The Haemophilia Society's Response to The Penrose Inquiry Report

"Efficient and effective provision for the care of vulnerable populations such as those with coagulation deficiencies is not a matter that should depend on narrow definitions of departmental or agency competency or their individual remits: responsibility rests ultimately with government as a whole."
Penrose Inquiry Report [paragraph 22.133]

"… if the UK Government had successfully implemented its 1974 commitment to make the UK self-sufficient in blood products then, at the least, hundreds of the some 1,200 people with haemophilia infected with HIV in 1979 and the early 1980s would not have been so infected and hundreds of lives would have been saved from the 900 who died from AIDS."
Haemophilia Society's Response to the Penrose Inquiry Report [Overview]

Overview

The Haemophilia Society has a direct interest in the Penrose Inquiry Report because of the many people with haemophilia or other bleeding disorders who became infected through blood products across the UK. The Society was active as a patients' organisation during the "reference period" of 1974 to 1991 covered by the Inquiry and it was a "Core Participant" of the Inquiry.

For shorthand, where we refer below to "people with haemophilia", this includes people with other bleeding disorders, especially von Willebrand Disease.

In order to keep our response to manageable length, we concentrate on three of the twelve Terms of Reference ("ToR"s) of the Inquiry. We have chosen the ToRs of most relevance to the survivors of those infected and to the families of the survivors and of the dead:

ToR 2 To investigate the systems in place for informing patients treated by the NHS in Scotland of the risks associated with the use in their treatment of blood or blood products, with particular reference to the risks of infection with the Hepatitis C virus and HIV.

ToR 8 To investigate the steps taken by those involved in, and those responsible for, the NHS in Scotland including NHS Boards and SNBTS[1], their officers and employees and associated agencies, to prevent the provision of infected blood and blood products.

ToR 11 To identify any lessons and implications for the future, and make recommendations.

Because of the Terms of Reference, the evidence is necessarily centred on events in Scotland. However, as political decisions were made at the UK level and as pathogens do not respect administrative boundaries, the evidence includes aspects of the wider picture across the UK. Unless otherwise stated, our conclusions relate to the UK as a whole. In doing so, we have taken care to ensure that we are using evidence which applies across the UK. Where we quote numbers of the infected and the dead, these are for the whole of the UK.

[1] Scottish National Blood Transfusion Service

We note that the Terms of Reference do not include reviewing the structure which Governments have put in place to support those infected and their families, and the resources made available for this purpose. The Society believes that the current structure and resources are not fit for purpose, and it is delighted that David Cameron as Prime Minister and Andy Burnham as Shadow Health Secretary committed to review and improve these in the next parliament and that the Scottish Government has made a similar commitment. We are working with the Department of Health to input into the Government's decision-making process.

Sections A, B, and C below deal in turn with each of the three Terms of Reference we have highlighted. Section D brings together all of our urgent recommendations.

We cover ToR 2 relatively briefly, as we believe that broadly the Report gives a fair and useful representation of the "paternalistic" culture prevalent among physicians during the reference period. However, we regret that it does not give any recommendations for action in this area; despite the immeasurable improvement in physicians' communicating with patients and allowing them to make informed choices, there remains much to do. The Haemophilia Society continues to hear from members who do not feel their voice is heard in their own treatment decisions and that their health professionals continue to have a paternalistic approach.

We deal with ToR 8 at the greatest length. Our core conclusion is:
The extensive evidence gathered by the Report demonstrates unequivocally that if the UK Government had successfully implemented its 1974 commitment to make the UK self-sufficient in blood products then, at the least, hundreds of the some 1,200 people with haemophilia infected with HIV in 1979 and the early 1980s would not have been so infected and hundreds of lives would have been saved from the 900 who died from AIDS. If the Government and health agencies had implemented appropriate public health measures based on the scientific knowledge of the 1970s, it is plausible that there would have been a material number of lives saved from those 4,670 people with haemophilia known to have been infected with Hepatitis C (HCV). Similarly, there could have been materially fewer people infected with HCV through whole blood or blood component transfusion.

