Executive Summary

Haemophilia Scotland believes the Penrose Inquiry and Report failed to fulfil the reasonable expectation of the affected community.

However, we are grateful to the Scottish Government not only for establishing the Inquiry but for recognising the pain and caused by the disaster. Their apology accepted a moral responsibility to those affected.

We have agreed with the Scottish Government that improving the financial support arrangements is the top priority and accept that progress on some of the other areas detailed in this submission have been reasonably deferred until after new arrangements are in place.

We believe that the Financial Support Review Group was a genuine attempt to find practical improvements which can be delivered by the Scottish Government. We do not contest that the recommendations are perfect, in particular in relation to the financial losses of those not eligible for ongoing support. However, they are a significant improvement, in particular in relation to those whose health has suffered most and many of the bereaved families. We, therefore, support their full and rapid implementation, and recognise the commitment to the affected community that would represent. The need for improved financial support is now extremely urgent. Many of those affected are seriously ill and facing pressing financial hardship.

1. The Penrose Inquiry Process

1.1. Haemophilia Scotland was a Core Participant in the Penrose Inquiry as were several of our members. The experience of involvement with the Inquiry process has led us to conclude that the Inquiries Act is not fit for purpose and the Penrose Inquiry failed to fulfil the reasonable expectations of those affected by the contaminated blood disaster in Scotland. This is particularly disappointing given the significant investment of public money and the extremely long length of the process. Below we detail these expectations against the record of the Inquiry.

1.2. EXPECTATION 1: That the concerns which had been raised by the campaign which led to establishment of the Inquiry would be investigated.

Many of issues raised during the campaign were not investigated by the Inquiry. Specifically,

1.2.1. Whether or not there had been a systematic destruction of medical records relating to the relevant years. Many individuals report that sections of their medical records for the late 1970s and/or early 1980s are missing. This is widely seen within the
community as evidence of a cover up. The Chairman of the Inquiry refused to investigate these claims. It is a weakness of the Inquiry system that decisions of the Chairman can only be appealed to the Chairman.

1.3. **EXPECTATION 2: The facts of the contaminated blood disaster should be established.**

Most campaigners have experienced being dismissed as conspiracy theorists when discussing the facts of the disaster. It was important, therefore, to have the details of the disaster officially documented. The Penrose Inquiry has been reasonably successful at documenting the events of the disaster and the Final Report provides a useful reference document.

1.4. **EXPECTATION 3: That those affected would “get their day in court.”**

It is shocking that an Inquiry costing over £12 million and taking seven years could not find time to listen in person to the experiences of those who were infected, their loved ones, and the bereaved. The result was that the oral hearing days heard from very few affected individuals. The vast majority of witnesses were former clinicians and former civil servants. The impression was given that their, often incomplete, recollection of events was given much greater weight than that of those affected. The Chairman made it clear that he gave more weight to evidence that had been tested in an oral evidence session but denied the opportunities to have their evidence tested to all but a handful of affected people. Some Haemophilia Scotland members have commented that information provided by affected people regarded as the Inquiry hearing their stories while contribution from unaffected witnesses was regarded as evidence. It was also notable that several individuals with the highest profile as campaigners were not selected as witnesses. This was widely seen as an attempt to limit, as far as possible, the evidence from patients to their own experience and not hear from them about the wider disaster.

1.5. **EXPECTATION 4: Once the facts were established, to provide a commentary on whether or not they were acceptable.**

Another weakness of the Penrose Inquiry was that it was explicitly not seeking to establish liability or apportion blame. However, there was an expectation that the Final Report would contain criticisms of either individuals or the system. The failure to make specific criticism implies that it was the view of the Chairman that the infection and deaths caused by the disaster were in some way acceptable. The statement read on behalf of the Chairman on the day the report was published gave greater prominence to the distress the disaster caused to clinicians than the suffering caused to the victims of the disaster. This confirmed the impression that the Chairman was an establishment figure and felt more affinity with the former civil servants and consultants than he did with those who had been infected. The lack of empathy or critical remarks, in the Executive Summary of the Final
Report in particular, accounts in large measure for the extreme anger which it engendered in the affected community.

1.6. **EXPECTATION 5**: That the experience of the disaster would be compared to current practice. Where practice had been had already been improved this should be highlighted and, where appropriate, recommendations made for ways in which practice could be further improved.

