IN THE INFECTED BLOOD PUBLIC INQUIRY

Chaired by Sir Brian Langstaff

INITIAL SUBMISSIONS OF THE COLLINS CORE PARTICIPANTS ON NON-FINANCIAL RECOMMENDATIONS - JUNE 2022

By §4(a) of the Statement of Approach for Submissions (issued on 1st April 2021 and revised on 18th March 2022), the Chair has invited Core Participants to

> *"... provide initial written submissions outlining any recommendations (not related to compensation) that they may want the Chair to consider."*

It is understood that these initial submissions are non-binding, in the sense that CPs may vary or develop them further in their final submissions, may add to them in their final submissions, or may choose no longer to press for some of the recommendations outlined here. But that the provision of initial submissions at this stage is so that the Chair can decide whether there is additional evidence that needs to be gathered relevant to the making of recommendations.

We provide these initial submissions in outline form because the reasoning behind almost all of them will be immediately apparent to the Chair, having heard and read the evidence as it has been given.

The Chair has expressly directed that these initial submissions should not address the question of compensation. What amounts to *"compensation"* is therefore relevant in delineating the scope of these initial submissions. For these purposes, we consider that expression to include all forms of redress including but not limited to the heads of loss which could be awarded as damages in civil claims in negligence. Those damages could include: pain suffering and loss of amenity; aggravated or exemplary damages; loss of congenial employment; loss of career; past and future loss of earnings or loss of earning opportunity; past and future care and assistance; past and future cost of medication and treatment; accommodation; inability to obtain a mortgage; inability to obtain life assurance or other insurance including travel insurance; additional transport and holiday costs; loss of relationship prospects; loss of chance to have children; bereavement; dependency; and "lost years" claims.

We take it also to include the additional recommendations in the report of Sir Robert Francis QC (*"Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework"* 14.3.22) such as a social impact award, an autonomy award and the extension of the categories of those who might be entitled to compensation (e.g. an affected person being entitled to an injury impact award without needing to prove their status in law as a foreseeable 'secondary victim').[1]

Those matters are all therefore excluded from these initial submissions. But they will be included within our detailed written submission in October, following the evidence Sir Robert gives to the Inquiry in July and the publication of the government's response to his recommendations.

[1] The Chair may nonetheless consider it prudent to seek additional evidence on the specific aspects of loss identified by Sir Robert Francis at §9.88 of his report to which he attributes a 'broad brush' value (e.g. the increased cost of insurance, of convenient medical treatment, additional transport costs, etc).

On that basis, the non-compensation recommendations which, following a consultation exercise with the Collins CPs, we are *presently* minded to invite the Chair to make at the conclusion of the Inquiry cover the following areas.

1. **Government apology**
2. **Memorials**
3. **Future network / support events**
4. **Criminal liability**
5. **Regular review of blood safety screening systems**
6. **Testing for those potentially infected**
7. **Improved patient information and treatment**
8. **Consent**
9. **Medical training**
10. **Civil Service**
11. **Burden of proof for schemes**
12. **Record-keeping**
13. **Independence from the pharmaceutical industry**
14. **Coroners**
15. **A Treasury review**
16. **Freedom of Information**
17. **Public Inquiries**

1 A recommendation that there should be a full and complete Government apology

1.1 In light of the treatment of the infected and affected, the length of time over which they have had to fight for justice and the history of obfuscation and incomplete explanation, there should be an unconditional and unqualified full apology by the Government to all those infected or affected, recognising that they were wronged by the use of contaminated blood and blood products and further wronged by the time it has taken for the scandal to be properly investigated, made openly in the House of Commons by the Prime Minister and published, along with:

1.1.1 A long-term commitment to remedy and make reparation to all victims (infected and affected), to put them so far as possible in the position they would have been in, had they not suffered the illnesses and/or injuries inflicted on them;

1.1.2 A Government undertaking not to seek the enforcement of any previous compromise agreements or settlements which required the waiver of the right to make further legal claims arising from contaminated blood or blood products;

1.1.3 A Government commitment to create and fund a body comprised of a representative cross-section of core participants/groups identified from this Inquiry, to consider annually and review: the processes of identification of infected and affected persons; their treatment; welfare; care; eligibility and payments systems made available to them, with scope to compare the provision of the same in other countries.

2 A recommendation that there should be memorials

2.1 A permanent, substantial, national memorial, funded by central government but organised by an independent group made up of representatives of the infected and affected in consultation with those impacted should be established to honour the deceased and living victims of the infected blood disaster in each of London, Cardiff, Edinburgh and Belfast.