This diverges sharply from the Inquiry's conclusion:
"Careful consideration of the evidence has, however, revealed few respects in which matters could or should have been handled differently…."
Penrose Inquiry Report [Volume 1 page x.]

In section C we therefore give extracts at some length from the Report to show the evidence we are relying on.

Under ToR 11, the Report makes only one recommendation, partly because it takes a very narrow interpretation of its remit. For example, in paragraph 1.21 it states:
"Owing to the significant changes which have taken place, it was not necessary for the Inquiry to identify measures required to prevent recurrence of infection with HIV and HCV through blood transfusion or therapy for bleeding disorders."

Our analysis of the Report draws the broader conclusion that the catastrophe of contaminated blood was the outcome of systemic failures in public health and political oversight. **We believe that aspects of these systemic failures are still relevant today and could contribute to future health catastrophes, most likely affecting groups other than those with haemophilia.** We therefore make our own recommendations for changes which the Government should implement urgently in order to protect the lives of patients and the public going forwards.

THE HAEMOPHILIA SOCIETY

Section A – Term of Reference 2

"To investigate the systems in place for informing patients treated by the NHS in Scotland of the risks associated with the use in their treatment of blood or blood products, with particular reference to the risks of infection with the Hepatitis C virus and HIV."

Many of those infected and their families tell us that their doctors never explained to them the risks of infection from the use of blood products or discussed possible treatment alternatives.

The Report produces extensive evidence and discussion to illustrate the medical culture of the 1970s and its development to the very different culture of today. To simplify the picture, in 1974 there was a paternalistic model in which the doctor knew best and decided for the patient. A doctor would spend relatively little time explaining risks and alternatives to patients, and would not generally expect patients to contribute to decisions on treatment. This picture changed slowly through the 1970s and 1980s, with developments in medical ethics recognising the need for patients' informed consent. It has further developed to the patient-centred culture which ideally is the norm today. We believe, however, there are still many times when the NHS stated policy of "No decision about me without me" is not upheld in the treatment of people with bleeding disorders.

The Report evidence supports patients' memories of receiving treatment without adequate explanation of risks or alternatives, although it cannot confirm the specific circumstances of individual cases after 30 or more years. In providing proof that the memories of those impacted are generally true, the Report does as much as seems possible to lighten the psychological burden in this area. It is hard to comprehend the trauma felt, for example, by a mother who infused her young son with blood products which turned out to be infected with HIV or HCV, but it is also hard to see how an Inquiry now can do more than to confirm that she was almost certainly not given adequate information at the time to understand the risks.

As noted in the Overview, we believe that while communication between physician and patient today is immensely improved, the Government and National Health need to do further work in this area.

THE HAEMOPHILIA SOCIETY

Section B - Term of Reference 8

"To investigate the steps taken by those involved in, and those responsible for, the NHS in Scotland including NHS Boards and SNBTS, their officers and employees and associated agencies, to prevent the provision of infected blood and blood products."

We point out that at the top level "those responsible for" were the Department of Health in London and the UK Government.

In our analysis we have been careful to ascribe to health professionals only that knowledge or reasonable belief which was available to them at the time. Key elements of this knowledge or belief were:

Pre-1970	Theoretical understanding of the risk of infection from donated blood from both known and unknown agents. Belief that domestically sourced blood was likely to be safer as patients would be more likely to have protection against local infections.
Pre-1970	Post-transfusion hepatitis, ie the fact that some recipients of blood or blood products subsequently developed jaundice or liver disease. Belief that this was relatively benign.
1970	Substantially greater risk of infection from blood donated for payment compared to voluntary donations.
Early 1970s	New treatment for haemophilia containing Factor VIII or Factor IX extracted from blood donations from multiple donors (ultimately thousands of donors per batch). This treatment hugely improved patients' quality of life.
1972	Test for Hepatitis B in blood (by identifying its antigen).
1972 [Paragraph 14.40]	Greater risk of infection from blood donated by intra-venous drug users.
1975 [Paragraph 21.151]	Greater risk of infection from blood products sourced from multiple donors; risk increased with number of donors.
1975	Recognition that there were agents in addition to Hepatitis A and Hepatitis B viruses causing post-transfusion hepatitis; this was named NANB hepatitis for "Non A, non B"
1976 [Executive Summary page 24]	Greater risk of infection from blood donated by prisoners.
1982	Possibility that AIDS was transmitted through blood products.
1984	Confirmation that AIDS was transmitted through blood products.
From about 1985	Growing recognition that NANB hepatitis was substantially more dangerous than had previously been believed.

