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Health Finance and Infrastructure Division

Scottish Government
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Mr JJ Evans

request-564840-d81b0fea@whatdotheyknow.com

Our ref: FoI/19/00901

14 May 2019

Dear Mr Evans

Thank you for requesting a review of our response to your request, under the Freedom of Information (Scotland) Act 2002 (FOISA), as follows:

"All correspondence between the Population Health Improvement Directorate and Nicola Sturgeon regarding The Penrose Inquiry during the period 21st March 2015 - 31st December 2015."

In your review request you asked that we only consider our application of section 30(b)(i) - Free and frank provision of advice.

I have now completed a review of our response, and have concluded that the original decision should be confirmed, with modifications. I have determined that some of the information withheld under section 30(b)(i) should have been released. I concluded that due to the passage of time, the harm test was not sufficiently met to enable us to withhold the information. Additionally, as some information is factual and some will be in the public domain, the exemption did not apply. A copy of this information is therefore included as an annex to this letter. Though some information is already available in the public domain, it is being provided here for ease of access.

An exemption under section 30(b)(i) continues to apply to some information for the reasons outlined in our initial response to your request; I have indicated where these redactions have been made in the annex below, both for s30(b)(i) and s38(i)(b).

If you are unhappy with the outcome of this review you have the right to appeal to the Scottish Information Commissioner about our decision within 6 months of receiving this letter. Information on how to make an appeal, along with an application form, is available on the Commissioner's website at:

http://www.itspublicknowledge.info/YourRights/Unhappywiththeresponse/AppealingtoCommissioner.aspx.

You can also contact the Commissioner at:

The Scottish Information Commissioner
Kinburn Castle
Doubledykes Road
St Andrews
Fife
KY16 9DS

E-mail: enquiries@itspublicknowledge.info
Telephone: 01334 464610

Should you then wish to appeal against the Commissioner's decision, there is a right of appeal to the Court of Session on a point of law only.

Yours sincerely

David Bishop

Document 1

From: Brown GJ (Gareth) <Gareth.Brown@scotland.gsi.gov.uk>
Sent: 26 March 2015 08:39
To: [*text redacted – personal data*]@scotland.gsi.gov.uk>; Hutchison D (David) <David.Hutchison@scotland.gsi.gov.uk>; First Minister <FirstMinister@scotland.gsi.gov.uk>; Bowman K (Katy) <Katy.Bowman@scotland.gsi.gov.uk>
Cc: [*text redacted – personal data*]@scotland.gsi.gov.uk>
Subject: RE: 150326 FMQ Penrose

[*text redacted – personal data*]

Here you go, with a bit added on that point as well as little more detail on the payment schemes

Gareth Brown
Head of Health Protection | Public Health Division | Population Health Improvement Directorate
Scottish Government |Tel: [*text redacted – personal data*]

PENROSE INQUIRY

RECOMMENDATION

- Lord Penrose's report makes a single recommendation, that the Scottish Government should take all reasonable steps to offer a hepatitis C test to anybody who might have been infected before 1991 by a blood transfusion who has not already been diagnosed.
- **We have accepted this in full and we will now determine who this will be taken forward**.

ACTIONS IN RESPONSE TO REPORT FROM SCOTTISH GOVERNMENT

- We recognise that there are victims and families who are deeply disappointed with the independent inquiry's report.
- **Bill Wright of Haemophilia Scotland is absolutely correct in his assessment that despite his disappoint that "…there is a narrative setting out the case that cannot be avoided by the government and its moral responsibility."**
- **We agree with Mr Wright's observation, and that is why we will carry out**:
  - An immediate commitment to review and **improve** the financial support schemes on offer to the people affected, and their families, to be concluded before World Haemophilia Day in April 2016.
  - A reference group of patients and families set up to contribute to that review
  - We'll work with the rest of the UK nations in undertaking this review, but should this appear to lead to any delay for people in Scotland who are affected we will not hesitate in moving to a Scottish specific review.
  - In additional, funding for a pilot scheme for additional psychological support for those affected, rolled out wider if needed
  - We will also continue funding for Haemophilia Scotland and Scottish Infected Blood Forum for at least the next three years.
  - We will also review the report in detail to determine if there are further findings which can provide lessons today.

