SUBMISSION ON PROPOSED RECOMMENDATIONS TO BE MADE BY THE INFECTED BLOOD INQUIRY ON BEHALF OF THE CORE PARTICIPANT CLIENTS REPRESENTED BY THOMPSONS SCOTLAND

General

This Inquiry has inevitably concerned itself with investigating events of the past as fully as possible, despite obvious limitations imposed on it by the passage of time. In certain areas it has been able to investigate in detail certain matters relating to current practice and service provision (including but not limited to services available for the care and support of the infected and affected, medical treatments available to patients with HIV, HCV etc). In other areas, where the evidence has shown there to have been shortcomings in the systems relating to the care of the infected or affected, these appear to be of more general aetiology and impact, such that the investigation of them may have been considered to have been disproportionate to the legitimate aims of this Inquiry. In our submission, that does not make the discovery of shortcomings of more general application, as seen through the eyes of this Inquiry, any less valuable. However, we recognise that in such areas, the ability of this Inquiry to make specific recommendations at this time may be inevitably limited. It is important, though, that what this Inquiry has discovered be acted upon and the opportunity be taken for improvements to be implemented to the system which may be necessary in light of the analysis of past events which the Inquiry has undertaken. Therefore, where we submit below that the evidence has demonstrated systemic shortcomings which appear to us to merit action, we have proposed that the Inquiry make recommendations to the effect that further investigation be undertaken as to the specific ways in which the shortcomings might be further analysed and addressed.

The Inquiry has asked the core participants on whose behalf this submission has been prepared to provide initial written submissions outlining any recommendations (not related to compensation) that they may want to invite the Chair to consider. [1] The Inquiry has clarified that the purpose of asking for such submissions at this time is to enable the Chair to decide

[1] Statement of Approach on "Submissions at the End of the Oral Evidence" (updated to 18 March 2022)

whether there is any additional evidence that needs to be gathered relevant to the making of recommendations and, if so, to make the necessary arrangements to obtain that evidence. In order to assist with that aspect of the process, we have made submissions below relating to a number of the recommendations we have proposed where we have suggestions to make to the Inquiry as to what such additional evidence might include. The Inquiry has also stated that it is not necessary for these initial submissions to address the question of compensation, because the Inquiry is already well aware that this is a recommendation which it will be asked to consider.[2] Inquiry Counsel have subsequently clarified that the reference to "compensation" should be construed widely as relating to financial payment which might be made to the infected and as such includes any proposed extension or alteration to the operation of the existing financial support schemes. Accordingly, this initial submission does not address any such recommendations, which will be included in our final written submission to the Inquiry.

A) ENFORCEMENT

1. Task force

1.1 As per the recommendations of the Cumberlege review, this Inquiry ought to recommend that a task force be set up to implement this Inquiry's recommendations.[3] Its first task should be to set out a timeline for their implementation. It should include a Scottish sub-committee to report to the main task force in order to deal with the implementation of the measures which are specific to Scotland, whilst drawing on the progress of the main task force (on the assumption that many of the Scottish specific recommendations proposed in this paper may well be recommended for separate implementation elsewhere in the UK).

1.2 It is submitted that it is imperative that the task force include representation from the infected and affected communities, so that their voice continues to be heard

[2] ibid.
[3] Cumberlege report, final report, page 188, recommendation 9

in the implementation of the recommendations of the Inquiry. In Scotland, this could be provided by the charitable organisations Haemophilia Scotland and the Scottish Infected Blood Forum, whose activities in support of the infected and affected communities are considered in more detail below. The task force should also be subject to political scrutiny via the Health and Sport Committee of the Scottish Parliament to ensure that it is fulfilling its function and ensuring that the Inquiry's recommendations are implemented within a reasonable time frame. In turn, this will allow the Committee to hold the Scottish Government and NHS Scotland to account, as necessary.

B) APOLOGY AND MEMORIALS

2. A full and clear apology

2.1 The evidence heard by the Inquiry has demonstrated that the NHS in the United Kingdom, the UK government and the Scottish government failed the infected and affected community. Previous apologies issued by the governments of the United Kingdom have been general, inspecific, incomplete and insincere. The importance of those infected and affected receiving a full and specific apology from those who have caused the infections (or take responsibility for their occurrence) with which the Inquiry is concerned was clearly recognised by the Inquiry's psychosocial group, whose testimony was detailed, incisive and unchallenged in that regard. The beginning of any true recovery from the blood contamination disaster is such an apology. Therefore, the Inquiry should recommend that the UK and Scottish governments, on behalf of its departments, former ministers, civils servants and advisors should issue an unreserved apology for their past failings which caused the blood contamination disaster and for their failure to respond appropriately to the needs and losses which were caused to the infected and affected as a result. In particular, it should be recognised publicly that:

(a) The UK government acknowledges its moral responsibility for occurrence of the blood contamination disaster and apologises for having failed the infected and affected community;

(b) The UK government recognises, clearly and unreservedly that significant harm, including death on an unprecedented scale has been caused to those infected and their loved ones as a result of NHS treatment and that such harm has been significantly compounded by the government's response to the occurrence of the infections;

(c) The Scottish government accepts responsibility and apologises for its part in compounding the harms by failing to recognise its moral responsibility for the infected and affected over many years, and the impact of its response to the occurrence of the infections; and

(d) The UK government accepts its legal and moral responsibility for the support and wellbeing of all those who have suffered as a result of the disaster, with the Scottish government specifically accepting responsibility for all the infected and affected who reside in Scotland.

2.2 The need for a fulsome government apology was recommended by the Cumberlege review.[4] It is submitted that the Inquiry should recommend that the apology should be made at the commencement of parliamentary debates in the Westminster and Scottish Parliaments on the issue of the contaminated blood disaster, the findings of the Inquiry and the plans for the implementation of its recommendations. Further, the recommendation should include provision that the apology should be made in writing to each of the infected and affected on behalf of the governments who are making it. A clear statement of what the UK and Scottish governments intend to do as a result and in implementation of the Inquiry's recommendations should be appended to these apologies.

3. Memorials

[4] Cumberlege report, final report, page 187, recommendation 1

3.1 The Inquiry should recommend that permanent memorials should be erected to those who were infected and have passed away as a result of the contaminated blood scandal and those who have passed away from the affected community. There should be one in a prominent part of the capital cities of all four of the home nations. These should be State funded and maintained. Appropriate ceremonies should be organised for their unveiling.

3.2 Representatives of the infected and affected communities should be involved in the design of the memorials. The Scottish campaign for a memorial has already raised a substantial sum for an appropriate Scottish memorial. It will therefore not require to be fully funded by the Government. It is suggested that the inquiry should recommend that the Scottish or UK Government should add to the funds available for the memorial, the planning for which should remain the right of the Scottish infected and affected community.

C) NON-COMPENSATORY SUPPORT FOR THE INFECTED AND AFFECTED

4. Access to financial products such as life and travel insurance, mortgage protection and mortgages

4.1 The Inquiry has heard significant evidence about the extent to which the infected and affected have experienced issues with accessing financial products based on the fact of their infections. These products have included life and travel insurance, mortgage protection insurance and mortgages. The lack of access to these products has caused significant difficulty for those who have fallen into this category. Important life experiences have been closed off to the infected and affected as a result. The significance of those restrictions should not be underestimated. The Inquiry should recommend that the government should work with providers to create bespoke insurance products for the infected and affected, underwritten by the government. A model for this has already been put in place in the Republic of Ireland for the infected and affected in that country. The significant work put into the creation of these products in that country should

prove to be of significant assistance in the establishment of such a scheme in the UK.

4.2 In addition, there is a need for there to be a formal system to enable the infected and affected to be able to access mortgages. At present, some of the infected and affected have been able to procure a letter from the SIBSS which has proved sufficient for a mortgage to be obtained from a single provider. The letter explains the nature of the payments made from the SIBSS and that single provider has been willing to accept that as sufficient proof of future income to make a mortgage offer. In order to increase the range of options available and competition, a formal system should be instituted within SIBSS along with a range of providers to provide government backed assurances that the individual will continue to receive an income for mortgage purposes from the SIBSS.

Proposed further investigations

4.3 It is understood to be the case that a system which might be used as a model for the recommendation which is proposed is operated for the infected and affected in the Republic of Ireland. Brian O'Mahony, CEO of the Irish Haemophilia Society is thought to have been closely involved in the negotiation and implementation of the system which is currently operated by the Irish government.[5] It is suggested that he would be able to provide an explanation as to how that system works or at least indicate to the Inquiry where such information might best be obtained. It will also be necessary to consider expert actuarial evidence to inform decision making about how such a system might work in the UK.

4.4 Sam Baker of the Scottish Government, who is involved in the administration of the SIBSS and has given evidence to the Inquiry, should be approached to provide more information about the problems which have been experienced in getting lenders to accept evidence of future income from SIBSS as a sufficient basis to obtain a mortgage offer and possible solutions in that regard.

[5] See https://haemophilia.ie/hiv-hepatitis-c/insurance-scheme/life-mortgage-protection/

5. Benefit and healthcare passporting

5.1 The Inquiry has heard significant evidence about the traumatic experiences of infected and affected individuals who have been subjected to shocking accusations or at least considerable hardship and inconvenience within the benefit system. The Inquiry should recommend that DWP guidance should be reviewed to ensure that those working within the benefits system are aware that payments made under the SIBSS or under any compensation tribunal mechanism are not to be taken into account for the assessment of benefits.