We believe that the correct framework for analysis is public health. That is to say, to look at the systems in place under the aegis of the Government, the Civil Service, the Health Service, and government agencies, "to prevent disease, promote health, and prolong life among the population as a whole." (World Health Organisation definition.)

We emphasise the difference between this approach, and an approach focused on the efforts of individual physicians to treat individual patients.

For example, a haemophilia physician in the 1970s had the option of treating a particular patient with commercial blood products from the USA with the knowledge that this carried the risk of "post-transfusion hepatitis". In the light of accepted knowledge at the time and of medical practice whereby the doctor typically decided on treatment without an informed discussion with the patient, it was reasonable for most physicians in most cases to prescribe the commercial product.

Only an earlier intervention by public health authorities could have created a situation in which the haemophilia physicians had the knowledge and the opportunity to prescribe consistently less risky blood products produced from UK voluntary donors. As discussed below, it may now be impossible to determine how much less risky such products would have been in preventing HCV infection and deaths, but they would have been substantially less risky in the period 1979 to early 1985 as regards HIV infection, and on a simple analysis explained below would have saved the lives of over half of the 900 people with haemophilia in the UK who have died from AIDS.

As evidenced by the Report, from the early 1970s the UK Government did recognise the greater risk of infection in commercially-sourced foreign blood products. In 1974 Dr David Owen, Secretary of State for Health, promised in the House of Commons to make the UK self-sufficient in blood products for Factor VIII within 3 years. The Inquiry evidence shows that had this been done, it would have directly prevented the infection with HIV of hundreds of those people with haemophilia who died from AIDS. The policy was never implemented. The chain of logic here is as follows:

1. By 1974 the Government recognised the greater infection risks of using foreign blood products (mostly made from commercially-sourced blood) to treat haemophilia, and accordingly committed to make the UK self-sufficient in blood products for Factor VIII[2] by the end of 1977.
2. The risks were the known incidence of "post-transfusion hepatitis[3]" and the known public health risk of future infective agents spreading through the blood supply.
3. The Government did not fulfil this commitment, and the Health Service continued to use massive quantities of imported product.
4. From 1979 UK haemophilia patients began to be infected with HIV/AIDS from blood product.
5. From studies done in 1984 and 1986, people treated with foreign blood product were from 4.5 to 6 times more likely to be infected with HIV/AIDS than those treated only with UK blood product.
6. Some 900 UK haemophilia patients have died from AIDS. A proper statistical analysis would be needed to give a fully accurate estimate of the deaths expected had all treatment been with UK products, but assuming that the ratios above are accurate the simple analysis below shows that, had no foreign product been used from1979, total AIDS deaths would have been limited to around 200 to 400.

[2] Factor VIII is used to treat haemophilia A, which is to say about 80% of people with haemophilia. It is not clear from the Inquiry evidence how close the UK was to being self-sufficient in Factor IX used to treat haemophilia B, but according to the evidence the number of deaths by AIDS among people with haemophilia B was much lower than its 20% share of patients would have predicted.

[3] Mortality from this hepatitis was greatly underestimated in the 1970s. The case made here is that the known risk of future infections should have been enough to drive public health measures to minimise exposure.

7. The Government failure to deliver its own commitment thus caused the death of about 500 to 700 haemophilia patients through AIDS.