BACKGROUND

- **SUMMARY:** The Penrose Inquiry into infected blood and blood products was published yesterday (Wednesday 25 March). Then Health Secretary Nicola Sturgeon established the independent inquiry under the Inquiries Act 2005 on 23 April 2008.
- ***NOTES:*** The Inquiry concluded that there were few respects in which things could have been done differently, and made only a single recommendation.
- Affected patients and their families who attended the publication of the report today were vocal in their dissatisfaction with the report, and in one case a copy of the report was publicly burnt.
- At PMQs David Cameron issued an apology for what happened on behalf of the Government, £25 million would be made available in 2015/16 to support any transitional arrangements to a different payment system that might be necessary in responding fully to Lord Penrose's findings.
- Affected patient groups are of the clear view that the financial support payments they receive are insufficient.
- **Bill Wright, Haemophilia Scotland summarised criticisms**: "At first sight the report appears to disorganised and impenetrable. Worse still it might appear on first reading to be a whitewash with frankly some of the chairman's assertions seemingly barely rational. **Look a bit deeper and there is a narrative setting out the case that cannot be avoided by the government and its moral responsibility."** (BBC 25 March)
- The Inquiry cost £12 million and took around 7 years.

REPORT SUMMARY OF THE NUMBERS AFFECTED

	Number infected	Number known to have died
Bleeding disorder infected with hep .C	478	193
Hep. C transmitted by transfusion	2,500 (estimate)	Unknown
Bleeding disorder infected with HIV	60	39
HIV transmitted by transfusion	18	15

FINANCIAL SUPPORT SCHEMES

- We have contributed £31 million over the last 10 years to the UK schemes which provide financial support to affected individuals and their families
- There are two schemes we contribute to for people affected by hepatitis C:
    - **Skipton Fund** – provides £20k stage 1 payment (infection); £50k stage 2 (advanced disease, cirrhosis); and stage 3 payments of £14k per year for all those who receive stage 2 payments
    - **Caxton Foundation** – provides financial assistance to those who have received payments from the Skipton Fund. Economic support for household goods, personal items and tax/mobility.
- Annual Scottish budget for these schemes is £2.5m (payments plus running costs)
- There have been around 700 beneficiaries in Scotland of which around 300 still alive.
- Lord Penrose's report acknowledges that many affected people believe that the payments they are receiving are insufficient.
- We will now commence a review of payment schemes to consider how they can be improved. We will include patients and their families in that work to ensure their voices are heard.
- We want this work to conclude no later than World Haemophilia Day 2016.

DAILY MAIL: ONLY SIX PATIENTS GAVE EVIDENCE

- Daily Mail states only 6 patients gave evidence despite 80 applying. More doctors that patients give evidence
- In total the Inquiry has taken statements from 159 patients and relatives. 6 patients were invited to give oral evidence.
- It was a matter for Lord Penrose and the Inquiry to determine which and how many witnesses and oral testimony he took. It is normal for Inquiries only to look in detail at a small number of specific cases. This avoids duplication of testimony and helps limit time and cost.
- Haemophilia Scotland criticised Lord Penrose's decision about testimony in 2012 "…it would be an understatement to say that we were disappointed by Lord Penrose's approach to this inquiry… the denial to hear the voices of those infected gives the impression of a whitewash"." (Herald 9 May 2012)

COMPENSATION/DAMAGES

- Compensation was not within the Terms of Reference of the Inquiry, but we recognise that individuals may wish to raise an action in the civil courts in relation to their own circumstances.
- Damages are a matter for the Courts to decide and it would be for individuals to seek their own legal advice on whether they had a case or not under the current law.

COST OF INQUIRY/LENGTH

- This was one of the most significant healthcare related tragedies we have ever seen – it was right and proper to look at this in detail.

- This Government was the first Government in the UK to commit to a statutory independent Inquiry on these matters – we listened to affected patients.
- There is much to be learned from Penrose about how the health service responds to emerging threats and issues where there is a lack of scientific evidence and significant uncertainty. We will consider this carefully.

FINDINGS NOT RECOGNISED BY AFFECTED INDIVIDUALS/NO CRITICISM

- Lord Penrose has concluded that little could have been done differently because of knowledge at the time, and cultural differences such as the previous paternalistic approach of some clinicians and the NHS.
- But we should also recognise that the NHS we have today is very different: if we were faced with similar circumstances today we would expect the NHS to be much more open about risks and uncertainty with a truly patient-centred approach.

BLOOD SAFETY

- As the inquiry acknowledges, there have been very considerable advances in medical and scientific knowledge with regard to blood safety and the prevention/treatment of HIV and hepatitis C infection since the early 1980s.
- Scotland is now leading the way on patient safety and was the first country in the world to implement a national patient safety programme across the whole healthcare system.