5.2 In addition, infected individuals who qualify for payments under the SIBSS should be issued with a passport which can be used as proof of status (for benefits and any other relevant purposes), in order to ensure that victims of the contaminated blood scandal do not have to endure the indignity of continually providing evidence of their incapacities and detriments which have been inflicted by the State. The requirement to do this has significantly compounded the harm suffered by the infected. Many have been stigmatised by the NHS based on assumptions as to the route of their infections. Such stigma must stop. There is a need within the NHS and the benefits system to have a user friendly, confidential, recognised way of proving that an individual's infection was caused by the State. Further, the card could indicate the level at which payments are made to the infected person under the SIBSS and/ or benefit entitlement, from which certain deductions could be made about level of disability. This issuing of such a card will, in turn, allow the infected to access associated entitlements to which they are already entitled as a result of their disabilities such as dental care and ophthalmic services more easily.

Proposed further investigations

5.3 Evidence should be taken from the DWP, in particular from the DWP office in Scotland about what such a card could be made to look like to fulfil the following purposes:

(a) Identification for the purposes of proving that SIBSS payments should not be taken into account for benefits purposes;

(b) Identification for the purposes of indicating to medical professionals SIBSS entitlement and thus previous proof of State caused infection; and

(c) Identification for the purposes of showing that the individual has previously proved disability such as to entitle the individual to benefits and thus the associated entitlements of care and support which flow from that.

5.4 It is understood that a system of passporting operates for the infected in the Republic of Ireland. Brian O'Mahony, CEO of the Irish Haemophilia Society is thought to have been closely involved in the negotiation and implementation of the system which is currently operated by the Irish government. It is suggested that he would be able to provide an explanation as to how that system works or at least indicate to the Inquiry where such information might best be obtained, though it is accepted that there are differences between the way that healthcare is provided in Eire and in Scotland which would require to be reflected in the way that any such system was implemented in Scotland.

6. Psychosocial Support Services

6.1 There should be a national psychosocial support service in Scotland so that everyone who has been infected and/or affected by past treatments with contaminated blood or blood products in Scotland or those affected by it (including any relatives, carers or close friends of an infected person) get the professional psychosocial support they need. The Inquiry should recommend that the existing services in this regard should be safeguarded for the future by guaranteed ring-fenced funding.

6.2 The Inquiry has evidence available to it as regards the current functioning of the Psychological Support Service (PSS) which was jointly commissioned by the SIBSS and National Services Division of NHS Scotland (NSD – which commissions certain specialist services on behalf of all of the territorial health boards in Scotland) in 2018, in the form of a witness statement from Belinda Hacking, director of

psychology services for Lothian.[6] In her statement she talks about the history of the service which is currently provided to those with bleeding disorders, Scotland-wide and their families. The service is currently funded by the Scottish government via the NSD.[7] It operates as part of the Scottish Inherited Bleeding Disorders Network ("SIBDN"). It is a nationally managed clinical network commissioned by NSD on behalf of NHS Scotland. The SIBDN is a reference group of patients and families which was established when the Scottish Government announced a review of financial support schemes in 2015. Its purpose is to oversee the delivery of Scottish Haemophilia Services and help coordinate all parties involved to achieve the best possible service for bleeding disorder patients in Scotland.

6.3 The Inquiry should recommend that the existing PSS service should include bespoke social work advice alongside the psychological and psychiatric service. Despite increased monies being available to the infected and certain affected individuals, there remains an entitlement to benefits, in connection with which advice may be required from social workers. The Inquiry has heard evidence that many infected individuals have issues with the euphemistically entitled "brain fog" (resulting from psychological impact and/ or organic brain damage resulting from infection) and fatigue. Assistance with accessing services is required from the State, in conjunction with the charitable assistance detailed elsewhere in this submission. There is a need to have advice provided to assist with the accessing and funding of treatment and other services (such as transport, therapies, care etc) for those who are sick or otherwise affected by State infections.

6.4 The Inquiry should recommend that the funding of the PSS should be ring-fenced and guaranteed by the Scottish government. The project was initially launched as a 2 year pilot project within NHS Lothian in 2015/ 16. Though the service has been rolled out nationally, it remains a pilot project with no guaranteed future funding. The service (and the separate service mentioned below) should continue to have the ability to liaise with the two Scottish charities mentioned in this submission as a means of accepting patients who wish to access the service via the charities as opposed to via the haemophilia centre or other medical services.

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[6] WITN4063001 (26 January 2020)

[7] WITN0713010_0002 (written statement of Sam Baker)

6.5 The Inquiry has available to it evidence that the infected and affected in the transfusion community were required to rely on accessing psychological services through normal NHS channels or via application for a support and assistance grant, available from the SIBSS. There had been few such applications.[8] It is understood that the system for the provision of such services to those infected via that community has changed. The Inquiry should obtain additional evidence from NHS Scotland about how these changes have been implemented and the extent to which they have been accessed throughout Scotland.

6.6 A newer system is available to the infected and affected from both the transfusion and bleeding disorder communities. It runs from the Astley Ainslie Hospital in Edinburgh and is called the Scottish Infected Blood Psychology Service (SIBPS), offering specialist psychological therapies to the infected and their families.[9] The service is run by two clinical psychologists with an understanding of the history of contaminated blood within the NHS, the ongoing national Inquiry and the specific needs of this population. Patients are mostly seen remotely (secure video calling or telephone) but face-to-face appointments can be arranged if there is a clinical need.

6.7 Some in the bleeding disorder community prefer to use the SIBPS as it operates outwith the SIBDN and hence independently from the haemophilia centres. In addition, the Inquiry ought to recommend that this separate service continue to be made available nationally to the infected and affected from the transfusion community (and to those in the bleeding disorders community who prefer to use it) with appropriate secured funding and resources. If it continues to be thought that this service would be better offered to that community via local territorial health boards based on local need, the Inquiry should seek evidence on how such a system would best be operated in practice in the future to ensure that it is both accessible and its existence adequately advertised within primary care.[10] In any event, the Inquiry should recommend that ring-fenced funding be provided by the

[8] WITN0713010_0005 (written statement of Sam Baker)
[9] See https://apps.nhslothian.scot/refhelp/mental-health-(psychology-other-services)/scottish-infected-blood-psychology-service; and https://www.sibps.scot.nhs.uk/
[10] As is suggested might be the case at WITN0713010_0004 (written statement of Sam Baker)

Scottish government for the service in the future as the long as the needs of that community to receive such support persists. Access to a social care service, similar to that suggested above for the PSS should also be made available Scotland-wide, in connection with this new service. It had originally been the intention of the psychological service pilot as rolled out through NHS Lothian that it would also offer a social work support service, but the pilot for this service did not progress as the psychological pilot did.[11]

6.8 Further, the Inquiry should recommend that these services should provide and advertise support for those who are involved in applications to or the process of SIBSS or any compensation tribunal. The need for support in such circumstances is shown by the good work done by the Red Cross who have provided support to the infected and affected during the course of the Inquiry when the infected and affected have experienced difficulties in reliving past experiences. The application processes involve similar such issues and support is needed for them as well.

6.9 The inquiry heard evidence from Professor John Collinge about the risks to those who have received blood or blood products in the UK of contracting vCJD. In his evidence, he indicated that the specialist service of which he is a part would be able and willing to provide advice/ counselling to those who either have been informed that they have been exposed to a possibly implicated vCJD batch or those who are otherwise worried about the possibility that they may have been exposed to vCJD.[12] The paucity of evidence about the risks of transmission of vCJD and the evolving nature of knowledge in that regard make it important that those who have potentially been exposed to blood or blood products have access to the most up to date expert advice from Professor Collinge and his team about the risks and possible consequences for that group. The Inquiry should recommend that there being liaison between the two psychosocial support services in Scotland and Professor Collinge in order that a method be devised as to how best the most up to date and best-informed advice be provided sensitively to those within the

[11] See pages 1 and 5 of interim report of the service (2017) - https://www.sibdn.scot.nhs.uk/wp-content/uploads/2017/05/Interim-Psychological-Support-Services-.pdf
[12] IBI transcript for 13/05/2022, page 127 (Professor John Collinge)

infected and affected community who are reasonably concerned about the possible implications for them of vCJD exposure.

Proposed further investigations

6.10 It is proposed that the Inquiry would be assisted by seeking written information from NHS Scotland concerning:

(a) The future plans for the PSS and SIBPS;
(b) Succession planning in the event of key staff leaving the PSS and SIBPS;
(c) The current funding of the PSS and SIBPS; and
(d) The future funding plans for the PSS and SIBPS.

6.11 Evidence about the operation of the SIBPS might be available from Belinda Hacking or another similarly qualified individual within NHS Scotland. The possibility of combining the two services to provide one psychological service to the infected and affected community might be explored, though (as highlighted above) there are certain advantages to the current system of two separate services being offered. If necessary, further evidence from the expert psychosocial group could be taken as to the appropriateness and effectiveness of these services and the importance to those who use them of there being a guarantee that they will continue to be available. Evidence from a suitably qualified individual about the social services function of the PSS (and SIBPS if applicable) and the extent to which such a function could be integrated into the PSS and SIBPS may also be required.

7. The provision of a national physiotherapy service for those with bleeding disorders in Scotland

7.1 The Inquiry should recommend that a physiotherapy service be provided for those with bleeding disorders in Scotland via the national haemophilia service, the SIBDN. The Inquiry is primarily concerned with the impact of infection. The infected bleeding disorder community comes from what is now the older

generation of bleeding disorder patients. They are the most likely to be infected but they are also the most likely to have a pressing need for physiotherapy, due to the relatively limited benefit they have derived from modern treatments over their lives. The infected are therefore the most likely to benefit from such a service.

7.2 At present, physiotherapy (unlike the PSS referred to above) is not provided via the SIBDN. This means that those with bleeding disorders who need to access essential physiotherapy services need to rely on the provision they can obtain via their local health boards.

