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INFECTED BLOOD INQUIRY

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JOINT POSITION PAPER

UK Contaminated Blood Inquiry

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Content

Executive Summary

We support the establishment of an UK Public Inquiry and are proposing ithas the following features,

1. The Inquiry be consulted on and established bythe Cabinet Office or Ministry of Justice.
2. A statutory Inquiry under the 2005 Inquiries Act.
3. The Inquiry to be led by a Chair and Panel, rather than a Chair alone(page 17).
4. That there are Scottish Core Participants with Scottish legal representation.
5. The procedures of the Inquiry to be flexible and responsive to the needs of those infected including,
    a. Those that wish to are able to give oral evidence.
    b. Hearings are held in locations throughout the UK at accessible venues.
    c. Proceedings are streamed live online.
    d. The questions that affected people want to be asked can be put.
    e. The privacy of those affected is protected.
    f. Different topics should be investigated simultaneously, potentially under different members of the Panel, to allow the Inquiry to proceed quickly and make interim recommendations.
6. Terms of Reference that include,
    a. All infections and pathogens
    b. All use of plasma derived clotting factor products
    c. Accountability and responsibility
    d. Consent, communications, and risks
    e. Blood donor selection
    f. Blood product selection
    g. Impact on those affected
    h. Access to justice

Introduction

In July 2017 the UK Government announced that it would hold a Public Inquiry into contaminated blood and blood products. This Public Inquiry will cover all four nations of the UK.

In the first instance, the Department of Health (DofH) has sought to conduct the initial consultation on the establishment of the Public Inquiry (hereafter known as Inquiry) on behalf of the Government and has asked MPs and affected people to indicate whether the Inquiry should be a Statutory Inquiry, using the powers of the Inquiries Act or whether it should be a 'Hillsborough-style' Inquiry. The DofH have also invited suggestions for what should be included in the Terms of Reference for the Inquiry.

However, campaigners and MPs have highlighted that it is inappropriate for the Department of Health to be leading the consultation and establishment of the Inquiry. Any Inquiry would have to look at the actions of the DofH during the relevant period. The Terms of Reference for the Inquiry should not be framed by the DofH as it will, itself, be under scrutiny during the Inquiry. Haemophilia Scotland (HS) has proposed, and the Scottish Infected Blood Forum (SIBF) has agreed, that another department, such as the Cabinet Office or Department for Justice, should oversee the Inquiry.

Other campaign groups have issued a joint letter boycotting the consultation until the DofH is removed as the lead department; HS and SIBF have declined to join the boycott. Due to the short notice of the single consultation meeting called by the DofH regrettably HS and SIBF have been unable, as yet, meet with the DofH.

Haemophilia Scotland, the Scottish Infected Blood Forum, and independent Scottish campaigners, have produced this paper because we believe that for the Inquiry to be a success the lessons from the Penrose Inquiry in Scotland must be learnt. We are keen to support the Inquiry by offering the benefit of our experience and the views of our members for the benefit of affected people throughout the UK.

Background

Haemophilia Scotland

Haemophilia Scotland is a charity for individuals and families with inherited bleeding disorders. We were established in 2012 and provide support, information, and advocacy services in Scotland. We were a Core Participant in the Penrose Inquiry and have trustees and members with decades of campaigning experience on the contaminated blood and blood products issue in Scotland and the UK.

Scottish Infected Blood Forum

The Scottish Infected Blood Forum is the only recognised charity in Scotland that seeks to provide support to all individuals who were infected with Hepatitis C as the result of NHS treatment from receiving blood transfusions and blood products. It includes people who received blood transfusions and people with haemophilia as well as family members.We were established in 2012 and provide support, information, and advocacy services in Scotland. Some of our members were Core Participants in the Penrose Inquiry and we have trustees and members with decades of campaigning experience on the contaminated blood and blood products issue in Scotland and the UK.