2.2 Furthermore, there should be a review by hospitals, transfusion centres, and other healthcare bodies, after consultation with that independent group, of the appropriateness of all existing installations / memorials / statues honouring any

medical staff involved in the administration of contaminated blood and blood products to such victims.

3 Recommendations for ongoing network and support events

3.1 Recommendations in respect of counselling and treatment are made separately below, but funding should be made available for a biannual networking/support event for those impacted (affected and infected), for a period of at least three events after the conclusion of the Infected Blood Inquiry. Many people impacted live in isolation and the time they have been able, under the auspices of the Inquiry, to spend with others similarly impacted has been greatly beneficial to their wellbeing and mental health. Such an event could usefully be combined with a public presentation / update as to the ongoing process of providing compensation and implementing the other recommendations the Inquiry will in due course make.

4 Recommendations in respect of action in relation to criminal liability

4.1 While recognising that s.2(1) of the Inquiries Act 2005 prohibits *determination by the IBI itself* of criminal liability, there is such strong feeling amongst the infected and the affected (who note that criminal proceedings have occurred in other jurisdictions) that the Inquiry will be invited to recommend that all relevant papers, evidence and information be passed to relevant prosecuting authorities in the four nations to allow them independently to consider whether criminal proceedings should be brought.

4.2 Similarly, the Inquiry will be invited to recommend that the GMC undertake an independent review of the conduct of doctors (practising, retired and deceased) who were engaged in Factor 8 product patient trials, advising governing bodies and societies (e.g. UKHCDO, Haemophilia Society, ACVSB, licensing bodies, the DoH) on the safety and use of blood products and administering unlicensed factor concentrate products on a 'named patient' basis.

5 Recommendations for regular review of blood safety screening systems

5.1 There should be a patients' charter / NHS protocol to ensure that blood and blood products supplied by or on behalf of the NHS are of the highest standard and the safest nature reasonably possible. Recipient safety should outweigh any perceived donor right to give blood. Decisions around who can donate, and when, should be taken on a purely scientific basis seeking to minimise or keep risks to recipients as low as possible, recognising that it will always be necessary to discriminate in respect of blood donation, in order to maximise safety and minimise risk.

5.2 Regular reviews of blood safety screening systems should be undertaken by an independent review panel, who should have regard to the history of the contaminated blood scandal and lessons learned from it, which should have representation on it not only from doctors but also from patients, lay members and independent (non-medical) professionals to provide the broadest possible holistic overview. In conjunction with those reviews, steps should be taken to ensure that:

5.2.1 There is a licensed blood register identifying the origin of all blood and plasma products produced within, and imported into, the UK, to include all commercial and non-commercial providers.

5.2.2 All SHOT reports are considered as part of the review process, along with consideration of the adequacy of systems of screening of blood donors in order to detect and respond to early warnings on the quality and efficacy of blood supply.

6 Recommendations for medical screening and testing for those potentially infected by contaminated blood or blood products

6.1 There should be provision of 'one stop' priority testing units, within existing Hospitals and/or Haemophilia Centres, to make freely accessible testing and scans for those who received blood products and blood transfusions, to test for HCV, HIV, vCJD, liver cancer and other blood or hepatic conditions. Testing staff should also be aware of and alert for signs of the other physical and psychological conditions which the Inquiry has heard may be linked to contaminated blood and blood products.

6.2 Consideration should be given to whether initial blood testing could be offered through pharmacies, to broaden ease of access to it, with confirmatory hospital testing to follow if positive.

6.3 Any adverse diagnosis should be given face-to-face (not in writing or by telephone), not rushed and there should be time for reflection, questions and answers including a follow-up consultation to allow the patient time to consider the diagnosis. Counselling should be made immediately available following an adverse diagnosis.

7 Recommendations relating to improved patient information and treatment

7.1 Psychosocial support should continue after the end of the IBI.

7.2 Improved psychological and counselling support should be made readily available at a comparable level across all nations, regions and NHS trusts to all the infected and affected, such counselling and support to be delivered by those trained in and familiar with the specific background of the contaminated blood scandal.

7.3 An assessment / study of the likely effects of the ongoing sequelae of HIV/HCV in later life should be commissioned, to allow planning for and provision of better-targeted health and social care in older age for the infected and affected.

7.4 Funded medical research should be commissioned on the co-infected and co-treated, to better understand their likely future prognosis and treatment needs.