7.3 The Inquiry should make this recommendation for the following combined reasons:

(a) The importance of physiotherapy to the infected bleeding disorder community, who are most likely to require such a service, given their history of treatment;

(b) The well documented benefits of physiotherapy to the health of bleeding disorder patients, which include the better management of joints;

(c) In this submission, many initiatives are proposed which will cost the government money. It is expected that the running of a more efficient physiotherapy service via the national haemophilia Network will save money and thus make these other initiatives more financially viable to be offered within NHS Scotland. This is because better, more accessible physiotherapy will decrease bleeds and thus decrease the need for haemophilia treatments to be purchased by the NHS;

(d) As has been the case with the PSS, a single, national physiotherapy service for patients with bleeding disorders will be easier to access and more efficient. This will be of great benefit to those with HCV infection, in particular, for whom navigating the local Health Board systems in order to access such service is difficult in light of the common mental consequences of HCV infection. The legitimacy of making the physiotherapy service part of the national service will be added to by the addition to the national service of a social work service, as is suggested elsewhere in this submission, as the national service will be larger as a result anyway;

(e) The Inquiry has heard a good deal of evidence that the infected community lost faith with the physicians who were responsible for their infections. As a result, some at least neglected their haemophilia treatment due to the reasonable concern that it would

be harmful to them. The result for these patients is that their joints are likely to be worse and their need for physiotherapy greater. In this regard, their infections have made a material contribution towards their need for physiotherapy; and

(f) The expansion of the national Clinical Network allows a far more direct and effective means by which budgets can be allocated to the care of patients with bleeding disorders in the future. An expansion of this service/ delivery mechanism for their care will be conducive to the better funding of care for this important service (*inter alios* for the infected) in future.

Proposed further investigations

7.4 The National Specialist Services Committee ("NSSC") appears to have been against the proposal that the national Network be expanded in this way at their meeting on 23 September 2021.[13] Their reasons for taking this position are unclear from the minute of their meeting. In particular, the suggestion of the landscape having changed since the proposal was originally made requires further explanation. This should be explored by the Inquiry.

7.5 The Inquiry should obtain further evidence from NHS Scotland and the Scottish Government about the possibility of offering this physiotherapy service through the national bleeding disorders Network to assess its viability and cost.

8. Access to and funding of treatments, therapies and other interventions

8.1 The Inquiry should recommend that the SIBSS and any compensation tribunal for infected and affected persons should operate and be funded completely separately from the system for the provision of treatments and interventions. This is necessary so that there is no risk that the funds which are designed for the support of victims or their compensation are diminished or diluted by the need for money for their treatment. The obligation of the NHS to provide these treatments

[13] See page 9 of Appendix 1 to letter from the Information Commissioner for Scotland to Haemophilia Scotland dated 18 May 2022

and interventions exists independently of the State's moral obligation to support and compensate the victims for their financial needs and losses respectively.

9. Funding patient support/ advocacy

9.1 In Scotland, the infected and affected are represented by Haemophilia Scotland ("HS") and the Scottish Infected Blood Forum ("SIBF"). The Inquiry has heard significant evidence about the reliance placed on these patient advocacy charities in this sector as well as the considerable reliance which has been placed on these organisations by the Scottish Government in informing and shaping exercises like the Penrose short life working party, the Financial and Clinical reviews groups which led to the formation of the SIBSS and ultimately to the other UK support schemes, amongst others. These charities have played an invaluable role for the sizeable and vulnerable cohort of infected and affected individuals within Scotland. They continue and will continue to play such a role after the Inquiry comes to an end. Further, it is imperative that future generations of UK citizens who require blood and blood products (and their parents or carers) benefit from expert independent support, advice, guidance and education. There will be a requirement for patient representative groups to be part of the Task Force recommended above. In Scotland, HS and SIBF are best placed to serve those functions.

9.2 In the aftermath of the Penrose Inquiry in 2015, the Scottish Government announced three years minimum continued core funding for key organisations supporting the infected and affected community. Such funding has diminished over the years since that time, despite the ongoing need for these charitable bodies to provide these key services to that community.

9.3 The Inquiry should recommend that a secure funding stream should be established for these charities. This should provide funding to secure the long-term future of patient support without restriction on its use. SIBF currently receives no such funding. HS has required to source funding from the pharmaceutical industry. Secure, unrestricted government funding is thus essential.

9.4 The recommendation should also provide access for the charities to restricted funding to provide targeted, project-based information and support to those affected by the disaster through their wider advocacy work to ensure that no decisions about the treatment or care of people with inherited bleeding disorders or transfusion victims/survivors are taken in future without the active involvement of charities which can speak on behalf of that community.

Proposed further investigations

9.5 The Inquiry has already been approached about procuring written evidence in response to a rule 9 request from the Scottish Infected Blood Forum about its operation, position (including financial position), achievements and ambitions in order to support the recommendation about that organisation being funded properly in the future. Such evidence has been presented to the Inquiry on behalf of Haemophilia Scotland by the written campaign statements of Bill Wright and Dan Farthing-Sykes and the oral evidence of the former.[14] The Inquiry could seek further evidence from both of these bodies about the financial projections which would enable them to deliver their essential services.

9.6 In addition, it is suggested that the Inquiry should call witnesses to give oral evidence from the infected and affected community in Scotland on the extent to which problems experienced in years gone by still exist in treatment and other services provided to this community now. This will assist the Inquiry both (a) in understanding the extent of ongoing gaps in provision now and (b) in further understanding the important advocacy role provided by the charities to help and support such individuals.

10. Locating the infected

10.1 The Penrose Inquiry made a single recommendation to the following effect:

[14] IBI witness statements at WITN2287019 and WITN4081001 respectively

"That the Scottish Government takes all reasonable steps to offer an HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HCV"[15]

10.2 The evidence heard by the Inquiry has (a) indicated that patients who have been could have been identified as being infected with HCV earlier were not and (b) not been provided with satisfactory evidence that those infected by blood transfusion in Scotland have all been located. Given the probability that there are individuals infected with HCV by blood transfusions who have not been located and the need that they be so located to access current treatments, a more proactive approach is required. This is all the more important given the success which has been achieved in Scotland with new treatments for HCV and its commitment to eradicate the disease from the country.[16] The Inquiry should recommend that:

a) A review be undertaken of the steps taken by the NHS in Scotland in light of the single recommendation made by the Penrose Inquiry; and
b) A renewed programme to locate patients infected in Scotland in this way be undertaken, to include more prominent public appeals to individuals who have had blood transfusions in the past to come forward for testing.

Proposed further investigations

10.3 The implementation of the Penrose Inquiry's single recommendation was undertaken after consultation with the Penrose Short Life Working Group. The Group produced a report in August 2016 addressing the recommendation titled "The Penrose Inquiry Recommendation - Report of a Scottish Government Commissioned Short-Life Working Group".[17] Those on whose behalf this

[15] Penrose Inquiry Final Report, page 1748
[16] IBI transcript for 26/02/20 (Professor Dillon); page 190 (8) to (17) on the Scottish HCV eradication target of 2024 and SVR rates from new treatments in Scotland
[17] See https://www.gov.scot/binaries/content/documents/govscot/publications/progress-report/2016/09/penrose-inquiry-recommendation/documents/00505099-pdf/00505099-pdf/govscot%3Adocument/00505099.pdf

submission is presented make no criticism of the process undertaken by the Scottish Government at that time. However, it may be advisable for the Inquiry to seek further explanation from the Scottish Government about the measures which were taken to try to trace infected individuals, any issues which were experienced with the process and the numbers traced as no further reports have been produced by this Group.

10.4 In addition, Professor John Dillon and Professor David Goldberg are part of the Inquiry's expert groups. They would be likely to be well placed to provide independent evidence to the Inquiry on these matters, in particular the perceived effectiveness of the measures taken, the likely further numbers of infected individuals who could be traced by further efforts being made and how best those efforts could be renewed at this stage. In particular, efforts were made to locate such individuals via GPs, though the GPs were not paid to take on the work of sifting through records to try to locate them. Funding for this exercise to be carried out more thoroughly by GPs would be of benefit. Further funding for a wider advertising campaign on television would also be likely to bear fruit.

10.5 It is also understood that efforts made by Dr Campbell Tait as part of this work led to the identification of around 70 mild bleeding disorder patients who it was thought had contracted HCV.[18] This built on work which had been done in around 2005. The short life working group enabled those who had been identified at that time to be identified by CHI. Certain efforts were made to locate these individuals.

10.6 In response to an FOI request an update is available on this element of the work.[19] Based on information received from Health Protection Scotland (HPS) in 2018, of 69 patients whose status was investigated as a result of the Short Life Working Group's recommendations, 33 patients were traced by CHI linkage analysis, and 36 could not be traced. Of those traced, 20 were alive and 13 had died. Of the surviving 20 individuals, 9 letters were issued to patients' GPs. 8 patients were contacted, one was found to have moved outside of the UK. One of the additional patients identified as being in England was having testing arranged for them at the time that HPS provided information to the Scottish Government. In addition, 7 of

[18] See page 6 of the SLWG report from 2016

[19] https://www.whatdotheyknow.com/request/penrose_short_life_working_group

those identified as living in Scotland had already, in the interim, been identified as being HCV negative and 4 of those identified as living in England had also already been tested for HCV. Of the 8 patients tested following letters to their GP, 1 tested positive for HCV. Dr Tait could provide details of how many of these were ultimately found and whether further efforts could reasonably made to locate them.

10.7 A letter from the Scottish CMO was issued to clinicians in September 2016 in line with the SLWG recommendations.[20] It remains unclear what audit was done of the success of that exercise.

