willing to be satisfied by a tariff payment, they will require advice enabling them to compare that with their prospects of large sums by undergoing the more complex process.