Since the Penrose Inquiry both charities have sought the best possible Scottish Government response to it by,

- Serving on the Scottish Contaminated Blood Financial Support Review Group (SCBFSG), including conducting the consultation on behalf of the Group.
- Sitting on the Penrose Inquiry Short Life Working Group, which advised the Scottish Government how best to implement the single recommendation of the Penrose Inquiry.
- Sitting on the newly established Scottish Infected Blood Support Scheme Advisory Group, giving practical advice to National Services Scotland (NSS) about the operation of the scheme, which in Scotland has replaced the Skipton Fund, Caxton Fund and MacFarlane Trust.
- Contributing to the work of the Clinical Review Group being conducted by Professor Goldberg which is addressing outstanding clinical questions, on the extra-hepatic effects of Hepatitis C and causes of death related to Hepatitis C, arising from the work of the SCBFSG.

Extent of the infections in Scotland

Hepatitis C

	People infected with Hepatitis C with bleeding disorders, including haemophilia.	People infected with Hepatitis C from a blood transfusion.	Total
Infected in Scotland (As reported in the Penrose Report)	478	Approx.2,500	2,978
Infected in Scotland and alive in Mar 2015	193	Unknown	Unknown
Originally infected in Scotland and has received a support payment	254	481	735
Infected in Scotland, claiming, and alive in Nov 2015	194	344	538
Infected in Scotland, claimed, and dead in Nov 2015	60	137	197
Number of beneficiaries of the Scottish Infected Blood Support Scheme (SIBSS) in Aug 2017			497

While the vast majority of infections were from blood transfusion, the lack of records and likely high death rate mean that it is unclear how many of these cases are still alive. The number of unidentified cases of blood transfusion infections was the subject of additional detailed work by the Penrose Short Life Working Group (http://www.gov.scot/Publications/2016/09/5853/downloads). Those who were regularly treated for a bleeding disorder were re-infected every time they were treated and thereby often exposed to multiple genotypes of the virus. Please note, some people without a bleeding disorder were treated with clotting factor products due to excessive bleeding while some of those with less severe bleeding disorders were infected from a single exposure. Therefore, categorizations like this are not always appropriate in individual cases.

HIV

60 of those with a bleeding disorder who were infected with hepatitis C were also infected with HIV. Of those 22 are still alive and receiving financial support. One person with a bloodtransfusion HIV infection received financial support before he died.

History of campaigning in Scotland

While campaigners in Scotland have been active since the earliest days of the infections the majority of the specifically Scottish elements to the campaign date from the establishment of the Scottish Parliament in 1999.

1999 – Affected people submit petitions to the Scottish Parliament Petitions Committee, two of the first petitions to be considered under the proceedings of the new Parliament

2000 – The Scottish Executive publish an internal report but the Scottish Parliament Health Committee concludes it needs more and conducts its own inquiry.

2001 – The Scottish Parliament Health Committee publishes a report recommending that an Expert Group is established to look at the issue.

2002 – An Expert Group is established under Lord Ross and calls for financial support payments to be made.

2004 – The Skipton Fund is established across the UK and makes ex-gratia payments to those infected with Hepatitis C.

2005 – The Scottish Parliament votes 56 to 52 against establishing a Public Inquiry.

2006 – The Scottish Parliament Health Committee calls on the Scottish Executive to hold a Public Inquiry but the call is rejected. Thompsons Solicitors works with affected people in Scotland to bring a Judicial Review of the decision not to hold a Public Inquiry. The Department of Health (UK) publish and internal report on Self-Sufficiency in Blood Products in England and Wales.

2007 – The SNP manifesto contains a pledge to hold a Public Inquiry. At the same time a UK-wide Independent Public Inquiry under The RT Hon the Lord Archer of Sandwell QC is established and based in London.

2008 – The Scottish Government loses the Judicial Review and must now investigate all deaths caused by contaminated blood or blood products. The Scottish Government announce that a Statutory Public Inquiry will be held and the UK Government declines to convert it into a UK-wide Statutory Public Inquiry.

2008 – Lady Cosgrove was initially appointed to be Chair of the Public Inquiry but she couldn't carry out the engagement and an alternative had to be sought.

2009 – Lord Penrose is appointed to conduct the Scottish Public Inquiry and holds a preliminary hearing. Affected people are invited to make written statements. The Archer Inquiry publishes its final report.

2010 – The Penrose Inquiry publishes a Preliminary Report of established facts and details topics it will be investigating. Of the over 80 affected individuals who applied to be Core Participants just 20 affected individuals are accepted.