11. Long-term follow-up of the infected and affected

11.1 Evidence which has been heard by the Inquiry highlights that monitoring of the effects of treatments is insufficient to identify all *sequelae* of those treatments. The Inquiry should recommend that a scheme (participation in which should require to be explained clearly to patients) be instituted for anyone infected by the disaster to monitor long-term impact of treatment with blood or blood products, in particular as the victims start to enter old age. An assessment of this will enable (a) greater knowledge to be obtained about the long-term dangers of using blood or blood products, including the possible effects of other pathogens, the full effects of which are not yet well understood and (b) greater planning for the needs of the victims, including palliative care in the future. This work should take a broad and holistic view of impact and include educational and employment opportunities as well as deaths from all causes. This work could be supported by the psychosocial support service detailed above which could conduct home visits to ensure even the most isolated and unwell can participate.

11.2 There is a clear need for there to be both facilities and a national commitment within the NHS in Scotland for hepatological follow-up of the infected, even after treatment has been deemed to have been successful. The Inquiry should recommend that the NHS in Scotland should commit to a minimum of annual

[20] https://www.sehd.scot.nhs.uk/cmo/CMO%282016%2917.pdf

follow up of all patients who have been infected by HBV, HCV or HIV as a result of having received contaminated blood or blood products by appropriate medical professionals (irrespective of treatment outcome) with appropriate medical facilities being provided in all health boards for this to be done, including fibroscan machines.

Proposed further investigations

11.3 The NHS in Scotland should be asked to provide further evidence to the Inquiry about its policy intentions in this regard and the availability of facilities to enable these follow-up measures to be taken in the future.

12. Palliative care

12.1 The Inquiry has heard powerful evidence about the difficulties experienced by individuals who have been required to care for loved ones who have died as a result of their infections and associated symptoms/ conditions from blood or blood products in Scotland. Those who have been infected by the State deserve the very best of care in planning and managing their end of life care. Literature confirms the paucity of palliative care available for the kinds of individuals who are facing death as a result of their infection from contaminated blood or blood products.

12.2 A 2015 Edinburgh study found that "Living, dying and caring in advanced liver disease is dominated by pervasive, enduring and universally shared uncertainty".[21] It concluded that in the face of high levels of multidimensional patient distress, professionals must acknowledge this uncertainty in constructive ways that value its contribution to the person's coping approach and that planning 'just in case' is vital to ensure that patients receive timely and appropriate supportive and palliative care alongside effective management of this unpredictable illness.

[21] "Managing uncertainty in advanced liver disease: a qualitative, multi-perspective, serial interview study" per Kimbell et al, BMJ Open 2015

12.3 In "The incompatibility of healthcare services and end-of-life needs in advanced liver disease: A qualitative interview study of patients and bereaved carers" it was found that there were escalating physical, psychological and social needs as liver disease progressed, including disabling symptoms, emotional distress and uncertainty, addiction, financial hardship and social isolation by a Bristol based group. The study found that end-of-life needs were incompatible with the healthcare services available to address them; these were heavily centred in secondary care, focussed on disease modification at the expense of symptom control and provided limited support after curative options were exhausted. Attitudes towards palliative care were mixed, however, participants valued opportunities to express future care preferences (particularly relating to avoidance of hospital admission towards the end of life) and an increased focus on symptomatic and logistical aspects of care.

12.4 It was recommended that novel strategies, which recognised the life-limiting nature of liver disease explicitly and improved co-ordination with community services were required if end-of-life care is to improve.[22]

12.5 In "Palliative care for people with advanced liver disease: A feasibility trial of a supportive care liver nurse specialist" an Edinburgh based group looked at the use of liver nurse specialists in the palliative care of such patients.[23] The study involved a feasibility trial of a complex intervention delivered by a supportive care liver nurse specialist to improve care coordination, anticipatory care planning and quality of life for people with advanced liver disease and their carers. Patients received a 6-month intervention (alongside usual care) from a specially trained liver nurse specialist. 47 patients, 27 family carers and 13 case-linked professionals were recruited for feedback. The proposed nurse-led intervention proved acceptable and feasible. The authors refined the recruitment processes and outcome measures for a future randomised controlled trial.

12.6 The expert group on palliative care in advanced liver disease which has given written and oral evidence to the Inquiry identified that there are various factors

[22] Hudson et al, Palliative Medicine 2018, Vol. 32(5) 908–918

[23] Kimbell et al, Palliative Medicine 2018, Vol. 32(5) 919– 929

which contribute to the poor or sub-optimal delivery of palliative care for these patients, which is therefore delivered inconsistently across the country.[24] There is therefore a need for reform of the system. The need for improvements in this area have been supported by the British Liver Trust.[25] Consistent with the evidence heard by the Inquiry from its expert group, there is support in the literature for (a) better use of clinical tools to identify the point of irreversible deterioration in advanced liver disease and (b) joint working between liver services and palliative care to improve care for people with cirrhosis.[26]

12.7 In light of this evidence, there is a need to overhaul the system of palliative care in Scotland, in particular for those who have advanced liver disease and associated conditions and those whose infections are complicated by HIV infection. The Inquiry should recommend that a new system of palliative care for these individuals should be implemented in Scotland (to be delivered through existing pathways in a more effective manner) comprising:

(a) Minimum standards of and commitments to the provision palliative care and support for these individuals which are clearly set out along with a clear strategy as to how and by which agencies these standards will be delivered in each Health Board area in Scotland. At present, there are considerable issues when the infected are nearing the end of life in understanding what services are available for palliative care for them locally in Scotland. By the time the services are identified and/ or accessed, it is often too late;

(b) Funding for the charities in Scotland (see above) which should include funding for a palliative care officer to assist those in need of palliative care and their families to access the services which are available to them and direct them to the appropriate agencies within the NHS and elsewhere. The need for such a service will only increase in the future as the infected get older and more palliative care will be required. A

[24] IBI transcript for 04/03/2022, pages 34 – 35 (Dr Fiona Finlay)

[25] https://britishlivertrust.org.uk/new-research-end-life-care-people-liver-disease/

[26] "Advanced chronic liver disease in the last year of life: a mixed methods study to understand how care in a specialist liver unit could be improved" by Low J, et al. BMJ Open 2017;7:e016887

trusted representative within the charitable sector to assist with applications to access services will be invaluable;

(c) Meaningful care plans, devised in accordance with the patients' wishes (see above); and

(d) The availability of a nation-wide service of expert palliative care nurses to be delivered in each health Board region, with a named nurse allocated to each patient and a lead nurse to co-ordinate care and treatment.

12.8 In order to facilitate discussion about further specific measures which might progress these important aims that the Scottish Government should convene a short life working group on this issue (with patient representation from the relevant charitable organisations mentioned elsewhere in this submission).

12.9 For the victims of the contaminated blood disaster, palliative care should include the right to die, with full palliative care, at home.

Proposed further investigations

12.10 The Inquiry should hear more evidence from its expert group in palliative care about the ways in which the palliative care system in Scotland could be improved in order to deliver better end of life care to those infected by the contaminated blood scandal. It will also be necessary to procure evidence from NHS Scotland concerning the factual position as to the current level of palliative care provision and commitment to the victims of the contaminated blood disaster in Scotland, in particular in connection with the availability of consistent services for the provision of adequate nursing care by nurses with specialist training in the management of advanced liver disease and, where appropriate, the effects of HIV infection and bleeding disorders. As noted above, Dr Fiona Finlay of the expert group is well placed to be able to offer both factual and opinion evidence on the palliative care system in Scotland for patients with advanced liver disease (in particular) as well as measures which might be taken to improve it.

D) MEDICAL INVESTIGATIONS

13. Testing and research

13.1 The ability of blood and blood products to transmit viruses and other pathogens in addition to those with which the Inquiry has primarily concerned itself (namely HBV, HCV and HIV) has been clearly established by the evidence heard by the Inquiry. In light of the possibility that victims of the disaster have been exposed to other pathogens or infected by them, the Inquiry should recommend that testing should be offered to all bleeding disorder patients and those who have been found to have been exposed to pathogens through blood transfusion already (including natural clearers of hepatitis viruses). Such blood tests are necessary to ascertain the precise nature and extent of viral exposure and infection amongst that community. It is only then that a fuller understanding can be ascertained of the nature and extent of the disaster and plans made to support and compensate and care for the victims fully. Recent press reporting suggests that single tests for multiple viruses may soon be available.[27] However, absent such scientific advancement in the immediate future, it is submitted that the Inquiry should recommend that the following tests should be offered to this community:

- Human parvovirus including B19 parvovirus and the new parvoviruses, human parvovirus 4 (PARV4) and new genotypes of parvovirus B19
- Herpes viruses, including Epstein-Barr virus, Cytomegalovirus and other herpes viruses which may be transmitted by blood including human herpesviruses 6 and 8 (HHV-6 and 8)
- SV 40
- HTLV I and II
- West Nile virus
- Dengue fever and dengue haemorrhagic fever
- Japanese encephalitis virus (JEV)
- Enteroviruses

[27] www.bbc.co.uk/news/science-environment-33008590

- Circoviruses, including torque-tenovirus (TTV) and torque-tenominivirus (TTMV)
- SEN virus
- Hepatitis D
- Hepatitis G
- Q fever

13.2 The Inquiry should also recommend that testing for the viruses with which an infected person is or was infected should be made available to those who have been carers for those infected individuals and their spouses.