The situation with Hepatitis C infection is more complex, and it does not seem possible to estimate from the evidence in the Report the reduced mortality from Hepatitis C which would have occurred had the Government implemented its commitment on self-sufficiency. In this context it should be noted that although the Report gives evidence that UK concentrate had a high probability of being infected with HCV, it also raises the possibilities that:

- the size of the inoculum (the amount of virus with which the patient is initially infected) would have been lower with UK product
- the number of different genotypes of HCV would have been lower in the UK product
- UK patients may have been more likely to carry antibodies to common UK genotypes of HCV
- patients infected with fewer genotypes of HCV may have had a better prognosis
- patients infected with fewer genotypes of HCV may have responded better to treatments when they became available.

The Report evidence makes clear that there are no exact figures for the prevalence of HCV infection in the UK population in the 1970s and 1980s, although it appears that the trend was upwards year by year.

Further improvements in mortality and morbidity could have been achieved had the Government and its health agencies more promptly and more consistently implemented public health measures identified at the time. These included measures on the blood supply such as stopping donation from prisoners and screening high-risk blood donors, and measures on treating haemophilia patients, such as ensuring that patients needing relatively little treatment received the lowest-risk blood products, or, where possible from a clinical perspective, less effective but still adequate non-blood products.

It should be noted that whole blood or blood component transfusions were generally sourced from a single donor, and so, had high-risk donors been excluded earlier, materially fewer non-haemophilia patients would have contracted HCV from this source. Even with the lack of exact evidence on the historic prevalence of HCV, it should be possible to model within a reasonable range the lives which would have been saved by this simple public health intervention.

The rest of this section quotes verbatim from the Report to evidence the case made above.

1. By 1974 the Government recognised the infection risks of using foreign blood products to treat haemophilia and accordingly committed to make the UK self-sufficient in blood products by the end of 1977.

[Paragraph 19.48] *There had already been a political commitment to self-sufficiency, however. In December 1974, Dr David Owen MP, the UK Minister of State for Health, had announced exceptional government funding of £500,000 with the primary aim of making the NHS self-sufficient in blood products for replacement of Factor VIII (the factor missing in haemophilia A and by far the largest proportion of blood products by volume) within two to three years, following recommendations by the World Health Organization (WHO). The WHO reinforced its position in 1975…*

2. The risks were the known incidence of "post-transfusion hepatitis" and the known public health risk of future viruses spreading through the blood supply.

[Paragraph 21.5] …*No form of therapy was without risk to the patient. As commented in Chapter 2, Patients at Risk, some risks are inherent in the use of human blood and its components and are always present. Whole blood, fresh and fresh frozen plasma and cryoprecipitate were all associated with risk of transmission of virus infections such as hepatitis.*

3. The Government did not fulfil this commitment, and the Health Service continued to use massive quantities of imported product.

This is a matter of historical record, and it is covered at length in various parts of the evidence.

The following paragraph is quoted to illustrate the lack of 'joined up thinking' among the civil servants and Health Service officers responsible for implementing the Government's commitment, while the paragraph below shows how the UK Government was still paying lip-service to creating self-sufficiency at the end of 1983.

[Paragraph 19.42] ….*The Annual Report of the SNBTS for the year ended 31 March 1976 noted that the plant*[4] *had been designed to accommodate material from England and that staff had been recruited and trained on the basis of shiftworking. But opposition from the trade unions, allied with demands relating to terms and conditions of employment which the employers found unacceptable, had made shift-working impracticable. In the result, the PFC could cope with Scottish needs on a day-staff only basis, but the absence of the other shifts decreased cost-effectiveness and precluded acceptance of plasma from south of Scotland.*

[Paragraph 12.89] *a letter dated 13 December 1983 written by Lord Glenarthur to John Maples MP … set out:*
[T]he Government is committed to making this country self-sufficient in blood products… Meanwhile, in the absence of a satisfactory alternative, we shall be dependent upon imports from the USA for an adequate supply of Factor VIII.