There was a disappointing lack of focus on current practice in both the oral evidence sessions and the Final Report. That lessons should be learnt from the disaster is particularly important to bereaved families who would like to know that the deaths of their loved ones might at least help prevent other families facing similar suffering. A potentially valuable opportunity has been missed to assess issues around the communication of risk, consent for testing or research, and access to new treatments in the light of the disaster. The failure of the Penrose Inquiry to conduct this work can be summarised by the fact that its single recommendation was extremely similar to one of the recommendations of the Ross Expert Group made more than a decade earlier.


2.1. On the day of the Final Report of the Penrose Inquiry, Haemophilia Scotland released two documents (appendix 1 and 2). The first highlighted some of the facts established by the Inquiry, *The Evidence*, and the second outlines what action Haemophilia Scotland believed was necessary to respond, *Our Recommendations*. In the absence of an appropriate range of recommendations from the Inquiry we, in effect, made our own. Responding to the Penrose Report the following day the First Minister and Cabinet Secretary for Health, Wellbeing, and Sport set out their approach to dealing with the issues arising from the Report. It is our intention, within this submission, to provide evidence of the progress which has been made, through that approach, towards meeting the challenges we set out at the time.

2.1.1. Acknowledging the disaster and supporting its victims.

2.1.1.1. **An apology.** We called for a full and unreserved apology which accepted the Scottish Government’s moral responsibility to those affected. We were pleased that both the First Minister and the Cabinet Secretary of Health, Wellbeing, and Sport apologised in these terms, in the Scottish Parliament, at their first opportunity the following day.

2.1.1.2. **A Scottish settlement for financial support.** We have had good access to the Cabinet Secretary during this process and were able to quickly agree with her that a financial support settlement was the top priority. We were members of the Contaminated Blood Financial Support Review Group she established under Ian Welsh to make recommendations to
her about how the financial support arrangements could be improved. That group has now reported and we are waiting for a statement from the Cabinet Secretary on whether or not its recommendations will be implemented. The recommendations reflect many of the priorities we set for such a scheme in our response to the Penrose Report.

Those which are well represented in the recommendations include,

- That the scheme should explicitly recognise both the pain and suffering, and the financial losses caused by the disaster to both the infected individuals and their families/carers.

- That there should be a Scottish scheme to improve accountability.

Those where more work needs to be done include,

- That medical records should not be required to make an application to the scheme because so many have been lost or destroyed. This issue was discussed by the review group which recommended that it be examined as part of a wider review of the criteria for financial support.

We had originally argued that the financial support scheme should be based on civil damages. However, the consultation conducted by the review group revealed that there was a high level of resistance to assessment, which would be a necessary part of a process based on civil damages. This is due in part for a desire for simplicity but we also believe that the experience of assessment as a tool in welfare cuts was also responsible for that resistance.

We particularly welcome the recommendation that there be a separate scheme in Scotland as we believe that this will provide the potential for a more flexible approach. For example, we are concerned that the underfunding of the Caxton Foundation will have resulted in pent up demand for discretionary support for the first two or three years of operation of any new discretionary scheme. We hope that a closer relationship between the scheme and the Scottish Government would allow for some creativity in dealing with this sort of issue.

We would like to draw the attention of the Health and Sport Committee to Proposal 5 – Further Work, Contaminated Blood: Financial Support Conclusions and Recommendations Report. This proposal details five specific areas of work where there was not sufficient time for the review group to
conduct the necessary work for a more complete recommendation. The six area identified covered,

1. Providing the option of converting entitlement to ongoing payments into a lump sum settlement.

2. Equitable access to financial products.

3. Periodic review of the operation of any new scheme(s).

4. Reviewing the threshold between Stage 1 and Stage 2 levels of support.

5. Review the attribution of Hepatitis C to the causes of death to ensure that all those widowed by the virus were entitled to the proposed widow(er)s pension.

6. Review the criteria for accessing financial support and allow reapplications to address the needs of those who have previously been rejected.

All six clauses of Proposal 5 are significant areas of work. We would respectfully suggest that the Committee may have a role in monitoring progress towards achieving them.

2.1.1.3. **Support for Families.** Similarly, if implemented, the recommendations would see a significant improvement in the support available for families. Immediate family members would have access to an enhanced discretionary support scheme. Many widow(er)s would also be eligible for a pension for life, dependent on the death being related to the infection. This is a very different approach to the scheme bases on civil damage which we had originally envisaged but we believe it would represent a significant and important step forward in the support available to the families who have been bereaved by this disaster.