7.5 A "one stop" advocacy service should be introduced on a national basis, by which trained staff who are familiar with the history of the contaminated blood scandal and the issues for the infected and affected, can swiftly and effectively assist with access to social care, benefits, medical support, etc. This would be akin to the services of a case manager in care regimes for serious personal injury and should save the infected and affected having to make the same case and explain the same issues many times over to different agencies. It should enable and assist those who may be less adept at form-filling and arguing their own case, and alert them to the full range of entitlements, benefits and services which are available for their conditions.

7.6 Fast-track NHS prioritisation of treatment for the infected and affected should be introduced, in recognition of the fact that their condition was inflicted on them by the state (noting that in damages for negligence the cost of private medical treatment would be awarded by a Court to ensure the swiftest possible and most efficient recourse to treatment).

7.7 A proactive annual "MOT" health assessment should be introduced for all infected and affected individuals to check on their physical and psychological welfare to provide peace of mind. It should be made available also to those said to have 'cleared' any infection (or reduced it to non-detectable levels).

7.8 An additional central fund should be provided for GPs to be able to draw upon to implement the same.

7.9 Any diagnosis of HIV or HCV for any person should trigger a bespoke individual look-back consideration of whether it may have been caused by infected blood or blood products.

7.10 Any diagnosis of HIV or HCV attributable to infected blood or blood products should trigger a pathway of further investigation and advice including physical and psychological treatment and support, follow-up screening and testing, and testing and screening of family and partners.

7.10.1 Those diagnosed should be provided with simple but comprehensive materials (printed and accessible online) in respect of their condition, its possible progression, next steps in their treatment, medication and its side-effects, risks of transmission, steps to be taken in family and social situations, recommended lifestyle changes, available counselling and support, available grants funds and benefits, support groups and the availability of access to their own medical records.

7.11 Equivalents of annual prescription certificates should automatically be available for the infected.

7.12 Regular liver investigations (to include ultrasound and fibroscans) should be available on a consistent basis (not to vary by nation, region or NHS trust) for all those who received contaminated blood and blood products, with the introduction of a 'best practice' protocol involving scans being done in the morning, a consultation with a Consultant the same afternoon and prompt and effective communication about all findings, positive tests and available psychological support.

7.13 Improved palliative care and hospice access, consistent across nations and regions, should be provided for those who received infected blood or blood products.

8 Consent

There should be:

8.1 Improved systems for patient understanding of, and consent to, proposed treatment.

8.2 Improved systems to ensure clinicians are trained in, understand the need for, and implement, the obtaining of full and informed consent from patients.

8.3 An obligation fully to inform patients afterwards if emergency treatment was required and provided when they could not consent.

9 Medical training

9.1 The contaminated blood scandal should be a required part of the syllabus for undergraduate medical and nursing training, to ensure lessons are learned and not lost.

9.2 There should be specific aspects of medical and nursing training so that the context in which patients were infected is understood and does have to be repeated, questioned or doubted at consultations.

9.3 Specific medical training (updated, reinforced and re-validated through CPD) should be introduced in *empathy* and how to communicate adverse diagnoses. Training to ensure that such consultations are undertaken face-to-face (not in writing or by telephone), not rushed and that there is time for reflection, questions and answers.

9.4 Doctors should provide written reasons to patients (also retained in their records) if prescriptions or treatment are given outside NICE guidelines (i.e. if the current equivalent of prescribing on a 'named patient basis' occurs).

9.5 A system of auditing or peer review of GP records should be introduced to avoid the situation which occurred for many HCV infected patients from whom the Inquiry has heard, of them returning with consistent complaints of symptoms only to be sidelined or misdiagnosed.

10 Civil service

10.1 Adoption of a duty of candour for the civil service.

10.2 Improved 'Chinese walls' / separation of responsibility within the civil service so that internal reviews of potential failings (such as the production of the now discredited chronology on self-sufficiency) or responses to external demands (such as the analysis of documents for disclosure in the HIV and HCV litigation) are not undertaken by

those who might potentially be open to criticism for the underlying matters ("marking your own homework").

10.3 The introduction of teaching modules in Civil Service training to ensure the lessons of this disaster are learned and not repeated.

11 Burden of proof for schemes / benefits

11.1 To the extent that the current schemes for the support of the infected and affected remain, for those whose records have been lost, the burden of proof should be relaxed so that their evidence of what transpired in procedures where blood or blood products were administered is taken at face value unless wholly implausible. i.e. reversal of the normal burden of proof.

12 Record-keeping

12.1 Improved and proper NHS record-keeping such that the immense disadvantages faced by the infected and affected of which the Inquiry has heard should never occur again. So far as we can presently tell, there are a range of regulations, guides and codes of practice across different HNS bodies and the four nations in respect of record-keeping, some of which still have discretionary rather than set periods for their retention.