TIMELINE OF INQUIRY CALLS SINCE DEVOLUTION

24 November 1999 – Brian Adam MSP (SNP) tabled a motion calling for an Independent Inquiry. The motion was signed by 71 MSPs.

24 October 2000 – Scottish Executive Internal Inquiry Report is published.

3 October 2001 –Health and Community Care Committee publish a report into the contaminated blood issue which recommended that the Executive set up an expert group to consider not only financial assistance to those who had been affected but the wider issue of the national health service making no-fault compensation payments.

19 December 2002– Nicola Sturgeon MSP tables amendment to budget motion seeking “30 million, £30 million and £29 million for 2003/04, 2004/05 and 2005/06 respectively to fund a discretionary trust that will make ex gratia payments to all people who can demonstrate, on the balance of probabilities, that they received blood, blood products or tissues from the NHS in Scotland and were subsequently found to be infected with the Hepatitis C virus."

9 September 2003 – Brian Adam MSP (SNP) tables a motion calling for a Public Inquiry into the contaminated blood disaster. The motion was signed by 19 MSPs (including Shona Robison)

3 June 2004 – Scottish Executive announces that the Skipton Fund is open and people can register their details.

18 April 2006 - Scottish Parliament's Health Committee calls for a public inquiry into the infection of people with Hepatitis C through NHS treatment – rejected by the then Scottish Executive.

16 August 2007 - then Health Secretary Nicola Sturgeon, at a meeting with representatives of the haemophilia community, confirmed that the Scottish Government would honour SNP manifesto commitment to hold an inquiry.

23 April 2008 – then Health Secretary Nicola Sturgeon instigates a judicially-led public inquiry into the transmission of Hepatitis C from blood and blood products to NHS patients in Scotland. Lady Cosgrove appoint as chair of inquiry.

12 January 2009 – Lord Penrose appointed as chair of the inquiry after Lady Cosgrove stands down.

8 March 2010 - First block of Penrose Inquiry Public Hearings starts. It finishes on 30 March 2010.

26 April 2010 – Second block of Penrose Inquiry Oral Hearings starts.

20 January 2012 – Last scheduled oral hearing of the Penrose Inquiry. There were 88 days of hearings.

8 May 2012 – Scottish Blood Infection Forum criticize inquiries approach to limit number of core participants - "it would be an understatement to say that we were disappointed by Lord Penrose's approach to this inquiry… the denial to hear the voices of those infected gives the impression of a whitewash".” (Herald 9 May 2012)

25 March 2015 – Penrose Inquiry report published.

PENROSE REPORT VOLUME/CHAPTER SUMMARY

Overview of Structure of Report

- 1,779 pages in total. 5 volumes and a further, separate Executive Summary.
- Each of the five volumes deals with different issues:
  - Volume 1: Patients' Experiences, including witness statements
  - Volume 2: Knowledge of HIV/AIDS and hepatitis C
  - Volume 3: Blood and Blood Products
  - Volume 4: Donor Selection and Screening of Donated Blood
  - Volume 5: Information to Patients, including an investigation of the look-back exercise
- There are five short appendices on procedural matters and listing witnesses and core participants.

Overall Context

- The Inquiry is presented largely as a narrative history of events, or a factual description of key topics such as bleeding disorders, viruses and statistics.
- On balance the report contains no significant criticism. In his foreword Lord Penrose says: "Much of the comment made over the years on the topics discussed in the Final Report has reflected strongly-held beliefs. Some commentators believe that more could have been done to prevent infection in particular groups of patients. Careful consideration of the evidence has, however, revealed **few respects in which matters could or should have been handled differently**."
- The only significant criticism relates to the 10-month delay in the introduction of screening for hepatitis C between November 1990 and September 1991
- The report explicitly recognise the devastating impact on individuals and families affected, but also comments on the suffering of clinical staff who were operating with the best of intentions.

Legal Implications

[*text redacted – s30(b)(i) (free and frank provision of advice)*]

- There is some criticism of a specific clinician in relation to one of the four specific cases the Inquiry investigated, but this is about lack of advice and counselling and nothing that contributed directly to the patient either acquiring hepatitis C infection or to her death.

Financial implications

- The Inquiry report provides a great deal of detail on the difficulties faced by affected individuals. The Report also acknowledges that many affected people believe that the payments they are receiving are insufficient – but our reading thus far does not find any point where the Inquiry comments in anyway on this opinion
- The detail on the impact on individuals will be relevant to the work of the UK administrations to review payment schemes. This may have financial implications if Ministers wish to provide additional funding.