13.3 In addition, the Inquiry should recommend that UK Government should establish a research fund to support work to address some key questions where there is simply not enough current evidence to enable it to reach reliable conclusions on important matters which would otherwise have fallen within its terms of reference. For example:

a) The clinical implications of being repeatedly infected/ exposed to viruses in blood/ blood products, in particular (i) on the immune system (i) as a result of repeated inflammatory response and (iii) in the developing child.
b) The clinical implications of being repeatedly infected/ exposed with multiple genotypes of Hepatitis C.
c) The clinical implications of having been exposed to the Hepatitis B virus amongst patients who are otherwise infected as a result of blood or blood products, including the possible additional *sequelae* of such exposure and its implications for prognosis, likely future medial and care requirements.
d) The impact of multiple viral exposure on the likelihood of clearing naturally, immune response fatigue, the success rate of treatment or prognosis.
e) Whether natural clearing rates of viral hepatitis lower for people affected by bleeding disorders, and if so, why;
f) Whether the long-term sexual partners or children of people with an inherited bleeding disorder, who have been exposed to contaminated blood products, experience an elevated rate of any condition or disease;

g) Whether there are any unique characteristics or issues for people whose viral infection was caused by contaminated blood or blood products compared to the much larger groups of people otherwise so infected; and

h) The health implications for those who have been exposed to but who are deemed to have "naturally cleared" the hepatitis C, including the long term impact on their immune systems and the possible connections between such exposure and the development of other medical conditions.

E) THE SAFETY OF BLOOD AND BLOOD PRODUCTS

14. Permanent ban on the use of blood or organs from incarcerated people

14.1 The Inquiry has heard evidence to the effect that blood collected from prisons, borstals or young offenders' institutions carries a significantly higher risk of transmitting disease than blood collected from regular volunteer donors. This has been known by the blood transfusion services for many decades. Blood, tissues and organs should never again be collected in prisons, borstals or other such institutions. The collection of such blood represents an unacceptably high risk to blood safety when the next blood borne infection emerges.

15. Better donor engagement in the blood collection system

15.1 The principles underpinning the "gift relationship" between the donor of blood, the system of collection and the ultimate recipients have formed an important part of blood transfusion in the UK. The Inquiry should recommend measures which seek to improve donor engagement and investment in the system in which they play such an important part such as the motivation of donors by providing them with more information about what their donations are used for/ when they are used/ when they have been used to save a life (as in Sweden).[28]

[28] See https://www.everplans.com/articles/swedish-blood-donors-get-a-text-message-when-their-blood-saves-a-life

16. Early adoption of new donor tests

16.1 Evidence heard by the Inquiry has indicated that the threshold for using blood tests, including surrogate tests, to exclude risky donors has been too high and too much emphasis placed on false positives reducing the blood supply. The Inquiry should recommend that the policy and guidance of the transfusion service must incorporate a precautionary approach to the collection of blood in the interests of end users of blood and blood products and that tests should be introduced as soon as reasonably practicable for safety with any shortfall in blood supply addressed by recruiting more donors. These measures are an important means of ensuring that all reasonable steps are being taken to eliminate future pathogens which emerge from the blood supply.

17. Medical education

17.1 The Inquiry should recommend that the Royal Colleges should promote teaching of the circumstances of the contaminated blood disaster and the findings/ recommendations of this Inquiry to all medical and nursing students, in particular in connection with the dangers of blood and blood derived products, public health, the requirements of informed consent, the possibility for a bad reaction to a medical mistake or disaster to compound the harm caused, patients' rights to information about research, patients' rights to consent to and access to information about testing, the impact of medical mistakes or disasters on the families of the patients and other relevant areas.

17.2 Further, the Inquiry should promote through medical education (and otherwise) the removal from medical vocabulary of the use of the terms (a) "natural clearance" after exposure to HCV and (b) "cure" from viral infection with HIV or HCV after treatment as opposed to sustained virological response to treatment, in connection with the response to treatment for HIV or HCV infection. Both of these terms are medically inaccurate, in the sense that they create the impression that the absence of progression to the chronic phase of infection or the presence a sustained virological reaction to treatment respectively result in the patient being

left with no *sequelae* which are connected with exposure to or infection with the virus. The evidence heard by the Inquiry demonstrates that patients who are in these categories may well have ongoing physical, psychological or psychiatric consequences of such viral exposure. The continued use of these terms creates the inaccurate impression amongst medical professionals that clearance or successful treatment represents the end of problems for such a patient.

F) LITIGATION

18. Lift the time bar and prescription rules in relation to obligations to make reparation

18.1 In Scotland, court actions are required to be commenced within the limitation rules provided for by sections 17 and 18 of the Prescription and Limitation (Scotland) Act 1973. The Act also provides rules whereby obligations to make reparation prescribe as a matter of law under section 6 of the Act. In addition, the Act provides for limitation rules and prescription rules relating to actions arising out of the Consumer Protection Act 1987 under sections 22B and 22C and section 22A respectively.

18.2 Any infected or affected person who asserts a legal right to receive damages as a matter of law arising from the blood contamination disaster should have recourse to the courts to do so. The Inquiry should recommend that the existing rules on limitation and prescription in this regard should be removed by legislation. The unique circumstances and scale of the blood contamination disaster, along with the practical limitations on the ability of the civil court system to be accessed by the infected and affected community over the decades merit that such a recommendation be made.

18.3 In addition, the Inquiry should also recommend that the right of any defender (defendant) to rely on any waiver of the right to litigate should also be removed.

G) AVOIDING AND ADDRESSING ADVERSE TREATMENT OUTCOMES

19. Reform of the MHRA

19.1 The Medicines and Healthcare Products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. The MHRA is an executive agency, sponsored by the DHSS.

19.2 The Cumberlege review recommended that:

> *"The Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work."* [29]

19.3 This Inquiry should make similar recommendations in particular in relation to adverse event reporting and regulation in respect of blood products, blood and blood components.

Proposed further investigations

19.4 The Inquiry should seek evidence from the MHRA and the DHSS relating to steps they have taken or intend to take to implement the recommendation of the Cumberlege report in order that any similar recommendation made by this Inquiry can be effective and specific.

20. New treatment fund

20.1 The Inquiry has heard evidence about the difficulties faced by governments in the UK in finding money necessary for the financial support of those infected or affected by contaminated blood products. This financial burden has been required to be borne by the State in the UK. In many cases, infections were caused by contamination of blood products introduced into the market by pharmaceutical

[29] Cumberlege report, final report, page 188, recommendation 6

companies which have made fortunes out of the sale of those products. These companies have largely evaded financial responsibility for the consequences of their products causing infection and devastating lives, either through litigation or other means. The Inquiry should recommend that the UK licensing regime should require companies introducing new treatments/ products to the UK to pay into an appropriate financial vehicle ("the new treatment fund"), to be managed by the government, to provide financial support payments to any patients harmed by their products.

20.2 Such a scheme would share the financial burden between the State, whose moral responsibility it is to look after its citizens when harmed in such circumstances and private companies which have profited from access to the lucrative UK market. Such a scheme would also lessen the financial incentive for governments to cover-up the details of such disasters as the financial burden to be borne by them would be reduced by such a fund. This would also have the effect of increasing the chances that such disasters could be examined quickly and relevant lessons learnt early, so as to minimise the risk of their re-occurrence. It would achieve this by allowing payment to be made quickly to those who have been adversely affected, removing or minimising the incentive to postpone or deny inquiry into or examination of the circumstances of the harm have been caused.

Proposed further investigations

20.3 The Inquiry should consider evidence as to the financial implications of such a fund being operated, including the levels at which such payment could generally be levied so as to ensure the continued availability of the treatments but also to provide for adverse consequences of their use. Evidence should be taken from the MHRA as to how the requirement to pay into such a fund could be integrated into the existing licensing regime.

H) PATIENTS' RIGHTS

21. Handling when things go wrong in medical care

21.1 The need for a clear system to be available to meet the needs of patients and parents/ guardians when their care is not delivered in accordance with their wishes for their healthcare is an essential component of any modern healthcare system. Failures both in advertising the availability of a system for complaints and in the effectiveness of the complaints system itself have had a number of serious adverse consequences for the infected and affected community. The ineffectiveness of the complaints system has led to patients not being heard/ listened to, loss of confidence in the system and feeling disconnected from their own medical care. As a result, opportunities have been lost to the medical profession to learn from things going wrong in the way that medical care had been provided. In order to make improvements in this important area of healthcare for the future, the Inquiry ought to recommend that there be a review of the system for handling NHS complaints in Scotland, in particular involving:

(a) The extension of the duty of candour;
(b) An integrated and effective system for whistleblowing within the NHS;
(c) Reform the system of NHS complaints in Scotland with a particular role for the Patient Safety Commissioner for Scotland and patient advocacy groups, in connection with which separate recommendations are proposed elsewhere in this submission.

The current system

21.2 The current system dealing with complaints by patients within the NHS in Scotland is complex. The following are aspects of that system which seek, in principle, to promote and protect the rights of patients. The system is currently unwieldy and hard for patients to navigate.

(a) The Patient Rights (Scotland) Act 2011 ("the 2011 Act") aims to improve the patient's experience of using health services and to provide support for patients to become more involved in their healthcare. It enshrines in legislation that it is the right of every patient to receive health care which (a) is patient focused and must take into account

the patient's needs (b) has regard to the importance of providing the optimum benefit to the patient's health and wellbeing (c) allows and encourages the patient to participate as fully as possible in decisions relating to the patient's health and wellbeing and (d) has regard to the importance of providing such information and support as is necessary to enable the patient to participate in accordance with paragraph (c) and in relation to any related processes, taking all reasonable steps to ensure that the patient is supplied with information and support in a form that is appropriate to the patient's needs.[30] It is the right of every patient to give feedback or comments, or raise concerns or complaints about health care received.[31] NHS bodies are required to encourage patient feedback, comment or complaint which they must consider with a view to improving the performance of their functions.[32] A patient advice and support service is required.[33] Health care is required to be delivered in accordance with certain principles.[34]

(b) The Act created a Charter of Patient Rights and Responsibilities. Amongst other things, it states that patients have the right to be given all the information they need about medicines, any possible side effects, and other options which may be available, in an understandable way. It states that patients have the right to be involved in decisions about their care and treatment, and be able to take an active part in discussions and decisions about their health and treatment.