2.1.1.4. **Psychosocial support.** The statements made in the Scottish Parliament reiterated the commitment of the Scottish Government to conduct psychosocial support pilots. The psychologist led pilot, in Edinburgh, has just started. We particularly welcome the statement that it is the intension of the Scottish Government that these pilots lead in time to the provision of a national service.

2.1.2. Securing the safety of the blood supply.

2.1.2.1. **Prison Blood Donations.** We believe that the experience of the contaminated blood disaster shows that incarcerated populations are at increased risk from blood borne pathogens. New pathological threats develop on a regular basis so we believe that the precautionary principle
dictates that the Scottish Blood Transfusion Service should never again accept donations from incarcerated people. Although we believe that these donations do not currently make up any part of Scotland’s blood supply, we would like a clear and unambiguous statement that they will not be used in the future. At the time of writing such as statement has not been made.

2.1.2.2. **Donor tests.** In our view the Penrose Report exposed the weakness of a seemingly ad hoc approach to whether or not donor screening tests, or surrogate tests, should be implemented in response to either emerging pathogens or improvements in testing technology. We believe there should be a stronger presumption in favour of testing and increased transparency around these decisions. So far, these issues have not been addressed, following the publication of the Penrose Report. We are hopeful that they will be tackled once the issue of financial support has been dealt with.

2.1.2.3. **Look-back.** The Cabinet Secretary has established a Penrose Report Short Life Working Group which is working to implement the recommendation of the Penrose Report to offer testing to those who may have been exposed to contaminated blood or blood products. We have joined the working group which has had its first meeting.

2.1.3. The patient at the centre of decision making.

2.1.3.1. **Nothing about me without me:** The Penrose Final Report described the relationship between clinicians and patients during the contaminated blood disaster as paternalistic. While the vast majority of people with bleeding disorders have a constructive partnership with the clinicians in their specialist Haemophilia Centre the feedback we receive from our members when interacting with other parts of the NHS isn’t always as positive.

2.1.3.2. **Nothing about us without us:** Haemophilia Scotland has consistently argued that an important lesson to be learnt from the contaminated blood disaster is that patient organisations and representatives must be involved in all decisions relating to the provision of treatment and care. Since the Penrose Final Report was published a National Managed Clinical Network for Inherited Bleeding Disorders has been established. Although it is in its early days, having a national haemophilia committee provides an exciting opportunity to deepen the partnership between patients, carers, and healthcare professionals providing specialist care for people with bleeding disorders.
2.1.3.3. **Duty of Candour:** The communications failures, detailed in the Penrose Inquiry Final Report, have exasperated the sense of mistrust and anger in the affected community. The Duty of Candour is an excellent opportunity to lock in a culture of openness. While we accept that having the duty placed on organisations does not usurp or prohibit the role of individual clinicians in discharging it we believe it would be strengthened if the duty was placed on treating individuals rather than organisations.

2.1.4. Research

2.1.4.1. **Full and informed consent in the use of samples for research.** The Penrose Inquiry process did not provide any reassurance that patients had a complete right to give or refuse consent in the use of their samples in research. In fact oral evidence providing by practicing clinicians made is clear that this is not the case in practice and historic sample are used in research without gaining consent to do so. We believe that this is particularly important in rare diseases where the chances of individuals being identified within supposedly anonymous published papers is greater, as happened with papers published during the course of the contaminated blood disaster in relation to immune challenges and Haemophilia.

2.1.4.2. **More research.** We are not aware of any new research commissioned in response to the Penrose Inquiry Final Report which would address the lack of data on the effects of the viruses those exposed multiple times and/or with multiple genotypes.

**Haemophilia Scotland**

**Further Reading**

- The Penrose Inquiry Final Report
- The Lord Ross Expert Panel – 10 years on
• The Archer Report
• Factor 9
  https://vimeo.com/96851355 password: Inverness
• Newsnight – Haemophiliacs used in trials
  https://www.youtube.com/watch?v=7NViX1RP94U
• Frontline Scotland
  https://www.youtube.com/watch?v=0QT88bVPgoM
• The Scottish Infected Blood Scoping Exercise
  http://sibf.ninedesignstudio.co.uk/SIBF-Scoping-Exercise.pdf
APPENDIX 1
Haemophilia Scotland Response to the Penrose Report
The Evidence

Introduction

The Scottish Government has been committed to investigating the contaminated blood disaster for many years. By setting up the Penrose Inquiry they showed a commendable commitment to uncovering the truth of this scandal. That commitment to truth must now be matched by an equal commitment to justice and fulfilling the moral duty of care to those devastated by the disaster.