Volume 1: Patients' Experiences

- **Patients at risk -** focus is on the groups of people who were potentially at risk from infection and the procedures that gave rise to risk.
  - Noted that successive developments in clinical practice reduced risks to patients, although, on the whole, they did not change patients' needs for treatment.
- **Statistics -** Estimate of numbers of patients infected with one or other or both viruses. The search for reliable data has proved for the most part to be extremely difficult.
  - Further epidemiological investigation would not produce a more reliable estimate, at least without disproportionate expense.
  - Excluding the extremes, a wide range of values remain as indications of the possible incidence of infection. Only a rough and speculative estimate is possible.
  - If the Scottish Government is persuaded that, for health policy and strategy, or budgeting or other reasons, it is necessary to develop a more accurate figure, it may be that further research

and further expert opinion might eventually converge. That cannot be recommended by this Inquiry.

- **Experiences of the patients and their families – witness statements -** Explores evidence available to the Inquiry from patients and their families about their experiences of the infections and of the impact of these on their lives.
  - In total the Inquiry has taken statements from 159 patients and relatives.
  - The Inquiry selected six witnesses to give oral evidence in respect of the effects of infection with HIV, including the effects of treatment, on patients and their families, and seven witnesses to give oral evidence in respect of the effects of infection with Hepatitis C, including the effects of treatment, on patients and their families.
  - It paints a distressing picture of seriously debilitating and sometimes fatal illness that makes its own impact. Many witnesses described having to deal with the stigma associated with the viruses as being the worst aspect of the infection.
  - A number of patients stated that they had lost substantial earnings as a result of having had to reduce their working hours or stop working altogether due to their symptoms or to the side-effects of treatment.
  - A number of patients highlighted the difficulties they had faced obtaining life assurance, travel insurance, critical illness cover and private health insurance.
  - Many patients and their relatives are of the view that the payments they receive from the Skipton Fund are insufficient.
  - A number of patients had accrued debt as a result of their infection. A number of patients were declared bankrupt. Others had their homes and other possessions repossessed.
- **Examination of the effects of infection with HIV on patients and their families, including treatment -** Deals specifically with the evidence given by six witnesses at the Oral Hearings on their own or their relative's infection with HIV.
- **Examination of the effects of infection with Hepatitis C on the patients and their families, including treatment -** It is a matter of sorrow to the Inquiry team that some of the witnesses who provided statements and Gordon, who gave oral evidence to the Inquiry, died before this report was published.
- **Investigation into the deaths of the Reverend David Black, Mrs Eileen O'Hara, Mr Alexander Black Laing and Mr Victor Tamburrini.** Term of Reference 6 required the investigation of the deaths of certain named individuals.

Volume 2: Knowledge of HIV/AIDS and Hepatitis C

- **Knowledge Of HIV/AIDS Now -** Provides an account of what is known now, in 2014, about HIV infection and the AIDS complex of diseases, in particular in relation to the two affected groups.
  - Almost none of this would or could have been known before 1991.
- **Knowledge of the geographical spread and prevalence of HIV/AIDS -**The evolving picture is examined from a narrow perspective, tracing developing knowledge of the incidence of diseases associated with HIV infection from the end of 1980, when cases of AIDS were first observed in the USA, to 1984, when testing for antibodies for HIV began to become available in the USA.
- **HIV/AIDS aetiology -** Discusses the cause or causes of the AIDS that exposed individuals to disproportionate risk of opportunistic infection, cancers and other diseases of the AIDS complex, as disclosed in public debate, professional literature and the written and oral evidence provided to the Inquiry.
- **HIV/AIDS: Response And Clinical Practice -** Discusses aspects of the response to HIV/AIDS by haemophilia clinicians over the early and middle years of the 1980s.
  - In particular, the question to be addressed is whether clinicians in Scotland should have adapted their treatment regimes sooner than they did, in response to the threat of AIDS.
- **Knowledge of viral hepatitis now -** Provides an account of what is known now, in 2014, about Hepatitis C virus (HCV) infection, in particular in relation to the two affected groups with whom. T
  - The Inquiry is concerned: blood disorder patients receiving therapy and people infected by blood transfusion in the course of medical or surgical procedures. Includes material in relation

to the pain and discomfort associated with investigative procedures and the side-effects of drug therapy.