(c) Individual Health Boards in Scotland operate their own complaints and feedback processes, in accordance with their obligations under the 2011 Act. The way in which they operate varies.

(d) An appeal against the way in which a Health Board handles a complaint can be made under the Scottish Public Services Ombudsman Act 2002 to the Scottish Public Services Ombudsman ("SPSO"). The SPSO is an independent Scottish Parliamentary Supported Body.

(e) There is a Patient Advice and Support Service ("PASS") which seeks to (a) promote an awareness and understanding of patients' rights and responsibilities and in particular,

[30] 2011 Act, section 3(2)
[31] 2011 Act, section 3(3)
[32] 2011 Act, section 14
[33] 2011 Act, section 14
[34] 2011 Act, section 6 and schedule

promotes awareness of the Charter (b) advise and support people who want to give feedback or comments or raise concerns or complaints about healthcare (c) provides information and advice on matters it considers people using the health service would be interested in and (d) make people aware of and, if appropriate, direct them to: other sources of advice and support and those who can represent them.

(f) Bodies which have a role in professional regulation within the health sphere include the General Medical Council, the General Pharmaceutical Council, the Health and Care Professions Council and the Nursing and Midwifery Council, each with its on jurisdiction and procedures.

(g) The MHRA (addressed below) operates a yellow card system which is open to the public to access.

Reforming the duty of candour

21.3 Patients and the groups representing them must be advised as early as possible when any potential apparent risks or problems with past, current or future treatments or products are identified. At present, sections 21 and 23 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 (and the associated Duty of Candour Procedure (Scotland) Regulations 2018) provide as follows:

21 Incident which activates duty of candour procedure

(1) A responsible person must follow the duty of candour procedure set out in section 22 as soon as reasonably practicable after becoming aware that subsection (2) applies to a person who has received—

(a) a health service from the responsible person,

(b) a care service from the responsible person, or

(c) a social work service from the responsible person.

(2) This subsection applies to a person if—

(a) an unintended or unexpected incident occurred in the provision of a health service, a care service or a social work service to the person, and

(b) in the reasonable opinion of a registered health professional—

(i) that incident appears to have resulted in or could result in an outcome mentioned in subsection (4), and

(ii) that outcome relates directly to the incident rather than to the natural course of the person's illness or underlying condition

23 Apologies

(1) For the purposes of this Part, an "apology" means a statement of sorrow or regret in respect of the unintended or unexpected incident.

(2) An apology or other step taken in accordance with the duty of candour procedure under section 22 does not of itself amount to an admission of negligence or a breach of a statutory duty.

Section 25 of the Act defines a "responsible person" as:

a) a Health Board constituted under section 2(1) of the 1978 Act,

b) a person (other than an individual) who has entered into a contract, agreement or arrangement with a Health Board to provide a health service,

c) the Common Services Agency for the Scottish Health Service constituted under section 10(1) of the 1978 Act,

d) a person (other than an individual) providing an independent health care service mentioned in section 10F(1) of the 1978 Act,

e) a local authority,

f) a person (other than an individual) who provides a care service,

g) an individual who provides a care service and who employs, or has otherwise made arrangements with, other persons to assist with the provision of that service (unless the assistance in providing that service is merely incidental to the carrying out of other activities),

h) a person (other than an individual) who provides a social work service

21.4 Both Healthcare professionals and patients should be encouraged to voice concerns without fear of prosecution, reduction in service provision, or impact damage to career prospects. The infected and affected community has serious concerns about the way in which the duty of candour obligations operate in practice. The Inquiry should recommend that NHS Scotland undertake a review of compliance with the duty of candour procedure in order the inform the implementation task force in taking further steps to ensure that the duty of candour is being complied with in Scotland. This review would ultimately be subject to the jurisdiction of the task force, as with the other proposed recommendations. One particular concern of the infected and affected community in Scotland relates to the way in which the duty of candour operates in circumstances where things have gone wrong. The fact that the obligations under the statute apply to organisations or service providers, as opposed to being incumbent upon individuals within the system is reasonably seen as being part of that problem. In reality, the need for analysis, reflection and candid apology for rebuilding of the relationship of trust in such circumstances requires the involvement of individual clinicians and the patient as opposed to an organisation, like the relevant Health Board. At present, such institutionally driven processes or apologies can be impersonal and thus ineffective. The Inquiry should recommend:

(a) That the duty of candour should be extended from organisations to individual healthcare professionals. This would allow patients to be involved as equal partners in the reflective practice of clinicians and facilitate the re-building of the essential relationship of trust and partnership between the patient and the clinician;

(b) In any event, that protocols used as guidance for employees of the NHS in Scotland should include clear guidance on the requirement to observe the organisation's duty of candour, as agents of it; and

(c) That a confidential, effective system of "whistleblowing" open to patients and medical practitioner alike be implemented into codes of practice and contracts of employment within the NHS to ensure that problematic practices come to light and are handled appropriately.

21.5 It seems difficult to understand why the duty of candour extends to the organisations to which it applies when it does not also extend to elected government. The Inquiry has heard considerable amounts of evidence to the effect that in the past and today, important decisions made which affect the operation of the healthcare system are made within government. Therefore, in order to support the protections which they duty of candour is there to protect for patients, it is submitted that the Inquiry ought also to recommend that the duty of candour should extend beyond healthcare into both local and national government.

Patient Safety Commissioner for Scotland

21.6 The measures detailed above set out how it is proposed that the Inquiry should promote and champion patient involvement in the provision of care and putting the rights of the patient/ parent/ guardian to access information to enable informed decisions to be made about treatment at the forefront. The obligations in this regard require to be accessible in practice to patients like those who have significant health or social needs, as is the case with many of the victims of the blood contamination disaster. There is also a need (in respect of which it is also proposed that the Inquiry make recommendations) for the patient voice to be heard and prioritised on a macro/ governmental level, as well as within the context of individual cases. The Inquiry should lend its weight by way of a recommendation to the need for a Patient Safety Commissioner in Scotland, with appropriate case workers and other staff within its office, such as the model proposed in England

by the Cumberlege report.[35] This role should be independent of government and operate via the Health and Sport Committee of the Scottish Parliament, given that health is a devolved matter. As was the case in the Cumberlege report, this Inquiry has also learned that when patients and their families have identified and reported harms, these reports have not been acted on until forced into public attention by campaigns or media interest.[36]

21.7 Scottish Ministers committed in 'Protecting Scotland, Renewing Scotland: The Government's Programme for Scotland 2020-2021, to creating the role of Patient Safety Commissioner. The Scottish Government has already undertaken a consultation process in connection with the possibility of having a Patient Safety Commissioner for Scotland (March 2021).[37] It remains unclear what actual progress in light of the consultation is proposed by the Scottish Government.

21.8 Legislation establishing an equivalent Patient Safety Commissioner role in England was passed in April 2021. The Patient Safety Commissioner for Scotland (the existence of which should be underpinned by legislation) should have a role in:

(a) promoting the role of patient safety and patient priority in the NHS in Scotland at governmental level and in the Health and Sport Committee of the Scottish Parliament. At present, the system for complaints is too cumbersome and slow. This means that (even where the system works relatively well) by the time there is an opportunity for lessons to be learned, things have moved on and little effective change can be implemented;

(b) assisting patients and patient advocacy organisations in the co-ordination and presentation of patient involvement/perspective in complaints and disciplinary proceedings involving medical professionals. The role of the Commissioner should allow a single point of entry for patients and their representatives into the complaints system which can have a labyrinthine structure, involving numerous agencies at times. This would, in turn, help improve consistency of patient involvement in these

[35] See the details of this proposal at Appendix 2 to the Cumberlege final report, page 187, recommendation 2 and from page 202

[36] Para 2 of appendix 2 to the Cumberlege final report

[37] See https://www.gov.scot/publications/consultation-patient-safety-commissioner-role-scotland/pages/2/

processes throughout Scotland. There should be clear and visible advertising of the complaints procedure in order that every patient is aware of his or her rights and the mechanism by which they can be enforced, available after every procedure/ treatment; and

(c) making recommendations to government from the patient perspective as to circumstances where it would be in the public interest to hold a public inquiry into aspects of the healthcare system in Scotland in accordance with section 1 of the Inquiries Act 2005 (in connection with which see submissions below).

21.9 Though the role should have a wide remit as a champion of patient safety and interest, the remit of the Patient Safety Commissioner for Scotland should certainly include blood and blood products, given the evidence heard by this Inquiry as to the dangers posed by them and should not be limited to medicines and medical devices.

Proposed further investigations

21.10 The NHS in Scotland should be asked to report to the Inquiry in respect of practical initiatives which have been taken to ensure that it adheres to its obligations under the 2011 Act and what audit has been done of the access of those initiatives in achieving that aim.

21.11 The issue of whistleblowing as part of the system *inter alia* to bring to light ethical breaches is being considered as part of the private members Whistleblowing Bill, which was introduced to Parliament as a private member's Bill. The Bill seeks:

"to establish an independent Office of the Whistleblower to protect whistleblowers and whistleblowing in accordance with the public interest; to make provision for the Office of the Whistleblower to set, monitor and enforce standards for the management of whistleblowing cases, to provide disclosure and advice services, to direct whistleblowing investigations and to order redress of detriment suffered by whistleblowers; to create offences relating to the treatment of whistleblowers and

the handling of whistleblowing cases; to repeal the Public Interest Disclosure Act 1998; and for connected purposes."[38]

21.12 In introducing the Bill, it was said that *"according to the whistleblowing charity Protect, just 4% of employment cases are successful, and PIDA* [the Public Interest Disclosure Act 1998]*, our world-leading legislation, is now seen as a discredited and distrusted law that has failed to protect whistleblowers or the public against wrongdoing and harm. Where we once led the way, we now lag behind".*[39] The Inquiry could seek more evidence about the nature and scope of the Bill in order to ascertain whether its objective would meet the concerns as set out above.