The Penrose Report reveals the enormous levels of suffering that has been endured for decades by individuals and families all over Scotland. 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. We stand ready to work with the Scottish Government to make that happen. This is now in their hands and we feel sure they won’t let us down.

Finally, we’d like to acknowledge the bravery of patients who gave oral and written evidence; the hard work of the patient interest legal team; Lord Penrose and his Inquiry Team; and the dedication of hard-working medical and fractionating staff, not implicated in the report, who spent their careers to provide treatment and care to people with bleeding disorders. We would also like to remember those who have not survived the contaminated blood disaster. We hope that the Penrose Inquiry, and the Scottish and UK Government’s response will alleviate the suffering of the survivors and their families as well as the bereaved.

The Facts

The Penrose Inquiry investigations have uncovered some shocking revelations about the contaminated blood disaster in Scotland. With a comparatively short period of time we cannot claim to present a comprehensive list but only to highlight the strength of the evidence contained within the report.

1. **Prisoner Blood Donation.** There is a specific finding that there were good scientific and medical grounds for terminating prison collections by the early 1980’s [26.247]. There is a finding that there was a higher prevalence of Hepatitis C in the prison population in the 1970’s and 1980s and patients were infected because of the continuation of the
practice of Prison collection [26.264] Haemophilia Scotland concludes that the practice of using taking blood donations from prisoner should have stopped years earlier than it did.

2. **Blood Donor Selection.** Despite the existence of International Standards from 1976 onwards that illicit drug use should debar donation, the SNBTS failed to insist that direct questions were asked of donors relative to the their intravenous drug use until the later 1980’s [26.25]. Haemophilia Scotland concludes that direct questions about high risk behaviour should have been integral part of the donor selection system.

3. **Patient Information.** There are countless examples where it is recorded that patients were given insufficient information about the risk of HCV infection [e.g. Patient “Christine” Patient “Alex” [34.106 - 34.108]. No well-established or generally accepted procedural 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. [34.195]. Edinburgh Cohort Patients who wanted to know their HIV status should have been told of this by early 1985, in fact some patients were not told for many years [33.437]. 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. At a basic human level help is needed in real time as it becomes clear that the patient has acquired a serious infection or other illness. [34.225] Haemophilia Scotland concludes that patients infected with Hepatitis C or HIV should have been given the option to know about their status straight away.

4. **Scottish Blood Products.** For those using domestic products, the Inquiry questions the faith which clinicians had in the UK blood supply [12.26]. Scottish research showed immunosupression in patients treated exclusively with the PFC products. In 1983 it was no longer reasonable to think that they were safer than the imported products [12.152] Haemophilia Scotland concludes that all blood products should have been considered to carry a significant risk from blood borne viruses from 1983.

5. **Commercial Blood Products from America.** The use of commercial factor VIII concentrate was responsible for the infection with HIV of around a quarter of the children treated for Haemophilia A at Yorkhill hospital in the early 1980s [Executive Summary Page 18]. As far as commercial products were concerned, the Inquiry points out that these products were unlicensed until 1983 [21.348] Haemophilia Scotland concludes that the decision to import commercial clotting factor
products, despite Scotland being able to produce sufficient domestic product, led to an increased number of HIV infections.

6. **Contradictory Government Information on AIDS.** Transfusion doctors in Edinburgh published a leaflet for donors which said that that AIDS could “almost certainly” be transmitted by blood and blood products in September 1983 [9.110]. Advice which was given my medical experts to the Haemophilia Society in March 1983 regarding the safety of concentrates provided false reassurance to the patients [9.98]. The Inquiry expresses “sympathy” for the position of Dr Mark Winter which was critical of the UK Government line that there was “no conclusive evidence” that HIV was transmitted by blood or blood products and concludes that it (the line) led to a real risk of misrepresentation [9.123]. **Haemophilia Scotland concludes that people with bleeding disorders were given misleading information about the risk they faced from AIDS.**