- **Knowledge of viral hepatitis 1 -** Discusses more fully the response of the UK Government and other agencies to the emerging knowledge of viral hepatitis during the period when it presented a threat to NHS patients receiving blood, blood components or blood products in the course of medical treatment.
- **Knowledge of viral hepatitis 2 – 1975 to 1985 -** Traces developments in the understanding of viral hepatitis from 1975 to around 1985.
- **Knowledge of viral hepatitis 3 – 1986 onwards -** Continues the account of the development of knowledge of non-A, non-B Hepatitis (NANB Hepatitis) from 1986 through to the discovery of the Hepatitis C virus (HCV) and beyond.
  - There was no generally accepted view prior to 1985 that NANB Hepatitis had other than a generally benign prognosis. From 1985 it became increasingly understood that NANB Hepatitis infection could be associated with serious disease.

Volume 3: Blood and Blood Products

- **Blood And Blood Products Management.** This part of the report deals generally with questions related to the collection of blood and its adaptation for clinical use.
- **Collection Of Blood – General.** - discusses blood donation collection practice generally. Ignoring later scientific developments, so far as general members of the public offering blood donation were concerned, there was no method of identifying with interview those potential donors who were infected with NANB Hepatitis, but who remained asymptomatic at the donor session.
  - No such interview could have been conceived at the time.
- **Production Of Blood Products – Facilities.** - deals with the provision of facilities for the production of blood components and blood products, and in particular with the assumptions made as to process capacity in the development of plans for capital projects in the 1970s.
  - In the circumstances, it is somewhat surprising that Scottish needs were as well catered for as, in the event, they proved to be.
- **Haemophilia Therapy – The Period Up To The Early 1980s.** - deals with developments in technology up to 1982–83. Up to that point the risk of infection, so far as it was understood, was of transmission of hepatitis, first Hepatitis B and then non-A, non-B Hepatitis (NANB Hepatitis).
  - On the eve of the outbreak of AIDS there was a step change in perception of the possibilities of heat treatment to inactivate hepatitis viruses, but continuing scepticism among scientists. Meantime, research in England, led by Dr John Craske, was reaching the conclusion that all Factor VIII concentrates in production in the early 1980s, imported or NHS, were potentially infective for NANB Hepatitis.
- **Haemophilia Therapy – Use Of Blood Products** Deals with treatment policy and self-sufficiency.
  - There was no evidence before the Inquiry that would support a finding that Scottish practitioners were influenced in their choice of therapeutic products by benefits provided by pharmaceutical companies. Nothing could have been done to prevent the provision of blood and blood products infected with NANB Hepatitis in the 1970s and early 1980s or, when it emerged, HTLVIII/HIV.
  - There was no possibility of detection of either virus until each had been identified (HIV in 1983–84 and HCV in 1988–89).
  - The NHS in Scotland could not have restricted the import and use of commercial products once they were licensed. That was a function of the UK Government.
  - There is no criticism that can legitimately be made of practice in relation to the use of factor concentrates over this period.
- **Haemophilia Therapy – Use Of Blood Products 1985–1987** - deals primarily with the treatment of patients with Haemophilia A following the introduction in Scotland in December 1984 of heat treatment of blood products.

- It cannot be concluded on the evidence available that a barter or other arrangement could have been negotiated that might have procured a supply of 8Y (heat treated concentrate) for use in Scotland in exchange for reciprocal supplies of PFC products.
- For these reasons, it is highly unlikely that regular supplies of 8Y would have been made available for use in Scotland.
- There was a failure to provide information that could have informed clinicians of the possibility of obtaining access to the product in appropriate circumstances.
- In addition, no steps were taken to draw to the attention of physicians outwith Edinburgh the fact that there was already a small stock of 8Y held there.