21.13 The Scottish Public Services Ombudsman has taken up the role of the Independent National Whistleblowing Officer (INWO). The aim of the role is to make sure everyone delivering NHS services in Scotland is able to speak out to raise concerns, ultimately contributing to ensuring that the NHS in Scotland is as well run as possible. The INWO developed a set of National Whistleblowing Standards that set out the high level principles and a detailed procedure for investigating concerns.[40] The Inquiry should obtain evidence form the SPSO about the extent to which these principles are adhered to and the extent to which the culture and system of whistleblowing in NHS Scotland works effectively.

21.14 In addition, the Inquiry should take evidence about the consultation process which has been undertaken by the Scottish government into the possibility of having a Patient Safety Commissioner for Scotland and the views expressed by interested parties as to how the role should be performed. The Scottish government should be consulted as to the progress of the legislation contemplated to underpin the role as well as how the plans fit in with its "Better Regulation" principles.

21.15 In this and in other regards, it may be of assistance for the Inquiry to obtain evidence from Baroness Cumberlege and her task force about their thinking and efforts which have been made for her recommendations to be implemented. This

[38] See https://hansard.parliament.uk/commons/2022-04-26/debates/9CD2DC9F-2DB8-4781-AAF0A3B7DCF4A710/Whistleblowing

[39] ibid. per Mary Robinson MP

[40] See https://inwo.spso.org.uk/national-whistleblowing-standards

will allow recommendations of this Inquiry to be useful additions to the recommendations of the Cumberlege Inquiry.

22. Care plans

22.1 The Inquiry has heard copious evidence about treatment plans for NHS patients being introduced without adequate patient (or parent where appropriate) involvement. It should be recommended by the Inquiry that a system be introduced (by legislation if necessary) so that patients receiving ongoing NHS care in Scotland have the right to receive a written care plan. Such a plan should be required to be co-produced with the patient (or parent/ guardian where appropriate) and be regularly updated. The purpose of such a requirement would be to ensure patient involvement in decision making and clarity about what care was proposed and its objectives with respect for patient autonomy and wishes.

22.2 The right to have a written care plan should include the right to have involvement in the compilation of a written plan for palliative care, where appropriate (addressed elsewhere in this submission). Such care plans should include a clear statement of how and to what extent an attorney would become involved in decision making, in appropriate cases, where there is a prospect of the patient losing capacity.

Proposed further investigations

22.3 The Inquiry should seek evidence from the NHS in Scotland of how minimum standards in care plans could be maintained, patient/ patient representative involvement in their compilation be maximised, consistency in their production be promoted and enforcement of their use be ensured, in practice.

23. Medical records

23.1 The Inquiry has heard copious evidence about problems have been experienced by patients/ parents/ patient representatives across the country in accessing medical records. This has had the effect of limiting the ability of patients or their relatives to gain a proper understanding of what happened to them or their loved ones. In many cases, missing or incomplete medical records have created a justifiable sense of injustice or, in many instances, suspicion about the fraudulent removal, destruction or concealment of records. Inexplicably missing or inaccurate records have prevented access to government support schemes in certain cases. The maintenance and retention of accurate records appears to have been seen by the NHS in the UK as an unimportant or at best ancillary element of medical care. In fact, medical records provide a means by which care is provided in the best way for the patient, with maximum clarity and consistency. Where things go wrong, medical records play an important part of any chance a patient has to get to the truth and to achieve justice. The lack of importance attached to the establishment, maintenance and retention of accurate and complete medical records must stop. The system relating to medical records should be overhauled, in particular for those who receive blood or blood products, tissues or organs derived in any way from other human beings. The usual systems relating to the maintenance and retention of medical records have failed many patients and families in such cases, in particular where the pathogens transmitted by the treatment have taken many years to manifest themselves in illness.

23.2 With the appropriate safeguards to protect personally sensitive content, all patient records should be held electronically for all patients. There is an ongoing system within the NHS in Scotland whereby medical records are maintained in different departments and are thus (i) not all entered into electronic systems and (ii) not available to all who may wish to access them to ensure continuity of care. These electronic records should be accessible to patients/ patient representatives and, once placed in the records, it should not be possible for the NHS to remove or amend documents within them retrospectively without consulting the patient/ their representative.

23.3 The Inquiry should recommend an overhaul of the system of making and retaining medical records in Scotland. The key principles which should underpin the reformed system should be:

(a) Allowing patients greater involvement in the creation of medical records, which will improve the accuracy of medical records but will also improve the involvement of the patient in decision making about his or her care. Notes of consultations with medical practitioners should be written with the patient's involvement and co-operation, insofar as reasonably practicable;

(b) The requirement that any substantive correspondence about a patient written to another part of the NHS (for example letters from a hospital consultant to a general practitioner) should be copied to the patient;

(c) The maintenance of a single electronically accessible set of official medical records for each patient. There are current systems (on which the Inquiry could and should take more evidence) of such systems being in existence in other part of the UK at present[41]; and

(d) Provision of a clear system whereby patients can seek to have their medical records corrected where there re inaccuracies in them or omissions from them, which can be adjudicated upon via complaints procedures supported by the Patient Safety Commissioner for Scotland.

23.4 In addition, and in response to issues relating to medical records about which the Inquiry has heard clear evidence, it should be recommended that:

(a) Requests to access medical records by patients or patient representatives in Scotland for the purposes of the Inquiry have proven difficult. Records have often been found and produced long after an original mandate was signed, in particular for bleeding disorder patients. The NHS in Scotland should undertake an investigation (on request by any individual patient or patient representative) into what records, blood, tissues

[41] See for example the "My Medical Record" system instituted by the University of Southampton NHS Foundation Trust, which is a secure patient owned medical record system to which patient can make contributions themselves, details of which can be found at https://www.uhs.nhs.uk/for-patients/my-medical-record

or other bodily substances are still held relating to those with bleeding disorders or who have received blood transfusions in Scotland (both in vivo and post mortem) and by which departments. The findings should be published to the individuals concerned or their representatives with reasons as to why these are retained. Patients (or their representatives) should be accorded the right to continue to agree to the retention of blood, tissues or other bodily substances or not;

(b) The NHS in Scotland introduce clear rules as part of the contract of employment of any health service providers in the NHS that the maintenance or storage of medical records relating to NHS patients outwith recognised NHS facilities for the storage of such records is prohibited. This is to prevent the possibility that medical records relating to patients can be held privately;

(c) The NHS in Scotland introduce clear rules as part of the contract of employment of any health service providers in the NHS that research records which contain any information which derives from NHS patients be held only within recognised NHS facilities for the storage of such records. This is to prevent the possibility that medical records relating to patients can be used for research privately;

(d) The NHS in Scotland introduce a system whereby patients/ patient representatives can seek and the NHS is obliged to provide a comprehensive list of all records held pertaining to the patient concerned (including records kept post mortem) and the details of all records relating to that patient which have been destroyed and the reasons for such destruction;

(e) The NHS in Scotland introduce a system whereby the medical records of all patients with bleeding disorders be held indefinitely, in order better to inform the treatment of these hereditary conditions for the relatives of the patients in future and to allow monitoring of the presence of any patients transmitted by treatment;

(f) Similarly, that the NHS in Scotland introduce a system whereby the medical records of all patients who have received blood transfusions in Scotland be held indefinitely; and

(g) The NHS in Scotland introduce a register of blood transfusions (including blood components) administered in Scotland given the dangers of blood. This should include a system whereby the entry onto the register is intimated to the patient/ patient representative concerned.

23.5 Though this submission is not required to cover recommendations which we would invite the Inquiry to make on compensation, it remains possible that the Inquiry will ultimately recommend a mechanism to compensate those involved in non-consensual treatment and/ or research to reflect the insult and affront to their autonomy which such an experience involved. In his study, Sir Robert Francis QC recommended that the compensation scheme which he has recommended should include an award for interference with autonomy and private life. This would include:

"as part of the autonomy award, for eligible infected persons an award equivalent to aggravated damages for the aggravated distress caused by interferences in their autonomy and private life such as lack of informed consent, information about the risks of treatment, and about diagnosis, treatment and testing"[42]

23.6 The Inquiry has heard evidence to the effect that these breaches of individual autonomy have had substantial effects on the psychological condition of patients due to the fact that the relationship between doctor and patient (in particular in patients with chronic conditions like haemophilia) has been seriously undermined and the treatment of the underlying condition(s) rendered less effective as a result. Many patients remain in the dark as to precisely what was done to them without their consent and what research was undertaken involving them without their knowledge. In some cases, medical records are incomplete and may not provide an accurate or full picture. Patients continue reasonably to suspect that records of their involvement in non-consensual studies or research may exist or have existed which contain details of their involvement in such work beyond what is contained in their medical records. Any such financial mechanism would require to be supported by a new system whereby the NHS in Scotland requires to provide (on application by a patient) what information it can about (a) testing undertaken on an infected patient or (b) research or other similar studies in which a patient

[42] Infected Blood Compensation Study by Sr Robert Francis QC, para 2.32 and recommendation 7 at page 35

was or may have been involved. The requirement to respond to such requests fully should be recommended by the Inquiry.

Proposed further investigations

23.7 This is an area in which the evidence heard by the Inquiry provides a clear evidential basis for wider reform to the system operated within the NHS. The Inquiry should seek further evidence relating to how the NHS in Scotland has instituted, intends to institute and could institute systems pertaining to medical records in order to promote and safeguard the principles and interests identified above. Evidence regarding attempts from elsewhere within the NHS in the UK to institute systems which aim to promote these principles should also be obtained.