7. **Access to safer treatment options.** The Inquiry states that a wholesale shift to cryoprecipitate use carrying a lower risk of HIV transmission in the 1980s was technically achievable [12.173]. The Inquiry concludes that a re-evaluation needed to take place of the risk/benefit analysis of the therapy in the middle of September 1983 [90] despite the fact that it also finds on the basis of the Scottish research alone, such a re-assessment was due in the spring of 1983 [12.153]. Professor Hann at Yorkhill offered his patients a choice of treatment in 1983 whereas Professor Forbes in Glasgow and Professor Ludlam in Edinburgh and the other Scottish clinicians did not [12.171]. They continued to use concentrates. **Haemophilia Scotland concludes that as the risks of clotting factor concentrates became clearer all people with bleeding disorders in Scotland should have been offered alternative treatment options. Whether or not to take these risks was properly a decision for patients to take with advice from clinicians.**

8. **The danger from Hepatitis C.** The Inquiry finds that by mid-1985 it was or should have been realised that hepatitis C was a progressive and potentially lethal disease [22.135 and 35.238 and 70]. The Inquiry observes without contradiction the evidence which suggested that by 1985, the pool size had become so large that infection as a result of a single exposure to a factor concentrate (whether domestic or commercial) would have resulted in inevitable infection. [15.125 and 15.126]. **Haemophilia Scotland concludes that by 1985 being treated with a blood product in Scotland meant being infected with a progressive and potentially lethal disease.**

9. **Treatment outside specialist centres.** Guidance should have gone to hospitals outwith main centres about the risks of the transmission of hepatitis C to previously untreated patients [22.152]. That guidance should have been promulgated by the government in Scotland [22.140] and such guidance would not have infringed the clinical independence of the doctors [22.153]. It was precisely in the circumstances in which
previously untreated patients were infected in Scotland over this period that guidance on the risks for such patients would have been useful [22.142]. There should have been guidance for junior doctors in hospitals about these particular risks and dangers. **Haemophilia Scotland concludes that appropriate guidance was not provided outside specialist Haemophilia Centres and as a result previously untreated people were put at risk.**

10. **Access to safer English clotting factor products.** 8Y (the English HCV safe factor VIII available at that time) could have been obtained for use in the treatment of Scottish virgin patients if it had been requested as part of the clinical trial of that product [22.147]. Physicians beyond Edinburgh and practitioners responsible for those with bleeding disorders should have been told that there was a supply of 8Y available after the summer of 1986 [22.149]. Concentrates should not have been used in the treatment of previously untreated patients from 1985 unless it was unavoidable [22.136]. **Haemophilia Scotland concludes that a supply of the safer 8Y product from England should have been made available throughout Scotland for the treatment of previously untreated people.**

11. **Surrogate Testing.** The Inquiry found it likely that ALT testing would have reduced the incidence of HCV from blood transfusions [Executive Summary page 31]. **Haemophilia Scotland concludes that ALT testing should have been introduced.**

12. **Routine Anti HCV Testing.** The Inquiry concludes that there was a delay in the introduction of routine anti-HCV testing in Scotland, which could have exposed individuals to infection with HCV from blood transfusions. It was concluded that routine testing of blood donations should have been recommended by the transfusion services to the government by May 1990 which, due to kit availability would have meant that routine testing could have commenced in autumn 1990 [35.233]. The Inquiry has concluded that there was no 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, as it was [35.234] **Haemophilia Scotland concludes that the delay in introducing routine anti-HCV testing was a missed opportunity to prevent infections.**

13. **Alerting blood donors to AIDS risks.** Leaflets were produced for blood donors to explain what activities were high-risk in relation to blood borne viruses from March 1983. AIDS was already known to be an extremely serious disease. The balance of opinion among transfusionists was moving towards a viral aetiology: [HIV] was apparently transmitted by blood. A precautionary approach to the possibility of risk required action (paragraph 28.92). However, no steps were taken to ensure that they had been read until November 1984. At this point donors were asked to sign a declaration to say that they had read the leaflet and should not be excluded. **Haemophilia Scotland concludes that the earlier passive approach inappropriately relied**
on people with no medical training, who believed that they were
well, to self-identify as potentially having a deadly and incurable
virus.

14. **AIDS caused by an infectious agent.** There is a general tendency in
the report to favour the need for things to be established with a
significant degree of medical certainty before being prepared to
recognise anything approaching an obligation to act. The report notes
[11.26] the independent evidence of Dr Mark Winter on the importance
of the case of the San Francisco baby in 1982 as proving that
immunodeficiency later to be known as AIDS was caused by an
infectious agent [11.79]. The Inquiry heard evidence that the latter half
of 1983 most people in Scotland came to accept that AIDS was caused
by the transmission of an infective agent [12.121]. Transfusion doctors
in Edinburgh published a leaflet for donors which said that that AIDS
could “almost certainly” be transmitted by blood and blood products in
September 1983 [9.110]. **Haemophilia Scotland concludes that it is
wrong to hold that it was not until the Autumn of 1984 that the
infective theory was established.**
APPENDIX 2
Haemophilia Scotland Response to the Penrose Report
Our Recommendations

Haemophilia Scotland believes the facts uncovered by the report constitutes an unanswerable case for the following actions.