- **Viral Inactivation Of Blood Products for Haemophilia therapy up to 1985** - examines the efforts of the Protein Fractionation Centre (PFC) in Edinburgh, in the period up to 1985, to inactivate viruses (initially hepatitis viruses and later HIV) which were present in its Factor VIII and Factor IX concentrates in this period.
  - The approach taken to viral inactivation at the Protein Fractionation Centre in the period 1980–84 was reasonable.
  - The degree of priority accorded to viral inactivation by the Protein Fractionation Centre during this period was also reasonable. In order to have advanced the provision of effectively heat-treated products so as to have ensured their supply in Scotland before the end of December 1984 as a matter of general prescription, the SNBTS would have required to be satisfied that the products were safe and effective to a degree that indicated that domestic research should be suspended or discontinued.
  - The evidence has not disclosed any rational basis on which that could have been decided. Nor could one form or express any view on the likely reaction of the regulatory agencies if a licence application had been made.
  - The work of the PFC was done effectively, and it was done with remarkable expedition.
  - There is no basis in evidence for a view that a UK policy decision directing collaboration between the two services would have resulted in more effective research progress than was achieved in Scotland.
- **Viral Inactivation of Blood Products For Haemophilia Therapy 1985–1987** - considers the steps undertaken at the Protein Fractionation Centre, Edinburgh (PFC) between 1985 and 1991 to inactivate virus in blood products so as to prevent transmission of non-A, non-B Hepatitis (NANB Hepatitis)/the Hepatitis C virus (HCV).
  - Until it was established that the processing of PFL/BPL's 8Y Factor VIII concentrate was effective to inactivate HIV and NANB Hepatitis/HCV in source plasma, there was no scientific basis for a decision to prefer dry heat treatment over pasteurisation in the manufacture of factor concentrates.
  - The PFC's research into pasteurisation was fully justified. There is no factual basis for any suggestion that the PFC should have decided to develop a Factor VIII product that could be severely heat-treated earlier than it did.
  - The PFC applied appropriate resources in the research and development work necessary to achieve an acceptable Factor VIII product dry heat-treated to inactivate HIV and NANB Hepatitis/HCV.
  - Professor Van Aken's assessment of the success of the PFC as 'quite an achievement' is accepted.
  - The demand by Haemophilia Directors (and Professor Ludlam in particular) for appropriate provision for compensation for individuals who agreed to undergo trials of and treatment with Z8 before licensing of the product was in the interests of patients and was reasonable.
  - The commitment of resources for compensation ought to have been dealt with by the Scottish Home and Health Department from the outset in consultation with the Treasury. Failure to address the specific issue with reasonable expedition resulted in the delay of clinical studies and the resultant availability of Z8 for therapy for PUPs by three months.
  - Because of policy decisions related to batch dedication the delay of clinical studies did not affect established patients.

- ‘Outstanding results’: Scotland appears to have been the first country in the world that was able to supply all of its haemophilia patients with a Factor VIII product that did not transmit Hepatitis C.

Volume 4: Donor Selection and Screening of Donated Blood

- **Screening Of donated blood for Hepatitis B:** In - screening tests are discussed in an attempt to understand their development and the reliance placed on them at the time.
- **Donor Selection – Higher Risk Donors:** - sets out donor selection policies and practice in the 1970s and early 1980s relating to the acceptance of blood from particular groups of donors who, either at the time or with the benefit of hindsight, might be considered to present a higher risk of transmitting hepatitis viruses than the general population.
  - The main groups under discussion in the chapter are intravenous drug users and prisoners.
  - All that can be concluded, with the benefit of hindsight, is that blood collected from prisoners during that period is likely to have had an increased risk of transmitting HCV, albeit the chance of receiving blood collected from prisoners was, overall, relatively low given that only approximately 1% of all donations collected in Scotland between 1975 and 1984 was collected from penal institutions.
- **Surrogate testing of donated blood for Non-A, Non-B Hepatitis** - deals with the topic of surrogate testing of blood donors for non-A, non-B Hepatitis (NANB Hepatitis) in the late 1980s. Where UK government funding was required for major projects, the SHHD had limited scope for major independent initiatives.
  - SHHD officials were not persuaded of the merits of surrogate testing and did not put the issue to ministers for a decision. As a result, ministers did not take part in the decision-making process, for which they were responsible**.**
  - With the establishment of the Advisory Committee on Virological Safety of Blood (ACVSB) in early 1989, it was reasonable for government to act on the expert advice received from that committee**.**
  - The ACVSB did not, in the event, recommend the introduction of surrogate testing. In the final outcome, there was no definitive decision by Scottish officials whether or not to recommend the introduction of surrogate testing.
  - The Inquiry does not attribute blame for the fact that surrogate testing was not introduced, given the diversity of respected medical and scientific views over the period 1986–91.
- **Donor Selection – AIDS.** ‘Donor selection’ was among the several approaches taken to minimise the emerging risk of AIDS transmission. So far as central government action is concerned, it is impossible to avoid the conclusion that, to some extent at least, leaflet preparation and distribution were hampered by the number of interests involved.
  - None of the many groups and individuals involved has suggested what else could have been done but was not done.
- **The discovery Of HIV and the development Of screening tests.** - describes the discovery of the Human Immunodeficiency Virus and the scientific research that led to the development in the UK of screening tests for infection.
- **Screening of donated blood for HIV** - deals with the general introduction of screening of donated blood in the UK for the AIDS virus, HIV. The production of screening tests for antibodies to HIV in 1984 and 1985 involved research and development work, in the USA, in France and in England, that was carried out with remarkable expedition and commendable success.
  - Suggestions that UK BTS researchers, and in particular SNBTS researchers, could have made more rapid progress with evaluation of an acceptable assay than was achieved by private sector researchers are without foundation.
  - There is no legitimate ground for criticism of the processes adopted for the introduction of anti-HIV screening that can be founded on delay. It was achieved as soon as was reasonably practicable.
- **The introduction Of screening of donated blood for Hepatitis C.** - concerns the introduction of screening for antibodies to the Hepatitis C