2011 – Following the publication of the Archer Report improvements are announced to the ex-gratia support payments available in England. The Scottish Government announces it will broadly match the changes and will review them again once the Penrose Inquiry reports.

2012 – The last public hearing of the Penrose Inquiry is held and statements from the Chair indicate a report can be expected within 18 months.

2013 – The Scottish Government announces it has asked the recently established Scottish Infected Blood Forum to conduct a Scoping Exercise into the impact of the infections to inform its review once the Penrose Report is published.

2014 – Haemophilia Scotland published a report on outstanding recommendations from the Lord Ross Expert Panel Report 10 years earlier.

2014 - Factor 9 was a powerful play, written and performed by Dogstar Theatre Company, attracts large audiences and wide acclaim during the Edinburgh International Arts Festival.

2015 - The Scottish Infected Blood Forum publish its Scoping Study Final Report in March 2015, before Penrose reports. It makes 16 recommendations.

2015 – The Final Report of the Penrose Inquiry is published. Campaigners are disappointed that there is little analysis of the events it describes and only one recommendation; that the Scottish Government takes all reasonable steps to offer a Hepatitis C test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HepatitisC. The Scottish Government issues an official apology and accepts it has a moral responsibility to those affected.Apologies are also made by the Scottish National Blood Transfusion Service (SNBTS) and the UK Government.The Scottish Government establishes the Scottish Contaminated Blood Financial Review Group to review the ex-gratia support payments and later accepts its recommendations. Representatives from Haemophilia Scotland and the Scottish Infected Blood Forum are appointed to the Group.

2016 – The Penrose Inquiry Short Life Working Group is convened to advise the Scottish Government on the most appropriate way to implement the Penrose recommendation. It recommends that an awareness campaign be conducted within the NHS and that detailed work is conducted to follow up on a previous look back for people with inherited bleeding disorders. Its recommendations are accepted by the Scottish Government.

2016 – A Memorial Service for those who died as a consequence of their infections hosted by Haemophilia Scotland is led by Richard Holloway, former Bishop of Edinburgh and attended by The First Minister, Deputy First Minister and Cabinet Secretary for Health.

2016 – The SIBSS is established offering enhanced payments to those infected in Scotland compared to payments made previously via the Alliance House Organisations.

2016 – Virtually all infected people with bleeding disorders have been offered the new Direct Acting Antiviral (DAA) treatments for Hepatitis C with the vast majority achieving a sustained virological response (SVR).Patients now expect to live longer and healthier lives.Access to DAA has not been as good in the rest of the UK.

2017 - The Scottish Government announce that the Clinical Review Group arising from the SCBFSG Report will be chaired by Prof David Goldberg. Representatives from Haemophilia Scotland and the Scottish Infected Blood Forum are appointed to the Group.

2017 - Following receipt of a cross party letter supporting a UK wide Inquiry the UK Government announces a Public Inquiry.

Lessons from the Penrose Inquiry

Access to the Inquiry

Many of those affected in Scotland did not feel that their voice had been heard during the Penrose Inquiry. Despite being a Public Inquiry opportunities were missed to make the process more open and accessible. These could be addressed by a UK Inquiry in the following ways,

1. For there to be a mechanism for all those who wish to give oral evidence to do so. Many individuals and families need to have their "day in court" and to have what has happened to them officially recorded. The statement taking process used by the Penrose Inquiry was insufficient to meet this need. Only a very small number of affected people were able to address the Inquiry directly. All affected people that want it should have a right to provide oral evidence. This will not only provide a more complete understanding on the impact of the infections but also help many people come to terms with their loss. Those giving evidence must have access to legal representation and advice to prevent them prejudicing any future case they may have when providing their evidence?

2. Public hearings of the UK Inquiry should be held in a variety of locations around the UK, including all four nations, so that as many affected people as possible have the opportunity to attend a hearing in person. All venues used for public procedures of the Inquiry must have sufficient disabled parking and be wheelchair accessible.