Acknowledgement of the disaster and supporting its victims

- **An apology:** There should be a formal apology from the First Minister on behalf of the Scottish institutions for their part in the contaminated blood disaster. The apology must include an acceptance by the Scottish Government that there is a moral duty to those infected as a result of NHS treatment.

- **A Scottish Settlement for Financial Support:** Scotland should provide proper financial support for those affected by the disaster. This should be in the form of lump sum payments based on civil damages. It should recognise the pain and suffering caused by the disaster as well as the loss of earning of those infected and those who have cared for them. No payments should be contingent on the ability to provide evidence from medical records as many of them are missing or incomplete. It is unacceptable that the current support arrangements are not fully accountable to Scottish families and the Scottish Government and leave some people living in poverty.

- **Support for families:** The families, widows and dependents of those infected must be supported. Many of the survivors of the disaster are extremely anxious that their reduced earning potential and lack of access to financial products means they have not been able to make provision for their families. Therefore, all those affected by the disaster should be entitled to make a claim under the scheme, assessed against the standards of civic damages for their loss.

- **Psychosocial support:** There should be a commitment to rolling out psychosocial support to everyone with a bleeding disorder in Scotland and to ensure that a sustainable Scottish patient association.

Securing the safety of the blood supply

- **Blood should never again be collected in prisons and borstals:** Although not current practice we fear that arguments that fulfilling civic duties, such as blood donation, can play an important role in reducing recidivism mean that constant vigilance is required. We believe the epidemiological evidence is clear that prisoners are at increased risk of transmitting blood borne infections and would therefore represent a threat to blood safety when the next blood borne infection emerges.

- **Early adoption of new donor tests.** The threshold for using a new blood test, including surrogate tests, to exclude donors is too high with too much emphasis placed on false positives reducing the blood
supply. Tests should be introduced early to increase patient safety with any shortfall in blood supply addressed by recruiting more donors. It is clear that with better funding the Scottish National Blood Transfusion Service (SNBTS) could do even more to recruit and retain donors.

- **Look-back.** The Report recommends a full look-back to find the untold number of people infected through a blood transfusion and offer them a test. It is vital that this work includes efforts to identify those with a mild bleeding disorder that have been lost to follow-up from Scottish Haemophilia Centres. At the end of this process we must be as sure as possible that all those infected have access to the medical care they need.

The patient at the centre of decision making

- **Nothing about me, without me:** All decisions about the treatment a patient receives should be taken by that patient (or where appropriate their carer) based on the professional advice of healthcare professionals. For example, when new risks are discovered in relation to a current treatment (such as when the risk of HIV in clotting factor products was identified) patients must have the risks explained to them and be offered alternative treatments or treatment regimes where they exist.

- **Nothing about us, without us:** No decisions about the healthcare services in Scotland should be taken without patient representation. This includes decisions about;
  
  o Service design
  
  o Service specification or standards, including auditing
  
  o Product safety or purchasing
  
  o Communicating risks

  The patient voice in all of these decisions should have statutory protection.

- **Duty of Candour:** Patient and the groups representing them, must be advised at an early stage when any potential risks or problems with past, current or future treatments, products are identified. The new Duty of Candour should be extended to ensure openness between all healthcare professionals and agencies. Both Healthcare professionals and patients should be encouraged to voice concerns without fear of prosecution, reduction in service provision, or impact damage to career prospects.
Research

- **Full and informed consent for the use of samples in research:** No blood or tissue sample, including historic samples, should be used for any purpose which the patient has not given full and informed consent for, or their next of kin if the person is deceased.

- **More research:** Government funded research is required to address some key question where the Penrose Inquiry found there was simply not enough evidence. For example,
  - Are there any clinical implications of being repeatedly infected with multiple genotypes of Hepatitis C?
  - In particular, does this have an impact on the likelihood of ‘clearing’ naturally; immune response fatigue; the success rate of treatment; or prognosis?
  - Why are natural clearing rates lower for people affected by bleeding disorders?