4. From 1979 UK haemophilia patients began to be infected with HIV/AIDS from blood product.

[Paragraph 10.57] *…later published in The Lancet on 3 August 1985.The introduction to the published paper reported as background that the virus HTLV-III/LAV was the most likely cause of AIDS and that tests carried out on stored serum samples from haemophilia patients showed that HTLV-III antibodies were first detectable in the USA in 1978 and in the UK no later than 1979.*

5. From studies done in 1984 and 1986, people treated only with foreign blood product were from 4.5 to 6 times more likely to be infected with HIV/AIDS than those treated only with UK blood product.

[Paragraph 10.78] *The source of infection in patients with coagulation defects continued to be debated. In discussion at the meeting on 7 February **[1986]**, Professor Tedder reported that, tests of stored **[blood]** samples dating from 1978 to 1984 showed that seropositivity **[for HIV]** rose rapidly from 33% in 1980 to 64% in 1982 in the case of patients who had received commercial concentrates. In the case of patients who had received NHS concentrates, samples were seronegative until 1982. Between 1983 and 1984 seropositivity rose from 1% to 11%.*

[4] The Protein Fractionation Centre – the then new Edinburgh plant for processing whole blood to produce blood products.

[Paragraph 10.83] *Dr Peter Jones, Director of the Newcastle Haemophilia Centre, also spoke specifically about the incidence in patients with haemophilia:* ***[in February 1986]*** *he estimated, extrapolating from the limited data available, that 1200 UK haemophilia patients would already have seroconverted. In relation to treatment, he said that of those who had been treated with cryoprecipitate only, 1% tested positive for the virus; of those treated with NHS concentrate only, 10% were positive; and of those treated with commercial concentrate only, 45% had tested positive.*

His basic data were not consistent with the data collected by Dr Rizza and Miss Spooner but referred to a cohort of similar size and with less variance than the data reported by Dr Foster.

6. Some 900 UK haemophilia patients, the vast majority with haemophilia A, have died from AIDS. A proper statistical analysis would be needed to estimate the deaths expected had all treatment been with UK products, but assuming that the ratios above of relative risk were accurate, then on the simple and high-level analysis below only around 200 to 400 would have died.

   In line with the indicative evidence of the Report, we assume 50% of patients received UK product consistently and 50% received foreign product consistently. Then, because of the higher infectivity of the foreign product, the 900 deaths would have arisen as:

Risk ratio foreign to UK	4.5	6
Deaths from UK product	164	129
Deaths from foreign product	736	771
Total deaths	900	900

   If the Government had achieved self-sufficiency before 1979, all patients would have received UK products and the deaths in the two 50% cohorts would have been the same as in the UK-product cohort in the table above:

Switch all to UK product		
Risk ratio foreign to UK	4.5	6
Deaths from UK product	164	129
Deaths from UK product	164	129
Total deaths	327	257
Lives saved	**573**	**643**

   We have widened the range of 257 to 327 deaths to a range of 200 to 400 accommodate the more complex situation which would have pertained in real life, together with lack of detailed information on people with disorders other than haemophilia A.

7. Thus the Government failure to deliver its own commitment directly caused the death of some 500 to 700 haemophilia patients through AIDS.

   Our arithmetic model based squarely on the Inquiry evidence bears out this claim. We would welcome independent expert analysis to validate and refine our estimate.

Section C - Term of Reference 11

"To identify any lessons and implications for the future, and make recommendations."

The analysis in section B shows that the causes of the excess infections and deaths through contaminated blood included:

- Failure of the Civil Service and the Health Service to implement policies adopted by the UK Government.
- Failure to allocate responsibilities clearly between the Government and the Civil Service and between organisational units in the Civil Service and the Health Service.
- Failure to implement basic disciplines of public health.
- Failure of measurement of key statistics in the Health Service and failure to have appropriate statistics properly analysed by responsible units in the Health Service and Civil Service.
- Failure to escalate to senior decision makers legitimate issues identified by middle-ranking civil servants, clinicians, and administrators. In the mid-1970s, many of these must have been aware of the failure to implement the Government policy of self-sufficiency in blood products and the consequent risk to lives. Similarly, many must have questioned the dangers of using blood from high-risk donors.