3. The procedures of the UK Inquiry must be streamed online. Many of those most seriously affected have extremely poor health can cannot be expected to travel to attend hearings if they want to see the evidence. Expecting people with serious fatigue to keep up with the Inquiry by reading daily transcripts is not appropriate. Streaming the procedures would also allow better access for those in remote or island areas to engage. Clause 17.3 of the Inquiries Act places a duty on the Inquiry Chair to act with regard to the need to avoid any unnecessary costs including to witnesses and others.

4. The need for an efficient procedural system for ensuring that appropriate questions are asked on behalf of patients.

5. The need to ensure that there are sufficient safeguards to protect the identity of individuals involved in the Inquiry.

Insufficient analysis and recommendations

The Penrose Inquiry did a reasonable job of cataloguing the relevant events as they related to Scotland. However, it was extremely weak on analysis of those events and comparing them to current practice. It failed to establish where lessons can be learned to improve public safety and the lives of those affected. The terms of reference for the new Inquiry must avoid this by requiring a series of conclusions and recommendations in specified areas.

Terms of Reference

For the Inquiry to be of benefit to those affected in Scotland it must have Terms of Reference which cover relevant issues for Scotland which weren't covered by the Penrose Inquiry. The Penrose Inquiry also has a role to pay in highlighting the issues which could most productively be examined by a UK Inquiry.

The remit must be sufficiently wide that the pattern of repeated exposure of people with inherited bleeding disorders to blood borne pathogens can be understood. It's welcome that the statement announcing the Public Inquiry said that it would be 'wide ranging'.

For the inquiry to maximise its value for money it must concentrate on where lessons can be learnt to improve public safety and the lives of those affected and focus on reaching conclusions which are of practical application. Those affected in the rest of the UK and the UK Government will benefit from using the Scottish experience to focus the UK Inquiry on the most relevant issues.

HS and SIBF believe that the Terms of Reference must do more than requiring general investigation, they must require the specifics to be examined and invite recommendations for each topic. It important that they also require investigation both of whether the procedures in place at the time were properly followed but also whether or not those procedures were appropriate. Where policy or procedures have changed that should be made clear and where they have not appropriate recommendations should be made.

To ensure we are presenting a balanced set of proposals we have indicated the majority applicability of each proposal in terms of the affected communities. 'BD' for Bleeding Disorders, 'BT' for Blood Transfusion, or 'Both.' We have also indicated which pathogens could be relevant; HIV, HBV, HCV, CJD, or All

Infections

Pattern of Exposure of people with inherited bleeding disorders

To investigate the pattern of the repeated exposure of people with inherited bleeding disorders to successive blood borne pathogens including a) HIV b) HBV c) HCV d) CJD to establish at each stage if the appropriate lessons were learnt to protect patients from future pathogens; and to make appropriate recommendations about how the risk of this pattern of exposure might be reduced for people with inherited bleeding disorders or other groups of vulnerable patients.

To achieve this an Inquiry should begin with whether the required lessons about reducing the transmission of blood borne virus were learnt following the identification of Hepatitis B. Could this have reduced the impact of HIV and/or Hepatitis C on either people with bleeding disorders or those who received blood transfusions? Similarly, successive Governments have maintained that all relevant lessons have been learnt from the HIV and Hepatitis C infections (Self-Sufficiency Report). The Inquiry must consider how the risk from CJD is being handled to establish if this is the case and make any relevant recommendations for how current practice can be improved. There is also a concern that other infectious agents which would have been transmitted by pre-heat treatment factor products may, as medical knowledge improves, come to be understood as causing specific conditions or being a contributory or risk factor for their development. Given the experience with Hep C, how can patients have confidence that these recommendations will be accepted and applied to minimise the risk to them, their families or the public?

BD, All

Evolving knowledge of Hepatitis B

To establish a) when it was, and b) when it should have been realised that hepatitis B was a progressive and potentially lethal disease; and to make any relevant recommendations about how the impact of known and classified pathogens is monitored and triggers relevant policy responses to protect patients and the safety of the blood supply.

Both, All

Evolving knowledge of Hepatitis C

To establish a) when it was, and b) when it should have been realised that hepatitis C was a progressive and potentially lethal disease; and to make any relevant recommendations about how the impact of known and classified pathogens is monitored and triggers policy relevant policy responses to protect patients and the safety of the blood supply.