- virus (HCV) in the blood donor population in Scotland. It follows the progress towards and up to the introduction of UK-wide screening on 1 September 1991. The decision to establish the ACVSB was well founded.
- There was a delay of almost ten months because a policy set at the outset – that the introduction of screening across the UK should take place at the same time – was maintained despite some areas being ready to begin considerably earlier than others.
- It is much less straightforward to explain why there was no deviation from this policy.
- The period 21 November 1990 to 12 June 1991 included a number of missed opportunities for more prompt introduction of screening in Scotland.
- Any suggestion that taking one or more of these steps would have led to earlier introduction of screening involves a determination that the position of the responsible Minister in Scotland would have permitted different dates for the introduction of screening in Scotland and in England/Wales.
- It is not possible to make such a determination. Serious problems in relation to the introduction of a measure which would improve that safety should have been communicated to Ministers, in order that they could decide what should be done.

Volume 5: Information to Patients

- **An investigation into the systems in place for informing patients about the risks – ethical context.** - looks at the development of the relationship between clinician and patient during the reference period. Best practice now in relation to informed consent and even in the sharing of information differs from the practices which prevailed during the reference period, or at least up until 1988 when the influence of HIV/AIDS helped to bring about significant changes.
  - The requirements for informed consent and information to patients were less onerous in relation to Hepatitis C.
- **An investigation into the systems in place for informing the patients about the risks – HIV/AIDS.** The treatment of events in - is largely chronological. Specific topics discussed include: tests of patients' immune functions; testing of patients' sera stored from earlier investigations; obtaining informed consent for anti- HTLV-III testing and pre- and post-test counselling.
  - Today failure to discuss treatment with patients and to obtain their consent to treatment would be unacceptable. It is clear that standards were different in 1984.
  - Professor Ludlam's approach of not telling patients their test results unless they asked for them was consistent with the UKHCDO advice and it is clear that many doctors at that time considered that testing for HIV was simply an extension of the monitoring of patients which was already being done.
  - Professor Ludlam did not make it *sufficiently* clear to all of his patients that they had to ask him if they wanted to know their results. It should be noted that with the emergence of AIDS, an entirely new disease, almost all haemophilia clinicians found themselves in an extraordinarily difficult situation.
  - If a new, potentially fatal disease like AIDS were to emerge today it is likely that patients would be made aware of the medical profession's ignorance of it and share all the uncertainties and anxieties consequent upon that. Unfortunately, patients would, in all likelihood, still suffer and die.
- **An investigation into the systems in place for informing the patients about the risks – Hepatitis C** - deals with the evidence on the information and advice given to patients, and where appropriate to their parents, in Scotland in the course of the reference period with regard to NANB Hepatitis/Hepatitis C.
  - Patients infected with a potentially fatal virus such as HIV, or infected with HCV and at risk of developing the serious complications of cirrhosis, possibly hepatocellular cancer, and other fatal complications, are entitled to this information and should not have to wait while the medical profession deliberates on general ethical issues.
- **An investigation into the steps taken to identify the individuals who were infected (look-back).** - deals with the methods available to identify patients put at risk of HCV transmission by treatment with blood or blood products, and with the steps taken in that regard.

- The look-back study lacked the highly efficient patient tracking systems available today. Early donor card records were not searchable and different transfusion centres and hospitals had different record keeping systems.
- Difficulties were encountered in cross referencing donation numbers and recipients and vice a versa. Medical records had been lost or destroyed.
- Some recipients had changed their names through marriage or other causes. Some recipients had changed addresses.
- Due to the inevitable limitations of the look-back exercise as described above, there will still be recipients of HCV positive blood who remained, or remain, unaware of that fact.