None of these failures has been fully rectified, and each continues as a risk to public health today. Each should be the subject of specific urgent action by the UK Government to ensure that everything possible is done to avoid future public health catastrophes.

We give our recommendations based on these failures below, along with a further recommendation as identified in section A, on improving communication between physicians and patients.

We recognise that since Health is now devolved to the Governments of Northern Ireland, Scotland, and Wales, some of our recommendations to the UK Government would be implemented for England only. We urge the UK Government to work with the devolved Governments to implement a consistent approach to public health across the UK, with the sharing of information, reporting, and planning.

Section D – Recommendations

Recommendation 1
That the Government and ideally the major opposition parties commit to the following:
Wherever a minister announces a policy decision in the Houses of Parliament, this will be done with appropriate metrics and target dates to enable post-hoc clarity as to whether the policy was implemented successfully. The Government will require the Civil Service to track implementation of the policy with suitable metrics on a suitable timescale, and where it becomes clear that the policy will not be implemented as originally announced then the minister (or his or her successor) shall report this to Parliament at the first available opportunity.

Recommendation 2
That the Governments clarifies how it implements protection of public health across the UK through the current mix of central, local, and devolved Departments and Agencies. The clarification should document clear lines of authority and responsibility, demonstrating that the Governments maintains ultimate responsibility for public health and has the authority and capability to take decisive action as needed.

The documentation should demonstrate structures of governance and reporting able to ensure that effective systems are in place to protect public health against known and emergent hazards, and also that there is appropriate contingency planning and adequate resources to enable corrective action in the event of emergencies across the UK.

It is unclear to the Society what the UK chain of responsibility is today, and indeed, given that the English NHS and Public Health England are now Agencies, whether the Secretary of State for Health has ***any*** responsibility for their actions.

Recommendation 3
That the Government commissions an independent report at least every three years which compares the implementation of public health across the UK with international norms from comparable developed countries, and reports an evaluation, an assessment of risks, and recommendations for corrective actions as appropriate, such report to be published promptly and unredacted without intervention by the Civil Service or any Government agency.

Recommendation 4
That the Government imposes on the NHS an explicit responsibility for gathering and analysing statistics to support public health, with an independent body driving standards and identifying areas needing analysis. There should be real-time as well as retrospective analysis of the data.

The UK Haemophilia Centres Doctors' Organisation maintains a database of all patients across the UK (some 25,000) with bleeding disorders, without such data it is not possible to observe rapidly-evolving trends which signify an immediate or emerging threat to patients. Clinicians should be required to provide data and long term funding should be provided for this valuable resource.

Recommendation 5
That the Government puts in place systems to encourage the escalation of issues within the Health Service and within other health Departments and Agencies on a "no blame" basis, and to support whistleblowing for staff who find that they are blocked from escalating important issues. These systems should include training, measurement, and reporting of comparative statistics. Where adverse events occur, there should be an investigation of whether relevant issues had been raised and ignored. There should be an annual independent report on the progress of shifting culture to embed positive behaviour on identifying and escalating issues.

We no longer take blood from prisoners and intravenous drug users, but there are still regular reported incidents of scandals in care homes and manipulation of statistics in A&Es - and perhaps other serious problems which insiders do not escalate because they fear the personal consequences of so doing.

Our recommendation relating to physician-patient communication is:

Recommendation 6
That the Government commissions an annual independent report of the implementation across the Health Services of its policy on "No decision about me without me". According to this, every decision about treatment should involve informed consent of the patient. This report should also examine the level of training and skills among physicians and other health service staff in contact with patients to ensure that they are effective in listening to and understanding patients and are consistent in ensuring that patients do understand the implications of proposed treatments and do give informed consent. The report should be published promptly and unredacted without intervention by the Civil Service or any Government agency.

Moreover, the "no decision about me without me" policy should be extended so that for chronic conditions, where patients together with their families acquire expertise in the management of their own conditions, the Health Service should have a statutory duty to set up permanent organisational structures through which representative physicians and patients can meet to identify, discuss, and resolve issues around treatment.