Both, HCV

Evolving knowledge of HIV/AIDS

To establish a) when it was, and b) when it should have been realised that AIDS was a caused by a blood borne agent and an agent which maybe transmittable by plasma derived clotting factor concentrates, and to make any relevant recommendations about how the impact of known and classified pathogens is monitored and triggers relevant policy responses.

Both, HIV

Evolving knowledge of CJD

To establish what is currently known about the risk to blood and blood product recipients from vCJD and sCJD; to establish if appropriate lessons have been learnt from previous infections to protect patients and the safety of the blood supply; and to make relevant recommendation including on the future of the categorisation of those at risk from vCJD for public health purposes.

BD, All

Full disclosure of pathogens

Which blood borne agents, including bacteria, viruses, and prions have a) people with inherited bleeding disorders, and b) blood transfusion recipients, been exposed too; and which of them are currently believed to be pathogenic and associated with which conditions. Any interactions between these agents should also be investigated. To make any relevant recommendations for where further research is required or for actions that could reduce the risk of patients or their family developing additional conditions as a result of their exposure.

Both, All

Responsibility and Accountability

Ultimate responsibility

To establish who was, and is, ultimately responsible for the safety of a) blood products and b) blood in the UK. This should include responsibility for clinical trials, licensing, importation, inspection, donor

selection, donor testing, manufacturing, public health, and political oversight. To make any relevant recommendations for how and whether the focus on safety and/or accountability could be increased.

> *Was there too much emphasis on reaching decisions by consensus? Or conversely was too much power left in the hands of Doctors arguing for their own clinical judgement to take precedence even though similar cases were arising across the UK. Was sufficient weight given to the consequences of inaction? Did those responsible have conflicting duties or interests which could have lessened their focus on safety?*

Both, All

Cross border issues

To establish if there was an appropriate level of cooperation between healthcare providers and blood transfusion services across the nations of the UK to maximise patient care and patient safety, with specific reference to,

a. the use of spare PFC capacity, from Liberton in Edinburgh, to assist with shortages out-with Scotland
b. the availability of BPL's 8Y product, from Elstree in London, for treating previously untreated people in Scotland.
c. whether there was any medical or scientific reason why the introduction of routine anti-HCV testing should have been delayed in Scotland to achieve simultaneous introduction with the rest of the UK

Consent, Communications, and Risk

Consent for testing and research

To establish what evidence there is of people with bleeding disorders being tested, entered into clinical trials, or used in published research without their consent, did any such practices comply with best practice at the time, could best practice have been better and would it meet current best practice; and to make recommendations about the when and how consent should be obtained for testing and research.

> *It was evident from the Penrose Inquiry that people with bleeding disorders were tested without their consent and were involved in clinical research without their knowledge. People were not automatically told of their infected status and when they were eventually informedit was without the appropriate support. People were not made aware of the risks and were not offered choices to help them mitigate those risks. Any new Inquiry must examine the medical ethics of consent in research and make clear recommendations about how results and risks are and were communicated to patients.*

BD, HIV, HCV

Communication of risk

To establish if there was well established or generally accepted procedures or protocols for communicating information to each individual patient about the risks associated with the use of therapeutic products, the relative risks of avoiding therapy and the nature of the choice that the patient had to make about their own condition and the treatment for it; and to make any appropriate recommendations about how risk should be communicated to patients making informed treatment choices.

Both, All

Timeliness of communication

To establish by what date all patients should have been informed that they were positive for a) HIV and b) Hepatitis C; what should have been the maximum reasonable gap between a test being conducted and the result being communicated to the patients; and to make any appropriate recommendations about how current practice in relation to communication of test results could be improved.

Both, All

Patient Choice

To establish if patients were offered a choice between commercial and domestic products, or between plasma derived factor concentrates and cryoprecipitate as the risks from blood borne infection became better known; and to make any appropriate recommendations about the role of patients in treatment selection.

BD, HIV

Constancy of information

To establish if there were discrepancies between information provided to potential blood donors and to blood and blood products recipients about whether AIDS was blood transmissible, and how any such differences were justified; and to make any appropriate recommendations about how information about risks to the blood supply can be communicated with the uppermost clarity.