23.8 It may prove difficult for the Inquiry to make detailed recommendations in the absence of evidence of the whole system pertaining to medical records, which obviously extends into all areas of medical practice. It may, therefore, be the case that more work will require to be recommended in order that the Inquiry be used as a springboard to reform of the system.

24. A research subjects' rights framework

24.1 The Inquiry should recommend a research subjects' rights framework, produced in consultation with patient advocacy groups. Research should be defined broadly to include clinical studies and similar patient observational studies. This should facilitate a set of obligations whereby those undertaking any such study are required to make it clear to any patient involved in research what their rights are, including the right to information about risks and expected benefits of the research, to withdraw from research, to see the results of any tests, to be made aware of any published materials relating to their case, and to be assured that no blood or tissue sample (including historic samples) should be used for any purpose for which the patient has not given full and informed consent (or their next of kin if the person is deceased). The contaminated blood and blood products disaster should be used as a case study in the teaching of the framework in medical schools.

I) ETHICS

25. GMC probe into possible ethical breaches relating to failure to take informed consent from patients/ parents on the part of living individuals, unethical research undertaken on patients with bleeding disorders in Scotland

25.1 The evidence heard by the Inquiry has raised serious questions about the ethics of certain practices, such as the lack of or inadequacy of informed consent to treatment, patients being the subject of medical research without their knowledge or consent or at least consent to such research being obtained inadequately, patients not being tested for diseases without their consent and patients not being informed about the fact of their infections as well as the practices of ethics committees in this regard. Where these matters have already been subject to complaint to the GMC, the processes which have been undertaken have been inadequate or at least without access to the full information to which this Inquiry has had access.

25.2 Further, the evidence heard by the Inquiry has largely been to the effect that the process of GMC complaints has often led to disengagement of the complainer. The Inquiry should recommend greater patient rights and patient involvement in the GMC process, including the right to access to evidence and to information about the progress of a complaint and the reasoning for decisions taken. The Inquiry should recommend that a review be undertaken of the processes and practices of the GMC in order to achieve these aims.

26. Ensuring patient consent in medical care and treatment

26.1 The Inquiry has heard copious and unequivocal evidence that patients, their guardians or representatives were not involved in decision making about their care. Proposals for the improved use of care plans within NHS in Scotland are described elsewhere in this submission. Part of the purpose of those proposals is to try to have the Inquiry recommend a mechanism whereby patient/ patient

representative involvement is central to the decision-making process about treatment and care. The Inquiry ought to make recommendations about the need for further and better measures to be taken by the NHS in Scotland to achieve this fundamental objective.

26.2 In 2016, the Scottish Government planned a review of the consent process within the NHS in Scotland in light of the Supreme Court decision in *Montgomery v Lanarkshire Health Board 2015 SC (UKSC) 63*.[43] In a March 2017 report entitled "Informed Consent – Learning from Complaints", the Scottish Public Services Ombudsman (SPSO) identified that inadequate medical consent was the most frequently recurring issue identified in its complaints investigations and recommendations to NHS Boards over the previous 5 years.[44] A Scottish Government report entitled "Shared decision-making and consent: good practice" (19 December 2018) set out the findings of a review on the practice of consent and shared decision-making within NHS Scotland. The report found effective shared decision-making between clinicians and patients was not yet by that time universally embedded. The then current challenge recognised by the Scottish Government was to devise effective ways for supporting cultural transformation, engaging the public and embedding best practice within mainstream clinical processes.[45] The recommendations made at that time were"

1. "Bring the conversation back to the room

Ensure mechanisms are in place to allow a rich and meaningful dialogue built on partnership to be placed at the heart of every interaction between those providing, and receiving, treatment and care. Suggested ways that this could be achieved include:

- *Provide more guidance on the effective ways of communication (including evidence-based methods and resources) to enable health professionals to clearly explain risks, benefits, outcomes and alternative treatments;*

[43] Scottish Government's Healthcare delivery plan (December 2016); http://www.gov.scot/Resource/0051/00511950.pdf
[44] SPSO report, page 3
[45] See https://www.gov.scot/publications/good-practice-shared-decision-making-consent/

- *Develop a national standardised repository of validated evidence-based information about treatments and procedures and the associated risks, in a range of formats;*
- *Provide clear guidance on the appropriate use of and better access to high-quality decision-making aids for both healthcare professionals and patients to guide shared decision-making;*
- *Provide staff with education and adequate skills to both communicate information clearly to the patient and to ensure the patient has understood the information (e.g. the 'teach-back' technique);*
- *Provide staff with training on how to build a more supportive relationship with the patient to enhance person-centred consultations in which the patient feels more actively involved in their own treatment plans.*

2. ***Promote cultural transformation***

Transformation is needed within the healthcare system in Scotland to promote and subsequently accept a more personalised and less hierarchical model. Patients must be recognised as equal partners in their care and treatment, feeling supported to express their own needs and priorities through a process of information-sharing, goal-setting and action-planning. This could be supported by the following actions:

- *Encourage NHS Boards to share examples of good practice in consent and shared decision-making across NHS Scotland;*
- *Increase training opportunities and embed shared decision-making into undergraduate education for all healthcare staff;*
- *Promote peer review of good consenting practice across NHS Scotland.*

3. ***Engage the public***

In addition to transforming the role of the healthcare professional, it is important to recognise the changing role of the patient as a more active partner in their own healthcare where possible. Individuals need to be made aware of their responsibility in managing their health and wellbeing, and to feel more empowered to take an active role in their own healthcare decisions. Suggested ways to do this include:

- *Create clear guidance for healthcare professionals on how to most effectively involve people in decisions about their health and care, with respect to individual needs and capabilities;*
- *Create patient/public campaigns to increase people's knowledge, understanding, skills and confidence to use health information and navigate health and social care systems;*
- *Make information and training on shared decision-making publicly available to encourage people to become actively involved in decisions about their health and care.*

4. Improve local systems and processes around consent and shared decision-making

To support implementation of the other recommendations, it is important to improve the local systems and processes around consent and shared decision-making to enable more meaningful conversations around healthcare with the patient and to necessitate more collaborative and supportive ways of working between health and social care practitioners. This could be achieved by the following suggested actions:

- *NHS Boards should encourage healthcare professionals to ask about (and record) any specific priorities and concerns raised by the patient;*
- *Consent discussions should encompass a range of options, including the option of no treatment;*

- *Create a system, across all NHS Boards, which enables a further conversation with the patient when there is a change in the planned treatment;*
- *Provide greater support from advocates to ensure patients with learning disabilities receive appropriate help and support. Provide support and guidance to help patients with low health literacy.*

5. Support effective ways of working

Supporting and promoting effective ways of working for health and social care staff is key in enabling better processes of consent and shared decision making with patients:

- *Improve the consent process by making better use of technology to record care-planning and shared decision-making conversations;*
- *Create a national set of principles of good consent practice;*
- *Consider an effective Scotland-wide approach to consent and standardised patient leaflets;*
- *Provide more electronic resources for healthcare staff on the benefits and risks of common treatments or procedures."*

Proposed further investigations

26.3 Evidence should be sought by the Inquiry from the NHS in Scotland, in particular Healthcare Improvement Scotland as well as the Scottish Public Services Ombudsman in connection with the current initiatives within Scotland to improve and ensure informed consent, as well as information about any audit done of the effectiveness of measures which have currently been taken, sanctions available within NHS Scotland for non-compliance and plans for the future. A detailed assessment of the extent to which the recommendations of the 2018 report have been implemented should be undertaken. This should include an analysis of

initiatives to ensure that patients' right to know about and consent to testing and investigation is fully and universally respected, as well as the right of representatives to be able to give full informed consent to post mortem examination and pathological investigations. In light of that evidence, the Inquiry will be better placed to make specific recommendations about what further steps could and should be taken to improve practices designed to ensure informed consent.

J) GOVERNMENT PAPERS

27. Retention of parliamentary papers

27.1 The Inquiry has heard that important parliamentary papers relating to the contaminated blood scandal have not been retained for various reasons. Important ministerial papers (such as the papers of Lord Owen when he was Minister of State for Health) have been lost with no adequate explanation being provided as to why. The Inquiry should recommend that parliamentary and ministerial documents relating to contested areas of public policy be held independently from the department involved.

K) INVESTIGATION OF MEDICAL ACCIDENTS IN THE PUBLIC INTEREST

28. Investigation reform

28.1 The Inquiry has heard considerable evidence about the difficulties experienced by the infected and affected in having any government accept that the contaminated blood disaster ought to be investigated in a public inquiry. Term of reference 9 enables the Inquiry to consider the response of government to the disaster, including the appropriateness of its response to calls for an independent public inquiry. Under section 1 of the Inquiries Act 2005, the power to call a public inquiry is vested in a minister (as defined by section 1(2)) who may cause an inquiry to be held under the Act in relation to a case where it appears to him that (a) particular

events have caused, or are capable of causing, public concern, or (b) there is public concern that particular events may have occurred.

28.2 The current system enables government to evade responsibility for its actions by allowing it to determine when medical public inquiries should take place. As far as medical accidents are concerned, there is a need for an independent body to be given the power to recommend that a public inquiry take place and by determining independently from government whether the tests in section 1(1) appear to have been met. The Inquiry should recommend that this power be vested in the Patient Safety Commission for Scotland. The role outlined above for the Patient Safety Commissioner for Scotland requires that a power of this nature be accorded to the holder of this office in order that there be a practical consequence (in the form of an inquiry) to investigations which he or she may undertake and conclusions which he or she may reach in the exercise of the other functions of the role. It should be recommended that in reaching a view on whether or not to recommend to ministers that a public inquiry take place, it will be necessary for the Patient Safety Commission for Scotland to take account of the views of those affected by the medical accident in question, to the extent that he or she considers it reasonable. Legal representation at public expense should be available for this purpose.

20 June 2022