12.1.1 The Inquiry should recommend consistent policies across NHS trusts and the four nations as to duration of keeping records, nature of the records to be kept, where and by that means they are to be kept. With audits or random checks to ensure so far as possible that records are being kept that way.

12.1.2 And simple and consistent, publicly-available policies across the four nations and NHS trusts as to access to those records by patients and in appropriate cases by their carers (suitably authorised by the patient) and next-of-kin.

13 Independence of the NHS, the DoH, medical charities and treating doctors from the pharmaceutical industry

13.1 Steps should be taken to ensure that all contacts with commercial pharmaceutical companies by clinicians, health bodies and medical charities are recorded and are

publicly-accessible. Effectively a full, thorough and public register of interests. To include sponsorship, funding, research funding, publishing, gifts, perks.

14 Recommendations in respect of Coroners' powers and procedure

14.1 Review of current Medical & Coronial Registration and Death Certificate Conclusions, with amendment to the notes to Schedule Form 2 of the Coroners (Inquests) Rules 2013, to add a new Short Form Conclusion of:

'Death from infectious illness [HCV, HIV, vCJD, liver carcinoma or other] arising from the provision of contaminated blood products / blood transfusion'.

15 Recommendation for a Treasury review

15.1 A Treasury review of the DWP benefits / tax systems applicable, and financial implications of receipt of support / compensation by those infected and/or affected. Consideration is suggested of:

15.1.1 A requirement of greater communication and exchange of information between the Inland Revenue, the NHS and the DWP departments, to:

15.1.1.1 facilitate expeditious processing of applications; and

15.1.1.2 avoid the infected and affected being placed under suspicion by the DWP as being benefit cheats because of receipt of awards under the schemes; and

15.1.1.3 avoid duplication of provision of information to differing Government departments and entities; while

15.1.1.4 avoiding breach of medical confidence, and affirming a right of non-disclosure;

15.1.2 Exemption for infected and affected persons from having to: (1) fill in DWP forms; and (2) attend 'Back to Work' interviews; upon proof of eligibility for compensation / support under formal compensation schemes.

15.1.3 Legislation, and provision of a DWP 'general exemption card' to ensure that compensation/support payments are wholly disregarded from means-tested benefits, regardless of which infectious disease has been occasioned through provision of contaminated blood / products.

16 Recommendation in respect of Freedom of Information / cover-up

16.1 In light of the difficulty CPs have experienced in battling to obtain information, there should be a review of public authority compliance with Freedom of Information Act 2000 requests, to consider:

16.1.1 Categories of exemptions under the Act, and whether such should only apply when 'necessity' is established for the same;

16.1.2 Compliance with requests made for medical information, and blood product supply information, and provision of all notes for those treated within their regions/remit;

16.1.3 Whether greater incentives and/or oversight on public authorities to comply, or comply within the time frames envisaged by the legislation is required;

16.1.4 Mandatory annual publication of the number of all FOI requests received by public authorities; their responses/replies or non-replies/responses or outstanding requests remaining; the timescales for such replies; and whether the applicant has appealed, pursued the request further, and/or raised the request with the ICO;

16.1.5 Whether greater powers of enforcement should be provided to the Information Commissioner's Office, to ensure greater adherence by public authorities to the requirements of the FOI Act 2000;

16.1.6 Whether there should be punitive measures imposed (fines, publication of non-compliance lists) on public authorities in the event of significantly poor or consistently poor performance and/or failures to meet the statutory targets, to incentivise maintenance of high standards, and better serve the public interest.

16.1.7 Whether individuals as well as organizations should be held to account for non-compliance under the FOI Act 2000.

17 Recommendation for review of access to a Public Inquiry

17.1 There should be a formal consultation in respect of the process of convening a Public Inquiry, and:

17.2 whether (and if so when) there should be an entitlement to the same; and

17.3 how the convening of Public Inquiries can be put on a fairer, more consistent and more transparent footing, removing them from the discretion and inclinations of politicians[2].

17.4 This should include consideration of the proposal that Public Inquiries should not be sponsored by a government department, if that department is alleged to be a potential responsible primary party or potential core participant.

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20.6.22

[2] See "Towards Justice: Law Enforcement & Reconciliation" (Cumberland Lodge) https://www.cumberlandlodge.ac.uk/read-watch-listen/towards-justice-law-enforcement-reconciliation-cumberland-lodge-report