Both, HIV

Communication to non-specialist treaters

To establish if sufficient guidance was provided to hospitals and healthcare professionals, including junior doctors, who are either specialist or non-specialist in the treatment of bleeding disorders, about a) the risks of the transmission of hepatitis C to previously untreated patients, and b) the risk of transmitting AIDS before HIV was identified; and to make any appropriate recommendations about how such guidance could have been and should be developed and propagated in comparable circumstances.

To examine what, if any, recorded procedures were in place to determine the use, or not, of blood derived concentrates on first time patients as growing knowledge of the risks evolved but were not communicated to patients.

Both, HIV, HCV

Blood Donor Selection in the UK

Self-identification of high risk groups

To establish if it was sufficiently robust to rely on potential blood donors in high risk groups to self-defer based on the information provided to them by blood transfusion services, and if this information was clear enough and distributed consistently; and to make recommendations about best practice in encouraging the self-deferral of high risk donors.

Both, All

Prison Blood

To establish when it was known that incarcerated populations had a higher prevalence of blood borne infections, and whether steps to protect blood and blood product recipients were sufficient and began early enough; were the impacts on safety of financial and non-financial incentives to donate in the UK and/or USA properly assessed; and to make recommendations about the appropriateness of the therapeutic use of blood collected from incarcerated populations in the future.

Both

Illicit Drugs and Blood Donation

To establish when there first was clear domestic or international advice that illicit drug use should result in the deferring of potential blood donors and whether steps taken to implement that advice were sufficient and begun early enough; and to make recommendations about the appropriateness of the therapeutic use of blood collected from people who are using illicit drugs in the future.

Both

Donor deferral decision-making

To establish if the current process for making decisions about the exclusion or deferral of potential blood donors has changed significantly since the 1970s and 1980s, if any change has altered the speed at which decisions can be made, and to make recommendations for further changes to the process.

Both

Surrogate ALT testing

To establish if the introduction of surrogate ALT tests for donor screening could have reduced the incidence of Hepatitis C infections from blood transfusion; and to make any appropriate recommendations about how surrogate tests are evaluated and decisions taken about their implementation. Was there unacceptable delay in introducing surrogate testing of blood donations?

BT, HCV

Routine anti-HCV testing

To establish if the earlier introduction of routine anti HCV testing was technically possible, whether it's earlier introduction would have prevented any infections with HCV from blood transfusions, and what were the reasons for any delay; and to make any appropriate recommendations about how the delays in the introduction of screening tests might be minimised.

BT, HCV

Targeted Look-Back

To establish how many positive results following the introduction of routine anti-HCV testing led to a targeted look-back to identify other infections, and were these efforts sufficient; and to make recommendations about what actions should follow positive results from blood donor screening.

BT, HCV

Blood Product Selection

Large pool manufacturing

To establish what safety assessments were conducted as the number of donors contributing to a manufacturing pool increased, whether those assessments were sufficient, and if any mitigating actions taken were sufficient; and to make recommendations about how the risks from new manufacturing processes are assessed.

BD, HIV, HBV, HCV

Manufacturing standards

To establish if the standards at domestic and commercial manufacturing plants were sufficiently stringent and rigorously enforced, and if crown immunity was used to allow state owned plants to operate at a lower standard than would have been permitted for a commercial operation; and to make recommendations about a) if current standard setting and inspection regimes can be improved, and b) if crown immunity was inappropriately applied in this case.

BD, HIV, HBV, HCV

Product Infectivity

To establish the likelihood of infection with a) HIV b) HBV, and c) HCV from a single treatment of pre-heat treatment plasma derived clotting factor concentrate, and whether there were significant differences between domestically and commercially produced products, whether the assumptions made about their comparative safety at the time were borne out by the available evidence; and to make appropriate recommendations about how the risks inherent in manufacturing processes are considered in the current licencing, importation, and purchasing of pharmaceutical products.

BD, HIV, HBV, HCV

Licencing

To establish what proportion of infections for a) HIV, b) Hep B, c) Hep C were caused by treatment with unlicensed products; why products continued to be used despite the lack of licensing; what action the lack of licencing should have prompted; and to make appropriate recommendations about the role of licencing in improving patient safety.