REACTIONS TO PUBLICATION

Haemophilia Scotland said: "The report contains powerful testimony of the horrendous damage to health, relationships and finances suffered by 478 Scottish families affected by bleeding disorders. For 193 of them, their loved one has not survived to see the Penrose report published. The Scottish public will be shocked and appalled at the level of suffering that has been caused by the greatest scandal ever to engulf the NHS…Haemophilia Scotland, those infected, and their families are determined that all the decades of pain, loss and suffering should lead to real improvements in patient safety."

Glenn Wilkinson, from the Contaminated Blood Campaign "I feel totally devastated. We didn't expect the world, we didn't expect this to be the final solution for this campaign but we certainly expected a lot more than that. It has created a new level of disappointment. I don't think we've had a single answer from what was said in there."

John Cassar, who attended the conference, said: "There was more sympathy for the doctors rather than for the patients. What about the people that were dying, there was no mention of them and it's shocking."

Document 2

From: Brown GJ (Gareth) <Gareth.Brown@scotland.gsi.gov.uk>
Sent: 25 March 2015 10:38
To: [*text redacted – personal data*]@scotland.gsi.gov.uk>; DG Health & Social Care <DGHSC@scotland.gsi.gov.uk>; First Minister <FirstMinister@scotland.gsi.gov.uk>
Cc: Hutchison D (David) <David.Hutchison@scotland.gsi.gov.uk>; [*text redacted – personal data*]@scotland.gsi.gov.uk>; Henderson D (Donald) <Donald.Henderson@scotland.gsi.gov.uk>; Cabinet Secretary for Health, Wellbeing and Sport <cabsechealth@scotland.gsi.gov.uk>
Subject: RE: PQ Reference: S4F-02695

[*text redacted – personal data*]

I attached the updated answer as discussed. [*text redacted – s30(b)(i) (free and frank provision of advice)*]

Gareth Brown
Head of Health Protection | Public Health Division | Population Health Improvement Directorate Scottish Government | [*text redacted – personal data*]

PENROSE INQUIRY

SUMMARY: The Penrose Inquiry into infected blood and blood products was published on 25 March. The Inquiry was an SNP Manifesto commitment in 2007. The Inquiry concluded that there were few respects in which things could have been done differently. Affected patient groups are of the view that the financial support payments they receive are insufficient and the Scottish Government has committed to reviewing these schemes. We will work with the other UK countries to do so. The Inquiry cost ~£12m and took around 8 years.

1) Financial support schemes

- We have contributed £31m over the last 10 years to the UK schemes which provide financial support to affected individuals and their families
- I recognise that many infected individuals do not believe current payments are sufficient – the Penrose report reflected this. The stories of individuals experiences make distressing reading.
- I want to make sure we do all we can to help. We will now commence a review of payment schemes to consider how they can be improved. We will include patients and their families in that work to ensure their voices are heard.
- We want this work to conclude no later than World Haemophilia Day 2016.

2) Compensation/damages

- Compensation was not within the Terms of Reference of the Inquiry but I recognise that individuals may wish to raise an action in the civil courts in relation to their own circumstances.
- Damages are a matter for the Courts to decide and it would be for individuals to seek their own legal advice on whether they had a case or not under the current law.

3) Cost of Inquiry/Length

- This was one of the most significant healthcare related tragedies we have ever seen – it was right and proper to look at this in detail.
- This Government was the first Government in the UK to commit to a statutory independent Inquiry on these matters – we listened to affected patients.
- There is much to be learned from Penrose about how the health service responds to emerging threats and issues where there is a lack of scientific evidence and significant uncertainty. We will consider this carefully.

4) Findings not recognised by affected individuals/no criticism

- I can't speak for those affected, but there can't be any doubt about the independence and rigour of Lord Penrose.
- Lord Penrose has concluded that little could have been done differently because of knowledge at the time, and cultural differences such as the previous paternalistic approach of some clinicians and the NHS.
- We have to recognise the very difficult circumstances that clinicians found themselves in dealing with newly emerging infections.
- But we should also recognise that the NHS we have today is very different: if we were faced with similar circumstances today we would expect the NHS to be much more open about risks and uncertainty with a truly patient-centred approach.

Gareth Brown – [*text redacted – personal data*]

[*second attachment redacted – s30(b)(i) (free and frank provision of advice)*]