BD

Purchasing

To establish if the lack of a central purchasing system for commercial clotting factor products had an impact on the quantity or quality of commercial clotting factor products imported into the UK; and to make any appropriate recommendations about improving patient safety through purchasing.

BD

Alternative treatments and treatment regimens

To establish if it was technically possible to offer patients wholesale or partial shift to cryoprecipitate or reduced frequency of infusion, and if these steps could have had a mitigating effect in relation to the risk from HIV/AIDS in regularly treated patients and/or Hepatitis C in previously untreated patients ; and to

make any appropriate recommendations about how clinicians and patients reach decisions balancing the perceived benefits of novel treatment with the safety record of established treatments.

BD

Risk benefit analysis

To establish if sufficient, and sufficiently regular, risk benefit analyses wereconducted in response to the emerging knowledge of the risks of exposure to Hepatitis C and HIV in relation to the use of plasma derived clotting factor concentrates, and the seriousness of these infections; and to make any appropriate recommendations about how risk benefit analysis can be triggered and managed in relation to emerging risks.

BD

Impact

To assess the impact of the infections emotionally and economically including on,

a. physical health,
b. life expectancy,
c. mental health,
d. finances,
e. family life,
f. social interactions/relationships, including work and employment

for all affected groups including,

i. infected people,
ii. partners,
iii. parents,
iv. children,

and to make recommendations a) about the level of historic losses and ongoing requirement for financial support, and b) the effectiveness of the current ex-gratia schemes at meeting these losses and ongoing requirements. And to make further recommendations onthe adequacy of support services across the UK such as counselling and psychological support for those impacted. To address the discrepancyin between the support schemes between devolved nations and differing support and treatment services among differing health boards or services. To examine the discrepancies for those who were likely to have been multi-infected in both Scotland and other UK countries; and examine the case for backdated financial payments to the point of infection. Tomake recommendations for the improvement of these provisions.

Both, HIV, HBV, HCV

Access to justice

Justice delayed

To establish if the criminal justice and political systems provided sufficient opportunity for those affected by contaminated blood and blood product to seekredress and establish civil or criminal liability; to further establish if there were actions which could lead to further criminal prosecutions, civil

prosecutions, or further disciplinary action whether or not time barred, and to make recommendation for improving current practice and whether specific exceptions to the time bar should be made.

Both, All

Conspiracy to conceal.

To investigate the persistent accusations that there has been a concerted effort to conceal the extent of and the events surrounding which led to the infections and that has frustrated the attempts of those seeking justice. This should include,

a. Former Ministers being denied access to their papers.

b. Individuals reporting gaps in their medical records which related to the relevant period. There should be a consensual and systematic examination of medical records to establish if there is any constant pattern of gaps.

c. The reported destruction of documents by junior civil servants. The Inquiry should specifically examine whether a department where this is possible is competent to maintain its own archive and whether documents related to disputed issues like this should be held out with the departments who are implicated.

To make relevant recommendations for the increased security of such records including protection from inadvertent destruction resulting from the actions of junior civil servants acting alone.

Are all ministerial, departmental, government agency medical records sufficiently well maintained, protected, and accessible?

Both, All

Powers and Procedures of an Inquiry

Statutory Panel

The form of the Inquiry should be chosen to maximise,

1. the powers it has to investigate, including the power to compel witnesses and evidence throughout the UK
2. the authority it has to make recommendations in the reasonable expectation they will be accepted
3. its responsiveness to the concerns of those affected

It is our view that this can be best delivered with a statutory Inquiry under the Powers of the Inquiries Act. However, where the Act provides flexibility the options selected should be used to make the process more open and responsive that was the case during the Penrose Inquiry.

The main examples of this flexibility in the Act are,

Clause 3.1 of the Inquiries Act provides the choice between an Inquiry under a Chair or an Inquiry under a Chair and panel. Our clear preference is for an Inquiry involving a panel. This could lessen the impact of any possible delay due to the illness of the Chair or a bereavement, as happened with the Penrose Inquiry.

Clause 17.1 which gives ultimate discretion about the procedure and conduct of an inquiry are to be such as the Chair of the inquiry may direct. This means that the selection of an appropriate Chair is vital and that in this case one must be found who is prepared to fully engage with those affected.

Liability

Section 2 of the Act states,

> "An inquiry panel is not to rule on, and has no power to determine, any person's civil or criminal liability."

Successive Governments have argued that they have no duty to provide compensation as liability has never been established without providing any opportunity for those affected to establish liability. As the a Statutory Inquiry would not rule on liability, the UK Government should either provide a process competent to do so or undertake not to defend the absence of compensation in these terms in the future.

Core Participants

The voice of patients and families is vital to the success of the Inquiry. Our experience of the Penrose Inquiry suggests that great care must be taken to make it clear what they role of Core Participant is, as many incorrectly assumed being a Core Participant would increase their chances of being called as a witness. The procedure for selecting patient interest witnesses should be set out in advance or at the same time as those for becoming a Core Participant to mitigate this risk.

When selecting Core Participants consideration should be given to the following criteria,

- Ensuring the whole range of experiences are reflected including,

    - Those infected with different viruses
    - People infected at different ages
    - Those whose infections have caused varying degrees of illness and financial loss
    - The partners of infected people, including the bereaved.
    - The parents of infected people, including the bereaved.
    - The children of infected people, including the bereaved.
- That the geography of the UK and variation in howevents unfolded is taken into account. There should be patient interest core participants from,
    - England
    - Scotland
    - Wales
    - Northern Ireland
    - Larger and smaller Haemophilia Centres
- The ability of individual or organisational Core Participants to spend sufficient time reading documents and bring sufficient insight to work effectively with legal representatives.

Patients and their representatives must be involved throughout the process including the establishment, conduct, reporting, and implementation of any accepted recommendations.

Legal Representation

We believe that the differences in policy framework, health service, legal system, in Scotland means that Scottish Core Participants require their own legal representation.

Structure of the investigation

It is not in the interests of Government or those affected for the Inquiry to take too long. We therefore propose that full advantage is taken of using a panel to allow different aspects in the Inquiry to proceed simultaneously. As each segment is dealt with preliminary recommendations could be published to allow appropriate bodies to respond immediately. Panel members could be selected with a view to them leading particular aspects of the investigation.

Selection of an Inquiry Chair and Panel

Chair alone or Chair with Panel

As detailed above we believe and Inquiry Chair and Panel is preferable to a Chair alone.

One of the consequences of the independence of a Public Inquiry is that the Chair has a large amount of power and discretion which are only limited by the ability of Ministers to alter the Terms of Reference and the prospect of Judicial Review. Judicial Reviews are expensive and have the potential to delay the progress on an Inquiry, this makes them a very blunt tool, especially when lives are still being lost.

The use of a Panel could help produce a more responsive Inquiry which was better able to listen to the concerns of those infected and their families.

Selection of a Chair and Panel

The names proposed for Chair and Panel will, almost by definition, be respected establishment figures who enjoy the confidence of the UK Government. There is an understandable suspicion of establishment figures amongst many of those impacted by the infections. The decades of official resistance to holding a Public Inquiry have resulted in an entirely understandable breakdown of trust.

Therefore, it is vital that the Chair and Panel enjoys a similar level of respect and confidence from infected people and their families as they will enjoy from the UK Government. The Inquiry cannot be seen as impartial if the Chair and Panel enjoys more confidence from those being questioned than they do from those who have suffered or vice versa. If the Inquiry Chair and Panel do not enjoy the confidence of those affected from the outset, the Inquiry will fail.

This means it is vital that affected individuals and families have a voice in the selection of the Chair and Panel. Haemophilia Scotland and the Scottish Infected Blood Forum are ready to work with other campaign groups and individuals in Scotland to facilitate this process. However, we recognise that the Chair and Panel cannot be selected by the affected communities alone as this would compromise the impartiality of the process.

The Chair and Panel should be young enough and healthy enough to inspire confidence that they will have the necessary personal resources to conduct the whole Inquiry with vigour and enthusiasm.

There should be no unnecessary delay in appointing the Chair and Panel. However, our primary concern is that the right individuals are appointed.